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.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried
Age Restrictions	N/A
Prescriber Restrictions	RA, SJIA, PJIA - Prescribed by or in consultation with a rheumatologist (initial therapy).
Coverage Duration	Initial-RA/SJIA 3 mos, 4 mos PJIA.Cont-RA, SJIA, PJIA-1 year. CRS-1 week
Other Criteria	RA, initial-approve if the patient meets ONE of the following criteria: 1) Patient has had a trial with TWO of the following: Enbrel, Humira, Rinvoq, Orencia or Xeljanz. [Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: Cimzia, infliximab, Simponi (IV/SC)]OR 2) According to the prescribing physician, the 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], or a biologic DMARD [eg, Kineret, a TNF inhibitor such as Enbrel, Humira or Remicade, or Ilaris (canakinumab for SC injection)], or a 1-month trial of a nonsteroidal anti-inflammatory drug [NSAID]). PJIA, initial-approve if the patient has tried TWO of the following: Enbrel, Orencia, Xeljanz or Humira. [Note: if they have had a trial with infliximab in the past it can count towards meeting the try two requirement.] OR if according to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder. Cytokine release syndrome associated with chimeric antigen receptor (CAR) T-Cell therapy-approve. Cont tx for RA, SJIA, PJIA- pt must have had a response as determined by the prescriber.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A

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). Lung disease-presc/consult-pulmonologist or rheum (initial and cont)
Coverage Duration	GCA-6 mo initial, 1 yr cont.PJIA-4 mo initial, 1 yr cont.All other dx-3 mo initial, 1 yr cont.
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, Humira, 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): A) patient has tried TWO of the following drugs in the past: Enbrel, Orencia, Xeljanz or Humira. (Note: if the patient does not meet this requirement, a 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

ACTHAR

Products Affected

- Acthar

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for diagnostic procedure.
Required Medical Information	Diagnosis, prescriber or consulting physician specialty, previous medications tried and response
Age Restrictions	Infantile spasms- less than 2yo. Acute MS exac-adult
Prescriber Restrictions	Infant spasms, prescr physician who has consulted w/or specializes in neurology.MS exacer, prescr/consult w/neuro/phys specializes MS.RA, JIA/JRA, AS, PsA, SLE, Systemic Dermatomyo, prescr/consult w/rheum.Severe Erythema Multiforme, prescr/consult w/derm.Serum Sickness,prescr/consult w/allergist.Severe acute/chronic allergic/inflamm process of eye and adnexa, prescr/consult w/ophthalmol.Symptomatic Sarcoidosis, prescr/consult w/pulm/cardio.Nephrotic Synd, prescr/consult w/nephrologist.
Coverage Duration	All diagnoses-1 month
Other Criteria	For acute MS exacerbation, approve if Acthar is NOT being used as pulse therapy on a monthly basis. For all other FDA approved diagnoses (other than Infantile spasms or MS exacerbation), approve if the patient has tried a systemic corticosteroid for the current condition and patient has experienced a severe adverse effect or treatment failure with the corticosteroid (e.g., a psychotic reaction).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ACYCLOVIR (TOPICAL)

Products Affected

- acyclovir topical cream
- acyclovir topical ointment
- Zovirax topical cream
- Zovirax topical ointment

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Medication history
Age Restrictions	Acyclovir 5% cream, 12 yrs or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	If the request is for brand name Zovirax 5% ointment, the patient is required to have tried generic acyclovir 5% ointment AND cannot use the generic product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ADAKVEO

Products Affected

- Adakveo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	16 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by, or in consultation with, a physician who specializes in sickle cell disease (initial and continuation)
Coverage Duration	1 year
Other Criteria	Sickle Cell Disease Initial-approve if the patient has had at least one sickle cell-related crisis in the previous 12-month period, AND patient meets one of the following criteria (a, b, or c): a. Patient is currently receiving a hydroxyurea product OR b. patient has tried a hydroxyurea product and has experienced inadequate efficacy or significant intolerance OR c. patient is not a candidate for hydroxyurea therapy. Cont-approve if the patient is receiving clinical benefit from Adakveo therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

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 one 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

AJOVY

Products Affected

- Ajovy Autoinjector
- Ajovy Syringe

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with Aimovig, 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 one 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

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

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	3 years
Other Criteria	metastatic NSCLC - is anaplastic lymphoma kinase (ALK)-positive as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ALPHA 1 PROTEINASE INHIBITORS

Products Affected

- Aralast NP
- Glassia
- Prolastin-C
- Zemaira

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

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	3 years
Other Criteria	Metastatic NSCLC, must be ALK-positive, as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

AMONDYS

Products Affected

- Amondys-45

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders
Coverage Duration	1 year
Other Criteria	DMD- patient has a confirmed mutation of the DMD gene that is amenable to exon 45 skipping
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ANABOLIC STEROIDS

Products Affected

- oxandrolone

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, Some Medically-accepted Indications.
Off-Label Uses	Patients w/Turner's Syndrome or Ullrich-Turner Syndrome (oxandrolone only), management of protein catabolism w/burns or burn injury (oxandrolone only), AIDS wasting and cachexia

ANTIBIOTICS (IV)

Products Affected

- amikacin injection solution 1,000 mg/4 mL, 500 mg/2 mL
- ampicillin sodium
- ampicillin-sulbactam
- Avycaz
- Azactam
- azithromycin intravenous
- aztreonam
- Baxdela intravenous
- Bicillin C-R
- Bicillin L-A
- Cefotan
- cefotetan in dextrose, iso-osm
- cefotetan injection
- cefoxitin
- cefoxitin in dextrose, iso-osm
- ceftazidime
- ceftazidime in D5W
- cefuroxime sodium injection recon soln 750 mg
- cefuroxime sodium intravenous
- ciprofloxacin in 5 % dextrose
- Cleocin injection
- clindamycin in 0.9 % sod chlor
- clindamycin in 5 % dextrose
- clindamycin phosphate injection
- clindamycin phosphate intravenous solution 600 mg/4 mL
- colistin (colistimethate Na)
- Coly-Mycin M Parenteral
- Dalvance
- Doxy-100
- doxycycline hyclate intravenous
- ertapenem
- Erythrocin intravenous recon soln 500 mg
- Fetroja
- Fortaz injection recon soln 1 gram, 2 gram, 500 mg
- gentamicin in NaCl (iso-osm) intravenous piggyback 100 mg/100 mL, 60 mg/50 mL, 80 mg/100 mL, 80 mg/50 mL
- gentamicin in NaCl (iso-osm) intravenous piggyback 100 mg/50 mL, 120 mg/100 mL
- gentamicin injection solution 40 mg/mL
- gentamicin sulfate (ped) (PF)
- imipenem-cilastatin
- Invanz injection
- Kimyrsa
- levofloxacin in D5W
- levofloxacin intravenous
- Lincocin
- lincomycin
- linezolid in dextrose 5%
- linezolid-0.9% sodium chloride
- meropenem intravenous recon soln 1 gram, 500 mg
- meropenem-0.9% sodium chloride intravenous piggyback 1 gram/50 mL, 500 mg/50 mL
- Metro I.V.
- metronidazole in NaCl (iso-os)
- Minocin intravenous
- moxifloxacin-sod.ace,sul-water
- moxifloxacin-sod.chloride(iso)
- nafcillin
- nafcillin in dextrose iso-osm
- Nuzyra intravenous
- Orbactiv
- oxacillin in dextrose(iso-osm)
- oxacillin injection
- penicillin G pot in dextrose
- penicillin G potassium
- penicillin G procaine
- penicillin G sodium
- Pfizerpen-G
- polymyxin B sulfate
- Primaxin IV intravenous recon soln 500 mg
- Sivextro intravenous
- streptomycin
- sulfamethoxazole-trimethoprim intravenous

- Tazicef
- Teflaro
- tigecycline
- tobramycin sulfate
- Tygacil
- Unasyn injection
- Vabomere
- vancomycin in 0.9 % sodium chl intravenous piggyback 1 gram/200 mL, 500 mg/100 mL, 750 mg/150 mL
- vancomycin in dextrose 5 % intravenous piggyback 1 gram/200 mL, 500 mg/100 mL, 750 mg/150 mL
- vancomycin injection
- vancomycin intravenous recon soln 1,000 mg, 10 gram, 5 gram, 500 mg, 750 mg
- vancomycin intravenous recon soln 1.25 gram, 1.5 gram, 250 mg
- vancomycin-water inject (PEG) intravenous piggyback 1 gram/200 mL, 1.25 gram/250 mL, 1.5 gram/300 mL, 1.75 gram/350 mL, 2 gram/400 mL, 500 mg/100 mL, 750 mg/150 mL
- Vibativ intravenous recon soln 750 mg
- Xerava
- Zemdri
- Zerbaxa
- Zithromax intravenous
- Zyvox 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

ANTIFUNGALS (IV)

Products Affected

- Cresemba
- fluconazole in NaCl (iso-osm)
- Noxafil intravenous
- Vfend IV
- voriconazole

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

APOKYN

Products Affected

- APOKYN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a serotonin 5-HT3 Antagonist
Required Medical Information	Diagnosis, other therapies
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's disease (PD)-approve if the patient has advanced PD, is experiencing off episodes such as muscle stiffness, slow movements, or difficulty starting movements, is currently receiving carbidopa/levodopa and has previously tried one other treatment for off episodes and had significant intolerance or inadequate efficacy. Patients new to therapy are required to try Kynmobi prior to approval of Apokyn.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ARANESP

Products Affected

- Aranesp (in polysorbate)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Anemia w/CRF not on dialysis.A hemoglobin (Hb) of less than 10.0 g/dL for adults and less than or equal to 11 g/dL for children required for start,Hb has to be less than or equal 11.5 g/dL adults or less than or equal to 12 g/dL in children if previously receiving epoetin alfa (EA), Mircera or Aranesp. Anemia due to myelosuppressive chemotx,Hb is 10.0 g/dL or less to start or less than or equal to 12.0 g/dL if previously on EA or Aranesp AND currently receiving myelosuppressive chemo. MDS, approve tx if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start. If the pt has previously been receiving Aranesp or EA, approve only if Hb is 12.0 g/dL or less. All conds, deny if Hb exceeds 12.0 g/dL.
Age Restrictions	MDS anemia = 18 years of age and older.
Prescriber Restrictions	MDS anemia, prescribed by or in consultation with, a hematologist or oncologist.
Coverage Duration	Anemia w/myelosupp=6 mos, Anemia CKD-1 year, MDS-1 year, Other=6 mos.
Other Criteria	For all covered uses, the patient is required to try Procrit or Retacrit first line.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anemia due to myelodysplastic syndrome (MDS)

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

ARIKAYCE

Products Affected

- Arikayce

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous medication history
Age Restrictions	MAC-18 years and older
Prescriber Restrictions	MAC-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-approve if the patient has NOT achieved negative sputum cultures for Mycobacterium avium complex within the past 3 months after completion of a background multidrug regimen 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). Cystic fibrosis-patient has pseudomonas aeruginosa in culture of the airway.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Cystic fibrosis pseudomonas aeruginosa infection

ASPARLAS

Products Affected

- Asparlas

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 month to 21 years
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

AUBAGIO

Products Affected

- Aubagio

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Aubagio 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	Initial treatment - approve if the patient has tried generic dimethyl fumarate. Cont tx - approve if the patient has been established on Aubagio.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

AURYXIA

Products Affected

- Auryxia

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

AUSTEDO

Products Affected

- Austedo oral tablet 12 mg, 6 mg, 9 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Chorea-prescribed by or in consult with a neuro. TD-Prescribed by or in consultation with a neurologist or a psychiatrist
Coverage Duration	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

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	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

AVSOLA

Products Affected

- Avsola

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medication, medications previously tried
Age Restrictions	CD/UC - Pts aged 6 years or more (initial therapy). Ulcerative Colitis. PP-18 years and older (initial therapy)
Prescriber Restrictions	All dx initial therapy only-Presc/consult with: RA/AS/Still's disease/JIA/JRA-rheum, Plaque Psoriasis/Pyoderma gangrenosum/Hidradenitis suppurativa-derm, Psoriatic Arthritis-rheum or derm, Crohn's Disease/UC-gastroenterologist, Uveitis ophthalmologist, GVHD-a physician affiliated with a transplant center, oncologist, or hematologist, Behcet's Disease- rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist, Sarcoidosis-pulmonol, ophthalmol, or dermatol.
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	Initial therapy-for all covered diagnoses-approve if the patient has tried Remicade. 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, Still's disease, Uveitis, Pyoderma gangrenosum, Hidradenitis suppurativa, Graft-versus-host disease, Juvenile Idiopathic Arthritis (JIA)/JRA, Sarcoidosis

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	3 years
Other Criteria	GIST-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation. Myeloid/Lymphoid Neoplasms with eosinophilia-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) D842V mutation.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid/Lymphoid neoplasms with Eosinophilia

BAFIERTAM

Products Affected

- Bafiertam

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Diagnosis
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	1 year
Other Criteria	Initial treatment - approve if the patient has tried generic dimethyl fumarate. Cont tx - approve if the patient has been established on Bafiertam.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

BALVERSA

Products Affected

- Balversa

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	3 years
Other Criteria	Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 or fibroblast growth factor receptor 2 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy or checkpoint inhibitor therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

BENLYSTA

Products Affected

- Benlysta

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics
Required Medical Information	Diagnosis, medications that will be used in combination, autoantibody status
Age Restrictions	18 years and older (initial).
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

BEOVU

Products Affected

- Beovu

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Administered by or under the supervision of an ophthalmologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

BETASERON/EXTAVIA

Products Affected

- Betaseron subcutaneous kit
- Extavia

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	For patients requesting Extavia, approve if the patient is new to therapy and has tried two of the following: interferon beta-1a intramuscular (Avonex), pegylated interferon beta-1a (Plegridy), interferon beta-1b (Betaseron), or glatiramer acetate (Copaxone).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

BEXAROTENE (ORAL)

Products Affected

- bexarotene
- Targretin

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	3 years
Other Criteria	If brand Targretin is requested, the patient has tried and cannot take generic bexarotene capsules due to a formulation difference in the inactive ingredient(s) between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or a serious adverse reaction.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

BLENREP

Products Affected

- Blenrep

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Per FDA labeling, approve if the patient has tried at least four prior systemic lines of therapy and has received at least one therapy from each of the following drug classes-proteasome inhibitor, immunomodulatory drug, anti-CD38 monoclonal antibody.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

BONIVA INJECTION

Products Affected

- ibandronate intravenous

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other medications for Osteoporosis
Required Medical Information	Diagnosis, test results
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Treatment of postmenopausal osteoporosis, must meet ONE of the following 1. T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, or total hip, 2. has had osteoporotic fracture or fragility fracture, 3. had a T-score (current or at any time in the past) between 1.0 and -2.5 at the lumbar spine, femoral neck, or total hip and the physician determines the patient is at high risk for fracture AND has had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing and significant loss of bone mineral density (BMD), lack of BMD increase), had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy, or experienced intolerability to an oral bisphosphonate (e.g., severe GI-related adverse effects) 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 the patient has had an osteoporotic fracture or a fragility fracture.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A

BOSENTAN/AMBRISENTAN

Products Affected

- ambrisentan
- bosentan
- Letairis
- Tracleer

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.CTEPH-prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Authorization will be for 1 year.
Other Criteria	CTEPH - pt must have tried Adempas, has a contraindication to Adempas, or is currently receiving bosentan for CTEPH. 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, Some Medically-accepted Indications.
Off-Label Uses	Chronic thromboembolic pulmonary hypertension (CTEPH) (bosentan)

BOSULIF

Products Affected

- Bosulif oral tablet 100 mg, 400 mg, 500 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. For CML/ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For ALL, prior therapies tried.
Age Restrictions	18 years and older
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 and has tried ONE other tyrosine kinase inhibitors that are used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia

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. Overactive bladder with symptoms of urge urinary incontinence, urgency and frequency Urinary incontinence-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.Plantar fasciitis-approve if the patient has tried two other treatment modalities.
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,Plantar fasciitis, Sialorrhea, chronic, Spasticity, other than limb (i.e., due to cerebral palsy, stroke, brain injury, spinal cord injury, MS, hemifacial spasm)

BRAFTOVI

Products Affected

- Braftovi oral capsule 75 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRAF V600 status
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

BRONCHITOL

Products Affected

- Bronchitol

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with hypertonic saline
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis
Coverage Duration	1 year
Other Criteria	Cystic fibrosis-approve if the patient has tried hypertonic saline, has passed the bronchitol tolerance test and will pre-medicate with a short-acting bronchodilator.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

BRUKINSA

Products Affected

- Brukinsa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Mantle Cell Lymphoma - approve for 3 years if the patient has tried at least one prior therapy. Chronic lymphocytic leukemia/small lymphocytic lymphoma-approve if the patient has tried at least one prior therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chronic lymphocytic Leukemia (CLL). Small Lymphocytic Lymphoma (SLL)

BYLVAY

Products Affected

- Bylvay

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	3 months and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, gastroenterologist, or a physician who specializes in progressive familial intrahepatic cholestasis (initial and continuation)
Coverage Duration	N/A
Other Criteria	Progressive Familial Intrahepatic Cholestasis, Initial therapy-approve if the patient meets the following (i, ii, iii, and iv): i. Patient has moderate-to-severe pruritus, according to prescriber AND ii. Diagnosis of progressive familial intrahepatic cholestasis type 1 or type 2 was confirmed by genetic testing AND iii. Patient does not have any of the following (a, b, or c): a) Cirrhosis OR b) Portal hypertension OR c) History of a hepatic decompensation event AND Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy. iv. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory. Progressive Familial Intrahepatic Cholestasis, continuation-approve if the patient has had a response to therapy and does not have any of the following (a, b, or c): a) Cirrhosis OR b) Portal hypertension OR c) History of a hepatic decompensation event. Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

C1 ESTERASE INHIBITORS

Products Affected

- Berinert intravenous kit
- Cinryze
- Haegarda
- Ruconest

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% of normal) at baseline and lower than normal serum C4 levels at baseline. Patient is currently taking 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 prophylactic therapy compared with baseline. HAE Due to C1-INH Deficiency [Type I or Type II], Treatment of Acute Attacks, 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% of normal) at baseline and lower than normal serum C4 levels at baseline. Patient who has treated previous acute HAE attacks: approve if the patient has a diagnosis of HAE Type I or Type II and according to the prescriber, the patient has had a favorable clinical response.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

CABOMETYX

Products Affected

- Cabometyx

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, histology, RET gene rearrangement status
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
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). GIST-approve if the patient has previously tried imatinib or avapritinib and has also tried one of the following: sunitinib, regorafinib or ripretinib. Bone cancer-approve if the patient has Ewing sarcoma or osteosarcoma and has tried at least one previous systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Non-Small Cell Lung Cancer with RET Gene Rearrangements, Gastrointestinal stromal tumors (GIST), Bone cancer

CALQUENCE

Products Affected

- Calquence

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	MCL, CLL and SLL-approve. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried one prior therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma.

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	3 years
Other Criteria	MTC - approve. DTC - approve if refractory to radioactive iodine therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma. Non-Small Cell Lung Cancer with RET Gene Rearrangements

CARBAGLU

Products Affected

- Carbaglu

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-3 mo. Pt had genetic test-12 mo, other-approve for 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

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 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

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

CERDELGA

Products Affected

- Cerdelga

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, 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 Gaucher disease or related disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient is a cytochrome P450(CYP) 2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an approved test
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

CEREZYME

Products Affected

- Cerezyme intravenous recon soln 400 unit

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic tests and lab 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	Gaucher Disease, Type 1-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting glucocerebrosidase gene mutation
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

CHENODAL

Products Affected

- Chenodal

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	For the treatment of gallstones, approve if the patient has tried or is currently using an ursodiol product.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

CHORIONIC GONADOTROPINS (HCG)

Products Affected

- chorionic gonadotropin, human intramuscular
- Novarel
- Pregnyl

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 Medically-accepted Indications.
Off-Label Uses	N/A

CIMZIA

Products Affected

- Cimzia
- Cimzia Powder for Reconst
- Cimzia Starter Kit

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).
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-prescribed by or in consultation with a rheumatologist
Coverage Duration	3 months initial, 1 year cont.
Other Criteria	AS initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, Humira, Taltz. PsA initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, Humira, Taltz, Stelara, Otezla, Orencia or Xeljanz/XR. RA initial tx, approve if the patient has tried two of the following drugs in the past: Enbrel, Humira, Orencia, Rinvoq or Xeljanz/XR. CD initial tx, approve if patient has previously tried Humira. Plaque Psoriasis (PP), initial tx-approve if the patient has tried TWO of the following drugs in the past: Enbrel, Humira, Skyrizi, Stelara SC, Otezla, or Taltz. Cont tx, AS/PsA/RA/CD/PP - approve if the pt had a response as determined by the prescriber. Non-radiographic axial spondylitis (nr-axSpA), initial tx-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. nr-axSpA continuation tx-approve if the patient has had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

CINQAIR

Products Affected

- Cinqair

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Xolair or another anti-Interleukin (IL) Monocloncal Antibody
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist, or pulmonologist
Coverage Duration	Authorization will be for 6 months initial, 12 months continuation.
Other Criteria	Initial therapy, approve if the pt meets all of the following criteria: 1)must have blood eosinophil count of greater than or equal to 400 cells per microliter within the previous 4 wks (prior to treatment with any anti-interleukin (IL)-5 therapy), AND 2) pt has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid and ONE of the following: inhaled LABA, inhaled long-acting muscarinic antagonist, leukotriene receptor antagonist, or theophylline, AND 3) Pt's asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy as defined by ONE of the following: pt experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, or pt experienced one or more asthma exacerbation requiring hospitalization or an ER visit in the previous year, or pt has a FEV1 less than 80 percent predicted, or pt has an FEV1/FVC less than 0.80, or 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 for at least 3 consecutive months. Continuation therapy, approve if the pt meets all of the following criteria: 1) pt has responded to Cinqair therapy as determined by the prescribing physician (eg, decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, ER/urgent care, or physician visits due to

PA Criteria	Criteria Details
	asthma, decreased requirement for oral corticosteroid therapy), AND 2) pt continues to receive therapy with an inhaled corticosteroid.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

CLOBAZAM

Products Affected

- clobazam oral suspension
- clobazam oral tablet
- Onfi oral suspension
- Onfi oral tablet
- Sympazan

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other medications tried
Age Restrictions	2 years and older (initial therapy)
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 FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Dravet Syndrome and treatment-refractory seizures/epilepsy

CLOMIPHENE

Products Affected

- clomiphene citrate

PA Criteria	Criteria Details
Exclusion Criteria	Use in patients for infertility
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Woman (a woman 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, Some Medically-accepted Indications.
Off-Label Uses	Male hypogonadism

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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma

COPIKTRA

Products Affected

- Copiktra

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	CLL/Follicular Lymphoma/SLL/MALT Lymphoma (gastric and non gastric)/marginal zone lymphoma-approve if the patient has tried two prior therapies
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	MALT Lymphoma (gastric and non gastric), Marginal Zone Lymphoma

COSENTYX

Products Affected

- Cosentyx (2 Syringes)
- Cosentyx Pen
- Cosentyx Pen (2 Pens)
- Cosentyx subcutaneous syringe 150 mg/mL, 75 mg/0.5 mL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis and previous medications use
Age Restrictions	PP initial-6 years and older.AS/PSA/Spondy initial - 18 years of age and older
Prescriber Restrictions	PP/PsA initial - prescribed by or in consultation with a dermatologist or rheumatologist. AS/spondylo initial- by or in consultation with rheumatologist
Coverage Duration	PP/AS/nr-axSpA - initial tx 3 mos, PsA-initial tx 3 mos, cont tx 1 year
Other Criteria	**Under CMS Review**
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

COTELLIC

Products Affected

- Cotellic

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Melanoma initial - must have BRAF V600 mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

CRESEMBA (ORAL)

Products Affected

- Cresemba

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, Some Medically-accepted Indications.
Off-Label Uses	Candidiasis of the esophagus - HIV infection, sepsis

CRINONE GEL

Products Affected

- Crinone vaginal gel 8 %

PA Criteria	Criteria Details
Exclusion Criteria	Use in patients to supplement or replace progesterone in the management of infertility.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Secondary amenorrhea, 12 months.Support of an established pregnancy, 9 months.
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Support of an established pregnancy

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

CYSTEAMINE (OPHTHALMIC)

Products Affected

- Cystadrops
- 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

CYSTEAMINE (ORAL)

Products Affected

- Cystagon
- Procysbi

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Cystagon and Procysbi
Required Medical Information	Diagnosis, genetic tests and lab results
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

DALFAMPRIDINE

Products Affected

- Ampyra
- 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 requested medication is being used to improve or maintain mobility in a patient with MS. Continuation-approve if 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

DALIRESP

Products Affected

- Daliresp

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

DANYELZA

Products Affected

- Danyelza

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 year and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Neuroblastoma-Approve if the requested medication is used as subsequent therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	3 years
Other Criteria	AML - approve if Daurismo will be used in combination with cytarabine AND the patient meets i. OR ii: i. patient is using Daurismo for treatment induction and is greater than or equal to 75 years old or the patient has comorbidities that preclude the use of intensive induction chemotherapy according to the prescribing physician, OR ii. patient is continuing Daurismo as post-induction therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients continuing Daurismo as post-induction therapy

DEFERASIROX

Products Affected

- deferasirox
- Exjade
- Jadenu
- Jadenu Sprinkle

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

DEFERIPRONE

Products Affected

- deferiprone
- Ferriprox
- Ferriprox (2 times a day)

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

DESOXYN

Products Affected

- Desoxyn
- methamphetamine

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

DIACOMIT

Products Affected

- Diacomit

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of diagnosis.
Age Restrictions	2 years and older (initial therapy)
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. Dravet Syndrome-Continuation-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

DICLOFENAC (TOPICAL)

Products Affected

- diclofenac epolamine
- Flector
- Licart

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 mos.
Other Criteria	Patients must try a generic oral NSAID or generic diclofenac 1% gel.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DIMETHYL FUMARATE

Products Affected

- dimethyl fumarate oral capsule,delayed release(DR/EC) 120 mg, 120 mg (14)- 240 mg (46), 240 mg
- Tecfidera 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	If the patient is requesting brand Tecfidera and has been established on brand Tecfidera for greater than or equal to 120 days, approve. If the patient is requesting brand Tecfidera and is new to therapy or has been taking brand Tecfidera for less than 120 days, they must try generic dimethyl fumarate.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

DOJOLVI

Products Affected

- Dojolvi

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medium-chain triglyceride products
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist or a physician who specializes in the management of long-chain fatty acid oxidation disorders
Coverage Duration	1 year
Other Criteria	Long-Chain Fatty Acid Oxidation Disorders-Approve if the patient has a molecularly confirmed diagnosis of a long-chain fatty acid oxidation disorder based on at least TWO of the following (TWO of i, ii, or iii): i. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma OR ii. Enzyme activity assay (in cultured fibroblasts or lymphocytes) below the lower limit of the normal reference range for the reporting laboratory OR iii. Genetic testing demonstrating pathogenic mutation in a gene associated with long-chain fatty acid oxidation disorders
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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
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 has tried one other therapy or if the patient has undergone splenectomy. 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

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	Concurrent use with Xolair or another Anti-interleukin (IL) Monoclonal Antibody.
Required Medical Information	Diagnosis, prescriber specialty, other medications tried and length of trials
Age Restrictions	**Under CMS Review**
Prescriber Restrictions	Atopic Dermatitis-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, immunologist or otolaryngologist.
Coverage Duration	AD-Initial-4 months, Cont-1 year, asthma/Rhinosinusitis-initial-6 months, continuation 1 year
Other Criteria	AD-Initial-meets both a and b: a.has used at least 1 medium, medium-high, high, and/or super-high-potency prescription topical corticosteroid OR has AD affecting ONLY the face, eyes/eyelids, skin folds, and/or genitalia and has tried tacrolimus ointment AND b.Inadequate efficacy was demonstrated with these previously tried topical prescription therapies, according to the prescribing physician.Cont-Approve if the pt has responded to Dupixent therapy as determined by the prescribing physician. Asthma-Initial-approve if pt meets the following criteria (i, ii, and iii):i.Pt meets ONE of the following criteria (a or b):a)has a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin (IL) therapy or Xolair OR b)has oral corticosteroid-dependent asthma, per the prescriber AND ii.has received at least 3 consecutive months combo therapy with BOTH of the following (a and b): a)An inhaled corticosteroid (ICS) AND b)At least one additional asthma controller/maintenance medication (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 or Xolair used concomitantly with an ICS for at least 3 consecutive months. Use of a combination inhaler

PA Criteria	Criteria Details
	containing both an ICS and a LABA would fulfil the requirement for both criteria a and b) AND iii.asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy or Xolair as defined by ONE of the following (a, b, c, d or e): a)experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b)experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department visit in the previous year OR c)has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d)has an FEV1/forced vital capacity (FVC) less than 0.80 OR e)The patient's asthma worsens upon tapering of oral corticosteroid therapy. Cont-Approve if meets the following criteria (i and ii): i.continues to receive therapy with one inhaled corticosteroid (ICS) or one ICS-containing combination inhaler AND ii.has responded to Dupixent therapy as determined by the prescribing physician. Chronic rhinosinusitis with Nasal Polyposis-Initial-pt is currently receiving therapy with an intranasal corticosteroid AND is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell according to the prescriber AND meets ONE of the following (a or b): a)has received treatment with a systemic corticosteroid within the previous 2 years or has a contraindication to systemic corticosteroid therapy OR b)has had prior surgery for nasal polyps. Cont-approve if the pt continues to receive therapy with an intranasal corticosteroid AND pt has responded to Dupixent therapy as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

DURYSTA

Products Affected

- Durysta

PA Criteria	Criteria Details
Exclusion Criteria	Re-treatment of previously treated eyes
Required Medical Information	Diagnosis
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist
Coverage Duration	Approve one time use for each treated eye (i.e., one implant per treated eye)
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

DYSPORT

Products Affected

- Dysport

PA Criteria	Criteria Details
Exclusion Criteria	Use in the management of cosmetic uses.
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, Some Medically-accepted Indications.
Off-Label Uses	Spasticity and blepharospasm

EGRIFTA

Products Affected

- Egrifta SV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician specializing in the treatment of human immunodeficiency virus (HIV) infection (initial therapy)
Coverage Duration	6 months initial, 1 year continuation
Other Criteria	Lipodystrophy in HIV-infected patients-Initial-approve if Egrifta is being prescribed for the reduction of excess abdominal fat and the patient meets one of the following-If male, waist circumference is greater than or equal to 95 cm (37.4 in) and waist-to-hip ratio is greater than or equal to 0.94 OR If female, waist circumference is greater than or equal to 94 cm (37 in) and waist-to-hip ratio is greater than or equal to 0.88 AND the patient has been stable on anti-retroviral regimen for at least 8 weeks. Continuation-approve if the patient has responded to Egrifta therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

ELELYSO

Products Affected

- Elelyso

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic tests and lab results
Age Restrictions	4 years and older
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	Gaucher Disease, Type 1-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting glucocerebrosidase gene mutation
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ELZONRIS

Products Affected

- Elzonris

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

EMFLAZA

Products Affected

- Emflaza

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty
Age Restrictions	2 years of age and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders (initial therapy)
Coverage Duration	1 year
Other Criteria	Initial therapy-approve. Continuation-approve if the patient has responded to or continues to have improvement or benefit from therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

EMGALITY

Products Affected

- Emgality Pen
- Emgality Syringe subcutaneous syringe 120 mg/mL, 300 mg/3 mL (100 mg/mL x 3)

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 one 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

EMPAVELI

Products Affected

- Empaveli

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Soliris or Ultomiris
Required Medical Information	Diagnosis, test results
Age Restrictions	PNH-18 years and older (initial therapy and continuation)
Prescriber Restrictions	PNH-prescribed by or in consultation with a hematologist (initial therapy and continuation)
Coverage Duration	PNH-initial 4 months, cont-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Paroxysmal Nocturnal Hemoglobinuria (PNH)-Initial therapy-Approve if diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least two cell lineages AND for a patient transitioning to Empaveli from Soliris (eculizumab intravenous infusion) or Ultomiris (ravulizumab intravenous infusion), the prescriber attests that these medications will be discontinued within 4 weeks after starting Empaveli. Continuation-approve if the patient is continuing to derive benefit (e.g., stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ENBREL

Products Affected

- Enbrel Mini
- Enbrel subcutaneous recon soln
- 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	PP-4 years and older (initial therapy)
Prescriber Restrictions	Initial only-RA/AS/JIA/JRA,prescribed/consult w/rheum. PsA, prescribed/consultation w/rheum or derm. PP, prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center.Behcet's disease,prescribed by or in consult w/ rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist. Uveitis, prescribed by or in consultation with an ophthalmologist.
Coverage Duration	FDA dx-3 mo init, 1 yr cont, Behcet's/uveitis init-3 mo, cont-12 mo.GVHD-3 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). 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)

PA Criteria	Criteria Details
	OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. GVHD-approve. Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. Uveitis-tried one of the following: periocular, intraocular, or systemic corticosteroid, immunosuppressives, Humira or an infliximab product.RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. Behcet's, GVHD, Uveitis Cont-if the patient has had 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 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, Some Medically-accepted Indications.
Off-Label Uses	Graft versus host disease (GVHD), Behcet's disease, Uveitis

ENDARI

Products Affected

- Endari

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty
Age Restrictions	Greater than or equal to 5 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, a physician who specializes in sickle cell disease (e.g., a hematologist)
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ENHERTU

Products Affected

- Enhertu

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.Breast Cancer-approve if the patient has unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease AND has received at least two prior anti-HER2-based regimens in the metastatic setting. Colon or Rectal Cancer-approve if the patient has human epidermal growth factor receptor 2 (HER2)-positive, RAS and BRAF wild-type tumors AND one of the following applies (i or ii): i. Patient has tried chemotherapy OR ii. Patient has unresectable or metastatic disease and is not a candidate for intensive therapy. Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has human epidermal growth factor receptor 2 (HER2)-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Colon or Rectal cancer, Non-small cell lung cancer

ENSPRYNG

Products Affected

- Enspryng

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Soliris, rituximab or Uplizna
Required Medical Information	Diagnosis, previous therapies tried, test results
Age Restrictions	NMOSD-18 years and older (initial and continuation)
Prescriber Restrictions	NMOSD-prescribed by or in consultation with a neurologist or ophthalmologist (initial and continuation)
Coverage Duration	NMOSD-initial-1 year, cont-1 year
Other Criteria	Neuromyelitis Optica Spectrum Disorder-initial therapy-approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and the patient has a history of at least 1 relapse in the last 12 months or two relapses in the last 2 years. Continuation- approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and the patient has had a clinical benefit from the use of Enspryng.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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). 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

EPCLUSA

Products Affected

- Epclusa oral tablet 200-50 mg, 400-100 mg

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin.
Required Medical Information	Genotype, prescriber specialty, other medications tried or used in combination with requested medication
Age Restrictions	3 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

EPIDIOLEX

Products Affected

- Epidiolex

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	Patients 1 year and older (initial therapy)
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 at least two other antiepileptic drugs or if the patient has tried Diacomit or clobazam. Lennox Gastaut Syndrome-approve if the patient has tried at least two other antiepileptics drugs or if the patient has tried one of lamotrigine, topiramate, Banzel, felbamate or clobazam. Tuberous Sclerosis Complex-approve if the patient has tried 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

EPOETIN ALFA

Products Affected

- Epogen injection solution 10,000 unit/mL, 2,000 unit/mL, 20,000 unit/2 mL, 20,000 unit/mL, 3,000 unit/mL, 4,000 unit/mL
- 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.MDS, approve if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start.Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. 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	MDS anemia = 18 years of age and older
Prescriber Restrictions	MDS anemia, myelofibrosis-prescribed by or in consultation with, a hematologist or oncologist.
Coverage Duration	Chemo-6m,Transfus-1m, CKD-1 yr, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr
Other Criteria	Myelofibrosis-Initial-patient has a Hb less than 10 or serum erythropoietin less than or equal to 500 Mu/mL. Cont-patient has a Hgb less than or equal to 12 and according to the prescriber the patient has had a response defined as Hb greater than or equal to 10 or an increase of greater than or equal to 2 g/dL. For all covered uses, if the request is for Epogen, then the patient is required to try Procrit or Retacrit first.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anemia due to myelodysplastic syndrome (MDS), myelofibrosis

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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years
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. Central nervous system cancer (this includes brain and spinal cord tumors)-approve if the patient has tried at least one chemotherapy agent and according to the prescriber, the patient has a mutation of the sonic hedgehog pathway.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central nervous System Cancer

ERLEADA

Products Affected

- Erleada

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
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

ERLOTINIB

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Advanced, recurrent, or metastatic non small cell lung cancer (NSCLC), EGFR mutation or gene amplification status, pancreatic cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Metastatic NSCLC, approve if the patient meets both of the following: 1. patient is EGFR mutation positive, AND 2. patient has EGFR exon 19 deletions OR exon 21 (L858R) substitution mutations as detected by an FDA-approved test. RCC, approve if the patient has relapsed or Stage IV non-clear cell histology RCC. Bone cancer-approve if the patient has chordoma and has tried imatinib, dasatinib or sunitinib. Pancreatic cancer-approve if the medication is used in combination with gemcitabine.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Renal Cell Carcinoma and Bone Cancer-Chordoma.

ESBRIET

Products Affected

- Esbriet oral capsule
- Esbriet 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

EVEKEO

Products Affected

- amphetamine sulfate
- Evekeo
- Evekeo ODT

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

EVENITY

Products Affected

- Evenity

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications for osteoporosis (e.g., oral or IV bisphosphonates, Prolia, Forteo, Tymlos, calcitonin nasal spray) except calcium and Vitamin D
Required Medical Information	Diagnosis, medications that have been tried in the past, other medications that will be used in combination
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months of therapy per course of treatment.
Other Criteria	Treatment of postmenopausal osteoporosis, must meet ONE of the following-1. T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, or total hip, 2. has had osteoporotic fracture or fragility fracture, 3. had a T-score (current or at any time in the past) between -1.0 and -2.5 at the lumbar spine, femoral neck, or total hip and the physician determines the patient is at high risk for fracture AND patient has had had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing and significant loss of bone mineral density (BMD), lack of BMD increase), or had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy, or experienced intolerability to an oral bisphosphonate (e.g., severe GI-related adverse effects) 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 in which IV bisphosphonate therapy may be warranted (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 patient has severe renal impairment (creatinine clearance less than 35 mL/min),

PA Criteria	Criteria Details
	chronic kidney disease or has had an osteoporotic fracture or a fragility fracture.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

EVEROLIMUS

Products Affected

- Afinitor
- Afinitor Disperz
- everolimus (antineoplastic) oral tablet 2.5 mg, 5 mg, 7.5 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer-HER2 status, hormone receptor (HR) status.
Age Restrictions	Relapsed or refractory classical Hodgkin lymphoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Breast Cancer-approve if pt meets ALL the following criteria (A, B, C, D, E, and F): A) pt has recurrent or Stage IV, hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease AND B)pt has human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND C)pt has tried at least one prior endocrine therapy (e.g., anastrozole, letrozole, or tamoxifen) AND D)pt meets ONE of the following conditions (i or ii): i.pt is a postmenopausal female or a male OR ii. pt is premenopausal or perimenopausal AND is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin]), or has had surgical bilateral oophorectomy or ovarian irradiation AND E) The patient meets ONE of the following conditions (i or ii): i. If patient is a male AND if everolimus will be used in combination with exemestane, the patient is receiving a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin]) OR ii. everolimus will be used in combination with exemestane, Faslodex (fulvestrant intramuscular), or tamoxifen AND F) The patient has not had disease progression while on everolimus. Renal Cell Carcinoma (Clear Cell or Non-clear cell histology)-approve if the patient has relapsed or Stage IV disease and if using for clear cell disease, the patient has tried one prior

PA Criteria	Criteria Details
	systemic therapy (e.g., Inlyta, Votrient, Sutent, Cabometyx, Nexavar).Tuberous sclerosis complex (TSC) Associated subependymal giant cell astrocytoma (SEGA)-approve if the patient requires therapeutic intervention but cannot be curatively resected. Thymomas and Thymic Carcinomas-approve if the patient has tried one prior chemotherapy (e.g., cisplatin plus doxorubicin, cisplatin plus etoposide, carboplatin plus paclitaxel). TSC associated renal angiomyolipoma -approve. WM/LPL - approve if patient has progressive or relapsed disease or if the patient has not responded to ONE primary therapy (e.g., Velcade with dexamethasone with or without Rituxan, Treanda with Rituxan, Rituxan with cyclophosphamide and dexamethasone, Treanda, Velcade with or without Rituxan, Velcade with dexamethasone, Kyprolis with Rituxan and dexamethasone, Imbruvica Rituxan). Differentiated (i.e. papillary, follicular, and Hurthle cell) Thyroid Carcinoma-approve if the patient is refractory to radioactive iodine therapy. Endometrial Carcinoma-approve if everolimus will be used in combination with letrozole and the patient has recurrent, metastatic or high-risk disease. GIST-approve if the patient has tried TWO of the following drugs: Sutent, Stivarga, or imatinib AND there is confirmation that everolimus will be used in combination with one of these drugs (Sutent, Stivarga, or imatinib) in the treatment of GIST.Tuberous sclerosis complex (TSC)-associated partial-onset seizures-approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Advanced, unresectable or metastatic neuroendocrine tumors of the thymus (Carcinoid tumors). Soft tissue sarcoma-Perivascular Epitheloid Cell Tumors (PEComa), Recurrent Angiomyolipoma, Lymphangioleiomyomatosis, relapsed or refractory classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Thymomas and Thymic carcinomas, Differentiated (i.e. papillary, follicular, and Hurthle cell) Thyroid Carcinoma, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST) and Recurrent or progressive Meningioma, men with breast cancer

EVKEEZA

Products Affected

- Evkeeza

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
Age Restrictions	12 years 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	HoFH-approve if pt meets (A, B, and C): A) Pt meets 1 of the following (i, ii or iii): i.Pt had genetic confirmation of 2 mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus OR ii.Pt has an untreated LDL-C level greater than 500 mg/dL AND meets one of the following (a or b):a)Pt had clinical manifestations of HoFH b/f age 10 yrs OR Note:Clinical manifestations of HoFH are cutaneous xanthomas, tendon xanthomas, acrus cornea, tuberous xanthomas, or xanthelasma. b)Both parents of pt had untreated LDL-C levels or total cholesterol (TC) levels consistent with HeFH OR Note: example of HeFH in both parents would be if both had an untreated LDL-C level greater than or equal to 190 mg/dL and/or an untreated TC level greater than 250 mg/dL. iii)Pt has a treated LDL-C level greater than or equal to 300 mg/dL AND meets one of the following (a or b): a) Pt had clinical manifestations of HoFH b/f age 10 yrs OR b)Both parents of pt had untreated LDL-C levels or TC levels consistent with HeFH AND B)Pt meets one of the following (i or ii): i.Pt meets all of the following criteria (a and b): a)Pt has tried one high-intensity statin therapy (i.e., atorva greater than or equal to 40 mg daily, rosuva greater than or equal to 20 mg daily [as a single-entity or as a combination product]) AND b)LDL-C level after this regimen remains

PA Criteria	Criteria Details
	greater than or equal to 70 mg/dL OR ii.Pt is determined to be statin intol by meeting one of the following criteria (a or b): a) Pt experienced statin-related rhabdomyolysis OR Note: Rhabdo is statin-induced muscle breakdown associated with markedly elevated creatine kinase levels (at least 10 times the upper limit of normal), along with evidence of end organ damage which can include signs of acute renal injury (noted by substantial increases in serum creatinine [Scr] levels [a greater than or equal to 0.5 mg/dL increase in Scr or doubling of the Scr] and/or myoglobinuria [myoglobin present in urine]) OR b)Pt meets all of the following criteria [(1), (2), and (3)]: (1) Pt experienced skeletal-related muscle symptoms AND Note: Examples of skeletal-related muscle symptoms include myopathy (muscle weakness) or myalgia (muscle aches, soreness, stiffness, or tenderness). (2)symptoms occurred while receiving separate trials of both atorva and rosuva AND (3)When receiving separate trials of both atorva and rosuva the skeletal-related muscle symptoms resolved upon d/c of each respective statin therapy (atorva and rosuva) AND C) Patient meets one of the following (i or ii): i) Pt meets both of the following (a and b): a) Pt has tried a PCSK9 inhibitor for greater than or equal to 8 continuous weeks AND b) The LDL-C level after this PCSK9 inhibitor therapy remains greater than or equal to 70 mg/dL OR ii) Pt is known to have two LDL-receptor negative alleles
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

EVRYSDI

Products Affected

- Evrysdi

PA Criteria	Criteria Details
Exclusion Criteria	Pregnant patients, female patients not utilizing effective contraception during treatment and for 1 month after the last dose of Evrysdi, patients with evidence of hepatic impairment
Required Medical Information	Diagnosis
Age Restrictions	Greater than or equal to 2 months (initial)
Prescriber Restrictions	Prescribed by a physician who has consulted with or who specializes in the management of patients with spinal muscular atrophy and/or neuromuscular disorders (initial and continuation)
Coverage Duration	4 months
Other Criteria	Spinal Muscular Atrophy, Initial Treatment - Approve if the patient has had a genetic test confirming the diagnosis of spinal muscular atrophy with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene reported as at least one of the following: homozygous deletion, homozygous mutation, or compound heterozygous mutation [documentation required] AND the patient meets both of the following criteria (a and b): a) has two to four survival motor neuron 2 (SMN2) gene copies [documentation required] AND b) the patient has objective signs consistent with spinal muscular atrophy Types 1, 2, or 3 [documentation required] AND for patients who are currently receiving or have received prior treatment with a survival motor neuron 2 (SMN2)-directed antisense oligonucleotide, the prescriber attests that further therapy with this product will be discontinued.Patients currently receiving Evrysdi - approve if the patient meets the requirements for initial therapy AND has responded to Evrysdi or continues to have benefit from ongoing Evrysdi therapy by the most recent (within the past 4 months) objective measurement and/or assessment tool [documentation required].
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

EXONDYS 51

Products Affected

- Exondys-51

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders
Coverage Duration	1 year
Other Criteria	DMD- patient has a confirmed mutation of the DMD gene that is amenable to exon 51 skipping
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

EYLEA

Products Affected

- Eylea

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Administered by or under the supervision of an ophthalmologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

EYSUVIS

Products Affected

- Eysuvis

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

FARYDAK

Products Affected

- Farydak

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	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

FASENRA

Products Affected

- Fasenra
- Fasenra Pen

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Xolair or another Anti-Interleukin (IL) Monoclonal Antibody
Required Medical Information	Diagnosis, severity of disease, peripheral blood eosinophil count, previous therapies tried and current therapies, FEV1/FVC
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist, or pulmonologist
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 at least 3 consecutive months of 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, OR d) Patient has an FEV1/FVC less than 0.80, 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 for at least 3 consecutive months. Continuation - The patient has responded to Fasenra therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, emergency department

PA Criteria	Criteria Details
	(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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

FINTEPLA

Products Affected

- Fintepla

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years and older (initial therapy)
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 or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	18 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

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 3 years
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

FULPHILA

Products Affected

- Fulphila

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. PBPC - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC-30 days.
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% 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% 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. Patients are required to try Ziextenzo and Nyvepria prior to approval of Fulphila unless patient has initiated therapy with Fulphila and requires additional medication to complete the current cycle of chemotherapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy

GALAFOLD

Products Affected

- Galafold

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	16 years and older
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, nephrologist, or a physician who specializes in the treatment of Fabry disease
Coverage Duration	1 year
Other Criteria	Approve if the patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

GAMIFANT

Products Affected

- Gamifant

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic test results, lab results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, oncologist, immunologist, transplant specialist, or physician who specializes in hemophagocytic lymphohistiocytosis or related disorders
Coverage Duration	6 months
Other Criteria	Hemophagocytic Lymphohistiocytosis, Primary. Patients must meet all of the following Criteria: i. The patient has a diagnosis of hemophagocytic lymphohistiocytosis determined by molecular genetic diagnosis consistent with hemophagocytic lymphohistiocytosis OR prior to treatment, the patient meets at least FIVE of the following diagnostic criteria at baseline (FIVE of: a, b, c, d, e, f, g, or h): a) Fever greater than or equal to 38.5 Celsius, b) Splenomegaly, c) Cytopenias defined as at least TWO of the following (1, 2, or 3): 1) Hemoglobin less than 9 g/dL (or less than 10 g/dL in infants less than 4 weeks of age) OR 2) Platelets less than 100 x 109/L OR 3) Neutrophils less than 1.0 x 109/L OR d) Fasting triglycerides greater than or equal to 265 mg/dL OR fibrinogen less than or equal to 1.5 g/L OR e) Hemophagocytosis in bone marrow, spleen, or lymph nodes OR f) Low or absent natural killer cell activity (according to local laboratory reference) OR g) Ferritin greater than or equal to 500 mcg/L OR h) Soluble CD25 (i.e., soluble interleukin-2 receptor) greater than or equal to 2,400 U/mL
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

GATTEX

Products Affected

- Gattex 30-Vial
- Gattex One-Vial

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 year and older
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 at least a 20 percent decrease from baseline in the weekly volume of parenteral nutrition.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

GAVRETO

Products Affected

- Gavreto

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	NSCLC-18 years and older. MTC/thyroid cancer-12 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
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. Medullary thyroid cancer (MTC)-approve if the patient has advanced or metastatic rearranged during transfection (RET)-mutant disease and the disease requires treatment with systemic therapy. Thyroid cancer (other than MTC)-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

GILENYA

Products Affected

- Gilenya oral capsule 0.5 mg

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Gilenya 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	Initial treatment-approve if the patient has tried generic dimethyl fumarate unless the patient is greater than or equal to 10 years of age but less than 18 years old or if the patient has highly active or aggressive multiple sclerosis defined as, rapidly advancing deterioration in physical functioning, disabling relapse with suboptimal response to systemic corticosteroids, Magnetic resonance imaging (MRI) findings suggest highly active or aggressive multiple sclerosis or manifestation of multiple sclerosis-related cognitive impairment. Cont tx - approve if the patient has been established on Gilenya.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	NSCLC EGFR pos - For the treatment of metastatic non small cell lung cancer (NSCLC) must be used in tumors with non-resistant EGFR mutation positive NSCLC as detected by an approved test. NSCLC metastatic squamous cell must have disease progression with first line treatment with platinum based chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

GIVLAARI

Products Affected

- Givlaari

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or a physician who specializes in acute hepatic porphyria.
Coverage Duration	1 year
Other Criteria	Acute hepatic porphyria-approve if patient demonstrated clinical features associated with acute hepatic porphyria AND the patient has elevated urinary aminolevulinic acid (ALA) greater than the upper limit of normal or elevated urinary porphobilinogen (PBG) greater than the upper limit of normal and prior to starting treatment with Givlaari, the patient has a history of one porphyria attack in the last 6 months that required a hospitalization, urgent healthcare visit or intravenous hemin administration at home.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

GLATIRAMER

Products Affected

- Copaxone subcutaneous syringe 20 mg/mL, 40 mg/mL
- 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

GLUCAGON-LIKE PEPTIDE-1 AGONISTS

Products Affected

- Adlyxin subcutaneous pen injector 10 mcg/0.2 mL- 20 mcg/0.2 mL, 20 mcg/0.2 mL
- Bydureon BCise
- Byetta subcutaneous pen injector 10 mcg/dose(250 mcg/mL) 2.4 mL, 5 mcg/dose (250 mcg/mL) 1.2 mL
- Ozempic subcutaneous pen injector 0.25 mg or 0.5 mg(2 mg/1.5 mL), 1 mg/dose (2 mg/1.5 mL), 1 mg/dose (4 mg/3 mL)
- Rybelsus
- Trulicity
- Victoza 2-Pak
- Victoza 3-Pak

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

GNRH AGONIST IMPLANTS

Products Affected

- Supprelin LA
- Vantas
- Zoladex

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Endometriosis-18 years and older
Prescriber Restrictions	Prostate cancer/Breast cancer-prescribed by or in consultation with an oncologist. Endometriosis/abnormal uterine bleeding-prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health.
Coverage Duration	Abnormal uterine bleeding-2 months, Breast/prostate cancer-1 year, Endometriosis-6 months
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast cancer- Zoladex is used in premenopausal or perimenopausal women. Abnormal uterine bleeding-Zoladex is used as an endometrial-thinning agent prior to endometrial ablation
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

GOCOVRI

Products Affected

- Gocovri oral capsule,extended release 24hr 137 mg, 68.5 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Previous medications tried, concurrent medications
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial and continuation).
Coverage Duration	Initial-3 months. Cont-1 year.
Other Criteria	Initial therapy Parkinson's disease - approve if the following criteria are met: 1) patient is currently receiving levodopa-based therapy (e.g., carbidopa/levodopa) AND, 2) patient has tried immediate-release amantadine (capsules, tablets, or oral solution) and derived benefit from the immediate-release formulation but had intolerable adverse events or the patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber AND 3) patients is experiencing dyskinesia or off episodes. Cont. therapy - approve if 1) the patient is currently receiving levodopa-based therapy (e.g., carbidopa/levodopa) AND 2) patient has tried immediate-release amantadine (capsules, tablets, or oral solution) and derived benefit from the immediate-release formulation but had intolerable adverse events or the patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber, and 3) has had a response to therapy (e.g., decrease in dyskinesia, decrease in off episodes), as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

Products Affected

- Eligard
- Eligard (3 month)
- Eligard (4 month)
- Eligard (6 month)
- Fensolvi
- leuprolide subcutaneous kit
- Lupaneta Pack (1 month)
- Lupaneta Pack (3 month)
- Lupron Depot
- Lupron Depot (3 month)
- Lupron Depot (4 month)
- Lupron Depot (6 Month)
- Lupron Depot-Ped
- Lupron Depot-Ped (3 month)
- Triptodur

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	For the treatment of cancer diagnosis must be prescribed by or in consultation with an oncologist.
Coverage Duration	uterine leiomyomata 3 mo.All other=12 mo
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ovarian cancer, breast cancer, prophylaxis or treatment of uterine bleeding in patients with hematologic malignancy or undergoing cancer treatment or prior to bone marrow/stem cell transplantation, head and neck cancer-salivary gland tumors

GRALISE/HORIZANT/LYRICA CR

Products Affected

- Gralise oral tablet extended release 24 hr 300 mg, 600 mg
- Horizant oral tablet extended release 300 mg, 600 mg
- Lyrica CR oral tablet extended release 24 hr 165 mg, 330 mg, 82.5 mg
- pregabalin oral tablet extended release 24 hr 165 mg, 330 mg, 82.5 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	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

GRANIX

Products Affected

- Granix

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Cancer patient receiving chemo-Prescribed by or in consultation with an oncologist, infectious disease specialist, or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist or physician that specializes in transplantation. Myelodysplastic syndromes-prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	PBPC-1 month, All others-6 months
Other Criteria	Cancer patients receiving Myelosuppressive Chemotherapy-Must meet ONE of the following - 1. be 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) 2. be 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 (e.g., at least 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, HIV infection) 3. have had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a CSF (e.g., filgrastim products, pegfilgrastim products, or Leukine) and a reduced dose or frequency of chemotherapy may compromise treatment OR 4. has received chemotherapy has febrile neutropenia and has at least one risk factor for poor clinical outcomes or for developing infection-associated complications according to the prescribing physician (e.g., sepsis syndrome, older than 65 years, severe neutropenia - ANC less than 100 cells/mm3, neutropenia expected to be

PA Criteria	Criteria Details
	more than 10 days in duration, invasive fungal infection, other clinically documented infections, or prior episode of febrile neutropenia). Patients are required to try Zarxio and Nivestym prior to approval of Granix unless patient has initiated therapy with Granix and requires additional medication to complete the current cycle of chemotherapy or patient requires a dose less than 180mcg.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing peripheral blood progenitor cell (PBPC) Collection and Therapy. Myelodysplastic syndromes.

GRASTEK

Products Affected

- Grastek

PA Criteria	Criteria Details
Exclusion Criteria	The patient is NOT currently receiving SC or SL allergen immunotherapy
Required Medical Information	Diagnosis
Age Restrictions	5 years through 65 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	The diagnosis of grass pollen-induced allergic rhinitis must be confirmed by either 1. positive skin test response to a grass pollen from the Pooideae subfamily of grasses (this includes, but is not limited to sweet vernal, Kentucky blue grass, Timothy grass, orchard, or perennial rye grass), or 2. positive in vitro test (i.e., a blood test for allergen-specific IgE antibodies) for a grass in the Pooideae subfamily of grasses. Therapy must be initiated 12 weeks prior to the expected onset of the grass pollen season or therapy is being dosed daily continuously for consecutive grass pollen seasons.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

GROWTH HORMONES

Products Affected

- Genotropin
- Genotropin MiniQuick
- Humatrope injection cartridge
- Norditropin FlexPro
- Nutropin AQ Nuspin
- Omnitrope
- Saizen
- Saizen saizenprep
- Serostim subcutaneous recon soln 4 mg, 5 mg, 6 mg
- Zomacton
- Zorbtive

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	HIV-1.wasting/cachexia d/t malabsorption, opportunistic infx, depression and other causes which have been addressed prior to starting tx, 2.on antiretroviral or HAART for more than 30 days and will cont throughout Serostim tx, 3.not being used for alternations in body fat distribution (abdom girth, lipodystrophy, buffalo hump, excess abdm fat), AND 4. unintentional wt loss greater than 10 percent from baseline, wt less than 90 percent of lower limit of IBW, or BMI less than or equal to 20 kg/m2. Cont-must be off therapy for 1 mo.GHD in Children/Adoles. Pt meets 1 of the following-1-had 2 GH stim tests with-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 lab 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

PA Criteria	Criteria Details
Age Restrictions	ISS 5 y/o or older, SGA 2 y/o or older, SBS and HIV wasting/cachexia 18 y/o or older
Prescriber Restrictions	GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, Noonan (initial), Prader Willi (initial for child/adult and cont tx in adults), SHOX (initial), SGA (initial) - prescribed by or in consultation with an endocrinologist. CKD (initial) endocrinologist or nephrologist.
Coverage Duration	ISS - 6 mos initial, 12 months cont tx, SBS - 1 month, HIV 6 months, others 12 mos
Other Criteria	GHD initial in adults and adolescents 1. endocrine must certify not prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalmic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or SAH, AND 3. meets one of the following - A. has known mutations, embryonic lesions, congenital or genetic defects or structural hypothalmic pituitary defects, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, age and gender adjusted IGF1 below the lower limits of the normal reference range, 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 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, Macrilen peak less than 2.8 ng/ml if BMI is less than or equal to 40 AND if a transitional adoles must be off tx for at least one month before retesting. Cont tx - endocrine must certify not 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 ht 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. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline ht less than 5th percentile. PW cont tx in adults or adolescents who don't meet child requir - physician certifies not used for anti-aging or to enhance athletic performance. SHOX initial - SHOX def by chromo analysis, open epiphyses, ht less than 3rd percentile for age/gender. SGA initial -baseline ht less than 5th percentile

PA Criteria	Criteria Details
	for age/gender and born SGA (birth wt/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 CKD, Noonan, PW in child/adolescent, SHOX, and TS - prescriber confirms response to therapy. SBS initial pt receiving specialized nutritional support.Cont tx - 2nd course if pt responded to tx with a decrease in the requirement for specialized nutritional support. If requesting Genotropin, Humatrope, Nutropin, Saizen, Norditropin or Zomacton must have tried Omnitrope prior to approval.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

HARVONI

Products Affected

- Harvoni oral pellets in packet 33.75-150 mg, 45-200 mg
- Harvoni oral tablet 45-200 mg, 90-400 mg

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin
Required Medical Information	N/A
Age Restrictions	3 years or older
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

HETLIOZ

Products Affected

- Hetlioz
- Hetlioz LQ

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-3 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 - patient 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 patient is totally blind with no perception of light and pt has achieved adequate results with Hetlioz 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

HIGH RISK MEDICATIONS - BENZODIAZEPINES

Products Affected

- Ativan injection
- Ativan oral tablet 0.5 mg, 1 mg, 2 mg
- clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg
- diazepam injection
- diazepam oral concentrate
- diazepam oral solution 5 mg/5 mL (1 mg/mL)
- diazepam oral tablet
- lorazepam injection
- Lorazepam Intensol
- lorazepam oral concentrate
- lorazepam oral tablet 0.5 mg, 1 mg, 2 mg
- Tranxene T-Tab
- Valium

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	Procedure-related sedation = 1mo. All other conditions = 12 months.
Other Criteria	All medically accepted indications other than insomnia, authorize use. Insomnia, may approve lorazepam if the patient has had a trial with two of the following: ramelteon, doxepin 3mg or 6 mg, eszopiclone, zolpidem, or zaleplon. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HIGH RISK MEDICATIONS - BENZTROPINE

Products Affected

- benztropine oral

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For all medically-accepted indications, approve if the prescriber confirms he/she has assessed risk versus benefit in prescribing benztropine for the patient and he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

Products Affected

- cyclobenzaprine oral tablet
- Fexmid

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	The physician has assessed risk versus benefit in using this High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

Products Affected

- Diphen oral elixir
- hydroxyzine HCl oral tablet
- promethazine oral

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For promethazine, authorize use without a previous drug trial for all FDA-approved indications other than emesis, including cancer/chemo-related emesis. For hydroxyzine hydrochloride, authorize use without a previous drug trial for all FDA-approved indications other than anxiety. For the treatment of non-cancer/chemo related emesis, approve promethazine hydrochloride if the patient has tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant) for the current condition. Approve hydroxyzine hydrochloride if the patient has tried at least two other FDA-approved products for the management of anxiety. Prior to approval of promethazine and hydroxyzine, approve if the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HIGH RISK MEDICATIONS - PHENOBARBITAL

Products Affected

- phenobarbital

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for use in sedation/insomnia.
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For the treatment of seizures, approve only if the patient is currently taking phenobarbital.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HIGH RISK MEDICATIONS- ESTROGENS

Products Affected

- Activella oral tablet 1-0.5 mg
- Alora
- Amabelz
- Angeliq
- Bijuva
- Climara
- Climara Pro
- CombiPatch
- Divigel
- Dotti
- Elestrin
- Estrace oral
- estradiol oral
- estradiol transdermal patch semiweekly
- estradiol transdermal patch weekly
- estradiol-norethindrone acet
- Evamist
- Femhrt Low Dose
- Fyavolv
- Jinteli
- Lyllana
- Menest
- Menostar
- Mimvey
- Minivelle
- norethindrone ac-eth estradiol oral tablet 0.5-2.5 mg-mcg, 1-5 mg-mcg
- Prefest
- Vivelle-Dot

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Previous medication use
Age Restrictions	Patients aged 65 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	For the treatment of Vulvar Vaginal Atrophy, approve if the patient has had a trial of one of the following for vulvar vaginal atrophy (brand or generic): Estradiol Vaginal Cream, Premarin Vaginal Cream, Estring, or estradiol valerate. For prophylaxis of Postmenopausal Osteoporosis, approve if the patient has had a trial of one of the following (brand or generic): alendronate, ibandronate, risidronate or Raloxifene.The physician has assessed risk versus benefit in using this High Risk medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HUMIRA

Products Affected

- Humira Pen
- Humira Pen Crohns-UC-HS Start
- Humira Pen Psor-Uveits-Adol HS
- Humira subcutaneous syringe kit 40 mg/0.8 mL
- Humira(CF) Pedi Crohns Starter subcutaneous syringe kit 80 mg/0.8 mL, 80 mg/0.8 mL-40 mg/0.4 mL
- Humira(CF) Pen Crohns-UC-HS
- Humira(CF) Pen Pediatric UC
- 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 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	initial 3 mo, cont tx 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. 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

IBRANCE

Products Affected

- Ibrance

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Breast cancer - approve advanced (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 postmenopausal and Ibrance will be used in combination with anastrozole, exemestane, or letrozole 2, pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonists, or has had surgical bilateral oophorectomy, or ovarian irradiation AND meets one of the following conditions: Ibrance will be used in combination with anastrozole, exemestane, or letrozole Ibrance will be used in combination with fulvestrant 3. 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 4. Pt is postmenopausal and Ibrance will be used in combination with fulvestrant
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Liposarcoma

ICATIBANT

Products Affected

- Firazyr
- 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% 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

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 3 years.
Other Criteria	Approve if the patient meets one of the following: 1. Patient has CML or ALL that is Ph+, T315I positive or, 2. patient has CML, chronic phase with resistance or intolerance to at least two prior TKIs or, 3. patient has accelerated phase or blast phase CML or Philadelphia chromosome positive ALL for whom no other TKIs are indicated.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

IDHIFA

Products Affected

- Idhifa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	IDH2-mutation status
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
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

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 meets one of the following: 1. has tried at least 2 other biologics for SJIA (tocilizumab, abatacet, TNF antagonists (e.g. etanercept, adalimumab, infliximab) OR 2. pt has features of poor prognosis (e.g. arthritis of the hip, radiographic damage, 6-month duration of significant active systemic disease, defined by fever, elevated inflammatory markers, or requirement for treatment with systemic glucocorticoids AND tried Actemra or Kineret OR 3. Pt has features of SJIA with active systemic features with concerns of progression to macrophage activation syndrome (MAS) [as determined by the prescribing physician] AND has tried Kineret. Still's Disease-Initial-approve if the patient has tried at least TWO other biologics or patient has features of poor prognosis and has tried Actemra or Kineret or patient has active systemic features with concerns of

PA Criteria	Criteria Details
	progression to macrophage activation syndrome (MAS) and has tried Kineret.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ILUMYA

Products Affected

- Ilumya

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist (initial therapy)
Coverage Duration	Initial therapy - 3 months. Continuation therapy - 1 year
Other Criteria	Initial Therapy - Approve if the patient has tried TWO of the following drugs in the past: Enbrel, Humira, Skyrizi, Stelara SC, Otezla, or Taltz. Cont tx - approve if the pt had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

IMATINIB

Products Affected

- Gleevec oral tablet 100 mg, 400 mg
- 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	ASM, DFSP, HES, MDS/MPD-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years.
Other Criteria	For ALL/CML, must have Ph-positive for approval of imatinib. Kaposi's Sarcoma-approve if the patient has tried at least one regimen AND has relapsed or refractory disease. Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT)-patient has tried Turalio or according to the prescriber, the patient cannot take Turalio. For all diagnoses-generic must be tried before brand. Approve brand Gleevec if the patient has tried generic imatinib mesylate tablets AND the Brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chordoma, advanced, aggressive or unresectable fibromatosis (desmoid tumors), cKit positive advanced/recurrent or metastatic melanoma, Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor.

IMBRUVICA

Products Affected

- Imbruvica oral capsule 140 mg, 70 mg
- Imbruvica oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	GVHD-1 year, all others-3 years
Other Criteria	Marginal Zone Lymphoma - Approve. GVHD-Approve if the patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus, mycophenolate mofetil, imatinib, Jakafi). B-cell lymphoma-approve if the patient is using Imbruvica as second-line or subsequent therapy according to the prescribing physician. Central nervous system Lymphoma (primary)/Hairy Cell Leukemia-approve if relapsed or refractory.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma (e.g., follicular lymphoma, gastric MALT lymphoma, nongastric MALT lymphoma, AIDS related, post-transplant lymphoproliferative disorder).

IMPAVIDO

Products Affected

- Impavido

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious diseases specialist
Coverage Duration	1 month
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

INBRIJA

Products Affected

- Inbrija inhalation capsule, w/inhalation device

PA Criteria	Criteria Details
Exclusion Criteria	Asthma, COPD, other chronic underlying lung disease
Required Medical Information	Diagnosis, medications that will be used in combination
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Approve if the patient is currently taking carbidopa-levodopa, is experiencing off episodes and has previously tried one other treatment for off episodes and experienced intolerance or inadequate efficacy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

INFLECTRA

Products Affected

- Inflectra

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medication, medications previously tried
Age Restrictions	CD/UC - Pts aged 6 years or more (initial therapy). PP - Pts aged 18 years or more (initial therapy)
Prescriber Restrictions	All dx initial therapy only-Presc/consult with: RA/AS/Still's disease/JIA/JRA-rheum, Plaque Psoriasis/Pyoderma gangrenosum/Hidradenitis suppurativa-derm, Psoriatic Arthritis-rheum or derm, Crohn's Disease/UC-gastroenterologist, Uveitis ophthalmologist, GVHD-a physician affiliated with a transplant center, oncologist, or hematologist, Behcet's Disease- rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist, Sarcoidosis-pulmonol, ophthalmol, or dermatol.
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 agent for CD OR the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR the patient has had ileocolonic resection. 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 requirement for a trial of one

PA Criteria	Criteria Details
	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 tumor necrosis factor 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 1 tx (eg, high-dose CS, antithymocyte globulin, CSA, thalidomide, tacrolimus, MM, etc.) or receiving IFX concurrently. 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. FDA approved indications cont tx - approve if patient has had a response, as determined by the prescriber.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

INGREZZA

Products Affected

- Ingrezza
- Ingrezza Initiation Pack

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or psychiatrist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- Aveed
- Depo-Testosterone
- Testopel
- testosterone cypionate intramuscular oil 100 mg/mL, 200 mg/mL, 200 mg/mL (1 ML)
- testosterone enanthate
- Xyosted

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, lab results
Age Restrictions	Delayed puberty or induction of puberty in males-14 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

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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 3 years.
Other Criteria	Advanced Renal cell carcinoma-approve. Differentiated thyroid cancer, approve if patient is refractory to radioactive iodine therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma

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

INREBIC

Products Affected

- Inrebic

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
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

IRESSA

Products Affected

- Iressa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Metastatic NSCLC - The patient has epidermal growth factor receptor (EGFR) exon 19 deletions OR has exon 21 (L858R) substitution mutations as detected by an FDA-approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ISTURISA

Products Affected

- Isturisa oral tablet 1 mg, 10 mg, 5 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 disease/syndrome
Coverage Duration	Cushing's dx/synd-Initial-4 mo, Cont-1 yr. Pt awaiting surgery/response after radiotherapy-4 mo
Other Criteria	Cushing's Disease-Approve if the patient is not a candidate for surgery or surgery has not been curative.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Endogenous Cushing's Syndrome, including patients awaiting surgery or awaiting a response after radiotherapy

IVIG

Products Affected

- Asceniv
- Bivigam
- Flebogamma DIF
- Gammagard Liquid
- Gammagard S-D (IgA < 1 mcg/mL)
- Gammaked injection solution 1 gram/10 mL (10 %), 10 gram/100 mL (10 %), 20 gram/200 mL (10 %), 5 gram/50 mL (10 %)
- Gammaplex
- Gammaplex (with sorbitol)
- Gamunex-C
- 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

JAKAFI

Products Affected

- Jakafi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	ALL-less than 21 years of age, GVHD-12 and older, MF/PV/CMML-2-18 and older
Prescriber Restrictions	N/A
Coverage Duration	GVHD-1 year, all others-3 years.
Other Criteria	For polycythemia vera patients must have tried hydroxyurea. ALL-approve if the mutation/pathway is Janus associated kinase (JAK)-related. GVHD, chronic-approve if the patient has tried one conventional systemic treatment for graft versus host disease. GVHD, acute-approve if the patient has tried one systemic corticosteroid. Polycythemia vera-approve if the patient has tried hydroxyurea. Atypical chronic myeloid leukemia-approve if the patient has a CSF3R mutation or a janus associated kinase mutation. Chronic monomyelocytic leukemia-2 (CMML-2)-approve if the patient is also receiving a hypomethylating agent.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Acute lymphoblastic leukemia, graft versus host disease, chronic, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2)

JEMPERLI

Products Affected

- Jemperli

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Endometrial cancer-approve if the patient has mismatch repair deficient (dMMR) disease and has tried a platinum-containing regimen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

JUXTAPID

Products Affected

- Juxtapid oral capsule 10 mg, 20 mg, 30 mg, 5 mg

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.
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 meet ALL of the following criteria: 1) 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 both parents of the patient 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 both parents of the patient had untreated LDL-C levels or total cholesterol levels consistent with HeFH, AND 2) patient tried at least one PCSK9 inhibitor for greater than or equal to 8 continuous weeks and the LDL-C level after this PCSK9 inhibitor therapy remains greater than or equal to 70 mg/dL OR the patient is known to have two LDL-receptor negative alleles, AND 3) Patient has tried one high-intensity statin therapy (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than 20 mg daily [as a single-entity or as a combination product]) for greater than or equal to 8 continuous weeks and the LDL-C level after these treatment regimens remains greater than or equal to 70 mg/dL OR the patient has been determined to be statin intolerant defined by experiencing statin related

PA Criteria	Criteria Details
	rhabdomyolysis or patient experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

JYNARQUE

Products Affected

- Jynarque

PA Criteria	Criteria Details
Exclusion Criteria	Patient is currently receiving Samsca (tolvaptan tablets) . Patients with Stage 5 CKD
Required Medical Information	Diagnosis, renal function
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	1 year (initial and continuation)
Other Criteria	Approve if the patient has rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD) (e.g., reduced or declining renal function, high or increasing total kidney volume [height adjusted]),according to the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

KADCYLA

Products Affected

- Kadcyla

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Breast Cancer-Recurrent/metastatic-1 yr, Breast Cancer-Adjuvant tx-approve 1 yr total, other-1yr
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast Cancer-approve if the patient has human epidermal growth factor receptor 2 (HER2)-positive disease and the patient is using for recurrent or metastatic breast cancer OR if using for adjuvant therapy. NSCLC-approve if the patient has human epidermal growth factor receptor 2 (HER2) mutation-positive NSCLC. Salivary gland tumor-approve if the patient has recurrent, unresectable, or metastatic disease and the patient has human epidermal growth factor receptor 2 (HER2)-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-small cell lung cancer (NSCLC), salivary gland tumor

KALBITOR

Products Affected

- Kalbitor

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders (initial and continuation)
Coverage Duration	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 - approve if patient has HAE type I or type II as confirmed by the following diagnostic criteria (a and b): a) Patient has low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values [documentation required] AND b) Patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required]. Patient who has treated previous acute HAE attacks with Kalbitor-approve if the patient has a diagnosis of HAE type I or II [documentation required] AND ii. According to the prescriber, the patient has had a favorable clinical response with Kalbitor treatment.'
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	4 months of age and older
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

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

KERENDIA

Products Affected

- Kerendia

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with spironolactone or eplerenone
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Diabetic kidney disease, initial-approve if the patient meets the following criteria (i, ii, iii and iv): i. Patient has a diagnosis of type 2 diabetes, AND ii. Patient meets one of the following (a or b): a)Patient is currently receiving a maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b)According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy, AND iii.At baseline (prior to the initiation of Kerendia), patient meets all of the following (a, b, and c): a)Estimated glomerular filtration rate greater than or equal to 25 mL/min/1.73 m2 AND b)Urine albumin-to-creatinine ratio greater than or equal to 30 mg/g AND c)Serum potassium level less than or equal to 5.0 mEq/L, AND iv. Patients must have a trial of Farxiga prior to approval of Kerendia (a trial of another SGLT-2 inhibitor or SGLT-2 inhibitor-containing combination product would also meet this requirement if Farxiga has not been tried). Diabetic kidney disease, continuation-approve if the patient meets the following criteria (i, ii and iii): i.Patient has a diagnosis of type 2 diabetes, AND ii. Patient meets one of the following (a or b): a.Patient is currently receiving a maximally tolerated labeled doseage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b.According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy, AND iii. Patients must have a trial of Farxiga prior to approval of Kerendia (a trial of another SGLT-2 inhibitor or

PA Criteria	Criteria Details
	SGLT-2 inhibitor-containing combination product would also meet this requirement if Farxiga has not been tried).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

KESIMPTA

Products Affected

- Kesimpta Pen

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	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis
Coverage Duration	Authorization will be for 1 year
Other Criteria	**Under CMS Review**
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

KEVEYIS

Products Affected

- Keveyis

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of condition, prior medications tried and results, potassium levels
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial 2 months, cont 12 months.
Other Criteria	HypoPP and Related Variants initial must meet all - 1. HypoPP has been confirmed by one of the following - serum potassium concentration of less than 3.5 mEq/L during a paralytic attack, family history of the condition, or a genetically confirmed skeletal muscle calcium or sodium channel mutation, 2. had improvements in paralysis attack symptoms with potassium intake, and 3. tried oral acetazolamide therapy, and 4. according to the prescribing physician, acetazolamide therapy did not worsen the paralytic attack frequency or severity in the patient, and 5. the prescribing physician has excluded other reasons for acquired hypokalemia (e.g., renal, adrenal, thyroid dysfunction, renal tubular acidosis, diuretic and laxative abuse). HyperPP and Related Variants initial must meet all - 1. HyperPP has been confirmed by one of the following - an increase from baseline in serum potassium concentration of greater than or equal to 1.5 mEq/L during a paralytic attack, serum potassium concentration during a paralytic attack of greater than 5.0 mEq/L, a family history of the condition, or genetically confirmed skeletal muscle sodium channel mutation, 2. prescribing physician has excluded other reasons for acquired hyperkalemia (e.g., drug abuse, renal and adrenal dysfunction), 3. tried oral acetazolamide therapy, 4. according to the prescribing physician, acetazolamide therapy did not worsen the paralytic attack frequency or severity in the patient. Cont tx HypoPP and HyperPP - patient has

PA Criteria	Criteria Details
	responded to Keveyis (e.g., decrease in the frequency or severity of paralytic attacks) as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

KEVZARA

Products Affected

- Kevzara

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist (initial therapy).
Coverage Duration	Initial-3 months, cont-1 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, Humira, Orencia (IV/SC), 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, an infliximab product, golimumab SC/IV, Actemra), OR B) patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx - approve if the pt had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

KEYTRUDA

Products Affected

- Keytruda

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.
Coverage Duration	Adjuvant treatment of melanoma-approve up to 1 year total, all other dx-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	adrenal gland tumor, anal carcinoma, extranodal NK/T-Cell Lymphoma, nasal type, Gestational trophoblastic neoplasia, malignant pleural mesothelioma, mycosis fungoides/Sezary syndrome, soft tissue sarcoma, squamous cell skin cancer, thymic carcinoma, vulvar cancer

KINERET

Products Affected

- Kineret

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another 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, SJIA and Still's disease, prescribed by or in consultation with a rheumatologist. CAPS (Neonatal-Onset Multisystem Inflammatory Disease or Chronic Infantile Neurological Cutaneous and Articular [CINCA] syndrome), prescribed by or in consultation with a pediatrician, rheumatologist, geneticist, or dermatologist. DIRA-rheum, geneticist, dermatologist, or physician specializing in the treatment of autoinflammatory disorder.
Coverage Duration	RA/CAPS/DIRA/SJIA - initial 3 mos, cont 1 year. Stills-initial 3 months, cont 12 mos
Other Criteria	RA initial, approve if the patient has tried TWO of the following drugs in the past: Enbrel, Humira, Orencia (IV/SC), 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: Actemra, Cimzia, infliximab, Kevzara, golimumab IV/SC.] RA cont tx, approve if the pt had a response as determined by the prescriber. DIRA initial-approve if genetic testing has confirmed a mutation in the IL1RN gene. Still's Disease (SD), initial- approve if patient has tried a corticosteroid or has had an inadequate response to 1 conventional synthetic DMARD (eg, methotrexate) for at least 2 months or was intolerant to this therapy OR the patient has at least moderate to severe active systemic features of this condition, according to the prescriber or the patient has active systemic features with concerns of progression to macrophage activation syndrome as determined by the prescriber. SJIA initial-approve if the patient meets one of the following criteria (A or B): A)has tried one other systemic agent (e.g., corticosteroid [oral, intravenous], conventional DMARD [e.g., methotrexate, leflunomide,

PA Criteria	Criteria Details
	sulfasalazine], NSAID). [Note: A previous trial of a biologic also counts towards a trial of one other systemic agent for SJIA], or B) patient has at least moderate to severe active systemic features of this condition or the patient has active systemic features with an active joint count of one joint or greater or the patient has active systemic features with concerns of progression to macrophage activation syndrome (MAS). DIRA/SD/SJIA cont tx - approve if the patient had responded to therapy as determined by the prescriber.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Still's disease (SD). Systemic Juvenile Idiopathic Arthritis (SJIA)

KISQALI

Products Affected

- Kisqali Femara Co-Pack oral tablet 200 mg/day(200 mg x 1)-2.5 mg, 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Breast cancer - approve advanced 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 postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Kisqali will be used in combination with anastrozole, exemestane, or letrozole 3. 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 Kisqali with be used in combination with anastrozole, exemestane or letrozole. 4. Patient is postmenopausal, pre/perimenopausal (patient receiving ovarian suppression/ablation with a GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man, and Kisqali (not Co-Pack) will be used in combination with fulvestrant. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane, or letrozole. Patients must have a trial of Ibrance or Verzenio prior to approval of Kisqali/Kisqali Femara Co-Pack unless the patient meets one

PA Criteria	Criteria Details
	of the following-a) Patient has been taking Kisqali or Kisqali Femara Co-Pack and is continuing therapy OR b) Patient is pre/perimenopausal and will be using Kisqali or Kisqali Femara Co-Pack in combination with an aromatase inhibitor as initial endocrine-based therapy OR c) Kisqali will be used in combination with fulvestrant in postmenopausal female or male patients as initial endocrine-based therapy
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Men with breast cancer

KORLYM

Products Affected

- Korlym

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. Patients awaiting surgery or response after radiotherapy-4 mo
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 Korlym 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, Some Medically-accepted Indications.
Off-Label Uses	Patients with Endogenous Cushing's Syndrome, awaiting surgery, Patients with Endogenous Cushing's syndrome, awaiting a response after radiotherapy

KOSELUGO

Products Affected

- Koselugo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	For patients 2 to 18 years of age, approve if prior to starting Koselugo, the patient has symptomatic, inoperable plexiform neurofibromas. For patients greater than or equal to 19 who have been previously started on therapy with Koselugo prior to becoming 19, approve if prior to starting Koselugo, the patient has symptomatic, inoperable plexiform neurofibromas.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

KYNMOBI

Products Affected

- Kynmobi sublingual film 10 mg, 15 mg, 20 mg, 25 mg, 30 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	Parkinson's Disease-Approve if the patient is experiencing off episodes, such as muscle stiffness, slow movements or difficulty starting movements, is currently receiving carbidopa/levodopa and has previously tried one other treatment for off episodes and experienced intolerance or inadequate efficacy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

LACRISERT

Products Affected

- Lacrisert

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

LAPATINIB

Products Affected

- lapatinib
- Tykerb

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	Authorization will be for 3 years.
Other Criteria	HER2-positive advanced or metastatic breast cancer, approve if the patient has received prior therapy with trastuzumab and lapatinib will be used in combination with capecitabine OR lapatinib will be used in combination with trastuzumab. HER2-positive HR positive metastatic breast cancer, approve if the patient is a man receiving a GnRH agonist, a premenopausal or perimenopausal woman receiving ovarian suppression/ablation with a GnRH agonist, surgical bilateral oophorectomy or ovarian radiation, or a postmenopausal woman and lapatinib will be used in combination with an aromatase inhibitor, that is letrozole (Femara), anastrozole, or exemestane. In this criteria, man/woman is defined as an individual with the biological traits of a man/woman, regardless of the individual's gender identity or expression. Colon or rectal cancer-approve if the patient has unresectable advanced or metastatic disease that is human epidermal receptor 2 (HER2) amplified and with wild-type RAS and the medication is used as subsequent therapy in combination with trastuzumab (the requirement of use in combination with trastuzumab only applies to beneficiaries enrolled in an MA-PD plan) and the patient has not been previously treated with a HER2-inhibitor. Bone Cancer-chordoma-approve if the patient has epidermal growth-factor receptor (EGFR)-positive recurrent disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Bone cancer-chordoma, colon or rectal cancer

LEDIPASVIR/SOFOSBUVIR

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	3 years or older
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. And, patients with genotype 1, 4, 5 and 6 must have a trial with Harvoni, Vosevi or Epclusa prior to approval of ledipasvir-sofosbuvir, unless Harvoni, Vosevi and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance

LEMTRADA

Products Affected

- Lemtrada

PA Criteria	Criteria Details
Exclusion Criteria	Current Use of Lemtrada with Other Disease-Modifying Agents Used for Multiple Sclerosis (MS). Patients with HIV infection.
Required Medical Information	Diagnosis, Previous medication use
Age Restrictions	MS - 17 years of age and older (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS (initial and continuation)
Coverage Duration	MS, has not completed 1 course of Lemtrada-5 days.MS, has completed prior course Lemtrada-3 days
Other Criteria	MS pts who have not completed a course of Lemtrada tx (including pt who started but not completed Lemtrada tx) - patient must have had an inadequate response or was unable to tolerate according to the prescribing physician TWO disease modifying agents used for MS or according to the prescribing physician the patient has a highly-active or aggressive multiple sclerosis by meeting one of the following-the patient has demonstrated rapidly-advancing deterioration(s) in physical functioning (e.g., loss of mobility/or lower levels of ambulation, severe changes in strength or coordination OR disabling relapse(s) with suboptimal response to systemic corticosteroids OR magnetic resonance imaging (MRI) findings suggest highly-active or aggressive multiple sclerosis (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium lesions) OR manifestation of multiple sclerosis-related cognitive impairment. MS patients who already completed a prior course of Lemtrada tx - Approve if at least 12 months has elapsed from the last dose of any prior Lemtrada treatment course for relapsing MS.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

LENVIMA

Products Affected

- Lenvima

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
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 is being used in combination with pembrolizumab OR ii. Lenvima is used in combination with everolimus and the patient meets a or b - a. Patient has clear cell histology and patient has tried one antiangiogenic therapy or b. patient has non-clear cell histology. MTC-approve if the patient has tried Caprelsa or Cometriq. Anaplastic thyroid cancer-approve if the disease does not have a curative option. 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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Medullary Thyroid Carcinoma (MTC) and anaplastic thyroid carcinoma.

LEUKINE

Products Affected

- Leukine injection recon soln

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Neuroblastoma-less than 18 years of age
Prescriber Restrictions	AML if prescribed by or in consultation with an oncologist or hematologist, PBPC/BMT - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation, Radiation syndrome-prescribed by or in consultation with physician with expertise in treating acute radiation syndrome. Neuroblastoma-prescribed by or in consultation with an oncologist.
Coverage Duration	Radiation Syndrome/BMT - 1 mo, AML/Neuroblastoma-6 months, PBPC-14 days
Other Criteria	Neuroblastoma-approve if the patient is receiving Leukine in a regimen with dinutuximab.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Neuroblastoma

LIBTAYO

Products Affected

- Libtayo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous surgeries or radiation
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Locally advanced or metastatic CSCC-approve if the patient is not a candidate for curative surgery or curative radiation. Basal Cell Carcinoma-approve if the patient has locally advanced or metastatic disease and has received previous treatment with at least one hedgehog pathway inhibitor or a hedgehog pathway inhibitor is not an appropriate therapy for the patient. NSCLC-approve if the patient has locally advanced disease and is not eligible for surgical resection or chemoradiation or if the patient has metastatic disease, the tumor proportion score (TPS) for programmed death ligand-1 (PD-L1) as determined by an approved test is greater than or equal to 50 percent AND the tumor is negative for actionable mutations.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

LIDOCAINE PATCH

Products Affected

- lidocaine topical adhesive patch,medicated 5 %
- Lidoderm
- ZTlido

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, Some Medically-accepted Indications.
Off-Label Uses	Diabetic neuropathic pain, chronic back pain

LONG ACTING OPIOIDS

Products Affected

- Belbuca
- buprenorphine transdermal patch
- Butrans
- ConZip
- hydrocodone bitartrate oral capsule, oral only, ER 12hr
- hydrocodone bitartrate oral tablet,oral only,ext.rel.24 hr
- hydromorphone oral tablet extended release 24 hr
- Hysingla ER
- 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 capsule, ER multiphase 24 hr
- morphine oral capsule,extend.release pellets
- morphine oral tablet extended release
- MS Contin
- Nucynta ER
- oxycodone oral tablet,oral only,ext.rel.12 hr 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg
- OxyContin oral tablet,oral only,ext.rel.12 hr 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg
- oxymorphone oral tablet extended release 12 hr
- tramadol oral capsule,ER biphase 24 hr 17-83
- tramadol oral capsule,ER biphase 24 hr 25-75 100 mg, 200 mg
- tramadol oral tablet extended release 24 hr
- tramadol oral tablet, ER multiphase 24 hr
- Xtampza ER
- Zohydro ER

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 optimized and are being used in conjunction with opioid therapy according to the prescribing

PA Criteria	Criteria Details
	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.
Off-Label Uses	N/A

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 3 years.
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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

LORBRENA

Products Affected

- Lorbrena oral tablet 100 mg, 25 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, ALK status, ROS1 status, previous therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	NSCLC - Approve if the patient has ALK-positive metastatic NSCLC, as detected by an approved test. NSCLC-ROS1 Rearrangement-Positive- approve if the patient has tried at least one of crizotinib, entrectinib or ceritinib.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-small cell lung cancer (NSCLC)-ROS1 Rearrangement-Positive

LOTRONEX

Products Affected

- alosetron
- Lotronex

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

LUCEMYRA

Products Affected

- Lucemyra

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 14 days
Other Criteria	Opioid withdrawal symptoms-patient is using requested medication to facilitate abrupt opioid discontinuation
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

LUCENTIS

Products Affected

- Lucentis

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Administered by or under the supervision of an ophthalmologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Retinopathy of prematurity

LUMAKRAS

Products Affected

- Lumakras

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 3 years
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

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

LUMOXITI

Products Affected

- Lumoxiti

PA Criteria	Criteria Details
Exclusion Criteria	Creatinine clearance less than 30 ml/min
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	6 months
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. HCL-approve if the patient has tried at least two prior systemic therapies including therapy with a purine analog (cladribine and/or pentostatin).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

LUPKYNIS

Products Affected

- Lupkynis

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologics or with cyclophosphamide
Required Medical Information	Diagnosis, lab results
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or rheumatologist (initial and continuation)
Coverage Duration	Initial therapy-6 months, continuation-1 year
Other Criteria	Lupus Nephritis, Initial therapy- Approve if the patient meets all of the following criteria (A, B, and C): A) Patient has autoantibody-positive systemic lupus erythematosus (SLE), defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody B) Patient meets ONE of the following (a or b)a) Medication is being used concurrently with mycophenolate mofetil and a systemic corticosteroid OR b) Patient is not a candidate for mycophenolate mofetil and a systemic corticosteroid due to inadequate efficacy OR significant intolerance with these medications C) Patient has an estimated glomerular filtration rate (eGFR) greater than 45 mL/min/m2. Lupus Nephritis, Continuation therapy- Approve if the patient meets all of the following criteria (A and B):A) Patient meets ONE of the following (a or b): a) Medication is being used concurrently with mycophenolate mofetil and a systemic corticosteroid OR b) Patient is not a candidate for mycophenolate mofetil and a systemic corticosteroid due to inadequate efficacy OR significant intolerance with these medications B) Patient has responded to therapy with the requested medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	3 years
Other Criteria	Ovarian Cancer - Treatment-initial-Approve if the patient meets the following criteria (i and ii): i. patient has a germline BRCA-mutation as confirmed by an approved test AND per product labeling the patient has progressed on three or more prior lines of chemotherapy. Continuation-approve if patient has a BRCA mutation (germline) as confirmed by an approved test. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer-Maintenance monotherapy-Approve if patient meets one of the following criteria (A or B): A) patient meets both of the following criteria for first-line maintenance therapy (i and ii): i. 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, combo tx-approve if Lynparza is used in combo with bevacizumab, pt has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and pt is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast Cancer-Approve if the patient meets the following criteria (A, B, and C)-A. The patient has metastatic, germline BRCA mutation-positive breast cancer

PA Criteria	Criteria Details
	AND B. The patient meets ONE of the following criteria (i or ii)- i. The patient meets BOTH of the following criteria (a and b)-a) The patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive ER+ and/or progesterone receptor positive PR+] disease AND b) The patient meets ONE of the following criteria (1 or 2)-1-The patient has been treated with prior endocrine therapy OR-2 The patient is considered inappropriate for endocrine therapy OR ii. Patient has triple negative disease (i.e., ER-negative, PR-negative, and HER2-negative) AND C. The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. 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 pt has metastatic disease, Lynparza is used concurrently with a GnRH analog or pt has had a bilateral orchiectomy, pt has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test, pt does not have a PPP2R2A mutation and the pt has been previously treated with abiraterone or Xtandi.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

MAVENCLAD

Products Affected

- Mavenclad (10 tablet pack)
- Mavenclad (4 tablet pack)
- Mavenclad (5 tablet pack)
- Mavenclad (6 tablet pack)
- Mavenclad (7 tablet pack)
- Mavenclad (8 tablet pack)
- Mavenclad (9 tablet pack)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis
Required Medical Information	Diagnosis, other medications that will be used in combination
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.
Coverage Duration	1 year
Other Criteria	Initial treatment-approve if the patient has tried one S1P drug (Gilenya or Zeposia) AND one fumarate product (generic dimethyl fumarate or Vumerity or Bafiertam) prior to approval of Mavenclad. Cont tx-approve if the patient has been established on Mavenclad.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

MAVYRET

Products Affected

- Mavyret

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	3 years or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. And, patients with genotype 1, 4, 5 and 6 must have a trial with Harvoni, Vosevi or Epclusa prior to approval of Mavyret, unless Harvoni, Vosevi and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Genotype 2 and 3 must have an Epclusa or Vosevi trial prior to approval of Mavyret, unless Epclusa and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance

MAYZENT

Products Affected

- Mayzent oral tablet 0.25 mg, 2 mg
- Mayzent Starter Pack

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.
Coverage Duration	1 year
Other Criteria	Initial treatment-approve if the patient does not have active secondary progressive MS and the patient has tried one S1P drug (Gilenya or Zeposia) AND one fumarate product (generic dimethyl fumarate or Vumerity or Bafiertam) prior to approval of Mayzent. Cont tx-approve if the patient has been established on Mayzent or if the patient has active secondary progressive MS.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

MEGACE

Products Affected

- megestrol oral suspension 400 mg/10 mL (10 mL), 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

MEKINIST

Products Affected

- 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 3 years.
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. Ovarian/fallopian tube/primary peritoneal cancer-approve if the patient has recurrent disease and the medication is used for low-grade serous carcinoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ovarian/Fallopian Tube/Primary Peritoneal Cancer

MEKTOVI

Products Affected

- Mektovi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRAF V600 status, concomitant medications
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

MEMANTINE

Products Affected

- memantine oral capsule,sprinkle,ER 24hr
- memantine oral solution
- memantine oral tablet
- memantine oral tablets,dose pack
- Namenda oral tablet
- Namenda Titration Pak
- Namenda XR
- 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, Some Medically-accepted Indications.
Off-Label Uses	Patients with mild to moderate vascular dementia.

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

METHYLERGONOVINE

Products Affected

- Methergine
- 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

MIGLUSTAT

Products Affected

- miglustat
- Zavesca

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 geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of Gaucher disease or related disorders
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

MODAFINIL/ARMODAFINIL

Products Affected

- armodafinil
- modafinil oral tablet 100 mg, 200 mg
- Nuvigil
- Provigil 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	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD) - approve if patient is working at least 5 overnight shifts per month. Adjunctive/augmentation treatment for depression in adults (modafinil only) if the patient is concurrently receiving other medication therapy for depression. 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, Some Medically-accepted Indications.
Off-Label Uses	Excessive daytime sleepiness (EDS) associated with myotonic dystrophy - modafinil only. Adjunctive/augmentation for treatment of depression in adults - modafinil only.

MONJUVI

Products Affected

- Monjuvi

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
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-Cell Lymphoma - Approve if the patient meets one of the following criteria (A or B): A) Patient has been treated with at least one prior chemotherapy regimen AND the patient is not eligible for autologous stem cell transplant AND Monjuvi will be used in combination with Revlimid (lenalidomide) OR B) Patient has already received 12 cycles of Monjuvi
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

MULPLETA

Products Affected

- Mulpleta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, platelet count, date of procedure
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	7 days
Other Criteria	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 8 to 14 days after starting Mulpleta therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

MYCAPSSA

Products Affected

- Mycapssa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
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 has responded to an octreotide acetate injection product (e.g., Bynfezia Pen, Sandostatin [generics], Sandostatin LAR Depot) or Somatuline Depot.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

MYFEMBREE

Products Affected

- Myfembree

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, test results
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health
Coverage Duration	24 months of total therapy between Myfembree or Oriahnn
Other Criteria	Uterine Fibroids (Leiomyomas)-approve if the patient is premenopausal (before menopause) and is experiencing heavy menstrual bleeding associated with the uterine fibroids, the uterine fibroids have been confirmed by a pelvic ultrasound, including transvaginal ultrasonography or sonohysterography, hysteroscopy, or magnetic resonance imaging.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

NATPARA

Products Affected

- Natpara

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.
Coverage Duration	1 year
Other Criteria	Chronic hypoparathyroidism, initial therapy - approve if before starting Natpara, serum calcium concentration is greater than 7.5 mg/dL and 25-hydroxyvitamin D stores are sufficient per the prescribing physician. Chronic hypoparathyroidism, continuing therapy - approve if during Natpara therapy, the patient's 25-hydroxyvitamin D stores are sufficient per the prescribing physician, AND patient is responding to Natpara therapy, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

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	N/A
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 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, advanced 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 in the metastatic setting.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

NEULASTA

Products Affected

- Neulasta
- Neulasta Onpro

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Cancer patients receiving chemotherapy, if prescribed by or in consultation with an oncologist or hematologist. PBPC - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation. Radiation syndrome-prescribed by or in consultation with physician with expertise in treating acute radiation syndrome.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC/Radiation Syndrome-1 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% 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% 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. Patients are required to try Ziextenzo and Nyvepria prior to approval of Neulasta unless patient has initiated therapy with Neulasta and requires additional medication to complete the current cycle of chemotherapy or has a diagnosis of radiation syndrome.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Patients undergoing PBPC collection and therapy

NEUPOGEN

Products Affected

- Neupogen

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Cancer/AML, MDS, ALL, 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. SCN, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS. Radiation-prescribed by or in consult with a physician who has expertise in acute radiation syndrome
Coverage Duration	chemo/SCN/AML-6 mo.HIV/AIDS-4 months.MDS-3 mo.PBPC,Drug induce A/N,AA,ALL,BMT-3 mo.Radiation-1 mo
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% 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% 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 or renal dysfunction, poor performance status, HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute

PA Criteria	Criteria Details
	neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection). Patients are required to try Zarxio and Nivestym prior to approval of Neupogen unless patient has initiated therapy with Neupogen and requires additional medication to complete the current cycle of chemotherapy or patient requires a dose less than 180mcg.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL).

NEXAVAR

Products Affected

- Nexavar

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 3 years.
Other Criteria	Osteosarcoma, approve if the patient has tried standard chemotherapy and have relapsed/refractory or metastatic disease. GIST, approve if the patient has tried TWO of the following: imatinib mesylate (Gleevec), sunitinib (Sutent), or regorafenib (Stivarga). Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test. 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). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and Nexavar is used in combination with topotecan.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Osteosarcoma, angiosarcoma, desmoids tumors (aggressive fibromatosis), gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, Chordoma with recurrent disease, solitary fibrous tumor and hemangiopericytoma, ovarian, fallopian tube, primary peritoneal cancer

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
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 for greater than or equal to 8 continuous weeks 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 meets all of the following: Pt has one of the following conditions: prior MI, history of ACS, diagnosis

PA Criteria	Criteria Details
	of angina (stable or unstable), history of stroke or TIA, PAD, undergone a coronary or other arterial revascularization procedure, 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 for greater than or equal to 8 continuous weeks 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
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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
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) for greater than or equal to 8 continuous weeks 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 meets all of the following: Pt has one of the following conditions: prior MI, history of ACS, diagnosis of angina (stable or

PA Criteria	Criteria Details
	unstable), history of stroke or TIA, PAD, undergone a coronary or other arterial revascularization procedure, 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) for greater than or equal to 8 continuous weeks 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

NEXVIAZYME

Products Affected

- Nexviazyme

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 year and older
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	Acid alpha-glucosidase deficiency (Pompe Disease)-approve if the patient has late-onset acid alpha-glucosidase deficiency (late-onset Pompe Disease) and the diagnosis is established by laboratory test demonstrating deficient acid alpha-glucosidase activity in the 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

NILUTAMIDE

Products Affected

- Nilandron
- nilutamide

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
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

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 3 years.
Other Criteria	MM - be used in combination with Revlimid and dexamethasone OR pt had received at least ONE previous therapy for multiple myeloma OR the agent will be used following autologous stem cell transplantation (ASCT). Systemic light chain amyloidosis-approve if the patient has tried at least one other regimen for this condition. Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma-approve if used in combination with a rituximab product and dexamethasone (applies only to beneficiaries enrolled in an MA-PD plan).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with systemic light chain amyloidosis, Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma

NITISINONE

Products Affected

- nitisinone
- Nityr
- Orfadin

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of therapy with nitisinone products
Required Medical Information	Diagnosis, genetic tests and lab results
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

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, MDS, ALL, 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, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
Coverage Duration	chemo/SCN/AML-6mo.HIV/AIDS-4mo.MDS-3mo.PBPC,Drug induce A/N,AA,ALL,BMT-3mo.Radi-1 mo,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% 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% 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), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia

PA Criteria	Criteria Details
	[absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL). Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome).

NOCDURNA

Products Affected

- Nocdurna (men)
- Nocdurna (women)

PA Criteria	Criteria Details
Exclusion Criteria	Currently receiving loop diuretics, systemic or inhaled glucocorticoids OR renal impairment with an estimated glomerular filtration rate less than 50 mL/min/1.73 per meter squared OR heart failure OR polydipsia OR known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretio
Required Medical Information	Diagnosis, lab values, other medications that will be used in combination
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a urologist, a geriatrician, or an endocrinologist
Coverage Duration	12 months
Other Criteria	Prior to desmopressin therapy, the patient awakens at least two times per night to void AND the patient has serum sodium concentrations within the normal range (135 to 145 mmol/L) AND the diagnosis of nocturnal polyuria has been confirmed with a 24-hour urine collection before treatment initiation and the patient meets one of the following (i or ii): i. The nocturnal urine volume exceeds 20% of the total 24-hour urine volume in patients less than 65 years of age OR ii. The nocturnal urine volume exceeds 33% of the total 24-hour urine volume in patients greater than or equal to 65 years of age.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

NON-INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- Androderm
- AndroGel transdermal gel in metered-dose pump
- AndroGel 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)
- Fortesta
- Jatenzo oral capsule 158 mg, 198 mg, 237 mg
- Natesto
- Testim
- testosterone transdermal gel
- testosterone transdermal gel in metered-dose pump 10 mg/0.5 gram /actuation, 12.5 mg/ 1.25 gram (1 %), 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
- Vogelxo

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

PA Criteria	Criteria Details
	(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.
Off-Label Uses	N/A

NORTHERA

Products Affected

- droxidopa
- Northera

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Medication history
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

NOURIANZ

Products Affected

- Nourianz

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	3 years
Other Criteria	Parkinson's disease, patients with off episodes-approve if the patient is experiencing off episodes and if the patient is currently taking carbidopa-levodopa.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

NUBEQA

Products Affected

- Nubeqa

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

NUCALA

Products Affected

- Nucala

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 initial, HES-8 months. 12 months continuation.
Other Criteria	**Under CMS Review**
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

NULIBRY

Products Affected

- Nulibry

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 pediatrician, geneticist, or a physician who specializes in molybdenum cofactor deficiency (MoCD) Type A
Coverage Duration	Authorization will be 1 year
Other Criteria	Molybdenum Cofactor Deficiency (MoCD) Type A-approve if the patient has genetic testing confirmation of a mutation in the MOCS1 gene
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

NUPLAZID

Products Affected

- Nuplazid oral capsule
- Nuplazid oral tablet 10 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	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	Migraine, Acute treatment-approve. Preventive treatment of episodic migraine-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

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. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC-1 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% 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% 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, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy

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 therapy)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial therapy)
Coverage Duration	6 months initial, 1 year continuation.
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

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
Prescriber Restrictions	Prescribed by or in consultation with, a physician who specializes in the treatment of MS and/or a neurologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

OCTREOTIDE INJECTABLE

Products Affected

- octreotide acetate
- Sandostatin injection solution 100 mcg/mL, 50 mcg/mL, 500 mcg/mL

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 Medically-accepted Indications.
Off-Label Uses	N/A

ODACTRA

Products Affected

- Odactra

PA Criteria	Criteria Details
Exclusion Criteria	The patient is NOT currently receiving SC or SL allergen immunotherapy
Required Medical Information	Diagnosis
Age Restrictions	Greater than or equal to 18 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	House Dust Mite (HDM)-Induced Allergic Rhinitis (AR)-approve if the diagnosis is confirmed by meeting ONE of the following conditions (i or ii): i. The patient has a positive skin test response to house dust mite allergen extracts OR ii. The patient has a positive in vitro test (i.e., a blood test for allergen-specific IgE antibodies) for house dust mite (HDM).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
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. Metastatic BCC - approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Metastatic BCC

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% of the predicted value AND according to the prescriber the patient has fibrosing lung disease impacting more than 10% 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

OLUMIANT

Products Affected

- Olumiant

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics, DMARDs, or other potent immunosuppressants
Required Medical Information	Diagnosis, previous medication use, concurrent medication
Age Restrictions	18 years of age and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist (initial therapy).
Coverage Duration	Initial - 3 months, continuation - 1 year
Other Criteria	Initial therapy - approve if the patient has tried TWO of the following drugs in the past: Enbrel, Humira, Orencia (IV/SC), 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: Actemra IV/SC, Cimzia, infliximab, Simponi golimumab IV/SC, Kevzara.] Cont tx - approve if the pt had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ONGENTYS

Products Affected

- Ongentys

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	Parkinson's Disease-Approve if the patient is currently receiving carbidopa/levodopa therapy and if the patient has tried an entacapone product and had significant intolerance or inadequate efficacy or if the patient is currently receiving Ongentys.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ONPATTRO

Products Affected

- Onpattro

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Tegsedi or a tafamidis product
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Approve if the patient has a documented transthyretin (TTR) mutation verified by genetic testing, the patient has symptomatic polyneuropathy (e.g., reduced motor strength/coordination, impaired sensation [e.g., pain, temperature, vibration, touch]) AND the patient does not have a history of liver transplantation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	3 years
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

OPDIVO

Products Affected

- Opdivo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	cHL, mesothelioma, NSCLC- 18 years of age or older, colon/rectal-12 years and older, pediatric hodgkin lymphoma-less than 18 years old
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Adjuvant treatment of melanoma-approve up to 1 year total, all other dx-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	anal carcinoma, endometrial carcinoma, extranodal NK/T-Cell Lymphoma, nasal type, gestational trophoblastic neoplasia, merkel cell carcinoma, pediatric hodgkin lymphoma, small bowel adenocarcinoma, vulvar cancer

OPSUMIT

Products Affected

- Opsumit

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	PAH WHO group, right heart catheterization
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 3 years.
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

ORALAIR

Products Affected

- Oralair sublingual tablet 300 indx reactivity

PA Criteria	Criteria Details
Exclusion Criteria	The patient is NOT currently receiving SC or SL allergen immunotherapy
Required Medical Information	Diagnosis
Age Restrictions	5 years through 65 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	The diagnosis of grass pollen-induced AR must be confirmed by either 1. positive skin test response to a grass pollen from the Pooideae subfamily of grasses (this includes, but is not limited to sweet vernal, Kentucky blue grass, Timothy grass, orchard, or perennial rye grass), or 2. positive in vitro test (i.e., a blood test for allergen-specific IgE antibodies) for a grass in the Pooideae subfamily of grasses. Therapy must be initiated 16 weeks prior to the expected onset of the grass pollen season or therapy is being dosed daily continuously for consecutive grass pollen seasons.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	SC-3 mos initial, 1 year cont
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

ORENITRAM

Products Affected

- Orenitram

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, results of right heart cath
Age Restrictions	N/A
Prescriber Restrictions	PAH must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	3 years
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). For initial Orenitram therapy, approve Orenitram if the patient has tried Uptravi or if the patient is receiving a strong cytochrome P450 2C8 inhibitor (e.g., gemfibrozil).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	3 years
Other Criteria	Prostate Cancer-approve
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ORIAHNN

Products Affected

- Oriahnn

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies, test results
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health
Coverage Duration	24 months of total therapy
Other Criteria	Heavy menstrual bleeding associated with uterine fibroids-approve if the patient is premenopausal and uterine fibroids have been confirmed by a pelvic ultrasound, hysteroscopy or magnetic resonance imaging.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	2 years of age and older
Prescriber Restrictions	prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	3 years
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

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	12 years and older (initial and continuation)
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 [documentation required] AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required]. Continuation-According to the prescriber the patient has had a favorable clinical response since initiating Orladeyo prophylactic therapy compared with baseline [documentation required to confirm diagnosis of HAE type I or II for continuation].
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

OSMOLEX

Products Affected

- Osmolex ER oral tablet, IR - ER, biphasic 24hr 129 mg, 193 mg, 322 mg/day(129 mg x1-193mg x1)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Previous medications tried, concurrent medications
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial and continuation).
Coverage Duration	Initial-3 months. Cont-1 year.
Other Criteria	Initial therapy - approve if the following criteria are met: patient has tried immediate-release amantadine capsules, tablets, or oral solution and derived benefit but had intolerable adverse events as determined by the prescriber OR the patient could not achieve a high enough dosage to gain adequate benefit as determined by the prescriber. Continuation therapy - approve if the following criteria are met: patient has tried immediate-release amantadine capsules, tablets, or oral solution and derived benefit but had intolerable adverse events as determined by the prescriber OR the patient could not achieve a high enough dosage to gain adequate benefit as determined by the prescriber AND the patient has had a response to therapy as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

OTEZLA

Products Affected

- Otezla
- Otezla Starter oral tablets,dose pack 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	18 years and older (initial)
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	4 months initial, 1 year cont
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

OXBRYTA

Products Affected

- Oxbryta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by, or in consultation with, a physician who specializes in sickle cell disease (initial and continuation)
Coverage Duration	1 year
Other Criteria	Sickle Cell Disease Initial-approve if the patient has had at least one sickle cell-related crisis in the previous 12-month period, AND baseline hemoglobin level was less than or equal to 10.5 mg/dL (before initiating Oxbryta therapy) AND patient meets one of the following criteria (a, b, or c): a. Patient is currently receiving a hydroxyurea product OR b. patient has tried a hydroxyurea product and has experienced inadequate efficacy or significant intolerance OR c. patient is not a candidate for hydroxyurea therapy. Cont-approve if the patient is receiving clinical benefit from Oxbryta therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

OXERVATE

Products Affected

- Oxervate

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 an optometrist.
Coverage Duration	2 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

OXLUMO

Products Affected

- Oxlumo

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 nephrologist or urologist (initial therapy)
Coverage Duration	Initial-6 months, Cont-1 year
Other Criteria	Primary Hyperoxaluria Type 1 Initial therapy-Approve if the patient meets i, ii, and iii: i. Patient has had a genetic test confirming the diagnosis of Primary Hyperoxaluria Type 1 via identification of an alanine:glyoxylate aminotransferase gene (AGXT) mutation AND ii. Patient has elevated urine oxalate excretion as demonstrated by ONE of the following (a or b): a) Patient has a urinary oxalate excretion greater than or equal to 0.7 mmol/24 hours/1.73 meters2 OR b) Patient has a urinary oxalate:creatinine ratio above the age-specific upper limit of normal AND iii. Patient has not previously received a liver transplant for primary hyperoxaluria Type 1. Primary Hyperoxaluria Type 1 Continuation therapy-approve if the patient is continuing to derive benefit from Oxlumo as determined by the most recent (i.e., within the past 6 months) objective measurement. Note: Examples of objective measurements of a response to Oxlumo therapy are reduced urinary oxalate excretion, decreased urinary oxalate:creatinine ratio, or reduced plasma oxalate levels from baseline (i.e., prior to Oxlumo therapy) or improved or stabilized clinical signs/symptoms of Primary Hyperoxaluria Type 1 (e.g., nephrocalcinosis, formation of renal stones, renal impairment).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PADCEV

Products Affected

- Padcev

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Urothelial carcinoma-approve if the patient has locally advanced or metastatic disease and has tried at least one other systemic therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PALYNZIQ

Products Affected

- Palynziq subcutaneous syringe 10 mg/0.5 mL, 2.5 mg/0.5 mL, 20 mg/mL

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with sapropterin (continuation therapy)
Required Medical Information	Diagnosis, phenylalanine concentrations
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	1 year (initial and continuation)
Other Criteria	Initial therapy - approve if the patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on at least one existing treatment modality (e.g., prior treatment with Kuvan). Maintenance therapy - approve if the patient has experienced improvement while on Palynziq.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

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 3 years
Other Criteria	Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease with 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

PENICILLAMINE

Products Affected

- Cuprimine
- Depen Titratabs
- penicillamine

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

PEPAXTO

Products Affected

- Pepaxto

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Multiple Myeloma-approve if the patient meets ALL of the following (A, B and C): A) The medication will be used in combination with dexamethasone B) Patient has tried at least four regimens for multiple myeloma AND C) Among the previous therapies tried, the patient has received at least one drug from each of the following classes (i, ii, and iii): i. Proteasome inhibitor AND Note: Examples include bortezomib injection, arfilzomib infusion, ixazomib capsules. ii. Immunomodulatory drug AND Note: Examples include lenalidomide capsules, pomalidomide capsules, thalidomide capsules. iii. Anti-CD38 monoclonal antibody AND Note: For example, daratumumab infusion, daratumumab and hyaluronidase-fihj subcutaneous injection, or isatuximab-irfc infusion.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PHENYLBUTYRATE

Products Affected

- Buphenyl
- Ravicti
- sodium phenylbutyrate

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Ravicti and Buphenyl
Required Medical Information	Diagnosis, genetic tests and lab results
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 testing confirmed a mutation resulting in a urea cycle disorder or if the patient has hyperammonemia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PHEOCHROMOCYTOMA

Products Affected

- Demser
- Dibenzyline
- metyrosine
- phenoxybenzamine

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 therapy for phenoxybenzamine, initial and continuation therapy for metyrosine)
Coverage Duration	Authorization will be for 1 year
Other Criteria	If brand Dibenzyline is being requested, approve if the patient has tried and cannot take generic phenoxybenzamine due to a formulation difference in the inactive ingredients between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or a serious adverse reaction. 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) AND the patient has tried phenoxybenzamine (brand or generic). 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

PHESGO

Products Affected

- Phesgo

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
Coverage Duration	Neoadjuvant or adjuvant-1 year (total), metastatic disease-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast Cancer-Neoadjuvant or Adjuvant Therapy-approve if the patient has human epidermal growth factor receptor 2 (HER2)-positive disease and the patient meets one of the following criteria (i or ii): i. The medication will be used in combination with chemotherapy OR ii. Phesgo is continued after chemotherapy to complete 1 year of neoadjuvant or adjuvant therapy. Breast Cancer-Metastatic Disease-approve if the patient has human epidermal growth factor receptor 2 (HER2)-positive disease AND the patient has not been previously treated with anti-HER2 therapy or chemotherapy for metastatic disease AND the medication will be used in combination with chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Products Affected

- Adcirca
- Alyq
- Revatio intravenous
- Revatio oral suspension for reconstitution
- Revatio oral tablet
- sildenafil (Pulmonary Arterial Hypertension) intravenous solution 10 mg/12.5 mL
- sildenafil (Pulmonary Arterial Hypertension) oral suspension for reconstitution 10 mg/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 and suspension (Revatio, generics) 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

PIQRAY

Products Affected

- Piqray

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Breast Cancer. Approve if the patient meets the following criteria (A, B, C, D, E and F): A) The patient is a postmenopausal female or a male or premenopausal and is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) analog AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene) AND F) Piqray will be used in combination with fulvestrant injection.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Treatment of breast cancer in premenopausal women

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	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PLIAGLIS

Products Affected

- Pliaglis

PA Criteria	Criteria Details
Exclusion Criteria	Cosmetic uses
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 week
Other Criteria	Superficial dermatological procedures-approve for non-cosmetic conditions if the medication will be applied to intact skin and the patient has tried generic lidocaine cream and generic lidocaine/prilocaine cream.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

POLIVY

Products Affected

- Polivy

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	6 months
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-cell lymphoma/B-Cell Lymphoma-Approve if the patient has been treated with at least one prior chemotherapy regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	B-Cell Lymphoma

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 3 years
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). CNS Lymphoma-approve if the patient has relapsed or refractory disease. MM-approve if the patient has received at least one other Revlimid (lenalidomide tablets)-containing regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Systemic Light Chain Amyloidosis, Central Nervous System (CNS) Lymphoma

PONVORY

Products Affected

- Ponvory
- Ponvory 14-Day Starter Pack

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis
Coverage Duration	1 year
Other Criteria	Patients new to therapy-approve if the patient has tried one fumarate-based product (generic dimethyl fumarate, or Vumerity, or Bafiertam) AND one Preferred S1P receptor modulator (Gilenya or Zeposia).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

POSACONAZOLE (ORAL)

Products Affected

- Noxafil oral suspension
- Noxafil oral tablet,delayed release (DR/EC)
- 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 prophy, mucormycosis-6 mo, all others-3 months
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	esophageal candidiasis - treatment, mucormycosis - maintenance, fusariosis, invasive - treatment fungal infections (systemic) in patients with human immunodeficiency virus (HIV) infections (e.g., histoplasmosis, coccidioidomycosis) - treatment.

POTELIGEO

Products Affected

- Poteligeo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Mycosis fungoides/Sezary-prescribed by, or in consultation with an oncologist or dermatologist. ATLL-prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Mycosis Fungoides/Sezary Syndrome-Approve. ATLL-patient has relapsed or refractory disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Adults with T-cell leukemia/lymphoma (ATLL)

PRADAXA

Products Affected

- Pradaxa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior medication history
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	A fib/flutter/DVT/PE tx/reduce risk of recurr-1 yr,DVT/PE prophy(hip)/DVT prophy(knee)-60days.
Other Criteria	Atrial Fibrillation (or Atrial Flutter). Approve if the patient has tried Eliquis or Xarelto. Deep Vein Thrombosis or Pulmonary Embolism, Treatment. Approve if the patient meets one of the following criteria (A or B): A) The patient has tried Eliquis or Xarelto OR B) The patient is currently receiving Pradaxa for this condition. Deep Vein Thrombosis or Pulmonary Embolism, to reduce the risk of recurrence. Approve if the patient has tried Eliquis or Xarelto. Deep Vein Thrombosis or Pulmonary Embolism, Prophylaxis Following Hip Replacement Surgery. Approve if the patient meets one of the following (A or B): A) The patient has tried Eliquis or Xarelto OR B) The patient is currently receiving Pradaxa for this condition. Deep Vein Thrombosis in Patients Undergoing Knee Replacement Surgery, Prophylaxis. Approve if the patient meets one of the following criteria (A or B): A) The patient has tried Eliquis or Xarelto OR B) The patient is currently receiving Pradaxa for this condition.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Deep Vein Thrombosis in patients undergoing knee replacement surgery, prophylaxis

PRALUENT

Products Affected

- Praluent Pen

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Juxtapid or Repatha
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history
Age Restrictions	18 years of age 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	Authorization will be for 1 year
Other Criteria	Hyperlipidemia in patients with HeFH -approve if meets all of the following 1. Pt has been diagnosed with 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 3. LDL-C remains greater than or equal to 70 mg/dL unless is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during d/c. Hyperlipidemia Pt with Clinical ASCVD -approve if meets all of the following: has one of the following conditions prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND tried ONE high intensity statin (as defined above) AND LDL-C remains greater than or equal to 70 mg/dL unless the pt 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 d/c. Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if the patient has 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

PA Criteria	Criteria Details
	(defined above). For all covered diagnoses, patients are required to try Repatha prior to approval of Praluent.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PRETOMANID

Products Affected

- pretomanid

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, concomitant therapy
Age Restrictions	Patients 18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with an infectious diseases specialist
Coverage Duration	9 months
Other Criteria	Tuberculosis, Pulmonary Extensively Drug Resistant or Treatment-Intolerant or Nonresponsive Multidrug-Resistant-approve if prescribed in combination with Sirturo (bedaquiline tablets) and linezolid tablets or oral suspension.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

PROMACTA

Products Affected

- Promacta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy. MDS-platelet counts.
Age Restrictions	N/A
Prescriber Restrictions	Immune Thrombocytopenia or Aplastic Anemia, approve if prescribed by, or after consultation with, a hematologist (initial therapy). Thrombocytopenia in pt with chronic Hep C, approve if prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease (initial therapy). MDS-presc or after consult with heme/onc (initial therapy).
Coverage Duration	Immune Thrombo/MDS initial-3 mo, cont 1yr, AA-initial-4 mo, cont-1 yr, Thrombo/Hep C-1 yr
Other Criteria	Thrombocytopenia in patients with immune thrombocytopenia, initial-approve if the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and the patient is at an increased risk for bleeding AND the patient has tried ONE other therapy or has undergone a splenectomy. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Treatment of thrombocytopenia in patients with Chronic Hepatitis C initial-approve if the patient will be receiving interferon-based therapy for chronic hepatitis C AND to allow for initiation of antiviral therapy if the patient has low platelet counts at baseline (eg, less than 75,000 microliters). Aplastic anemia initial - approve if the patient has low platelet counts at baseline/pretreatment (e.g., less than 30,000 microliters) AND tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate moefetil, sirolimus) OR patient will be using Promacta in combination with standard immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response. MDS initial-approve if patient has low- to intermediate-risk MDS AND the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and is at an increased risk

PA Criteria	Criteria Details
	for bleeding. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Thrombocytopenia in Myelodysplastic Syndrome (MDS)

PYRIMETHAMINE

Products Affected

- Daraprim
- pyrimethamine

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Patient's immune status
Age Restrictions	N/A
Prescriber Restrictions	Toxoplasma gondii Encephalitis, Chronic Maintenance and Prophylaxis (Primary)-prescribed by or in consultation with an infectious diseases specialist. 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	Toxoplasma gondii Encephalitis, Chronic Maintenance, approve if the patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary), approve if the patient is immunosuppressed.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis

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 3 years
Other Criteria	Gastrointestinal stromal tumor (GIST), advanced-approve if, according to labeling, the patient has been previously treated with imatinib and at least two other kinase inhibitors, in addition to imatinib.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

RADICAVA

Products Affected

- Radicava

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	ALSFRS-R score, FVC %, time elapsed since 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 (initial and continuation).
Coverage Duration	Initial, 6 months. Continuation, 6 months
Other Criteria	ALS, initial therapy - approve if the patient meets ALL of the following criteria: 1. According to the prescribing physician, the patient has a definite or probable diagnosis of ALS, AND 2. Patient has a score of two points or more on each item of the ALS Functional Rating Scale - Revised (ALSFRS-R) [ie, has retained most or all activities of daily living], AND 3. Patient has a FVC greater than or equal to 80% (ie, normal respiratory function), AND 4. Patient has been diagnosed with ALS for less than or equal to 2 years. ALS, continuation therapy - approve if, according to the prescribing physician, the patient continues to benefit from therapy AND the patient is not requiring invasive ventilation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

REBIF

Products Affected

- Rebif (with albumin)
- Rebif Rebidose subcutaneous pen injector 22 mcg/0.5 mL, 44 mcg/0.5 mL, 8.8mcg/0.2mL-22 mcg/0.5mL (6)
- Rebif Titration Pack

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	Initial treatment-approve if the patient has tried TWO of the following: Avonex, Plegridy, Betaseron, or generic copaxone. Cont tx-approve if the patient has been established on Rebif.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

REBLOZYL

Products Affected

- Reblozyl

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Beta-thal-Prescribed by or in consultation with a hematologist (initial therapy), MDS/Myelodysplastic/myeloproliferative neoplasm-prescribed by or in consultation with oncologist or hematologist (initial therapy)
Coverage Duration	Beta thal-Ini-4 mo,cont-1 yr.MDS/myelodysplastic/myeloproliferative neoplasm ini-6 mo, cont-1 yr
Other Criteria	Beta-Thalassemia-initial therapy-approve if according to the prescriber, the patient requires regular red blood cell transfusions Note: This includes patients who are transfusion-dependent. Beta-Thalassemia-continuation-approve if according to the prescriber, the patient has experienced a clinically meaningful decrease in transfusion burden. MDS-approve if the patient has myelodysplastic syndromes with ring sideroblasts AND patient has very low- to intermediate-risk myelodysplastic syndromes Note: This is determined using the International Prognostic Scoring System (IPSS) AND patient does not have a confirmed mutation with deletion 5q (del 5q) AND patient currently requires blood transfusions, defined as at least two red blood cell units over the previous 8 weeks AND patient meets ONE of the following (a or b): a)patient tried an erythropoiesis stimulating agent for at least 3 months, unless intolerant OR b) Serum erythropoietin level is greater than m500 U/L AND Pretreatment hemoglobin level is less than 10.0 g/dL AND Reblozyl will not be used in combination with an erythropoiesis stimulating agent.Continuation of Therapy-approve if the patient has experienced a clinically meaningful decrease in transfusion burden. Myelodysplastic/myeloproliferative neoplasm-approve if the patient has myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis-associated anemia AND patient has very low- to intermediate-risk disease.Note: This is determined using the

PA Criteria	Criteria Details
	International Prognostic Scoring System (IPSS) AND patient does not have a confirmed mutation with deletion 5q (del 5q) AND pt currently requires blood transfusions, defined as at least two red blood cell units over the previous 8 weeks AND patient meets ONE of the following (a or b): a) The patient tried an erythropoiesis stimulating agent for at least 3 months, unless intolerant OR b) Serum erythropoietin level is greater than 500 mU/L AND Pretreatment hemoglobin level is less than 10.0 g/dL AND Reblozyl will not be used in combination with an erythropoiesis stimulating agent.Continuation of Therapy-approve if the patient has experienced a clinically meaningful decrease in transfusion burden.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

RECLAST

Products Affected

- Reclast
- zoledronic acid-mannitol-water intravenous piggyback 5 mg/100 mL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Medications for Osteoporosis (e.g., other bisphosphonates, Evenity, Prolia, Forteo/Bonsity, Tymlos, calcitonin nasal spray)
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Paget's 1 month. Others 12 months.
Other Criteria	Tx of osteo in post menopausal pt or osteo in men (a man defined as an individual with biological traits of man, regardless of the individual's gender identity/gender expression), must meet ONE of the following: pt had inadequate response after 12 mo (eg,ongoing and sign loss of BMD, lack of BMD increase) or pt had osteo fracture or fragility fracture while receiving therapy or pt experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because pt cannot swallow or has difficulty swallowing or pt cannot remain in upright position post oral bisphos admin or pt has pre-existing GI condition (eg, pt with esophageal lesions/ulcers, or abnormal of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt had an osteo fracture or a fragility fracture OR pt has tried IV Reclast (zoledronic acid). Tx of PMO may have also tried IV Boniva (ibandronate) for approval. Prevent or tx of GIO, approve if: pt is initiating or cont therapy with systemic glucocorticoids, AND had an inadequate response after 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had an osteo fracture or fragility fracture while on therapy or pt experienced intol (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because pt cannot

PA Criteria	Criteria Details
	swallow or has difficulty swallowing or pt cannot remain in an upright position post oral bisphos 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 has tried Reclast OR patient had an osteo fracture or a fragility fracture. Tx of Paget's disease, approve if pt has elevations in serum alkaline phos of two times higher than the upper limit of the age-specific normal reference range, OR pt is symptomatic (eg,bone pain, hearing loss, osteoarthritis), OR pt is at risk for complications from their disease (eg,immobilization, bone deformity, fractures, nerve compression syndrome). Prevent of PMO - meets 1 of the following had inadequate response after trial duration of 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had osteo fracture or fragility fracture while receiving therapy or patient experienced intol (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphos admin or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions/ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried Reclast or the patient has had an osteo fracture or fragility fracture.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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-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.
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 agent for CD OR the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR the patient has had ileocolonic resection. 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 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

PA Criteria	Criteria Details
	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. FDA approved indications 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

REMODULIN

Products Affected

- Remodulin
- treprostinil sodium

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	PAH WHO group, right heart catheterization results, WHO functional status, previous drugs tried
Age Restrictions	N/A
Prescriber Restrictions	PAH WHO Group 1, prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. PAH WHO Group 1, initial-pt required to have had a right-heart catheterization to confirm the diagnosis of WHO Group 1 PAH AND have Class III or IV functional status or if functional class II must have tried or is currently receiving one oral agent for PAH or patient has tried one inhaled or parenteral prostacyclin product for PAH.If pt has idiopathic PAH, they must have one of the following: 1. had an acute response to vasodilator testing that occurred during the right heart cath AND has tried an oral CCB or 2. pt did not have an acute response to vasodilator testing or 3. cannot undergo vasodilator test or cannot take CCB or 4. has tried a CCB. Continuation-pt required to have had a right heart catheterization to confirm the diagnosis of WHO Group 1PAH.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

RENFLEXIS

Products Affected

- Renflexis

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medication, medications previously tried
Age Restrictions	CD/UC - Pts aged 6 years or more (initial therapy). PP-Pts aged 18 years and older (initial therapy)
Prescriber Restrictions	All dx initial therapy only-Presc/consult with: RA/AS/Still's disease/JIA/JRA-rheum, Plaque Psoriasis/Pyoderma gangrenosum/Hidradenitis suppurativa-derm, Psoriatic Arthritis-rheum or derm, Crohn's Disease/UC-gastroenterologist, Uveitis ophthalmologist, GVHD-a physician affiliated with a transplant center, oncologist, or hematologist, Behcet's Disease- rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist, Sarcoidosis-pulmonol, ophthalmol, or dermatol.
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	Initial therapy-for all covered diagnoses-Approve if the patient has tried Remicade. 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, Still's disease, Uveitis, Pyoderma gangrenosum, Hidradenitis suppurativa, Graft-versus-host disease, Juvenile Idiopathic Arthritis (JIA)/JRA, Sarcoidosis

REPATHA

Products Affected

- Repatha
- Repatha Pushtronex
- Repatha SureClick

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Juxtapid or Praluent
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history
Age Restrictions	ASCVD/HeFH/Primary Hyperlipidemia - 18 yo and older, HoFH 13 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: prior MI, h/o ACS, diagnosis of angina, h/o 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 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, Kynamro 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 statin (defined above) for 8 weeks or longer and LDL remains 70 mg/dL or

PA Criteria	Criteria Details
	higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if the patient has 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).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

RETEVMO

Products Affected

- Retevmo oral capsule 40 mg, 80 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Medullary Thyroid Cancer/Thyroid Cancer-12 years and older, all others 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has 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.Thyroid Cancer-approve if the patient has advanced or metastatic RET fusion positive disease, the disease is radioactive iodine-refractory (if radioactive iodine is appropriate) and the disease requires treatment with systemic therapy. Anaplastic thyroid cancer-approve if the patient has RET fusion-positive anaplastic thyroid carcinoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anaplastic thyroid carcinoma

REVCOVI

Products Affected

- Revcovi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, lab values, genetic tests
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

REVLIMID

Products Affected

- Revlimid

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 (except Kaposi's Sarcoma, Castleman's Disease, CNS Lymphoma)
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Follicular lymphoma-approve if the patient is using Revlimid in combination with rituximab or has tried at least on prior therapy. MCL-approve -if the patient is using revlimid in combination with rituximab or has tried at least two other therapies or therapeutic regimens. MZL-approve if the patient is using revlimid in combination with rituximab or has tried at least one other therapy or therapeutic regimen. Multiple myeloma-approve. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). B-cell-lymphoma (other)-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia and the pt has serum erythropoietin levels greater than or equal to 500 mU/mL or according to the prescriber the patient has anemia, has serum erythropoietin levels less than 500 mU/mL and patient has experienced no response or loss of response to erythropoietic stimulating agents. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve if the pt has tried at least one other therapy or regimen. CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease. Hodgkin lymphoma, classical-approve if the patient has tried at least one other therapy or therapeutic

PA Criteria	Criteria Details
	regimen. Castleman's disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease. Systemic light chain amyloidosis-approve if Revlimid is used in combination with dexamethasone.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical), Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma, Central nervous system Lymphoma,Kaposi's sarcoma.

REYVOW

Products Affected

- Reyvow 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	Approve if the patient has tried Nurtec or Ubrelvy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

REZUROCK

Products Affected

- Rezurock

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Graft-versus-host disease-approve if the patient has chronic graft-versus-host disease and has tried at least two conventional systemic treatments (e.g., ibrutinib, cyclosporine) for chronic graft-versus-host disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

RIABNI

Products Affected

- Riabni

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	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Patients are required to try Ruxience prior to approval of Riabni unless the patient has already been started on or has previously received Riabni.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

RILUZOLE

Products Affected

- Exservan
- Rilutek
- riluzole
- Tiglutik

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

RINVOQ

Products Affected

- Rinvoq

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic DMARD. Concurrent use with other potent immunosuppressants.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	18 years and older
Prescriber Restrictions	RA, prescribed by or in consultation with a rheumatologist.
Coverage Duration	Authorization will be for 3 months initial, 1 year cont.
Other Criteria	RA initial-approve if the 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). Continuation Therapy - Patient must have responded, as determined by the prescriber
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

RITUXAN

Products Affected

- Rituxan
- Rituxan Hycela

PA Criteria	Criteria Details
Exclusion Criteria	Rituximab will not be used concurrently with another biologic or with a targeted synthetic DMARD (RA diagnosis)-initial therapy
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	RA-prescribed by or in consultation with a rheumatologist (initial therapy)
Coverage Duration	RA-1 month, all others-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. RA (initial course), approve if patient has tried one conventional synthetic DMARD for at least 3 months. Note-if the patient has already had a 3-month trial of at least one biologic, these patients are not required to step back and try a conventional synthetic DMARD. Continuation-approve if 16 weeks or more will elapse between treatment courses and if the patient has already received two or more courses of therapy, the patient has responded to therapy as determined by the prescriber. Patients are required to try Ruxience prior to approval of Rituxan unless the patient has already been started on or has previously received Rituxan, if the patient has a diagnosis of RA, Pemphigus vulgaris or if the patient has a diagnosis of granulomatosis with polyangitis and is greater than or equal to 2 years of age but less than 18.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ROZLYTREK

Products Affected

- Rozlytrek oral capsule 100 mg, 200 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Solid Tumors-12 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
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

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 3years
Other Criteria	Ovarian, Fallopian Tube or Primary Peritoneal Cancer-treatment - Approve if the patient meets the following criteria (i and ii): i.The patient has a BRCA-mutation (germline or somatic) as confirmed by an approved test, AND ii.The patient has progressed on two or more prior lines of chemotherapy. Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-Approve if the patient is in complete or partial response after at least two 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

RUFINAMIDE

Products Affected

- Banzel
- rufinamide

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Patients 1 years of age or older
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, Some Medically-accepted Indications.
Off-Label Uses	Treatment-Refractory Seizures/Epilepsy

RUXIENCE

Products Affected

- Ruxience

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	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

RUZURGI

Products Affected

- Ruzurgi

PA Criteria	Criteria Details
Exclusion Criteria	History of seizures (initial therapy)
Required Medical Information	Diagnosis, seizure history, lab and test results
Age Restrictions	Patients between the ages of 6 years old and less than 17 years old (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 Ruzurgi, according to the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

RYBREVANT

Products Affected

- Rybrevant

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Non-Small Cell Lung Cancer (NSCLC) - approve if the has epidermal growth factor receptor exon 20 insertion mutations, as detected by an approved test AND has progressed on or following treatment with platinum-based chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	3 years
Other Criteria	AML (for PDP enrollees) -approve if the patient is FLT3-mutation positive as detected by an approved test. AML (for MAPD enrollees)-approve if the patient is FLT3-mutation positive as detected by an approved test AND the patient is receiving Rydapt in one of the following settings (i, ii, iii, or iv)-i. Induction therapy in combination with cytarabine and daunorubicin OR ii. After standard-dose cytarabine induction/reinduction, along with cytarabine and daunorubicin OR iii. Post remission or consolidation therapy in combination with cytarabine OR iv. Maintenance therapy. Myeloid or lymphoid Neoplasms with eosinophilia-approve if the patient has an FGFR1 rearrangement or has an FLT3 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid or lymphoid Neoplasms with eosinophilia

RYLAZE

Products Affected

- Rylaze

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
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Acute lymphoblastic leukemia/lymphoblastic lymphoma - approve if the patient has a systemic allergic reaction or anaphylaxis to a pegylated asparaginase product.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

SANDOSTATIN LAR

Products Affected

- Sandostatin LAR Depot intramuscular suspension,extended rel recon

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

SAPHNELO

Products Affected

- Saphnelo

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist (initial and continuation)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	Systemic lupus erythematosus, initial-approve if the patient has autoantibody-positive SLE, defined as positive for at least one of the following: antinuclear antibodies (ANA), anti-double-stranded DNA (anti-dsDNA) antibodies, anti-Smith (anti-Sm) antibodies AND if the medication is being used concurrently with at least one other standard therapy (e.g., hydroxychloroquine, prednisone) OR the patient is determined to be intolerant to standard therapy due to a significant toxicity. Systemic lupus erythematosus, continuation-approve if the medication is being used concurrently with at least one other standard therapy (e.g., hydroxychloroquine, prednisone) OR the patient is determined to be intolerant to standard therapy due to a significant toxicity and if the patient has responded to Saphnelo.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

SAPROPTERIN

Products Affected

- Kuvan
- sapropterin

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Palynziq (continuation only)
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 - approve if the patient has had a clinical response (e.g., cognitive and/or behavioral improvements) as determined by the prescribing physician OR patient had a 20 percent or greater reduction in blood Phe concentration from baseline OR treatment with sapropterin has resulted in an increase in dietary phenylalanine tolerance.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

SARCLISA

Products Affected

- Sarclisa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Multiple myeloma-approve if the requested medication will be used in combination with Pomalyst and dexamethasone and the patient has tried at least TWO prior regimens for multiple myeloma and a proteasome inhibitor was a component of at least one previous regimen and Revlimid was a component of at least one previous regimen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

SAVAYSA

Products Affected

- Savaysa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior medication history
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Atrial fib/flutter/DVT/PE treatment-1 year
Other Criteria	Atrial Fibrillation (or Atrial Flutter). Approve if the patient meets both of the following criteria (A and B): A) The patient has an estimated creatinine clearance (CrCl) less than or equal to 95 mL/min AND B) The patient has tried Eliquis or Xarelto. Deep Vein Thrombosis or Pulmonary Embolism, Treatment. Approve if the patient meets one of the following-patient has tried Eliquis or Xarelto OR patient is currently receiving Savaysa for this condition.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

SENSIPAR

Products Affected

- cinacalcet
- Sensipar

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Hypercalcemia d/t parathyroid CA-prescr/consult w/onco or endo.Hypercalcemia w/primary hyperparathyroidism/Secondary Hyperparathyroidism-prescr/consult w/nephro or endo. Hyperparathyroidism in post-renal transplant-prescr/consult w/transplant physician/nephro/endo.
Coverage Duration	12 months
Other Criteria	Hypercalcemia due to parathyroid carcinoma-approve. Hypercalcemia in patients with primary hyperparathyroidism-approve if the patient has failed or is unable to undergo a parathyroidectomy due to a contraindication. Secondary Hyperparathyroidism-approve if the patient has chronic kidney disease and is on dialysis AND the baseline (prior to starting cinacalcet therapy) intact parathyroid hormone (iPTH) level is at least two times the upper limit of normal as defined by the laboratory reference value measured on two separate occasions. Hyperparathyroidism in Post-Renal Transplant Patients-approve if the baseline (prior to starting cinacalcet therapy) calcium and intact parathyroid hormone (iPTH) levels are above the normal range, as defined by the laboratory reference values.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	hyperparathyroidism in post-renal transplant patients

SIGNIFOR

Products Affected

- Signifor
- Signifor LAR

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/synd-Initial-4 mo, Cont-1 yr.Pt awaiting surgery/response after radiotherapy-4 mo
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

SILIQ

Products Affected

- Siliq

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Previous medication use
Age Restrictions	18 years of age and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist (initial therapy)
Coverage Duration	Initial therapy - 3 months, Continuation therapy - 1 year
Other Criteria	Initial therapy-Plaque Psoriasis-Approve if the patient has tried TWO of the following drugs in the past: Enbrel, Humira, Skyrizi, Stelara SC, Otezla, or Taltz. Continuation tx - approve if the pt had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

SIMPONI

Products Affected

- Simponi subcutaneous pen injector 100 mg/mL, 50 mg/0.5 mL
- Simponi subcutaneous syringe 100 mg/mL, 50 mg/0.5 mL

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	UC-18 years and older (initial therapy)
Prescriber Restrictions	All dx-initial only-RA/Ankylosing spondylitis, prescribed by or in consultation with a rheumatologist. Psoriatic arthritis, prescribed by or in consultation with a rheumatologist or dermatologist. UC-prescribed by or in consultation with a gastroenterologist
Coverage Duration	3 mos initial, 1 year cont
Other Criteria	AS, initial -approve if the patient has tried TWO of the following drugs in the past: Enbrel, Humira, Taltz. PsA, initial-approve if the patient has tried TWO of the following drugs in the past: Enbrel, Humira, Taltz, Stelara, Otezla, Orencia, Xeljanz/XR. RA, initial- approve if the patient has tried two of the following drugs in the past: Enbrel, Humira, Orencia, Rinvoq or Xeljanz/XR. Ulcerative colitis, initial - approve if the patient has had a trial with Humira. Continuation tx - approve if the pt had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

SIMPONI ARIA

Products Affected

- Simponi ARIA

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	N/A
Prescriber Restrictions	RA, AS/JIA/JRA - Prescribed by or in consultation with a rheumatologist (initial therapy). PsA - Prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy).
Coverage Duration	3 mos initial, cont-1 year
Other Criteria	RA - Approve if the patient has tried TWO of the following: Enbrel, Humira, Orencia, or Xeljanz/XR. (Note: if the patient has not tried TWO of these drugs listed, a previous trial with Cimzia, infliximab, Actemra, Kevzara, Kineret or Rituxan can count toward meeting the try TWO requirement.) PsA - Approve if the patient has tried TWO of the following: Enbrel, Humira, Taltz, Stelara, Otezla, Orencia, Xeljanz/XR. (Note: if the patient has not tried TWO of these drugs listed, a previous trial with Cimzia, Cosentyx or infliximab can count toward meeting the try TWO requirement.) AS-Approve if the patient has tried TWO of the following: Enbrel, Humira, Taltz (Note: if the patient has not tried TWO of these drugs listed, a previous trial with Cimzia, Cosentyx or infliximab can count toward meeting the try TWO requirement.) 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 if the patient has tried one other medication for this condition OR b) Patient has aggressive disease, as determined by the prescriber. Cont tx - must have a response to therapy as according to prescriber
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

SIRTURO

Products Affected

- Sirturo

PA Criteria	Criteria Details
Exclusion Criteria	Patients weighing less than 15 kg
Required Medical Information	Diagnosis, concomitant therapy
Age Restrictions	Patients 5 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with an infectious diseases specialist
Coverage Duration	9 months
Other Criteria	Tuberculosis, Pulmonary Multidrug-resistant or extensively drug resistant-prescribed as part of a combination regimen with other anti-tuberculosis agents
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

SKYRIZI

Products Affected

- Skyrizi subcutaneous pen injector
- Skyrizi subcutaneous syringe 150 mg/mL
- Skyrizi subcutaneous syringe kit

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)
Coverage Duration	3 mos initial, 1 year cont
Other Criteria	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], 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], Taltz [ixekizumab 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

SOFOSBUVIR/VELPATASVIR

Products Affected

- sofosbuvir-velpatasvir

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin.
Required Medical Information	Genotype, prescriber specialty, other medications tried or used in combination with requested medication
Age Restrictions	3 years or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied according to AASLD guidelines. And, patients with genotype 1, 4, 5 and 6 must have a trial with Harvoni, Vosevi or Epclusa prior to approval of sofosbuvir-velpatasvir, unless Harvoni, Vosevi and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Genotype 2 and 3 must have an Epclusa or Vosevi trial prior to approval of sofosbuvir-velpatasvir, unless Epclusa and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance

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

SOLIRIS

Products Affected

- Soliris

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with a rituximab product, Enspryng or Uplizna
Required Medical Information	Diagnosis, previous therapies tried, test results
Age Restrictions	gMG and PNH-18 years and older (initial therapy) neuromyelitis optica-18 years and older
Prescriber Restrictions	aHUS-prescribed by or in consultation with a nephrologist (initial therapy), gMG-prescribed by or in consultation with a neurologist (initial therapy), neuromyelitis optica-prescribed by or in consultation with a neurologist, PNH-prescribed by or in consultation with a hematologist (initial therapy)
Coverage Duration	aHUS, neuromyelitis-1 year, gMG/PNH-initial 6 months, cont-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Atypical Hemolytic Uremic Syndrome (aHUS)-Approve if the patient does not have Shiga toxin E. coli related hemolytic uremic syndrome. Generalized Myasthenia Gravis (gMG)-Initial therapy-approve if the patient meets the following criteria (A, B, and C):A) Patient has confirmed anti-acetylcholine receptor (AchR) antibody positive generalized Myasthenia Gravis (gMG) AND B) Patient is currently receiving or has tried and has contraindications, intolerance, or failed pyridostigmine AND C) Patient has evidence of unresolved symptoms of generalized Myasthenia Gravis (gMG), such as difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility).Continuation-approve if the patient is continuing to derive benefit (e.g., reductions in exacerbations of myasthenia gravis, improvements in speech, swallowing, mobility, and respiratory function) from Soliris, according to the prescribing physician. Paroxysmal Nocturnal Hemoglobinuria (PNH)-Initial therapy-Approve if diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at

PA Criteria	Criteria Details
	least two cell lineages. Continuation-approve if the patient is continuing to derive benefit (e.g., stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis) from Soliris, according to the prescribing physician. Neuromyelitis Optica Spectrum disorder initial-approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and the patient has a history of at least 1 relapse in the last 12 m months or two relapses in the last 2 years. Continuation-approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and according to the prescriber, patient has had clinical benefit from the use of Soliris.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

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

SOVALDI

Products Affected

- Sovaldi oral pellets in packet 150 mg, 200 mg
- Sovaldi oral tablet 200 mg, 400 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Genotype 1 and 4 -18 years or older, Genotype 2 and 3-3 years or older
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. And, patients with genotype 1 and 4 must have a trial with Harvoni, Vosevi or Epclusa prior to approval of Sovaldi, unless Harvoni, Vosevi and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Patients with Genotype 2 and 3 must have a trial of Epclusa or Vosevi prior to approval of Sovaldi, unless Epclusa and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance

SPRYCEL

Products Affected

- Sprycel 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 for which Sprycel is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
Age Restrictions	GIST-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For CML, new patient must have Ph-positive CML for approval of Sprycel. For ALL, new patient must have Ph-positive ALL for approval of Sprycel. GIST - approve if the patient has tried at least two other therapies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	GIST, chondrosarcoma, chordoma

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 only). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy only). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy only).
Coverage Duration	PP/PsA Init-3mo,CD/UC load-approve 1 dose IV,CD/UC post IV load-SC 3 mo,cont tx-SC 1 yr
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). 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 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

PA Criteria	Criteria Details
	therapy for CD. 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

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 3 years.
Other Criteria	For GIST, patient must have previously been treated with imatinib (Gleevec) and sunitinib (Sutent). For HCC, patient must have previously been treated with at least one tyrosine kinase inhibitor (e.g., Nexavar, Lenvima). Soft tissue sarcoma-approve if the patient has non-adipocytic extremity/superficial trunk, head/neck or retroperitoneal/intra-abdominal sarcoma OR pleomorphic rhabdomyosarcoma. Osteosarcoma-approve if the patient has relapsed/refractory or metastatic disease and the requested medication is being used as subsequent therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Soft tissue Sarcoma, Osteosarcoma

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

SUCRAID

Products Affected

- Sucraid

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, 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

SUNOSI

Products Affected

- Sunosi

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	Excessive sleepiness associated with Obstructive Sleep Apnea-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

SUTENT

Products Affected

- sunitinib
- Sutent

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 3 years.
Other Criteria	Gastrointestinal stromal tumors (GIST), approve if the patient has tried imatinib (Gleevec). Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried chemotherapy or radiation therapy. 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, Some Medically-accepted Indications.
Off-Label Uses	Chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), differentiated (ie, papillary, follicular, and Hurthle) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma.

SYMDEKO

Products Affected

- Symdeko

PA Criteria	Criteria Details
Exclusion Criteria	Patients with unknown CFTR gene mutations, Combination therapy with Orkambi, Kalydeco or Trikafta
Required Medical Information	Diagnosis, specific CFTR gene mutations
Age Restrictions	Six years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	3 years
Other Criteria	CF - must be homozygous for the F508del mutation or have 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

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 yea
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

SYNERCID

Products Affected

- Synercid

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	Skin and Skin Structure Infections, Complicated-approve if the patient meets the following criteria-patient has an infection that is proven or strongly suspected to be caused by Staphylococcus aureus (methicillin-susceptible) or Streptococcus pyogenes
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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 3 years.
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

TADALAFIL

Products Affected

- Cialis oral tablet 2.5 mg, 5 mg
- tadalafil oral tablet 2.5 mg, 5 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Indication for which tadalafil is being prescribed.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 mos.
Other Criteria	Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed as once daily dosing, to treat the signs and symptoms of BPH and not for the treatment of erectile dysfunction (ED).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TAFAMIDIS

Products Affected

- Vyndamax
- Vyndaqel

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
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

TAFINLAR

Products Affected

- Tafinlar

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 3 years.
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. Thyroid Cancer, differentiated (i.e., papillary, follicular, or Hurthle cell) AND the patient has disease that is refractory to radioactive iodine therapy AND the patient has BRAF-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Differentiated Thyroid Cancer

TAGRISSO

Products Affected

- Tagrisso

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	NSCLC - prior therapies and EGFR T790M mutation or EGFR exon 19 deletion or exon 21 (L858R) substitution
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	NSCLC - EGFR mutation positive-must meet one of the following-metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC as detected by an approved test AND has progressed on one of the EGFR tyrosine kinase inhibitors (e.g., Tarceva, Iressa, Vizimpro or Gilotrif) therapy or metastatic Non-Small Cell Lung Cancer (NSCLC) who have EGFR exon 19 deletion or exon 21 (L858R) mutation as detected by an approved test or if the medication is used as adjuvant therapy after tumor resection and the tumor is positive for EGFR exon 19 deletions or exon 21 L858R mutations as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TAKHZYRO

Products Affected

- Takhzyro

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other HAE Prophylactic Therapies (e.g., Cinryze, Haegarda)
Required Medical Information	Diagnosis, lab values
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	1 year
Other Criteria	Prophylaxis, initial therapy-approve if the patient meets all of the following criteria: 1) patient has HAE due to C1 Inhibitor (C1-INH) deficiency (Type I or II), AND 2) patient has low levels of functional C1-INH protein (less than 60% of normal) at baseline, as defined by the laboratory reference values, AND 3) patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Prophylaxis, continuation therapy-approve if the patient meets all of the following criteria: 1) patient is currently receiving Takhzyro for HAE type I or II, AND 2) according to the prescribing physician, the patient has had a favorable clinical response to therapy (e.g., decrease in number of HAE acute attack frequency, decrease in HAE attack severity, decrease in duration of HAE attacks).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TALTZ

Products Affected

- Taltz Autoinjector
- Taltz Autoinjector (2 Pack)
- Taltz Autoinjector (3 Pack)
- Taltz Syringe

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	PP-6 years and older (initial therapy), all other dx-18 years of age and older (initial therapy)
Prescriber Restrictions	All dx initial therapy only-PP-Prescribed by or in consultation with a dermatologist. PsA prescribed by or in consultation with a rheumatologist or a dermatologist. AS/spondylo-prescribed by or in consultation with a rheum.
Coverage Duration	Initial authorization will be for 3 months, 1 year continuation.
Other Criteria	Initial Therapy - Plaque Psoriasis-approve if the patient has tried 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 prescribing physician. 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. PsA-Approve. AS initial-approve. Non-Radiographic Axial Spondyloarthritis-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory or sacroiliitis reported on magnetic resonance imaging. Continuation Therapy - approve if the patient has responded, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TALZENNA

Products Affected

- Talzenna oral capsule 0.25 mg, 1 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRCA mutation status, HER2 status
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Locally-advanced or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive AND human epidermal growth factor receptor 2 (HER2) negative disease
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TARGRETIN TOPICAL

Products Affected

- Targretin

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	3 years
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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 and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For indication of gastrointestinal stromal tumor (GIST) and ALL, prior therapies tried.
Age Restrictions	ALL/GIST-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For CML, new patient must have Ph-positive CML for approval of Tasigna. For GIST, patient must have tried TWO or more therapies. For ALL, Approve if the patient has tried one other tyrosine kinase inhibitor that is used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST).

TAVALISSE

Products Affected

- Tavalisse

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies or surgeries
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by, or in consultation with a hematologist (initial therapy)
Coverage Duration	Initial-3 months, cont-1 year
Other Criteria	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 has tried one other therapy or the patient has undergone splenectomy. 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

TAZAROTENE

Products Affected

- Arazlo
- Fabior
- tazarotene topical cream
- tazarotene topical foam
- Tazorac

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

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	3 years
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

TEGSEDI

Products Affected

- Tegsedi

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Onpattro or a Tafamidis product
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.
Coverage Duration	1 year
Other Criteria	Approve if the patient has a documented transthyretin (TTR) mutation verified by genetic testing and the patient has symptomatic polyneuropathy (e.g., reduced motor strength/coordination, impaired sensation [e.g., pain, temperature, vibration, touch]).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TEPEZZA

Products Affected

- Tepezza

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist, endocrinologist, or a physician who specializes in thyroid eye disease.
Coverage Duration	6 months
Other Criteria	Thyroid Eye Disease-approve if according to the prescriber, the patient has been assessed as having active disease of at least moderate severity based on signs and symptoms (e.g., the degree of inflammation, degree of proptosis, presentation of diplopia, etc.) and the patient is not receiving re-treatment of eye(s) previously treated with Tepezza.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	3 years
Other Criteria	NSCLC-approve if the patient has metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping alterations.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TERIPARATIDE

Products Affected

- Forteo subcutaneous pen injector 20 mcg/dose (620mcg/2.48mL)
- teriparatide

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 CKD or has had an osteoporotic fracture or fragility fracture. If the request is for brand name Forteo, patients must have a trial of teriparatide first.

PA Criteria	Criteria Details
	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

TETRABENAZINE

Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg
- Xenazine 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, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist.
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. If the brand is requested the patient must have tried and cannot take generic tetrabenazine tablets as identified by the prescribing physician.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.

THALOMID

Products Affected

- Thalomid

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	MM, myelofibrosis-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Erythem Nodosum Leprosum-approve. Multiple Myeloma-approve. Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried at least two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). Myelofibrosis, approve if according to the prescriber the patient has anemia and has serum erythropoietin levels greater than or equal to 500 mU/mL or if the patient has serum erythropoietin level less than 500 mU/mL and experienced no response or loss of response to erythropoietic stimulating agents. Prurigo nodularis, approve. Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried at least two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and has relapsed or refractory disease. Castleman's disease-approve if the patient has multicentric Castleman's disease, is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi's Sarcoma, Castleman's Disease.

TIBSOVO

Products Affected

- Tibsovo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, IDH1 Status
Age Restrictions	All diagnoses (except chondrosarcoma)-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
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 (chemotherapy requirement only applies to beneficiaries enrolled in an MA-PD plan). Chondrosarcoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chondrosarcoma

TOLCAPONE

Products Affected

- Tasmar oral tablet 100 mg
- tolcapone

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, current medications and medication history
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's disease-approve if the patient is currently receiving carbidopa/levodopa therapy and the patient has tried entacapone and according to the prescriber, experienced significant intolerance or inadequate efficacy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TOLSURA

Products Affected

- Tolsura

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, current medications and medication history
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	Blastomycosis-pulmonary or extrapulmonary, treatment, Histoplasmosis (Including Chronic Cavitary Pulmonary Disease and Disseminated, Non-Meningeal)-treatment, Aspergillosis-pulmonary or extrapulmonary, treatment-approve if the patient has tried itraconazole capsules or oral solution OR if the patient is currently receiving Tolsura for the diagnosis provided
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TOLVAPTAN

Products Affected

- Samsca
- tolvaptan oral tablet 15 mg
- tolvaptan oral tablet 30 mg

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	N/A
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

TOPICAL AGENTS FOR ATOPIC DERMATITIS

Products Affected

- Elidel
- Eucrisa
- pimecrolimus
- Protopic
- 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 Medically-accepted Indications.
Off-Label Uses	N/A

TOPICAL ALPHA-ADRENERGIC AGENTS FOR ROSACEA

Products Affected

- Mirvaso topical gel with pump
- Rhofade

PA Criteria	Criteria Details
Exclusion Criteria	Use in the treatment of erythema not caused by rosacea (ie, transient) [eg, during times of stress, sunburn, or skin irritation from cosmetic products].
Required Medical Information	N/A
Age Restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TOPICAL RETINOID PRODUCTS

Products Affected

- adapalene topical cream
- adapalene topical gel
- adapalene topical gel with pump
- adapalene topical solution
- adapalene topical swab
- adapalene-benzoyl peroxide
- Aklief
- Altreno
- Atralin
- Avita topical cream
- Avita topical gel
- clindamycin-tretinoin
- Differin topical cream
- Differin topical gel with pump
- Differin topical lotion
- Epiduo Forte
- Epiduo topical gel with pump
- Retin-A
- Retin-A Micro
- tretinoin microspheres
- tretinoin topical
- Veltin
- Ziana

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

TOPIRAMATE/ZONISAMIDE

Products Affected

- Qudexy XR
- Topamax
- topiramate
- Trokendi XR
- Zonegran oral capsule 100 mg, 25 mg
- zonisamide

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for weight loss or smoking cessation.
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 Medically-accepted Indications.
Off-Label Uses	N/A

TRANSDERMAL FENTANYL

Products Affected

- fentanyl

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 optimized 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

TRANSMUCOSAL FENTANYL DRUGS

Products Affected

- Actiq
- fentanyl citrate buccal lozenge on a handle
- fentanyl citrate buccal tablet, effervescent
- Fentora
- Lazanda nasal spray,non-aerosol 100 mcg/spray, 400 mcg/spray
- Subsys

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate). Clinical criteria incorporated into the quantity limit edits for all transmucosal fentanyl drugs require confirmation that the indication is breakthrough cancer pain (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TREMFYA

Products Affected

- Tremfya

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	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 dermatologist or rheumatologist (initial therapy).
Coverage Duration	Initial therapy - 3 months, Continuation therapy - 1 year
Other Criteria	PP-Initial Therapy - Approve if the patient has tried TWO of the following: Enbrel, Humira, Skyrizi, Stelara SC, Otezla, or Taltz. PsA-Approve if the patient has tried TWO of the following: Enbrel, Humira, Taltz, Stelara, Otezla, Orencia or Xeljanz/XR (Please note-a trial of Cimzia, Simponi and Cosentyx would also count towards the try TWO requirement). Continuation Therapy - Patient must have responded, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TRIENTINE

Products Affected

- Syprine
- trientine

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medication history, 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 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TRIKAFTA

Products Affected

- Trikafta

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	Six years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	3 years
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

TRODELVY

Products Affected

- Trodelvy

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast Cancer-approve if the patient has metastatic triple-negative breast cancer and has been previously treated with at least two systemic therapy regimens for metastatic disease. Urothelial Cancer-approve if the patient has locally advanced or metastatic urothelial cancer AND has tried at least one systemic chemotherapy AND has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TRUSELTIQ

Products Affected

- Truseltiq oral capsule 100 mg/day (100 mg x 1), 125 mg/day(100 mg x1-25mg x1), 50 mg/day (25 mg x 2), 75 mg/day (25 mg x 3)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease, has fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test and Truseltiq will be used as subsequent therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TRUXIMA

Products Affected

- Truxima

PA Criteria	Criteria Details
Exclusion Criteria	Rituximab will not be used concurrently with another biologic or with a targeted synthetic DMARD (RA diagnosis)-initial therapy
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	RA-prescribed by or in consultation with a rheumatologist (initial therapy)
Coverage Duration	RA-1 month, all others-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. RA-initial therapy-approve if the patient has tried ONE conventional synthetic disease-modifying Antirheumatic drug (DMARD) for at least 3 months. Note-if the patient has already had a 3-month trial of at least one biologic, these patients are not required to step back and try a conventional synthetic DMARD. Continuation-approve if 16 weeks or more will elapse between treatment courses and if the patient has already received two or more courses of therapy, the patient has responded to therapy as determined by the prescriber. Patients are required to try Ruxience prior to approval of Truxima unless the patient has already been started on or has previously received Truxima, or if the patient has a diagnosis of Rheumatoid arthritis (RA).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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 3 years.
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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TURALIO

Products Affected

- Turalio

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
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

TYMLOS

Products Affected

- Tymlos

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications for osteoporosis
Required Medical Information	Previous medications tried, renal function
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Auth will be for 2 yrs of total therapy between Tymlos and teriparatide over a patient's lifetime.
Other Criteria	Treatment of PMO, approve if the patient meets ONE of the following criteria: patient has tried one oral bisphosphonate or cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or patient cannot remain in an upright position post oral bisphosphonate administration or patient 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 patient has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR patient has severe renal impairment or CKD, OR patient has had an osteoporotic fracture or fragility fracture. Patients must have a trial of teriparatide prior to approval of Tymlos.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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-3 mo. CD, cont therapy-1 year.
Other Criteria	Adults with a relapsing form of MS. Patient has had an inadequate response to, or is unable to tolerate, one disease modifying agent used for MS (eg, interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron, Extavia), glatiramer acetate (Copaxone/Glatopa), Plegridy, fingolimod (Gilenya), Tecfidera, Lemtrada, daclizumab (Zinbryta), Aubagio) OR the patient has highly active or aggressive disease according to the prescribing physician by meeting one of the following-the patient has demonstrated rapidly-advancing deterioration(s) in physical functioning (e.g., loss of mobility/or lower levels of ambulation, severe changes in strength or coordination OR disabling relapse(s) with suboptimal response to systemic corticosteroids OR magnetic resonance imaging (MRI) findings suggest highly-active or aggressive multiple sclerosis (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium lesions) OR manifestation of multiple sclerosis-related cognitive impairment. 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 each: adalimumab, certolizumab pegol, infliximab, vedolizumab, ustekinzumab, OR pt has had an inadequate response or was intolerant to these agents. CD, continuation

PA Criteria	Criteria Details
	therapy. Patient has had a response to Tysabri, as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

UBRELVY

Products Affected

- Ubrelvy

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	Migraine, Acute treatment-approve
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

UDENYCA

Products Affected

- Udenyca

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. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC-1 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% 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% 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. Patients are required to try Ziextenzo and Nyvepria prior to approval of Udenyca unless patient has initiated therapy with Udenyca and requires additional medication to complete the current cycle of chemotherapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy

UKONIQ

Products Affected

- Ukoniq

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	1 year
Other Criteria	Follicular Lymphoma-approve if the patient has received at least three prior lines of systemic therapy. Marginal Zone Lymphoma-approve if the patient has received at least one prior anti-CD20-based regimen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ULTOMIRIS

Products Affected

- Ultomiris intravenous solution 100 mg/mL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, test results
Age Restrictions	PNH-18 years and older
Prescriber Restrictions	PNH-Prescribed by or in consultation with a hematologist, aHUS-prescribed by or in consultation with a nephrologist
Coverage Duration	PNH-Initial 6 months, cont-1 year, aHUS-1 year
Other Criteria	PNH-Initial therapy-Approve if diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least two cell lineages.Continuation-approve if the patient is continuing to derive benefit (e.g., stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis) from Ultomiris, according to the prescribing physician. aHUS-approve if the patient does not have Shiga toxin E. coli related hemolytic uremic syndrome.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

UPLIZNA

Products Affected

- Uplizna

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with a rituximab product, Enspryng or Soliris
Required Medical Information	Diagnosis
Age Restrictions	NMOSD-18 years and older (initial and continuation)
Prescriber Restrictions	NMOSD-prescribed by or in consultation with a neurologist (initial and continuation)
Coverage Duration	NMOSD-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Neuromyelitis Optica Spectrum Disorder initial-approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and patient has a history of at least 1 relapse in the last 12 months or two relapses in the last 2 years. Continuation-approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and according to the prescriber, patient has had clinical benefit from the use of Uplizna.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

UPTRAVI

Products Affected

- Uptravi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Confirmation of right heart catheterization, medication history.
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 Uptravi 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

VALCHLOR

Products Affected

- Valchlor

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Cutaneous Lymphomas (Note-includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders)-approve. Adult T-Cell Leukemia/Lymphoma-approve if the patient has chronic/smoldering subtype of adult T-cell leukemia/lymphoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Adults with T-cell leukemia/lymphoma

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

VANCOMYCIN

Products Affected

- Vancocin oral capsule 125 mg, 250 mg
- vancomycin oral capsule 125 mg, 250 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	2 weeks
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	3 years
Other Criteria	CLL with or without 17p deletion - approve. SLL-approve. Mantle Cell Lymphoma-approve if the patient has tried one prior therapy. AML-approve if the patient is using Venclexta in combination with either azacitidine, decitabine, or cytarabine.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Mantle Cell Lymphoma

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	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Breast cancer - approve advanced 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 postmenopausal and Verzenio will be used in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Verzenio will be used in combination with anastrozole, exemestane, or letrozole 3. Patient is postmenopausal and meets the following conditions: Verzenio will be used in combination with fulvestrant. 4. patient is premenopausal or perimenopausal and meets the following conditions: The patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND Verzenio will be used in combination with fulvestrant 5. patient is postmenopausal, premenopausal/perimenopausal (patient is receiving ovarian suppression/ablation with GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or 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) and meets the following conditions: Verzenio will be used as monotherapy AND patient's breast cancer has progressed on at least one prior endocrine

PA Criteria	Criteria Details
	therapy (e.g., anastrozole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus everolimus, fulvestrant, everolimus plus fulvestrant or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol) AND patient has tried chemotherapy for metastatic breast cancer. 6. pt is a man who is receiving GnRH analog AND Verzenio with be used in combination with anastrozole, exemestane or letrozole 7. Patient is a man and Verzenio will be used in combination with fulvestrant
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Men with breast cancer

VIEKIRA

Products Affected

- Viekira Pak

PA Criteria	Criteria Details
Exclusion Criteria	Previous failure of Viekira/Viekira XR or Technivie in patients with minimal liver disease. Combination use with other direct acting antivirals, excluding ribavirin
Required Medical Information	Genotype 1, Cirrhosis status and genotype 1 subtype
Age Restrictions	18 years or older
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. And, patients with genotype 1 must have a trial with Harvoni, Vosevi or Epclusa prior to approval of Viekira, unless Harvoni, Vosevi and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance

VILTEPSO

Products Affected

- Viltepso

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 physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders
Coverage Duration	1 year
Other Criteria	DMD- patient has a confirmed mutation of the DMD gene that is amenable to exon 53 skipping
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

VISTOGARD

Products Affected

- Vistogard

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	Capecitabine or fluorouracil overdose-approve. Capecitabine or fluorouracil toxicity, severe or life threatening-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	3 years
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

VIZIMPRO

Products Affected

- Vizimpro

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, EGFR status, exon deletions or substitutions
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Metastatic-NSCLC-Epidermal Growth Factor Receptor (EGFR) mutation positive AND has epidermal growth factor receptor (EGFR) exon 19 deletion as detected by an approved test OR exon 21 (L858R) substitution mutations as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

VORICONAZOLE (ORAL)

Products Affected

- Vfend
- voriconazole

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Aspergillus-Prophy, systemic w/risk neutropenia-Prophy, systemic w/HIV-Prophy/Tx-6 mo, others-3 mo
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Aspergillus Infections - prophylaxis, oropharyngeal candidiasis (fluconazole-refractory) - treatment, candidia endophthalmitis - treatment, blastomycosis - treatment, fungal infections (systemic) in patients at risk of neutropenia - prophylaxis, fungal infections (systemic) in patients with human immunodeficiency virus (HIV) - prophylaxis or treatment.

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

VOTRIENT

Products Affected

- 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 3 years.
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. Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Uterine sarcoma, approve if the patient has recurrent, advanced or metastatic disease. Advanced Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or stage IV disease. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease. GIST - approve if the patient has tried TWO of the following: Gleevec, Sutent, or Stivarga. Medullary Thyroid Carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (ie, papillary, follicular, Hurthle cell) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma.

VPRIV

Products Affected

- VPRIV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic tests and lab 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	Gaucher Disease, Type 1-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting glucocerebrosidase gene mutation
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	Initial treatment-approve if the patient has tried generic dimethyl fumarate. Cont tx-approve if the patient has been established on Vumerity.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

VYEPTI

Products Affected

- Vyepti

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with Aimovig, Ajovy or Emgality
Required Medical Information	Diagnosis, prior therapies tried
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Approve if the patient has tried TWO of the following: Aimovig, Ajovy or Emgality.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

VYONDYS

Products Affected

- Vyondys-53

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 physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders
Coverage Duration	1 year
Other Criteria	DMD- patient has a confirmed mutation of the DMD gene that is amenable to exon 53 skipping
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

WAKIX

Products Affected

- Wakix

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	Excessive daytime sleepiness associated with Narcolepsy-Approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT) AND the patient has tried generic modafinil or generic armodafinil (Note: An exception to this requirement is allowed if the patient has previously tried brand Provigil or Nuvigil) OR patient has a history of misuse or abuse of controlled substances and a wakefulness-promoting agent that is not a controlled substance is necessary, per the prescriber. Cataplexy treatment in patients with narcolepsy-approve if the patient has been evaluated using polysomnography and a multiple sleep latency test (MSLT) and the diagnosis of narcolepsy has been confirmed.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	3 years
Other Criteria	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, and B)Patient 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

XALKORI

Products Affected

- Xalkori

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	ALK status, high level MET amplification status, MET Exon 14 skipping mutation, and ROS1. For soft tissue sarcoma IMT, ALK translocation.
Age Restrictions	Anaplastic large cell lymphoma-patients greater than or equal to 1 year of age and less than 21 years of age
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	NSCLC, must be ALK-positive as detected by an approved test, have high level MET amplification, have MET Exon 14 skipping mutation, or have ROS1 rearrangement if the patient has recurrent or metastatic 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, Some Medically-accepted Indications.
Off-Label Uses	Soft tissue sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation, NSCLC with high level MET amplification or MET Exon 14 skipping mutation.

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	N/A
Prescriber Restrictions	RA, JIA/JRA 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	PsA/RA/JIA/JRA-3 months initial, UC-16 weeks initial, All diagnoses-1 year cont.
Other Criteria	RA/PsA initial, approve Xeljanz/XR tablets if the 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). UC-Approve Xeljanz/XR tablets if the patient has tried at least ONE tumor necrosis factor inhibitor for ulcerative colitis. 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 ONE of the following: patient has tried one other medication (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID). A previous trial of a biologic also counts as a trial of one medication.) for this condition OR Patient has aggressive disease. Continuation Therapy - Patient must have responded, as determined by the prescriber.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A

XEOMIN

Products Affected

- Xeomin

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for cosmetic uses
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, Some Medically-accepted Indications.
Off-Label Uses	Spasticity

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

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

XOLAIR

Products Affected

- Xolair subcutaneous recon soln
- Xolair subcutaneous syringe 150 mg/mL, 75 mg/0.5 mL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with an Interleukin (IL) Antagonist Monoclonal Antibody
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
Coverage Duration	asthma/CIU-Initial tx 4 months, Polyps-initial-6 months, continued tx 12 months
Other Criteria	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 patient experienced one or more asthma exacerbation requiring

PA Criteria	Criteria Details
	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% 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	3 years
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. Lymphoid, Myeloid, or Mixed Lineage Neoplasms-approve if the patient has eosinophilia and the disease is FLT3-mutation positive as detected by an approved test.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Lymphoid, Myeloid, or Mixed Lineage Neoplasms

XPOVIO

Products Affected

- Xpovio

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	3 years
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 OR iii. 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 Darzalex (daratumumb infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Pomalyst (pomalidomide capsules). Note: Examples of regimens for multiple myeloma include bortezomib/Revlimid (lenalidomide capsules)/dexamethasone, Kyprolis (carfilzomib infusion)/Revlimid/dexamethasone, Darzalex (daratumumab injection)/bortezomib or Kyprolis/dexamethasone, or other regimens containing a proteasome inhibitor, immunomodulatory drug, and/or anti-CD38 monoclonal antibody. Diffuse large B-cell lymphoma-approve if the patient has been treated with at least two prior systemic therapies.
Indications	**Under CMS Review**
Off-Label Uses	N/A

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 3 years.
Other Criteria	Prostate cancer-castration-resistant (CRPC) [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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

XURIDEN

Products Affected

- Xuriden

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, lab results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic specialist, geneticist or physician specializing in the condition being treated
Coverage Duration	1 year
Other Criteria	Hereditary orotic aciduria (Orotic aciduria Type 1)-Approve if the patient has molecular genetic testing confirming mutation in the UMPS gene or clinical diagnosis supported by first degree family relative (i.e., parent or sibling) with hereditary orotic aciduria and urinary orotic acid level above the normal reference range for the reporting laboratory.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

XYREM

Products Affected

- Xyrem

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Medication history
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, dexmethylphenidate, dextroamphetamine), modafinil, or armodafinil 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

XYWAV

Products Affected

- Xywav

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Medication history
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, dexmethylphenidate, dextroamphetamine), modafinil, or armodafinil 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).For the diagnosis of EDS in patients with narcolepsy and cataplexy treatment in patients with narcolepsy patient must meet one of the following (i or ii): i. Patient has tried Xyrem and has experienced inadequate efficacy or significant intolerance OR ii. Patient has a concomitant diagnosis of heart failure, hypertension, or renal impairment. Idiopathic hypersomnia-approve if the diagnosis has been confirmed using polysomnography and a multiple sleep latency test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	3 years
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

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, MDS, ALL, 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, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
Coverage Duration	chemo/SCN/AML-6mo.HIV/AIDS-4mo.MDS-3mo.PBPC,Drug induce A/N,AA,ALL,BMT-3mo.Radi-1mo.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% 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% 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), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia

PA Criteria	Criteria Details
	[absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL). Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome).

ZEJULA

Products Affected

- Zejula

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	3 years
Other Criteria	Ovarian, fallopian tube, or primary peritoneal cancer, maintenance therapy - approve if the patient is in complete or partial response after platinum-based chemotherapy regimen. Ovarian, fallopian tube, or primary peritoneal cancer, treatment-approve per label if the patient has tried at least three prior chemotherapy regimens and has homologous recombination deficiency (HRD)-positive disease as confirmed by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ZELAPAR

Products Affected

- Zelapar

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medication history
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's Disease-approve if the patient is experiencing off episodes such as muscle stiffness, slow movements or difficulty starting movements, is currently receiving carbidopa/levodopa therapy and has tried oral selegiline tablets/capsules or rasagiline tablets and according to the prescriber had significant intolerance or has difficulty swallowing tablets/or capsules.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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 3 years.
Other Criteria	Melanoma, patient new to therapy must have BRAFV600 mutation for approval AND have unresectable, advanced or metastatic melanoma. HCL - must have tried at least one other systemic therapy for hairy cell leukemia. Thyroid Cancer-patient has disease that is refractory to radioactive iodine therapy. Erdheim-Chester disease, in patients with the BRAF V600 mutation-approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, Differentiated thyroid carcinoma (i.e., papillary, follicular, or Hurthle cell) with BRAF-positive disease

ZEPATIER

Products Affected

- Zepatier

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin or Sovaldi.
Required Medical Information	Genotype, prior medication therapy, concurrent medications, NS5A polymorphism status, prescriber specialty
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or 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. And, patients with genotype 1 and genotype 4 must have a trial with Harvoni, Vosevi or Epclusa prior to approval of Zepatier, unless Harvoni, Vosevi and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance

ZEPOSIA

Products Affected

- Zeposia
- Zeposia Starter Kit
- Zeposia Starter Pack

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. Ulcerative Colitis, initial-approve if the patient has tried Humira (a trial of Simponi SC or infliximab would also count) AND Stelara (a trial of Entyvio or Stelara IV would also count). Cont tx-approve if the patient has been established on Zeposia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ZEPZELCA

Products Affected

- Zepzelca

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
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Small cell lung cancer-approve if the patient has metastatic disease and has previously received platinum-based chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC-1 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% 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% 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, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy

ZOKINVY

Products Affected

- Zokinvy

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, test results
Age Restrictions	12 months and older
Prescriber Restrictions	Prescribed by or in consultation with a geneticist or pediatric cardiologist
Coverage Duration	1 year
Other Criteria	Hutchinson-Gilford Progeria Syndrome, approve if the patient meets (A and B): A) Patient has a body surface area greater than or equal to 0.39 m2 B) Genetic testing demonstrates a confirmed pathogenic mutation in the LMNA gene consistent with Hutchinson-Gilford Progeria Syndrome. Progeroid laminopathies, approve if the patient meets (A and B): A) Patient has a body surface area greater than or equal to 0.39 m2 B) Patient has Heterozygous LMNA mutation with progerin-like protein accumulation or Homozygous or compound heterozygous ZMPSTE24 mutations.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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	3 years
Other Criteria	Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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 3 years.
Other Criteria	CLL-approve if the patient has tried two prior therapies. Marginal Zone Lymphoma/Follicular Lymphoma/SLL - approve if the patient has tried two prior therapies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Marginal Zone Lymphoma

ZYKADIA

Products Affected

- Zykadia oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Must have metastatic NSCLC that is anaplastic lymphoma kinase (ALK)-positive as detected by an approved test or ROS1 Rearrangement. IMT - ALK Translocation status.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Soft Tissue Sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Patients with NSCLC with ROS1 Rearrangement- First-line therapy.

ZYNLONTA

Products Affected

- Zynlonta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse Large B-Cell Lymphoma- approve if the patient has tried at least two systemic regimens.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ZYTIGA

Products Affected

- abiraterone oral tablet 250 mg, 500 mg
- Zytiga 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 3 years.
Other Criteria	Prostate Cancer-Metastatic, Castration-Resistant (mCRPC) and Metastatic, Castration-Sensitive (mCSPC), high risk-Approve if abiraterone is being used in combination with prednisone and the medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog or the patient has had a bilateral orchiectomy. Prostate Cancer - Regional Risk Group - Approve if the patient meets all of the following criteria (A, B, and C): A)abiraterone is used in combination with prednisone AND B) Patient has regional lymph node metastases and no distant metastases AND C) Patient meets one of the following criteria (i or ii): i.abiraterone with prednisone is used in combination with gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron [leuprolide acetate for injection], Lupron Depot [leuprolide acetate for depot suspension], Trelstar [triptorelin pamoate for injectable suspension], Zoladex [goserelin acetate implant], Vantas [histrelin acetate subcutaneous implant], Firmagon, Orgovyx) OR ii. Patient has had an orchiectomy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Prostate Cancer-Regional Risk Group

PART B VERSUS PART D

Products Affected

- Abelcet
- Abraxane
- acetylcysteine
- Actimmune
- acyclovir sodium intravenous solution
- Adcetris
- Adriamycin intravenous recon soln 10 mg
- Adriamycin intravenous recon soln 50 mg
- Adriamycin intravenous solution
- Aggrastat Concentrate
- Aggrastat in sodium chloride
- albuterol sulfate inhalation solution for nebulization
- Alimta
- Aliqopa
- Alkeran
- Alkeran (as HCl)
- AmBisome
- Aminosyn II 15 %
- Aminosyn-PF 7 % (sulfite-free)
- amiodarone intravenous
- amphotericin B
- aprepitant
- arformoterol
- Arranon
- arsenic trioxide
- Arzerra
- Astagraf XL
- Atgam
- Avastin
- azacitidine
- Azasan
- azathioprine oral tablet 50 mg
- azathioprine sodium
- baclofen intrathecal
- Bavencio
- Beleodaq
- Bendeka
- Besponsa
- Bethkis
- BiCNU
- bleomycin
- Blincyto intravenous kit
- bortezomib
- Brovana
- budesonide inhalation suspension for nebulization 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL
- busulfan
- Busulfex
- Camptosar
- Cancidas
- carboplatin intravenous solution
- carmustine
- caspofungin
- CellCept
- CellCept Intravenous
- cidofovir
- cisplatin intravenous solution
- cladribine
- Clinimix 5%/D15W Sulfite Free
- Clinimix 4.25%/D10W Sulf Free
- Clinimix 4.25%/D5W Sulfit Free
- Clinimix 5%-D20W(sulfite-free)
- Clinimix 6%-D5W (sulfite-free)
- Clinimix 8%-D10W(sulfite-free)
- Clinimix 8%-D14W(sulfite-free)
- Clinimix E 2.75%/D5W Sulf Free
- Clinimix E 4.25%/D10W Sul Free
- Clinimix E 4.25%/D5W Sulf Free
- Clinimix E 5%/D15W Sulfit Free
- Clinimix E 5%/D20W Sulfit Free
- Clinimix E 8%-D10W sulfitefree
- Clinimix E 8%-D14W sulfitefree
- Clinisol SF 15 %
- Clinolipid
- clofarabine
- Clolar
- Cosmegen
- cromolyn inhalation
- Cutaquig
- Cuvitru
- cyclophosphamide intravenous recon soln
- cyclophosphamide intravenous solution
- cyclophosphamide oral capsule
- cyclophosphamide oral tablet

- cyclosporine intravenous
- cyclosporine modified
- cyclosporine oral capsule
- Cyramza
- cytarabine
- cytarabine (PF)
- CytoGam intravenous solution 50 mg/mL
- dacarbazine
- Dacogen
- dactinomycin
- Darzalex
- Darzalex Faspro
- daunorubicin intravenous solution
- decitabine
- deferoxamine
- Desferal injection recon soln 500 mg
- dexrazoxane HCl
- dobutamine in D5W intravenous parenteral solution 1,000 mg/250 mL (4,000 mcg/mL), 250 mg/250 mL (1 mg/mL), 500 mg/250 mL (2,000 mcg/mL)
- dobutamine intravenous solution 250 mg/20 mL (12.5 mg/mL)
- 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)
- dopamine in 5 % dextrose
- dopamine intravenous solution 200 mg/5 mL (40 mg/mL), 400 mg/10 mL (40 mg/mL)
- Doxil
- doxorubicin
- doxorubicin, peg-liposomal
- dronabinol
- Duopa
- Ellence
- Emend oral capsule 80 mg
- Emend oral capsule,dose pack
- Emend oral suspension for reconstitution
- Empliciti
- Engerix-B (PF)
- Engerix-B Pediatric (PF)
- Envarsus XR
- epirubicin intravenous solution
- epoprostenol
- epoprostenol (glycine)
- Erbitux
- Erwinase
- Etopophos
- etoposide intravenous
- everolimus (immunosuppressive)
- Evomela
- Faslodex
- Firmagon kit w diluent syringe
- Flolan
- floxuridine
- fludarabine
- fluorouracil intravenous
- Folotyn
- formoterol fumarate
- foscarnet
- fulvestrant
- Gablofen
- ganciclovir sodium
- Gazyva
- gemcitabine intravenous recon soln
- 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
- granisetron HCl oral
- Halaven
- Hepatamine 8%
- Herceptin Hylecta
- Herceptin intravenous recon soln 150 mg
- Herzuma
- Hizentra
- Hycamtin intravenous
- HyQvia
- Idamycin PFS
- idarubicin
- Ifex
- ifosfamide
- Imfinzi
- Imuran
- Infugem

- Infumorph P/F injection solution 10 mg/mL, 25 mg/mL
- Intralipid intravenous emulsion 20 %
- Intralipid intravenous emulsion 30 %
- Intron A injection
- ipratropium bromide inhalation
- ipratropium-albuterol
- irinotecan
- Istodax
- Ixempra
- Jevtana
- Kabiven
- Kanjinti
- Khapzory
- Kitabis Pak
- Kyprolis
- leucovorin calcium injection
- levalbuterol HCl
- levoleucovorin calcium intravenous recon soln 50 mg
- levoleucovorin calcium intravenous solution
- Lioresal
- Marinol
- Marqibo
- Medrol
- melphalan
- melphalan HCl
- mesna
- Mesnex intravenous
- methotrexate sodium
- methotrexate sodium (PF)
- methylprednisolone oral tablet
- Millipred oral tablet
- milrinone
- milrinone in 5 % dextrose
- mitomycin intravenous
- mitoxantrone
- Mozobil
- Mutamycin
- Mvasi
- mycophenolate mofetil
- mycophenolate mofetil (HCl)
- mycophenolate sodium
- Myfortic
- Mylotarg
- Nebupent
- Neoral
- Nexterone
- Nipent
- nitroglycerin in 5 % dextrose intravenous solution 100 mg/250 mL (400 mcg/mL), 25 mg/250 mL (100 mcg/mL), 50 mg/250 mL (200 mcg/mL)
- nitroglycerin intravenous
- Nulojix
- Nutrilipid
- Ogivri
- Omegaven
- Oncaspar
- ondansetron
- ondansetron HCl oral solution
- ondansetron HCl oral tablet 4 mg, 8 mg
- Onivyde
- Ontruzant
- Orapred ODT
- oxaliplatin
- paclitaxel
- Paraplatin
- pentamidine inhalation
- Perforomist
- Perikabiven
- Perjeta
- Plenamine
- Portrazza
- prednisolone sodium phosphate oral tablet,disintegrating
- Premasol 10 %
- Prialt
- Procalamine 3%
- Prograf
- Prosol 20 %
- Pulmicort inhalation suspension for nebulization 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL
- Pulmozyme
- Rapamune
- Recombivax HB (PF)
- romidepsin intravenous solution
- Sandimmune
- Simulect
- sirolimus

- SMOFlipid
- sodium nitroprusside
- Syndros
- Synribo
- tacrolimus oral
- Tecentriq
- Temodar intravenous
- temsirolimus
- thiotepa
- Thymoglobulin
- Tice BCG
- Tobi
- tobramycin in 0.225 % NaCl
- tobramycin inhalation
- Toposar
- topotecan intravenous recon soln
- topotecan intravenous solution 4 mg/4 mL (1 mg/mL)
- Torisel
- Travasol 10 %
- Trazimera
- Treanda
- Trelstar intramuscular suspension for reconstitution
- Trexall
- Trisenox
- TrophAmine 10 %
- Tyvaso
- Tyvaso Institutional Start Kit
- Tyvaso Refill Kit
- Tyvaso Starter Kit
- Unituxin
- valrubicin
- Valstar
- Varubi oral
- Vectibix
- Velcade
- Veletri
- Ventavis
- Vidaza
- vinblastine
- Vincasar PFS
- vincristine
- vinorelbine
- Vyxeos
- Xatmep
- Xembify
- Xgeva
- Xopenex
- Xopenex Concentrate
- Yervoy
- Yondelis
- Yupelri
- Zaltrap
- Zanosar
- Zirabev
- Zofran oral tablet 4 mg
- zoledronic acid intravenous solution
- zoledronic acid-mannitol-water intravenous piggyback 4 mg/100 mL
- zoledronic ac-mannitol-0.9NaCl
- Zortress
- Zuplenz

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.

Index

F

N

S

U

V