ACITRETIN

Products Affected

- *acitretin*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For initial therapy in the treatment of psoriasis: trial and failure, contraindication, or intolerance to methotrexate or cyclosporine is required. For continuation of therapy, approve if patient has already been started on Acitretin.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ACTIMMUNE

Products Affected

- ACTIMMUNE

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 Medically-accepted 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

ALOSETRON

Products Affected

- *alosetron*

PA Criteria	Criteria Details
Exclusion Criteria	Alosetron will not be approved for use in men, as safety and efficacy in men has not been established.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Alosetron is considered medically necessary for the treatment of severe IBS-D. At least one of the following must be present for diarrhea to be considered severe: frequent and severe abdominal pain or discomfort, frequent bowel urgency or fecal incontinence, and disability or restriction of daily activities due to IBS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ALPHA 1 PROTEINASE INHIBITORS

Products Affected

- PROLASTIN-C

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

AMBRISENTAN

Products Affected

- AMBRISENTAN

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 must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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 (INJECTABLE)

Products Affected

- *amikacin injection solution 1,000 mg/4 ml, 500 mg/2 ml*
- *ampicillin sodium*
- *ampicillin-sulbactam*
- *azithromycin intravenous*
- *aztreonam*
- BICILLIN L-A
- *cefepime intravenous*
- *cefotaxime injection recon soln 2 gram*
- *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*
- *clindamycin in 0.9 % sod chlor*
- *clindamycin in 5 % dextrose*
- *clindamycin phosphate injection*
- *clindamycin phosphate intravenous*
- *colistin (colistimethate na)*
- *doxy-100*
- ERYTHROCIN INTRAVENOUS RECON SOLN 500 MG
- *gentamicin in nacl (iso-osm) intravenous piggyback 100 mg/100 ml, 100 mg/50 ml, 120 mg/100 ml, 60 mg/50 ml, 80 mg/100 ml, 80 mg/50 ml*
- *gentamicin injection solution 40 mg/ml*
- *gentamicin sulfate (ped) (pf)*
- *levofloxacin in d5w*
- *levofloxacin intravenous*
- *lincomycin*
- *linezolid in dextrose 5%*
- *linezolid-0.9% sodium chloride*
- *metronidazole in nacl (iso-os)*
- *moxifloxacin-sod.ace,sul-water*
- *moxifloxacin-sod.chloride(iso)*
- *nafcillin in dextrose iso-osm*
- *nafcillin injection*
- *nafcillin intravenous recon soln 2 gram*
- NUZYRA INTRAVENOUS
- *oxacillin injection*
- *penicillin g potassium injection recon soln 20 million unit*
- *pfizerpen-g*
- SIVEXTRO INTRAVENOUS
- *streptomycin*
- *sulfamethoxazole-trimethoprim intravenous*
- *tazicef*
- TEFLARO
- *tigecycline*
- *tobramycin sulfate*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A

PA Criteria	Criteria Details
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

- *caspofungin*
- *fluconazole in nacl (iso-osm)*
- *voriconazole intravenous*

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

ANTIFUNGALS, POLYENE

Products Affected

- ABELCET
- AMBISOME
- *amphotericin b*
- *amphotericin b liposome*

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

ANTINEOPLASTICS, MONOCLONAL ANTIBODIES

Products Affected

- ABRAXANE
- ADCETRIS
- ALIMTA
- ALIQOPA
- BAVENCIO
- BESPONSA
- BLENREP
- *bortezomib injection*
- *bortezomib intravenous recon soln*
- CYRAMZA
- DANYELZA
- DARZALEX
- DARZALEX FASPRO
- ELZONRIS
- EMPLICITI
- ENHERTU
- EVOMELA
- GAZYVA
- HALAVEN
- IMFINZI
- JEMPERLI
- KADCYLA
- KANJINTI
- KEYTRUDA
- KIMMTRAK
- *lapatinib*
- LIBTAYO
- LUMOXITI
- MARGENZA
- MONJUVI
- MVASI
- MYLOTARG
- OGIVRI
- ONIVYDE
- OPDIVO
- OPDUALAG
- *paclitaxel protein-bound*
- PADCEV
- *pemetrexed disodium intravenous recon soln*
- PERJETA
- PHESGO
- POLIVY
- POTELIGEO
- RUXIENCE
- RYBREVANT
- SARCLISA
- TECENTRIQ
- *thiotepa*
- TIVDAK
- TRAZIMERA
- TRODELVY
- TRUXIMA
- UNITUXIN
- VECTIBIX
- VELCADE
- YERVOY
- YONDELIS
- ZEPZELCA
- ZIRABEV
- ZYNLONTA

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

PA Criteria	Criteria Details
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	B vs D coverage determination
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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, 3 years cont. DIRA-6 mos initial, 3 years 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

ATYPICAL ANTIPSYCHOTIC

Products Affected

- FANAPT
- LYBALVI
- *paliperidone*
- VRAYLAR

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	Approve if the patient has tried two of the following: olanzapine, quetiapine fumarate, risperidone, ziprasidone. Approve requests for paliperidone ER in Schizoaffective Disorder without the trial of other treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

BENLYSTA

Products Affected

- BENLYSTA INTRAVENOUS

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-3 years. 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

BESREMI

Products Affected

- BESREMI

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other interferon products
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or an oncologist
Coverage Duration	1 year
Other Criteria	Initial, patient has tried Pegasys unless patient has experienced treatment failure, intolerance, or therapy is contraindicated. For continuation of therapy, approve if patient has already been started on Besremi.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

BETASERON

Products Affected

- BETASERON SUBCUTANEOUS KIT

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple sclerosis
Required Medical Information	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 3 years.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

BEXAROTENE (ORAL)

Products Affected

- *bexarotene*

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

BOTOX

Products Affected

- BOTOX

PA Criteria	Criteria Details
Exclusion Criteria	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 prophylaxis in patients with chronic migraine if 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. Cervial Dystonia (spasmodic torticollis)-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 Prophylaxis in patients with Chronic migraine -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 other prophylactic pharmacologic therapies, each from a different pharmacologic class (e.g., beta-blocker, anticonvulsant, tricyclic antidepressant). Urinary incontinence associated with a neurological condition (e.g., spinal cord injury, multiple sclerosis) approve after a trial with at least one other pharmacologic therapy (e.g., anticholinergic medication). Overactive Bladder with symptoms of Urge Urinary Incontinence, Urgency and Frequence-approve if the patient has tried at least one other pharmacologic therapy. Spasticity, lower limb-approve. Spasticity, upper limb-approve
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Achalasia, Anal Fissure (anal sphincter), Chronic facial pain/pain associated with TMJ dysfunction, Chronic low back pain, Hyperhidrosis (Palmar/Plantar, facial), Myofascial pain, Sialorrhea (chronic), Spasticity (other than lower and upper limb (eg, due to cerebral palsy, stroke, brain injury, spinal cord injury, MS, hemifacial spasm)), Essential tremor, Dystonia other than cervical (eg, focal dystonias, tardive dystonia, anismus, laryngeal dystonia/spasmodic dysphonia), Frey's syndrome (gustatory sweating), Ophthalmic disorders (other than blepharospasm or Strabismus (eg, esotropia, exotropia, nystagmus, facial nerve paresis))

BUPRENORPHINE

Products Affected

- *buprenorphine hcl sublingual*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of opioid dependence.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Induction therapy: 1 month. Pregnancy/intolerance to naloxone: 12 months
Other Criteria	The use of buprenorphine for maintenance therapy should be limited to patients who have experienced an intolerance to naloxone or require buprenorphine during pregnancy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CARBAGLU

Products Affected

- CARBAGLU
- *carglumic acid*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	NAGS-Pt meets criteria no genetic test - 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, Some Medically-accepted Indications.
Off-Label Uses	Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (generic carglumic acid)

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

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 disorder
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

CHORIONIC GONADOTROPIN

Products Affected

- CHORIONIC GONADOTROPIN, HUMAN INTRAMUSCULAR

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

CINRZYE

Products Affected

- CINRYZE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders
Coverage Duration	1 year
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Prophylaxis-approve Cinryze if the patient meets one of the following criteria (A or B): A) Initial therapy-Approve if the patient meets both of the following criteria: 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% of normal) at baseline, as defined by the laboratory reference values AND b) Patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values B) Patient is currently receiving Cinryze prophylaxis-Approve if the patient meets all of the following criteria (i and ii): i. patient has a diagnosis of HAE type I or II AND ii. According to the prescriber, the patient has had a favorable clinical response since initiating Cinryze prophylactic therapy compared with baseline (i.e., prior to initiating prophylactic therapy).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

CLOBAZAM

Products Affected

- *clobazam*
- 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

COPAXONE

Products Affected

- COPAXONE SUBCUTANEOUS SYRINGE

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

CORLANOR

Products Affected

- CORLANOR ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	CHF: Previous use of a Beta-blocker, LVEF. IST: Previous use of a Beta-blocker
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Chronic HF, adults- must have LVEF of less than or equal 35 percent (currently or prior to initiation of Corlanor therapy) AND tried or is currently receiving a Beta-blocker for HF (e.g., metoprolol succinate sustained-release, carvedilol, bisoprolol, carvedilol ER) unless the patient has a contraindication to the use of beta blocker therapy (e.g., bronchospastic disease such as COPD and asthma, severe hypotension or bradycardia). Heart failure due to dilated cardiomyopathy, children-approve. IST - tried or is currently receiving a Beta-blocker unless the patient has a contraindication to the use of beta blocker therapy (e.g., bronchospastic disease such as COPD and asthma, severe hypotension or bradycardia).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	inappropriate sinus tachycardia (IST)

CYSTEAMINE (OPHTHALMIC)

Products Affected

- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases
Coverage Duration	1 year
Other Criteria	Approve if the patient has corneal cysteine crystal deposits confirmed by slit-lamp examination
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

DALFAMPRIDINE

Products Affected

- *dalfampridine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	MS. If prescribed by, or in consultation with, a neurologist or MS specialist (initial and continuation).
Coverage Duration	Initial-4months, Continuation-1 year.
Other Criteria	Initial-approve if the 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

DEFERASIROX

Products Affected

- *deferasirox oral tablet, dispersible*

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

DERMATOLOGICAL WOUND CARE AGENTS

Products Affected

- REGRANEX

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

DIHYDROERGOTAMINE MESYLATE

Products Affected

- *dihydroergotamine nasal*

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

DIMETHYL FUMARATE

Products Affected

- *dimethyl fumarate*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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 (required only for patients with chronic liver disease scheduled to undergo a 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

DUAVEE

Products Affected

- DUAVEE

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	For the prevention of postmenopausal osteoporosis, trial, failure, or intolerance of raloxifene is required prior to the use of Duavee.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DUPIXENT

Products Affected

- DUPIXENT PEN
- DUPIXENT SYRINGE

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	AD-6 months and older, asthma-6 years of age and older. Esophagitis-12 and older, Chronic Rhinosinusitis/Prurigo nodularis-18 years of age and older
Prescriber Restrictions	Atopic Dermatitis/Prurigo nodularis-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist. Esophagitis-presc/consult-allergist or gastro
Coverage Duration	AD-Initial-4 mos, Cont-1 yr, asthma/Rhinosinusitis/esophagitis/prurigo nod-initial-6 mos, cont 1 yr
Other Criteria	Pending CMS Review
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, or plasma OR a molecular genetic test demonstrating iduronate-2-sulfatase gene mutation
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ENBREL

Products Affected

- ENBREL
- ENBREL MINI
- 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 by or in consult w/ rheum. PsA, prescribed by or in consultation w/ rheumatologist or dermatologist.PP, prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center. Uveitis, prescribed by or in consultation with an ophthalmologist.
Coverage Duration	FDA dx-6 mo init, 3 yrs cont, uveitis init-3 mo, cont-12 mo.GVHD-3 mo
Other Criteria	RA/PsA 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-approve if the patient meets ONE of the following: patient has tried one other medication for this condition (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID). A previous trial of a biologic or JAK inhibitor also counts as a trial of one medication.) OR Patient 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, 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. Uveitis initial, tried one of the following: periocular, intraocular, or systemic corticosteroid, immunosuppressives or other biologic therapy. GVHD, approve. Continuation-approve if the patient has had a response as determined by the prescriber. Clinical criteria incorporated into the Enbrel 25 mg quantity

PA Criteria	Criteria Details
	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), Uveitis

EPCLUSA

Products Affected

- EPCLUSA

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	For Lennox?Gastaut syndrome, prior use of 2 of the following is required: clonazepam, felbamate, lamotrigine, topiramate, rufinamide (Banzel), clobazam. For Dravet syndrome, prior use of 2 of the following is required: Diacomit, clobazam and Fintepla. For tuberous sclerosis complex, prior use of everolimus (tablets for suspension) is required
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

EPOETIN ALFA

Products Affected

- PROCRIT
- RETACRIT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	CRF anemia in patients not on dialysis.Hemoglobin (Hb) of less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children to start.Hb less than or equal to 11.5 g/dL for adults or 12 g/dL or less for children if previously on epoetin alfa, Mircera or Aranesp. Anemia w/myelosuppressive chemotx.pt must be currently receiving myelosuppressive chemo and Hb 10.0 g/dL or less to start.Hb less than or equal to 12.0 g/dL if previously on epoetin alfa or Aranesp.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(dialysis)-3yrs, 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-approve if according to the prescriber the patient has had a response to therapy. Anemia in patients with chronic renal failure on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundled payment benefit).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anemia due to myelodysplastic syndrome (MDS), myelofibrosis

ESBRIET

Products Affected

- ESBRIET
- *pirfenidone oral tablet 267 mg, 801 mg*
- PIRFENIDONE ORAL TABLET 534 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

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	3 years
Other Criteria	N/A
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 a neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Dravet Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex, clobazam or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. Lennox-Gastaut Syndrome, initial-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Lennox-Gastaut Syndrome, continuation-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

Products Affected

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

GROWTH HORMONES - GENOTROPIN

Products Affected

- GENOTROPIN
- GENOTROPIN MINIQUICK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	GHD in Children/Adolescents. Pt meets one of the following-1-had 2 GH stim tests with the following-levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon and both are inadequate as defined by a peak GH response which is below the normal reference range of the testing laboratory OR had at least 1 GH test and results show inadequate response and has at least one risk factor for GHD (e.g., ht for age curve deviated down across 2 major height percentiles [e.g., from above the 25 percentile to below the 10 percentile], growth rate is less than the expected normal growth rate based on age and gender, low IGF-1 and/or IGFBP-3 levels). 2.brain radiation or tumor resection and pt has 1 GH stim test and results is inadequate response or has def in at least 1 other pituitary hormone (that is, ACTH, TSH, gonadotropin deficiency [LH and/or FSH] are counted as 1 def], or prolactin).3. congenital hypopituitarism and has one GH stim test with inadequate response OR def in at least one other pituitary hormone and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk 4.pt has panhypopituitarism and has pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary bright spot on MRI or CT or pt has 3 or more pituitary hormone deficiencies or pt has had one GH test and results were inadequate 5.pt had a hypophysectomy. Cont-pt responding to therapy
Age Restrictions	ISS 5 y/o or older, SGA 2 y/o or older, SBS 18 y/o or older
Prescriber Restrictions	GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, Prader Willi (initial for child/adult and cont tx in adults), SHOX (initial), SGA (initial) - prescribed by or in consultation with an endocrinologist. CKD (initial) endocrinologist or nephrologist.
Coverage Duration	ISS - 6 mos intial, 12 months cont tx, SBS-1 month, others 12 mos
Other Criteria	GHD initial in adults and adolescents 1. endocrine must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either

PA Criteria	Criteria Details
	childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalmic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. has known mutations, embryonic lesions, congenital or genetic defects or structural hypothalmic pituitary defects, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, IGF1 less than 84 mcg/L (Esoterix RIA), AND other causes of low serum IGF-1 have been excluded, C. Neg response to ONE preferred GH stim test (insulin peak response less than or equal to 5 mcg/L, Glucagon peak less than or equal to 3 mcg/L (BMI is less than or equal to 25), less than or equal to 3 and BMI is greater than or equal to 25 and less than or equal to 30 with a high pretest probability of GH deficiency, less than or equal to 1 and BMI is greater than or equal to 25 and less than or equal to 30 with a low pretest probability of GH deficiency or less than or equal to 1 mcg/L (BMI is greater than 30), if insulin and glucagon contraindicated then Arginine alone test with peak of less than or equal to 0.4 mcg/L, or Macrilen peak less than 2.8 ng/ml AND BMI is less than or equal to 40 AND if a transitional adolescent must be off tx for at least one month before retesting. Cont tx - endocrine must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than the 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR) is a. less than 4 cm/yr for pts greater than or equal to 5 or b. growth velocity is less than 10th percentile for age/gender. Cont tx - prescriber confirms response to therapy. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline height less than 5th percentile. PW cont tx in adults or adolescents who don't meet child requir - physician certifies not being used for anti-aging or to enhance athletic performance. SHOX initial - SHOX def by chromo analysis, open epiphyses, height less than 3rd percentile for age/gender. SGA initial -baseline ht less than 5th percentile for age/gender and born SGA (birth weight/length that is more than 2 SD below mean for gestational age/gender and didn't have sufficient catch up growth by 2-4 y/o). Cont tx - prescriber confirms response to therapy. Cont Tx for CKD, Noonan, PW in child/adolescents, 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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	SHOX, SBS, CKD

HARVONI

Products Affected

- HARVONI
- *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	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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Non-24-patient is totally blind with no perception of light
Age Restrictions	Non-24-18 years or older (initial and continuation), SMS-16 years and older
Prescriber Restrictions	prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders (initial and continuation)
Coverage Duration	6 mos initial, 12 mos cont
Other Criteria	Initial - 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 - 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 10 mg, 5 mg*

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

- *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

HRM - SKELETAL MUSCLE RELAXANTS

Products Affected

- *methocarbamol oral tablet 500 mg, 750 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	The physician has documented the indication for the continued use of the HRM (high risk med) with an explanation of the specific benefit established with the medication and how that benefit outweighs the potential risk, AND the physician will continue to monitor for side effects. For patients concurrently taking multiple anticholinergeric medications, the physican has assessed the risk.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior authorization required for age 65 or older.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
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)
- HUMIRA(CF) PEDI CROHNS STARTER
- HUMIRA(CF) PEN
- HUMIRA(CF) PEN CROHNS-UC-HS
- HUMIRA(CF) PEN PEDIATRIC UC
- HUMIRA(CF) PEN PSOR-UV-ADOL HS

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	Crohn's disease (CD), 6 or older (initial therapy). Ulcerative colitis (UC), 5 or older (initial therapy), PP-18 or older (initial therapy)
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 6 mo, cont tx 3 years.
Other Criteria	RA/PsA 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-approve if the patient meets ONE of the following: patient has tried one other medication for this condition (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID). A previous trial of a biologic or JAK inhibitor also counts as a trial of one medication.) OR Patient 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, MTX, cyclosporine, acitretin,

PA Criteria	Criteria Details
	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, approve 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. UC initial, approve if the patient has had a trial of one systemic agent for UC. Uveitis initial, tried one of the following: periocular, intraocular, or systemic corticosteroid, immunosuppressives or other biologic therapy. HS initial, tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Continuation-approve if the patient has had a response as determined by the prescriber. 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

ICATIBANT

Products Affected

- *icatibant*
- SAJAZIR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50% 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

INCRELEX

Products Affected

- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Patients 2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

KALYDECO

Products Affected

- KALYDECO

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

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 and ii): 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. Diabetic kidney disease, continuation-approve if the patient meets the following criteria (i, and ii): 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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 Syndrome-1 year. Pt awaiting surgery or response after radiotherapy-4 months
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

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

LIDOCAINE PATCH

Products Affected

- *lidocaine topical adhesive patch,medicated 5 %*

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

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

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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance

MEGACE

Products Affected

- *megestrol oral suspension 400 mg/10 ml (10 ml), 400 mg/10 ml (40 mg/ml), 800 mg/20 ml (20 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

MODAFINIL

Products Affected

- *modafinil*

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 the patient is working at least 5 overnight shifts per month. Adjunctive/augmentation treatment for depression in adults 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. Adjunctive/augmentation for treatment of depression in adults.

MOLECULAR TARGET INHIBITORS

Products Affected

- *abiraterone*
- AFINITOR DISPERZ
- AFINITOR ORAL TABLET 10 MG
- ALECENSA
- ALUNBRIG
- AYVAKIT
- BALVERSA
- BOSULIF
- BRAFTOVI ORAL CAPSULE 75 MG
- BRUKINSA
- CABOMETYX
- CALQUENCE
- CALQUENCE (ACALABRUTINIB MAL)
- CAPRELSA
- COMETRIQ
- COPIKTRA
- COTELLIC
- DAURISMO
- ERIVEDGE
- ERLEADA
- *erlotinib*
- EVEROLIMUS (ANTINEOPLASTIC) ORAL TABLET 10 MG
- *everolimus (antineoplastic) oral tablet 2.5 mg, 5 mg, 7.5 mg*
- *everolimus (antineoplastic) oral tablet for suspension*
- EXKIVITY
- FARYDAK
- FOTIVDA
- GAVRETO
- GILOTRIF
- IBRANCE
- ICLUSIG
- IDHIFA
- *imatinib*
- IMBRUVICA
- INLYTA
- INQOVI
- INREBIC
- IRESSA
- JAKAFI
- KISQALI
- KISQALI FEMARA CO-PACK
- LENVIMA
- LONSURF
- LORBRENA
- LUMAKRAS
- LYNPARZA
- MEKINIST
- MEKTOVI
- NERLYNX
- NEXAVAR
- NINLARO
- NUBEQA
- ODOMZO
- ONUREG
- ORGOVYX
- PEMAZYRE
- PIQRAY
- POMALYST
- QINLOCK
- RETEVMO
- RUBRACA
- RYDAPT
- SCEMBLIX
- *sorafenib*
- SPRYCEL
- STIVARGA
- SUNITINIB
- SUTENT
- SYNRIBO
- TABRECTA
- TAFINLAR
- TAGRISSO
- TALZENNA
- TASIGNA
- TAZVERIK
- TEPMETKO
- TIBSOVO
- TRUSELTIQ
- TUKYSA
- VENCLEXTA

- VENCLEXTA STARTING PACK
- VIZIMPRO
- VONJO
- VOTRIENT
- XALKORI
- XOSPATA
- XPOVIO ORAL TABLET 100 MG/WEEK (50 MG X 2), 40 MG/WEEK (40 MG X 1), 40MG TWICE WEEK (40 MG X 2), 60 MG/WEEK (60 MG X 1), 60MG TWICE WEEK (120 MG/WEEK), 80 MG/WEEK (40 MG X 2), 80MG TWICE WEEK (160 MG/WEEK)
- XTANDI
- ZEJULA
- ZELBORAF
- ZOLINZA
- ZYDELIG
- ZYKADIA

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 Medically-accepted 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

NEXLETOL

Products Affected

- NEXLETOL

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	Patient has tried and failed or has a contraindication to a maximally tolerated statin or 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 two statins 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	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Patient has tried and failed or has a contraindication to a maximally tolerated statin or 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 two statins and during both trials the skeletal-related symptoms resolved during discontinuation.
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/MDS-6 mo.HIV/AIDS-4 mo.PBPC,Drug induce A/N,AA,ALL,BMT-3 mo.Radiation-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 an intermediate risk of febrile neutropenia (the risk is 10-20% 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 [absolute neutrophil account less than 100 cells/mm3], neutropenia

PA Criteria	Criteria Details
	expected to be greater than 10 days in duration, invasive fungal infection). Patient with MDS, approve if the patient has a low risk disease with a serum erythropoietin level less than or equal to 500 mU/mL.
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)

NMDA RECEPTOR ANTAGONIST

Products Affected

- *memantine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Automatic approval if member is greater than 26 years of age. Prior Authorization is required for age 26 or younger.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NON-INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- *testosterone transdermal gel*
- *testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1 %)*
- *testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram)*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]
Indications	All FDA-approved Indications.
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

NUCALA

Products Affected

- NUCALA SUBCUTANEOUS AUTO-INJECTOR
- NUCALA SUBCUTANEOUS SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Xolair or another Anti-Interleukin (IL) Monoclonal Antibody.
Required Medical Information	N/A
Age Restrictions	Asthma-6 years of age and older. EGPA/Polyps-18 years of age and older. HES-12 years and older.
Prescriber Restrictions	Asthma-Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. EGPA-prescribed by or in consultation with an allergist, immunologist, pulmonologist or rheumatologist. HES-prescribed by or in consultation with an allergist, immunologist, hematologist, pulmonologist or rheumatologist. Polyps-prescribed by or in consult with allergist, immunologist or Otolaryngologist.
Coverage Duration	Initial-Asthma/EGPA/polyps-6 months, HES-8 months. 12 months continuation.
Other Criteria	Asthma initial-must have blood eosinophil level of greater than or equal to 150 cells per microliter within the prev 6 wks(prior to treatment with any anti-interleukin (IL)-5 therapy) AND Pt has received at least 3 mo of combo tx with an inhaled corticosteroid AND at least 1 additional asthma controller/maintenance med AND pt's asthma cont to be uncontrolled, or was uncontrolled prior to starting any anti-IL tx as defined by 1 of the following-pt exp 2 or more asthma exacerbations requiring tx with systemic corticosteroids in the prev yr, pt experienced 1 or more asthma exacerbation requiring hospital or an ED visit in the prev yr, pt has a FEV1 less than 80 percent predicted, Pt has an FEV1/FVC less than 0.80, or Pt's asthma worsens upon taper of oral corticosteroid tx.NOTE:An exception to the requirement for trial of 1 additional asthma controller/maintenance medication can be made if the pt has already received anti-IL-5 tx used concomitantly with an ICS for at least 3 mo. Cont-pt has responded to Nucala tx as determined by the prescribing physician AND Pt continues to receive tx with an inhaled corticosteroid. EGPA initial-pt has/had a blood eosinophil level of greater than or equal to 150 cells per microliter within

PA Criteria	Criteria Details
	the previous 6 wks or within 6 wks prior to tx with any anti-interleukin (IL)-5 therapy. Cont-pt has responded to Nucala tx as determined by the prescribing physician. HES initial-pt has had hypereosinophilic syndrome for greater than or equal to 6 mo AND has FIP1L1-PDGFRalpha-negative disease AND the pt does NOT have an identifiable non-hematologic secondary cause of hypereosinophilic syndrome AND prior to initiating tx with any anti-interleukin-5 tx, pt has/had a blood eosinophil level of greater than or equal to 1,000 cells per microliter.Cont-approve if pt has received at least 8 mo of tx with Nucala (patients who have received less than 8 mo of tx or who are restarting tx should be reviewed under initial tx) and pt has responded to Nucala tx. Nasal polyps, initial-approve if pt meets ALL of the following criteria(A, B, C and D):A) pt has chronic rhinosinusitis with nasal polyposis as evidenced by direct exam, endoscopy, or sinus CT scan AND B)pt has experienced 2 or more of the following symptoms for at least 6 mo:nasal congestion/obstruction/discharge, and/or reduction/loss of smell AND C)pt meets BOTH of the following (a and b): a)Pt has received at least 8 weeks of tx with intranasal corticosteroid AND b)Pt will cont to receive tx with an intranasal corticosteroid concomitantly with Nucala AND D)pt meets 1 of the following (a, b or c): a)Pt has received at least 1 course of tx with a systemic corticosteroid for 5 days or more within the previous 2 yrs, OR b)Pt has a contraindication to systemic corticosteroid therapy, OR c)Pt has had prior surgery for nasal polyps.Cont-approve if pt has received at least 6 mo of tx, continues to receive tx with an intranasal corticosteroid and has responded to tx.
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

NUPLAZID

Products Affected

- NUPLAZID

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

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

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*

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

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

ORENCIA

Products Affected

- ORENCIA
- ORENCIA CLICKJECT

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	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	6 months initial, 3 years cont.
Other Criteria	RA, approve if the patient has tried one of the following: Enbrel, Humira, Rinvoq, Xeljanz. PsA, approve if the patient has tried one of the following: Enbrel, Humira, Rinvoq, Stelara, Skyrizi, Xeljanz. JIA/JRA, approve if the patient has tried one of the following: Enbrel, Humira or Xeljanz. Continuation-approve if the patient has had a response as determined by the prescriber.
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.
Coverage Duration	2 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PEGASYS

Products Affected

- PEGASYS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous medications tried, liver disease compensation status, concomitant medications for HCV
Age Restrictions	HCV - patients 5 years of age or older, HBV - patients 3 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PHENYLBUTYRATE

Products Affected

- *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

- *metyrosine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior medication trials
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial and continuation therapy for metyrosine)
Coverage Duration	Authorization will be for 1 year
Other Criteria	If the requested drug is metyrosine for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin) 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

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Products Affected

- ALYQ
- *sildenafil (pulm.hypertension) oral tablet*
- TADALAFIL (PULM. HYPERTENSION)

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 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

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

- *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

QUININE SULFATE

Products Affected

- *quinine sulfate*

PA Criteria	Criteria Details
Exclusion Criteria	Excluded if used for treatment or prevention of nocturnal leg cramps.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Babesiosis, uncomplicated Plasmodium vivax malaria.

RAYALDEE

Products Affected

- RAYALDEE

PA Criteria	Criteria Details
Exclusion Criteria	patients with stage 5 chronic kidney disease or end-stage renal disease on dialysis
Required Medical Information	Diagnosis is for treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease
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

REMICADE

Products Affected

- REMICADE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Biologic DMARD or Targeted Synthetic.
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 consultation with: RA/AS/Still's disease/JIA/JRA-rheumatologist, PP/Pyoderma gangrenosum/Hidradenitis supperativa-dermatologist, Psoriatic Arthritis-rheum or derm, CD/UC-gastroenterologist, Uveitis ophthalmologist, GVHD-a physician affiliated with a transplant center, oncologist, or hematologist, Behcet's Disease- rheum, derm, ophthalmologist, gastroenterologist, or neurologist, Sarcoidosis-pulmonol, ophthalmol, or derm
Coverage Duration	GVHD intl-1 mo, cont-3 mo.Pyoderma Gangrenosum-intl 4 mo, cont 1 yr.all others-intl 6 mo, cont-12 m
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients already started on infliximab for a covered use, 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 PUSHTRONEX
- REPATHA SURECLICK
- REPATHA SYRINGE

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/Primary Hyperlipidemia - 18 yo and older, HoFH/HeFH - 10 yo and older.
Prescriber Restrictions	Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
Coverage Duration	Approve for 3 years for ASCVD/HeFH/HoFH/primary hyperlipidemia.
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 Crestor 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 Crestor 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

REVLIMID

Products Affected

- *lenalidomide*
- REVLIMID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and previous therapies or drug regimens tried.
Age Restrictions	N/A
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 one prior therapy. MCL-approve. MZL-approve. 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, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). Diffuse, Large B Cell Lymphoma (Non-Hodgkin's Lymphoma)-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. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve if the pt has tried at least one other therapy or regimen. CNS cancers (primary)-approve if according to the prescriber the patient has relapsed or refractory disease. Hodgkin lymphoma, classical-approve if the patient has relapsed or refractory disease. Castleman's disease-approve if the patient has relapsed/refractory or progressive disease. AIDS Related Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
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 cancer (primary), Acquired immune deficiency syndrome (AIDS)-related Kaposi's sarcoma.

RINVOQ

Products Affected

- RINVOQ

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	Atopic Dermatitis - 12 years and older. All others - 18 years and older
Prescriber Restrictions	RA, Ankylosing spondylitis prescribed by or in consultation with a rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Atopic Dermatitis-Prescribed by or in consultation with an allergist, immunologist or dermatologist. UC prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Authorization will be for 6 months initial, 3 years cont.
Other Criteria	RA/PsA 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). Atopic Dermatitis-Initial-meets both a and b: has used at least one medium, medium-high, high, and/or super-high-potency prescription topical corticosteroid OR has atopic dermatitis 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. UC initial, approve if the patient has had a trial of one systemic agent for UC. Continuation-approve if the patient has had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ROMIDEPSIN

Products Affected

- ROMIDEPSIN INTRAVENOUS RECON SOLN
- *romidepsin intravenous solution*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of diagnosis and past medication history.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Use of romidepsin is considered medically necessary for the treatment of cutaneous T-cell lymphoma in patients that have tried and failed at least 1 prior therapy. B vs D coverage determination.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ROZLYTREK

Products Affected

- ROZLYTREK

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

RUFINAMIDE

Products Affected

- *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

SABRIL

Products Affected

- *vigabatrin*
- *vigadrone*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medication history (complex partial seizures)
Age Restrictions	Refractory complex partial seizures - patients 2 years of age or older. Infantile spasms/West Syndrome - patients 1 month to 2 years of age
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

SAPROPTERIN

Products Affected

- *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% 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

SIGNIFOR

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome (initial therapy)
Coverage Duration	Cushing's-Initial-4 mo, Cont therapy - 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

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 INTRAVENOUS
- SKYRIZI SUBCUTANEOUS PEN INJECTOR
- SKYRIZI SUBCUTANEOUS SYRINGE 150 MG/ML
- SKYRIZI SUBCUTANEOUS SYRINGE KIT
- SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR

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	18 years of age and older (initial therapy)
Prescriber Restrictions	PP-Prescribed by or in consultation with a dermatologist (initial therapy). Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. CD, prescribed by or in consultation with a gastroenterologist.
Coverage Duration	6 mos initial, 3 years 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 - axial disease (sacroiliitis), patient has tried one conventional synthetic DMARD or NSAID for at least 3 months, unless intolerant. (note: patients who have already had a 3-month trial of a biologic are not required to step back and try a conventional synthetic DMARD or NSAID). Continuation-approve if the patient has had a response as determined by the prescriber. CD initial, approve 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.
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 TABLET 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

STELARA

Products Affected

- STELARA

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	18 years and older CD/UC (initial therapy). PP-6 years and older (initial therapy).
Prescriber Restrictions	PP-Prescr/consult w/derm.PsA-prescr/consult w/rheum or derm.CD/UC-prescr/consult w/gastro.
Coverage Duration	PP/PsA Init-3mo,CD/UC load-approve 1 dose IV,CD/UC post IV load-SC 6 mo,cont tx-SC 3 yr
Other Criteria	PsA 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). 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. CD initial, approve 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. UC initial, approve if the patient has had a trial of one systemic agent for UC.
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

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

TALTZ

Products Affected

- TALTZ SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
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-prescribed by or in consultation with a rheum.
Coverage Duration	Initial authorization will be for 6 months, 3 years continuation
Other Criteria	PP, approve if the patient has tried two of the following: Enbrel, Humira, Skyrizi, or Stelara. PsA, approve if the patient has tried two of the following: Enbrel, Humira, Rinvoq, Stelara, Skyrizi, Xeljanz. AS, approve if the patient has tried two of the following: Enbrel, Humira, Xeljanz. Non-radiographic axial spondylitis (nr-axSpA)-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroiliitis reported on MRI. Continuation-approve if the patient has had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

TARGRETIN TOPICAL

Products Affected

- *bexarotene*
- TARGRETIN TOPICAL

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

TAZAROTENE

Products Affected

- *tazarotene topical cream*
- TAZORAC TOPICAL CREAM 0.05 %

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

TERIPARATIDE

Products Affected

- 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. Patients who

PA Criteria	Criteria Details
	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*

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.
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	N/A
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). AIDS Related 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) and has hyaline vascular histology.
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, AIDS related Kaposi's Sarcoma, Castleman's Disease.

TOLVAPTAN

Products Affected

- SAMSCA ORAL TABLET 15 MG
- 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/Samsca 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

- *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 RETINOID PRODUCTS

Products Affected

- *avita*
- *tretinoin*
- *tretinoin microspheres topical gel 0.1 %*
- *tretinoin microspheres topical gel with pump 0.1 %*

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

- EPRONTIA
- *topiramate oral capsule, sprinkle*
- *topiramate oral tablet*
- ZONISADE
- *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

TRANSMUCOSAL FENTANYL DRUGS

Products Affected

- *fentanyl citrate buccal lozenge on a handle*

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

TRELSTAR

Products Affected

- TRELSTAR INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION

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

TRIENTINE

Products Affected

- *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 3 years.
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, OR 6) the patient has been started on therapy with trientine.
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

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. Histiocytic Neoplasms-approve if the patient has a colony stimulating factor 1 receptor (CSF1R) mutation AND has one of the following conditions (i, ii, or iii): i. Langerhans cell histiocytosis OR ii. Erdheim-Chester disease OR iii. Rosai-Dorfman disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Histiocytic Neoplasms

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	Authorization will be for 2 yrs of total therapy between Tymlos/teriparatide over a pt'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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

UPTRAVI

Products Affected

- UPTRAVI ORAL

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. Langerhans cell histiocytosis-approve if the patient has unifocal Langerhans cell histiocytosis with isolated skin disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Adults with T-cell leukemia/lymphoma, Langerhans Cell Histiocytosis

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

- *vancomycin oral capsule*

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

VENTAVIS

Products Affected

- VENTAVIS

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	B vs D coverage determination
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VERZENIO

Products Affected

- VERZENIO

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	For use with an aromatase inhibitor in postmenopausal women or men as initial endocrine-based therapy, approve if the patient has tried Ibrance OR Kisqali. For use with fulvestrant in patients with disease progression following endocrine therapy, approve if the patient has tried Ibrance OR Kisqali. For use in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score greater than or equal to 20% no trial of Ibrance or Kisqali is required. For use as monotherapy of advanced or metastatic disease following endocrine therapy and chemotherapy in the setting of metastatic disease, no trial of Ibrance or Kisqali is required.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VITRAKVI

Products Affected

- VITRAKVI

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

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

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 MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
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, B) Does not require immediate surgery and C) Patient requires therapy for ONE of the following conditions (i, ii, iii, or iv): i. Central nervous system hemangioblastomas, OR ii. Pancreatic neuroendocrine tumors, OR iii. Renal cell carcinoma, OR iv. Retinal hemangioblastoma
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

XATMEP

Products Affected

- XATMEP

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

XCOPRI

Products Affected

- XCOPRI
- XCOPRI MAINTENANCE PACK ORAL TABLET 250MG/DAY(150 MG X1-100MG X1), 350 MG/DAY (200 MG X1-150MG X1)
- XCOPRI TITRATION PACK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the patient has tried one other anticonvulsant therapy (eg, carbamazepine, divalproex sodium, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, topiramate, valproic acid).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

XELJANZ

Products Affected

- XELJANZ
- XELJANZ XR

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologic therapy or targeted synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried.
Age Restrictions	N/A
Prescriber Restrictions	RA, JIA/JRA, Ankylosing spondylitis, 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/AS -6 months initial, UC-16 weeks initial, All diagnoses-3 years cont.
Other Criteria	RA/PsA initial, approve Xeljanz/XR tablets if 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 initial, approve Xeljanz/XR tablets if 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., Humira, an infliximab product) also counts as a trial of one systemic agent for UC. JIA/JRA-initial-approve Xeljanz immediate release tablets or solution if the patient meets ONE of the following: patient has tried one other medication for this condition (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID). A previous trial of a biologic or JAK inhibitor also counts as a trial of one medication.) OR Patient has aggressive disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

XGEVA

Products Affected

- XGEVA

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 Medically-accepted 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

XIFAXAN

Products Affected

- XIFAXAN ORAL TABLET 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Hepatic encephalopathy, irritable bowel syndrome - 18 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	Hepatic Encephalopathy-6 months, IBS with diarrhea-14 days
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

XOLAIR

Products Affected

- XOLAIR

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)patients 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 hospitalization or an Emergency Department (ED) visit in the previous year

PA Criteria	Criteria Details
	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 patients 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 at least 3 consecutive months. 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 - 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

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

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/MDS-6 mo.HIV/AIDS-4 mo.PBPC,Drug induce A/N,AA,ALL,BMT-3 mo.Radiation-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 an intermediate risk of febrile neutropenia (the risk is 10-20% 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 [absolute neutrophil account less than 100 cells/mm3], neutropenia

PA Criteria	Criteria Details
	expected to be greater than 10 days in duration, invasive fungal infection). Patient with MDS, approve if the patient has a low risk disease with a serum erythropoietin level ? 500 mU/mL.
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)

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 an intermediate risk of febrile neutropenia (the risk is 10-20% 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

ZTALMY

Products Affected

- ZTALMY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	1 year
Other Criteria	Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder-approve if the patient has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

ZTLIDO

Products Affected

- 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

ZYPREXA RELPREVV

Products Affected

- ZYPREXA RELPREVV

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis
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	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PART B VERSUS PART D

Products Affected

- *acetylcysteine*
- *acyclovir sodium intravenous solution*
- *albuterol sulfate inhalation solution for nebulization*
- AMINOSYN II 15 %
- AMINOSYN-PF 7 % (SULFITE-FREE)
- *amiodarone intravenous solution*
- *aprepitant*
- ARRANON
- *arsenic trioxide*
- ARZERRA
- ATGAM
- *azacitidine*
- *azathioprine oral tablet 50 mg*
- *azathioprine sodium*
- BELEODAQ
- BENDEKA
- *bleomycin*
- BLINCYTO INTRAVENOUS KIT
- *budesonide inhalation*
- BUSULFAN
- *carboplatin intravenous solution*
- *carmustine intravenous recon soln 100 mg*
- *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 4.25%/D10W SUL FREE
- CLINISOL SF 15 %
- *clofarabine*
- *cromolyn inhalation*
- *cyclophosphamide*
- *cyclosporine intravenous*
- *cyclosporine modified*
- *cyclosporine oral capsule*
- *cytarabine*
- *cytarabine (pf)*
- *dacarbazine*
- *dactinomycin*
- *daunorubicin intravenous solution*
- *decitabine*
- *docetaxel intravenous solution 160 mg/16 ml (10 mg/ml), 160 mg/8 ml (20 mg/ml), 20 mg/2 ml (10 mg/ml), 20 mg/ml (1 ml), 80 mg/4 ml (20 mg/ml), 80 mg/8 ml (10 mg/ml)*
- *doxorubicin intravenous recon soln 50 mg*
- *doxorubicin intravenous solution*
- *doxorubicin, peg-liposomal*
- *dronabinol*
- ELLENCE
- EMEND ORAL SUSPENSION FOR RECONSTITUTION
- ENGERIX-B (PF)
- ENGERIX-B PEDIATRIC (PF)
- *epirubicin intravenous solution*
- ERBITUX
- ETOPOPHOS
- *etoposide intravenous*
- *everolimus (immunosuppressive)*
- FIRMAGON KIT W DILUENT SYRINGE
- *floxuridine*
- *fludarabine*
- *fluorouracil intravenous*
- FOLOTYN
- *formoterol fumarate*
- *fulvestrant*
- *gemcitabine*
- *gengraf*
- *granisetron hcl oral*
- HIZENTRA
- HUMULIN R U-500 (CONC) INSULIN
- *idarubicin*
- *ifosfamide*
- INFUGEM
- INFUMORPH P/F
- INTRALIPID INTRAVENOUS EMULSION 20 %, 30 %

- INTRON A INJECTION RECON SOLN 10 MILLION UNIT (1 ML), 50 MILLION UNIT (1 ML)
- *ipratropium bromide inhalation*
- *ipratropium-albuterol*
- *irinotecan*
- IXEMPRA
- JEVTANA
- KABIVEN
- KYPROLIS
- MARQIBO
- *melphalan hcl*
- *mesna*
- *methotrexate sodium (pf)*
- *methotrexate sodium injection*
- *mitomycin intravenous*
- *mitoxantrone*
- MOZOBIL
- *mycophenolate mofetil*
- *mycophenolate mofetil (hcl)*
- *mycophenolate sodium*
- *nelarabine*
- NIPENT
- *nitroglycerin intravenous*
- NULOJIX
- *ondansetron*
- *ondansetron hcl oral solution*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *oxaliplatin*
- *paclitaxel*
- *pentamidine inhalation*
- PERFOROMIST
- PERIKABIVEN
- PLENAMINE
- PORTRAZZA
- PREHEVBRIO (PF)
- PREMASOL 10 %
- PRIVIGEN
- PROCALAMINE 3%
- PROGRAF INTRAVENOUS
- PROGRAF ORAL GRANULES IN PACKET
- PROLEUKIN
- PROSOL 20 %
- PULMOZYME
- RECOMBIVAX HB (PF)
- RYLAZE
- SANDIMMUNE ORAL SOLUTION
- SIMULECT
- *sirolimus*
- *tacrolimus oral*
- TEMODAR INTRAVENOUS
- *temsirolimus*
- TICE BCG
- *tobramycin in 0.225 % nacl*
- *toposar*
- *topotecan intravenous recon soln*
- *topotecan intravenous solution 4 mg/4 ml (1 mg/ml)*
- TRAVASOL 10 %
- TREANDA
- TROPHAMINE 10 %
- *valrubicin*
- *vinblastine*
- *vincasar pfs*
- *vincristine*
- *vinorelbine*
- VYXEOS
- ZALTRAP
- ZANOSAR
- ZOLADEX
- *zoledronic acid intravenous solution*
- *zoledronic acid-mannitol-water*
- *zoledronic ac-mannitol-0.9nacl*
- ZORTRESS ORAL TABLET 1 MG

Details

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

D

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