

ABRYSVO

Products Affected

- ABRYSVO (PF)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Non-pregnant individuals: 60 years of age or older OR adults aged 18 through 59 years who are at increased risk for lower respiratory tract disease
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	The patient has not already received an RSV vaccine. For Pregnant Individuals: patient is between 32 through 36 weeks gestational age.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ACITRETIN

Products Affected

- *acitretin*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For 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
Part B Prerequisite	No

ACTHAR

Products Affected

- ACTHAR
- ACTHAR SELFJECT

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for diagnostic procedure.
Required Medical Information	Diagnosis, prescriber or consulting physician specialty, previous medications tried and response
Age Restrictions	Infantile spasms- less than 2yo. Acute MS exac-adult
Prescriber Restrictions	Infant spasms, prescr physician who consulted w/specializes in neurology. MS exacer, prescr/consult w/neuro/phys specializes MS.RA, JIA/JRA, AS, PsA, SLE, Systemic Dermatomyositis, prescr/consult w/rheum.Severe Erythema Multiforme, prescr/consult w/derm.Serum Sickness,prescr/consult w/allergist.Severe acute/chronic allergic/inflam processes of eye and its adnexa, prescr/consult w/ ophthalmologist.Symptomatic Sarcoidosis, prescr/consult w/pulm/cardio.Nephrotic Syndrome, prescr/consult w/nephro.
Coverage Duration	All diagnoses-1 month
Other Criteria	For acute MS exacerbation, approve if Acthar is NOT being used as pulse therapy on a monthly basis. For all other FDA approved diagnoses (other than Infantile spasms or MS exacerbation), approve if the patient has tried a systemic corticosteroid for the current condition and patient has experienced a severe adverse effect or treatment failure with the corticosteroid (e.g., a psychotic reaction).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ACTIMMUNE

Products Affected

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Chronic granulomatous disease - prescribed by or in consultation with an immunologist, hematologist or infectious disease specialist. Malignant osteopetrosis- prescribed by or in consultation with an endocrinologist or hematologist.
Coverage Duration	1 year
Other Criteria	Chronic granulomatous disease - approve if diagnosis has been established by a molecular genetic test identifying a gene-related mutation linked to chronic granulomatous disease. Malignant osteopetrosis, severe - approve if pt has had radiographic (X-ray) imaging demonstrating skeletal features related to osteopetrosis or pt had a molecular genetic test identifying a gene-related mutation linked to severe, malignant osteopetrosis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADEMPAS

Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Phosphodiesterase Inhibitors Used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PAH and CTEPH- must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	1 year
Other Criteria	For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AIMOVIG

Products Affected

- AIMOVIG AUTOINJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with another cGRP inhibitor for migraine headache prevention
Required Medical Information	Diagnosis, number of migraine headaches per month
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AJOVY

Products Affected

- AJOVY AUTOINJECTOR
- AJOVY SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with another cGRP inhibitor for migraine headache prevention
Required Medical Information	Diagnosis, number of migraine headaches per month
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) If pt is currently taking Ajoovy, the pt has had significant clinical benefit from the medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AKEEGA

Products Affected

- AKEEGA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Prostate cancer- Approve if the patient meets the following (A, B, C, and D): A)Patient has metastatic castration-resistant prostate cancer, AND B)Patient has a BReast CAncer (BRCA) mutation, AND C)The medication is used in combination with prednisone, AND D)Patient meets one of the following (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog, Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), and Orgovyx (relugolix tablets).OR ii. Patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ALDURAZYME

Products Affected

- ALDURAZYME

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

ALECENSA

Products Affected

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Non-small cell lung cancer-approve if the patient has both (A and B): A) either (i or ii): i) medication is used as adjuvant treatment following tumor resection (note: for tumors greater than or equal to 4 cm or node positive) or ii) advanced or metastatic disease and B) anaplastic lymphoma kinase (ALK)-positive disease as detected by an approved test. Anaplastic large cell lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease and (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory Myofibroblastic Tumor- pt has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) pt has advanced, recurrent or metastatic disease, or (ii) tumor is inoperable. Large B-Cell Lymphoma- pt has ALK-positive disease AND pt has relapsed or refractory disease.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anaplastic large cell lymphoma, Erdheim Chester disease, Inflammatory Myofibroblastic Tumor, Large B-Cell Lymphoma
Part B Prerequisite	No

ALOSETRON

Products Affected

- *alosetron*

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

ALPHA 1 PROTEINASE INHIBITORS

Products Affected

- ARALAST NP
- GLASSIA
- PROLASTIN-C INTRAVENOUS SOLUTION
- ZEMAIRA

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

ALUNBRIG

Products Affected

- ALUNBRIG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	ALK status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has ALK positive disease and has advanced, recurrent or metastatic disease or the tumor is inoperable. NSCLC, must be ALK-positive, as detected by an approved test, have advanced or metastatic disease and patients new to therapy must have a trial of Alecensa prior to approval of Alunbrig. Peripheral T-Cell Lymphoma- approve if patient has ALK-positive anaplastic large cell lymphoma (ALCL).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Erdheim-Chester disease, Inflammatory myofibroblastic tumor (IMT), Peripheral T-Cell Lymphoma
Part B Prerequisite	No

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
Part B Prerequisite	No

ANKTIVA

Products Affected

- ANKTIVA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist (initial/maintenance therapy)
Coverage Duration	Initial-6 months, Maintenance-3 months
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. INITIAL-NON-MUSCLE INVASIVE BLADDER CANCER-all of (i, ii, iii): i) Patient has Bacillus Calmette-Guerin (BCG) unresponsive disease, AND ii) Patient has carcinoma in situ with or without papillary tumors, AND iii) Medication is used in combination with BCG. MAINTENANCE THERAPY-NON-MUSCLE INVASIVE BLADDER CANCER-all of (i and ii): i) Patient has an ongoing complete response defined as ONE of the following (a or b): a) Patient has negative cystoscopy and meets ONE of the following [(1) or (2)]: 1. Negative urine cytology, OR 2. Malignant urine cytology if cancer found in the upper tract or prostatic urethra and random bladder biopsies are negative, OR b) Patient has positive cystoscopy with biopsy-proven benign or low-grade Ta non-muscle invasive bladder cancer and negative urine cytology, AND ii) Medication is used in combination with BCG.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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
- *cefoxitin*
- *cefoxitin in dextrose, iso-osm*
- *ceftazidime*
- *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*
- *colistin (colistimethate na)*
- *doxy-100*
- *doxycycline hyclate intravenous*
- ERYTHROCIN INTRAVENOUS RECON SOLN 500 MG
- *erythromycin lactobionate*
- EXTENCILLINE
- *gentamicin in nacl (iso-osm) intravenous piggyback 100 mg/100 ml, 60 mg/50 ml, 80 mg/100 ml, 80 mg/50 ml*
- GENTAMICIN IN NAACL (ISO-OSM) INTRAVENOUS PIGGYBACK 100 MG/50 ML, 120 MG/100 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
- *metro i.v.*
- *metronidazole in nacl (iso-os)*
- MOXIFLOXACIN-SOD.ACE,SUL-WATER
- *moxifloxacin-sod.chloride(iso)*
- *nafcillin in dextrose iso-osm intravenous piggyback 2 gram/100 ml*
- *nafcillin injection*
- NUZYRA INTRAVENOUS
- ORBACTIV
- *oxacillin*
- *penicillin g potassium*
- *pfizerpen-g*
- *polymyxin b sulfate*
- 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
Part B Prerequisite	No

ANTIFUNGALS (IV)

Products Affected

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

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

ANTIFUNGALS, POLYENE

Products Affected

- ABELCET
- *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
Part B Prerequisite	No

ANTINEOPLASTICS, MONOCLONAL ANTIBODIES

Products Affected

- ABRAXANE
- ADCETRIS
- ADSTILADRIN
- ALIQOPA
- BAVENCIO
- BESPONSA
- BIZENGRI
- BORTEZOMIB INJECTION RECON SOLN 1 MG, 2.5 MG
- *bortezomib injection recon soln 3.5 mg*
- BORUZU
- COLUMVI
- CYRAMZA
- DANYELZA
- DARZALEX
- DARZALEX FASPRO
- ELREXFIO
- ELZONRIS
- EMPLICITI
- ENHERTU
- EPKINLY
- *eribulin*
- EVOMELA
- FYARRO
- GAZYVA
- HALAVEN
- IMFINZI
- IMJUDO
- JEMPERLI
- KADCYLA
- KEYTRUDA
- KIMMTRAK
- LIBTAYO
- LUNSUMIO
- MARGENZA
- MONJUVI
- MYLOTARG
- ONIVYDE
- OPDIVO
- OPDUALAG
- PACLITAXEL PROTEIN-BOUND
- PADCEV
- *pemetrexed disodium intravenous recon soln 1,000 mg, 100 mg, 500 mg*
- PEMETREXED DISODIUM INTRAVENOUS RECON SOLN 750 MG
- PERJETA
- PHESGO
- POLIVY
- POTELIGEO
- RUXIENCE
- RYBREVANT
- SARCLISA
- TALVEY
- TECENTRIQ
- TECENTRIQ HYBREZA
- TECVAYLI
- TEVIMBRA
- *thiotepa*
- TIVDAK
- TRAZIMERA
- TRODELVY
- UNITUXIN
- VECTIBIX
- YERVOY
- YONDELIS
- ZEPZELCA
- ZIRABEV
- ZYNLONTA
- ZYNYZ

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
Part B Prerequisite	No

ARANESP

Products Affected

- ARANESP (IN POLYSORBATE) INJECTION SOLUTION 100 MCG/ML, 200 MCG/ML, 25 MCG/ML, 40 MCG/ML, 60 MCG/ML
- ARANESP (IN POLYSORBATE) INJECTION SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Anemia w/CRF not on dialysis. A hemoglobin (Hb) of less than 10.0 g/dL for adults and less than or equal to 11 g/dL for children required for start, Hb has to be less than or equal to 11.5 g/dL adults or less than or equal to 12 g/dL in children if previously receiving epoetin alfa (EA), Mircera or Aranesp. Anemia in a patient with cancer due to cancer chemotherapy, patients must be currently receiving myelosuppressive chemotherapy which is considered non-curative treatment, Hb is 10.0 g/dL or less to start or less than or equal to 12.0 g/dL if previously on EA or Aranesp. MDS, approve tx if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start. If the pt has previously been receiving Aranesp or EA, approve only if Hb is 12.0 g/dL or less. All conds, deny if Hb exceeds 12.0 g/dL.
Age Restrictions	MDS anemia = 18 years of age and older.
Prescriber Restrictions	MDS anemia, prescribed by or in consultation with, a hematologist or oncologist.
Coverage Duration	Anemia w/myelosupp=6 mos, Anemia CKD-1 year, MDS-1 year, Other=6 mos.
Other Criteria	For anemia associated with CRF in patients 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)
Part B Prerequisite	No

ARCALYST

Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent biologic therapy
Required Medical Information	N/A
Age Restrictions	Initial tx CAPS/Pericarditis-Greater than or equal to 12 years of age.
Prescriber Restrictions	Initial tx CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA initial-rheum, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis-cardiologist or rheum
Coverage Duration	CAPS-3 mos initial, 1 yr cont. DIRA-6 mos initial, 1 yr cont. Pericard-3 mos initial, 1 yr cont
Other Criteria	INITIAL THERAPY: DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA) [all of A, B, and C]: A) weighs at least 10 kg, B) genetic test confirms a mutation in the IL1RN gene, and C) had clinical benefit with anakinra subcutaneous injection. PERICARDITIS: pericarditis is recurrent. CONTINUATION THERAPY: ALL INDICATIONS: patient had a positive response to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AREXVY

Products Affected

- AREXVY (PF)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	50 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	The patient has not already received an RSV vaccine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ARIKAYCE

Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous medication history (as described in Other Criteria field)
Age Restrictions	MAC-18 years and older (initial therapy)
Prescriber Restrictions	MAC initial-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections.
Coverage Duration	1 year
Other Criteria	<p>INITIAL THERAPY: MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE (all of A, B, and C): A) positive sputum culture for MAC [Note: any positive sputum culture taken after completion of a background multidrug regimen (throughout, see Example 1 below) fulfills this criterion], B) MAC isolate is susceptible to amikacin, and C) Arikayce will be used in combination with a background multidrug regimen.</p> <p>CONTINUATION THERAPY: MAC LUNG DISEASE (A and B): A) Arikayce prescribed in combination with a background multidrug regimen and B) patient meets one of the following (a or b): a) patient has not achieved negative sputum cultures for MAC or b) patient has achieved negative sputum cultures for MAC for less than 12 months. Example 1: background multidrug regimen example - a macrolide (azithromycin or clarithromycin), ethambutol, and a rifamycin (rifampin or rifabutin).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ARMODAFINIL

Products Affected

- *armodafinil*

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

ATYPICAL ANTIPSYCHOTIC

Products Affected

- FANAPT
- LYBALVI
- *paliperidone*

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
Part B Prerequisite	No

AUBAGIO

Products Affected

- AUBAGIO
- *teriflunomide*

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

AUGTYRO

Products Affected

- AUGTYRO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	NSCLC - 18 years and older, Solid tumors - 12 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer-approve if the patient has locally advanced or metastatic disease, patient has ROS1-positive non-small cell lung cancer and the mutation was detected by an approved test. Solid tumors - approve if tumor is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion AND tumor is locally advanced or metastatic or surgical resection will likely result in severe morbidity AND disease has progressed following treatment or there are no satisfactory alternative therapies.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AUSTEDO

Products Affected

- AUSTEDO
- AUSTEDO XR
- AUSTEDO XR TITRATION KT(WK1-4)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Chorea-prescribed by or in consult with a neuro. TD-Prescribed by or in consultation with a neurologist or a psychiatrist
Coverage Duration	1 year
Other Criteria	Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing. Tardive dyskinesia-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AVONEX

Products Affected

- AVONEX

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

AYVAKIT

Products Affected

- AYVAKIT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	GIST-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation or if the patient has tried two of the following: Gleevec (imatinib), Sutent (sunitinib), Sprycel (dasatinib), Stivarga (regorafenib) or Qinlock (ripretinib). Myeloid/Lymphoid Neoplasms with eosinophilia-approve if the tumor is positive for PDGFRA D842V mutation. Systemic mastocytosis-Approve if the patient has a platelet count greater than or equal to 50,000/mcL and patient has either indolent systemic mastocytosis or one of the following subtypes of advanced systemic mastocytosis-aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm or mast cell leukemia.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid/Lymphoid neoplasms with Eosinophilia
Part B Prerequisite	No

BALVERSA

Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies, test results
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy, other chemotherapy or checkpoint inhibitor therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BENLYSTA

Products Affected

- BENLYSTA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Biologics or Lupkynis
Required Medical Information	Diagnosis
Age Restrictions	Lupus Nephritis: 18 years and older (initial). SLE: 5 years and older (initial).
Prescriber Restrictions	SLE-Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus Nephritis-nephrologist or rheum. (Initial/cont)
Coverage Duration	SLE-Initial-4 months, cont-1 year, Lupus Nephritis-6 mo initial, 1 year cont
Other Criteria	Lupus Nephritis Initial-approve if the patient has a diagnosis of lupus nephritis confirmed on biopsy (For example, World Health Organization class III, IV, or V lupus nephritis), AND the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid). Cont-approve if the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid) AND the patient has responded to Benlysta subcutaneous or intravenous. SLE-Initial-The patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA [anti-dsDNA] antibody 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. 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,

PA Criteria	Criteria Details
	mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity AND The patient has responded to Benlysta subcutaneous or intravenous.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BESREMI

Products Affected

- BESREMI

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

BETASERON

Products Affected

- BETASERON SUBCUTANEOUS KIT

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

BEXAROTENE (ORAL)

Products Affected

- *bexarotene*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BOSENTAN

Products Affected

- *bosentan*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) WHO Group 1, results of right heart cath
Age Restrictions	N/A
Prescriber Restrictions	For treatment of pulmonary arterial hypertension, bosentan must be prescribed by or in consultation with a cardiologist or a pulmonologist. CTEPH-prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Authorization will be for 1 year.
Other Criteria	CTEPH - pt must have tried Adempas, has a contraindication to Adempas, or is currently receiving bosentan for CTEPH. Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chronic thromboembolic pulmonary hypertension (CTEPH) (bosentan)
Part B Prerequisite	No

BOSULIF

Products Affected

- BOSULIF

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	CML- 1 year and older. ALL - 15 years and older. Myeloid/lymphoid neoplasms w eosinophilia- 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For Ph-positive CML-patients-approve. For Ph-positive ALL-approve. Myeloid/lymphoid neoplasms with eosinophilia - approve if tumor has an ABL1 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia, myeloid/lymphoid neoplasms with eosinophilia
Part B Prerequisite	No

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, platysmal bands, rejuvenation of the peri-orbital region)
Required Medical Information	N/A
Age Restrictions	Blepharospasm/Strabismus-12 years and older. Pediatric NDO-5 years and older. Limb spasticity-2 years and older. All other dx-18 years and older.
Prescriber Restrictions	Migraine headache prevention if prescribed by, or after consultation with, a neurologist or HA specialist.
Coverage Duration	Authorization will be for 12 months
Other Criteria	Blepharospasm-approve. 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 prevention -must have 15 or more migraine headache days per month with headache lasting 4 hours per day or longer (prior to initiation of Botox therapy). 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). Adult Overactive Bladder with symptoms of Urge Urinary Incontinence, Urgency and Frequence-approve if the patient has tried at least one other pharmacologic therapy. Spasticity, limb-approve. Pediatric Neurogenic Detrusor Overactivity (NDO)- approve if pt tried at least one other pharmacologic therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Achalasia, Anal Fissure, Chronic facial pain/pain associated with TMJ dysfunction, Chronic low back pain, 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) Hyperhidrosis -Gustatory (Frey's Syndrome), Ophthalmic disorders (other than blepharospasm or Strabismus (eg, esotropia, exotropia, nystagmus, facial nerve paresis))
Part B Prerequisite	No

BRAFTOVI

Products Affected

- BRAFTOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRAF V600 status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation. In addition, patients new to therapy must have a trial of Zelboraf or Tafinlar prior to approval of Braftovi. Colon or Rectal cancer-approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer. NSCLC- approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Mektovi (binimetinib tablets). Appendiceal adenocarcinoma-approve if (A, B and C): A) BRAF V600E mutation-positive, and B) used as subsequent therapy for advanced or metastatic disease, and C) used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion).</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Appendiceal carcinoma
Part B Prerequisite	No

BRIUMVI

Products Affected

- BRIUMVI

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	For relapsing remitting disease - patient must have tried and failed two other MS therapies
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BRUKINSA

Products Affected

- BRUKINSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Follicular Lymphoma - approve if pt tried at least two other systemic regimens and will use this in combination with Gazyva (obinutuzumab intravenous infusion). Mantle Cell Lymphoma/CLL/SLL - approve. Marginal zone lymphoma-approve if the patient has tried at least one systemic regimen. Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma-approve. Hairy Cell Leukemia - approve if pt has received therapy for relapsed or refractory disease AND pt has progressive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Hairy Cell Leukemia, mantle cell lymphoma (not candidate for systemic tx, OR in combination with rituximab OR with TP53 mutation in combination with venetoclax)
Part B Prerequisite	No

CABOMETYX

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, histology, RET gene rearrangement status for NSCLC
Age Restrictions	Thyroid carcinoma-12 years and older, other dx (except bone cancer)-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Renal Cell Carcinoma-Approve if the patient has relapsed or stage IV disease. Bone cancer-approve if the patient has Ewing sarcoma or osteosarcoma and has tried at least one previous systemic regimen. Thyroid carcinoma-approve if the patient has differentiated thyroid carcinoma, patient is refractory to radioactive iodine therapy and the patient has tried a vascular endothelial growth factor receptor (VEGFR)-targeted therapy. Endometrial carcinoma-approve if the patient has tried one systemic regimen. GIST-approve if the patient has tried two of the following- imatinib, Ayvakit, sunitinib, dasatinib, Stivarga or Qinlock. NSCLC-approve if the patient has RET rearrangement positive tumor.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Non-Small Cell Lung Cancer, Gastrointestinal stromal tumors (GIST), Bone cancer, Endometrial Carcinoma
Part B Prerequisite	No

CALQUENCE

Products Affected

- CALQUENCE
- CALQUENCE (ACALABRUTINIB MAL)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	CLL and SLL-approve. Mantle Cell Lymphoma- approve if the patient meets (A or B): A) has tried at least one systemic regimen or is not a candidate for a systemic regimen (e.g., rituximab, dexamethasone, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, bortezomib, or lenalidomide) or B) this medication is used in combination with rituximab. Marginal Zone Lymphoma-approve if patient has tried at least one systemic regimen (e.g., bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, lenalidomide, or chlorambucil). Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen (e.g., Brukinsa [zanubrutinib capsules], Imbruvica [ibrutinib tablets and capsules], rituximab, bendamustine, cyclophosphamide, dexamethasone, bortezomib, fludarabine, or cladribine)
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Marginal zone lymphoma.
Part B Prerequisite	No

CAMZYOS

Products Affected

- CAMZYOS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by a cardiologist (initial and continuation)
Coverage Duration	Initial-8 months, continuation- 1 year
Other Criteria	<p>Obstructive hypertrophic cardiomyopathy, initial-Approve if the pt meets the following criteria (i, ii and iii): i.Pt meets both of the following (a and b): a)Pt has at least 1 symptom associated w/obstructive hypertrophic cardiomyopathy (Note: examples include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise), AND b)Pt has New York Heart Association Class II or III symptoms of heart failure (Note:Class II signifies mild symptoms with moderate physical activity and some exercise limitations whereas Class III denotes noticeable symptoms with minimal physical activity and patients are only comfortable at rest), AND ii.Pt has left ventricular hypertrophy and meets 1 of the following (a or b): a)Pt has maximal left ventricular wall thickness greater than or equal to 15 mm, OR b)Pt has familial hypertrophic cardiomyopathy with a maximal left ventricular wall thickness greater than or equal to 13 mm, AND iii.Pt has a peak left ventricular outflow tract gradient greater than or equal to 50 mmHg (at rest or after provocation [Valsalva maneuver or post exercise]). Cont-Approve if pt meets ALL of the following criteria (i, ii, iii and iv): i.Pt has been established on therapy for at least 8 months (Note: pt who has received less than 8 months of therapy or who is restarting therapy is reviewed under initial therapy), AND ii.Pt meets both of the following (a and b): a)Currently or prior to starting therapy, pt has or has experienced at least 1 symptom associated with obstructive hypertrophic cardiomyopathy, AND</p>

PA Criteria	Criteria Details
	<p>b)Currently or prior to starting therapy, pt is in or was in New York Heart Association Class II or III heart failure, AND iii.Pt has a current left ventricular ejection fraction of greater than or equal to 50 percent, AND iv.Pt meets at least 1 of the following (a or b): a)Pt experienced a beneficial clinical response when assessed by at least 1 objective measure (Note:Examples include improved peak oxygen consumption/mixed venous oxygen tension, decreases in left ventricular outflow tract gradient, reductions in N-terminal pro-B-type natriuretic peptide levels, decreased high-sensitivity cardiac troponin I levels, reduced ventricular mass index, and/or a reduction in maximum left atrial volume index), OR b)Pt experienced stabilization or improvement in at least 1 symptom related to obstructive hypertrophic cardiomyopathy (Note:Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, ability to perform physical exercise, and/or favorable changes in the Kansas City Cardiomyopathy Questionnaire-23 (KCCQ-23) Clinical Summary Score (CSS) or Hypertrophic Cardiomyopathy Symptom Questionnaire (HCMSQ) Shortness of Breath domain scores.)</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CAPRELSA

Products Affected

- CAPRELSA

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	MTC - approve. DTC - approve if refractory to radioactive iodine therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma.
Part B Prerequisite	No

CARGLUMIC ACID

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 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 than or equal to 50 micromol/L and the requested medication will be used in conjunction with other ammonia-lowering therapies.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CAYSTON

Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist, infectious diseases specialist or a physician who specializes in the treatment of cystic fibrosis.
Coverage Duration	1 year
Other Criteria	Approve if the patient has <i>Pseudomonas aeruginosa</i> in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CEREZYME

Products Affected

- CEREZYME INTRAVENOUS RECON SOLN 400 UNIT

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other approved therapies for Gaucher disease such as Cerdelga (eliglustat capsules), Elelyso (taliglucerase alfa injection), Vpriv (velaglucerase alfa injection), and Zavesca (miglustat capsules).
Required Medical Information	Diagnosis, genetic tests and lab results
Age Restrictions	Greater than or equal to 2 years of age
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 (non-neuronopathic Gaucher disease)-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting biallelic pathogenic variants in the glucocerebrosidase (GBA) gene. Gaucher Disease, Type 3 (chronic neuronopathic Gaucher disease)-approve if both (A and B): A) there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting biallelic pathogenic variants in the glucocerebrosidase (GBA) gene, and B) medication is not being used for management of neurological manifestations AND is being used for management of impaired growth, hematologic, or visceral symptoms.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Type 3 Gaucher Disease
Part B Prerequisite	No

CHEMET

Products Affected

- CHEMET

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

CHORIONIC GONADOTROPIN

Products Affected

- CHORIONIC GONADOTROPIN, HUMAN INTRAMUSCULAR
- NOVAREL INTRAMUSCULAR RECON SOLN 5,000 UNIT
- PREGNYL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CIALIS

Products Affected

- CIALIS ORAL TABLET 5 MG
- *tadalafil oral tablet 2.5 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Cialis (tadalafil) 2.5mg and 5mg are only covered under Part D for the treatment of benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribe as once daily dosing. Cialis (tadalafil) can be approved with a non-D authorization for the indication of erectile dysfunction if the EGWP customer has the lifestyle buy-up
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CIMZIA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologic therapy or targeted synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried.
Age Restrictions	18 years and older for CD and PP (initial therapy). 2 years and older for JIA (initial therapy).
Prescriber Restrictions	All dx initial therapy only. RA, AS, JIA, prescribed by or in consultation with a rheumatologist. Crohn's disease, prescribed by or in consultation with a gastroenterologist. PsA prescribed by or in consultation with a rheumatologist or dermatologist. PP, prescribed by or in consultation with a dermatologist. nr-axSpA-prescribed by or in consultation with a rheumatologist
Coverage Duration	End of the plan year
Other Criteria	AS, approve if the patient has tried two of the following: TNF, JAK or biologic. RA, approve if the patient has tried two of the following: TNF, JAK or biologic. PsA, approve if the patient has tried two of the following: TNF, JAK or biologic. PP, approve if the patient has tried two of the following: TNF, JAK or biologic. CD, approve if patient has previously tried two of the following: TNF, JAK or biologic. JIA, approve if the patient has tried two of the following: TNF, JAK, or biologic. 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

PA Criteria	Criteria Details
Part B Prerequisite	No

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 and/or is concomitantly receiving (a or b): a) one of the following: lamotrigine, topiramate, rufinamide, felbamate, Fintepla, Epidiolex or valproic acid OR b) at least two other antiepileptic drugs (e.g., valproic acid, levetiracetam, zonisamide, Fycompa/perampanel, vigabatrin). 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
Part B Prerequisite	No

CLOMID

Products Affected

- *clomid*

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	Clomiphene can be approved with a non-D authorization for the indication of infertility if the EGWP customer has the fertility buy-up
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

COMETRIQ

Products Affected

- COMETRIQ

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	MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and oncocyctic) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy and patient has tried a Vascular Endothelial Growth Factor Receptor (VEGFR)-targeted therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and oncocyctic) Thyroid Carcinoma
Part B Prerequisite	No

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
Part B Prerequisite	No

COPIKTRA

Products Affected

- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma - approve if the patient has tried one systemic regimen (e.g., Imbruvica (ibrutinib capsules, tablets and oral solution), Venclexta (venetoclax tablets), rituximab, Gazyva (obinutuzumab intravenous infusion), chlorambucil, fludarabine, cyclophosphamide, bendamustine, high-dose methylprednisolone, Campath (alemtuzumab intravenous infusion), Calquence (acalabrutinib capsules), Brukinsa (zanubrutinib capsules), or Arzerra (ofatumumab intravenous infusion). T-cell lymphoma- For peripheral T-cell lymphoma, approve. For breast implant-associated anaplastic large cell lymphoma, or hepatosplenic T-cell lymphoma, approve if the patient has relapsed or refractory disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	T-cell Lymphoma
Part B Prerequisite	No

CORLANOR

Products Affected

- CORLANOR ORAL TABLET
- *ivabradine*

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 or ivabradine 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)
Part B Prerequisite	No

COSENTYX

Products Affected

- COSENTYX
- COSENTYX (2 SYRINGES)
- COSENTYX PEN
- COSENTYX PEN (2 PENS)
- COSENTYX UNOREADY PEN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis and previous medications use
Age Restrictions	PP-6 yr and older.AS/Spondy/HS initial - 18 years of age and older. PsA-2 years and older. Enthesitis-4 years and older
Prescriber Restrictions	PP initial-presc/consult derm. PsA initial - prescribed by or in consultation with a dermatologist or rheumatologist. AS/spondylo/enthesitis initial- by or in consultation with rheumatologist. HS initial - by or in consult w/ dermatologist
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: HIDRADENITIS SUPPURATIVA (HS): tried at least one other therapy (e.g. systemic antibiotics, isotretinoin). NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: objective signs of inflammation and meets a or b: a) C-reactive protein elevated beyond the upper limit of normal or b) sacroiliitis reported on MRI. PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of at least one biologic that is not Cosentyx or a Cosentyx biosimilar also counts) or B) contraindication to MTX. CONTINUATION THERAPY: ALL INDICATIONS: patient has experienced benefit from the medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

COTELLIC

Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Melanoma initial - must have BRAF V600 mutation.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf. CNS Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma/neuroglioma/glioneuronal tumor OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c or d): a) glioma/circumscribed glioma OR b) isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma or d) Oligodendroglioma OR iii. Melanoma with brain metastases AND medication with be taken in combination with Zelboraf (vemurafenib tablets). Histiocytic Neoplasm-approve if the patient meets one of the following (i, ii, or iii): i. Patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR ii. Patient has Erdheim Chester disease OR iii. Patient has Rosai-Dorfman disease AND C) Patient has BRAF V600 mutation-positive disease.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central Nervous System Cancer

PA Criteria	Criteria Details
Part B Prerequisite	No

CRINONE

Products Affected

- CRINONE VAGINAL GEL 8 %

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	Crinone can be approved with a non-D authorization for the indication of infertility if the EGWP customer has the fertility buy-up
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CYSTEAMINE (OPHTHALMIC)

Products Affected

- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases
Coverage Duration	1 year
Other Criteria	Approve if the patient has corneal cysteine crystal deposits confirmed by slit-lamp examination
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DALFAMPRIDINE

Products Affected

- *dalfampridine*

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

DANZITEN

Products Affected

- DANZITEN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	ALL - 15 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	CML- Philadelphia chromosome positive. ALL-Philadelphia chromosome positive. Pigmented villonodular synovitis/tenosynovial giant cell tumor-patient has tried Turalio or cannot take Turalio.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Acute lymphoblastic leukemia, Pigmented villonodular synovitis/Tenosynovial giant cell tumor
Part B Prerequisite	No

DAURISMO

Products Affected

- DAURISMO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medications that will be used in combination, comorbidities
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML - approve if Daurismo will be used in combination with cytarabine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DEFERASIROX

Products Affected

- *deferasirox oral granules in packet*
- *deferasirox oral tablet*

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 if the patient is benefiting from therapy as confirmed by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DEFERIPRONE

Products Affected

- *deferiprone*
 - FERRIPROX
- FERRIPROX (2 TIMES A DAY)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Serum ferritin level
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias-Initial therapy - approve. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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
Part B Prerequisite	No

DIABETIC SUPPLIES

Products Affected

- ADVOCATE PEN NEEDLE NEEDLE 32 GAUGE X 5/32"
- *alcohol pads*
- ALCOHOL PREP PADS
- ALCOHOL SWABS
- ALCOHOL WIPES
- ASSURE ID INSULIN SAFETY SYRINGE 1 ML 29 GAUGE X 1/2"
- BD INSULIN SYRINGE ULTRA-FINE SYRINGE 0.5 ML 30 GAUGE X 1/2", 1 ML 31 GAUGE X 5/16
- BD SAFETYGLIDE INSULIN SYRINGE SYRINGE 1 ML 29 GAUGE X 1/2", 1 ML 31 GAUGE X 15/64"
- BD ULTRA-FINE NANO PEN NEEDLE
- BD ULTRA-FINE SHORT PEN NEEDLE
- CARETOUCH ALCOHOL PREP PAD
- CURITY ALCOHOL SWABS
- CURITY GAUZE TOPICAL BANDAGE 2 X 2 "
- CURITY GAUZE TOPICAL SPONGE 2 X 2 "
- DROPLET MICRON PEN NEEDLE
- DROPLET PEN NEEDLE NEEDLE 30 GAUGE X 5/16"
- DROPSAFE ALCOHOL PREP PADS
- DROPSAFE PEN NEEDLE NEEDLE 31 GAUGE X 3/16"
- EASY COMFORT ALCOHOL PAD
- EASY COMFORT SAFETY PEN NEEDLE NEEDLE 31 GAUGE X 3/16"
- EASY TOUCH ALCOHOL PREP PADS
- GAUZE PAD TOPICAL BANDAGE 2 X 2 "
- INCONTROL PEN NEEDLE NEEDLE 32 GAUGE X 5/32"
- INSULIN SYRINGE-NEEDLE U-100 SYRINGE 0.3 ML 29 GAUGE, 1 ML 29 GAUGE X 1/2", 1/2 ML 28 GAUGE
- IV PREP WIPES
- MAXICOMFORT SAFETY PEN NEEDLE NEEDLE 29 GAUGE X 5/16"
- NOVOFINE 32
- NOVOFINE PLUS
- PEN NEEDLE, DIABETIC NEEDLE 29 GAUGE X 1/2"
- PENTIPS PEN NEEDLE
- PRO COMFORT ALCOHOL PADS
- PURE COMFORT ALCOHOL PADS
- TECHLITE INSULIN SYRINGE SYRINGE 1 ML 30 GAUGE X 1/2", 1 ML 31 GAUGE X 15/64", 1 ML 31 GAUGE X 5/16
- TECHLITE INSULN SYR(HALF UNIT) SYRINGE 0.3 ML 31 GAUGE X 15/64", 0.3 ML 31 GAUGE X 5/16", 0.5 ML 30 GAUGE X 1/2", 0.5 ML 31 GAUGE X 15/64", 0.5 ML 31 GAUGE X 5/16"
- TECHLITE PEN NEEDLE NEEDLE 29 GAUGE X 1/2", 31 GAUGE X 3/16", 31 GAUGE X 5/16", 32 GAUGE X 1/4", 32 GAUGE X 5/32"
- TRUE COMFORT ALCOHOL PADS
- TRUE COMFORT PRO ALCOHOL PADS
- TRUEPLUS INSULIN
- TRUEPLUS PEN NEEDLE
- UNIFINE PENTIPS MAXFLOW
- UNIFINE PENTIPS NEEDLE 29 GAUGE X 1/2", 31 GAUGE X 1/4", 31 GAUGE X 3/16", 31 GAUGE X 5/16", 32 GAUGE X 1/4", 32 GAUGE X 5/32", 33 GAUGE X 5/32"
- UNIFINE PENTIPS PLUS
- UNIFINE PENTIPS PLUS MAXFLOW
- VERIFINE PLUS PEN NEEDLE-SHARP

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

DICLOFENAC

Products Affected

- *diclofenac sodium topical drops*
- *diclofenac sodium topical solution in metered-dose pump*

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	Patients must try a generic oral NSAID or generic diclofenac 1 percent gel.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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
Part B Prerequisite	No

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
Part B Prerequisite	No

DOPTELET

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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 (A and B): A) current platelet count less than 50 x 10 ⁹ /L and B) scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. CHRONIC ITP, INITIAL THERAPY (A and B): A): (i or ii): i) platelet count less than 30,000 microliters or ii) platelet count less than 50,000 microliters and patient is at an increased risk of bleeding, and B) tried one other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, eltrombopag tablets and oral suspension, romiplostim subcutaneous injection, fostamatinib tablets, rituximab) or had a splenectomy. CHRONIC ITP, CONTINUATION THERAPY: patient had beneficial clinical response and remains at risk for bleeding complications.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DROXIDOPA

Products Affected

- *droxidopa*
- NORTHERA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Medication history (as described in Other Criteria field)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a neurologist
Coverage Duration	12 months
Other Criteria	NOH, approve if the patient meets ALL of the following criteria: a) Patient has been diagnosed with symptomatic NOH due to primary autonomic failure (Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, AND b) Patient has tried midodrine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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
Part B Prerequisite	No

DUPIXENT

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Xolair or another Anti-interleukin (IL) Monoclonal Antibody (i.e., Adbry, Cinqair, Fasentra, Nucala, Tezspire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical].
Required Medical Information	Diagnosis, prescriber specialty, other medications tried and length of trials. COPD INITIAL: meets (all of A, B, C, and D): A) blood eosinophil at least 300 cells per microliter within previous 6 weeks or prior to Dupixent or another monoclonal antibody, and B) received at least 3 months of combination therapy with at least two of LAMA, LABA or ICS, and C) signs or symptoms of chronic bronchitis for at least 3 months in previous 12 months, and D) meets (i or ii): i) two or more COPD exacerbations in previous 12 months requiring systemic CS or antibiotics and at least one required systemic CS and at least one occurred while on two of LAMA, LABA, ICS therapy, or ii) COPD exacerbation requiring hospitalization in previous 12 months and occurred while on two of LAMA, LABA, ICS therapy. COPD CONTINUATION (all of A, B and C): A) received Dupixent for at least 6 months and B) continues LABA and LAMA, and C) beneficial response (e.g. reduced symptoms, exacerbations, hospitalizations, ED/urgent care visits, improved lung function).
Age Restrictions	Initial therapy only: AD-6 months and older, asthma-6 years of age and older, Esophagitis-1 yr and older, Chronic Rhinosinusitis- 12 and older, Prurigo nodularis/COPD-18 and older
Prescriber Restrictions	Initial therapy only: 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. COPD-prescribed by or in consultation with an allergist, immunologist, or pulmonologist
Coverage Duration	AD-Init-4mo, Cont-1 yr, asthma/Rhinosinusitis/esophagitis/prurigo nod/COPD-init-6 mo, cont 1 yr

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL CRITERIA: AD: tried at least 1 medium to super-high-potency topical corticosteroid (CS), unless topical CS therapy not advisable or pt is less than 2 years old. ASTHMA (all of A, B, and C): A) blood eosinophil greater than or equal to 150 cells per microliter within previous 6 weeks or within 6 weeks prior to Dupixent or another monoclonal antibody or has oral CS-dependent asthma, B) used an ICS in combination with at least one additional asthma controller/maintenance medication, and C) uncontrolled asthma prior to any asthma monoclonal antibody as defined by one of the following (one of a, b, c, d, or e): a) two or more asthma exacerbations requiring oral CS in the past year, b) one or more asthma exacerbations requiring hospital/urgent care/ED visit in the past year, c) FEV1 less than 80 percent predicted, d) FEV1/FVC less than 0.8, or e) worsened asthma with oral CS taper. CRSwNP (all of A, B, C and D): A) concurrent use with nasal CS, B) presence of at least two of the following symptoms for 6 months: nasal congestion, nasal obstruction, nasal discharge, reduction/loss of smell, C) received oral CS at least 5 days in last 2 years (unless contraindicated) or patient had prior surgery for nasal polyps, and D) diagnosis confirmed by direct exam, endoscopy, or sinus CT. EoE (all of A, B, C, and D): A) weighs 15 kg or more, B) endoscopic biopsy demonstrating greater than or equal to 15 intraepithelial eosinophils per high-power field, C) does not have a secondary cause of EoE, and D) received an Rx-strength PPI for at least 8 weeks. PRURIGO NODULARIS (all of A, B, and C): A) 20 nodular lesions or more, B) pruritus lasting at least 6 weeks, and C) tried at least 1 high- or super-high-potency topical CS. CONTINUATION CRITERIA: AD: responding positively to therapy. ASTHMA: responding positively to therapy and concurrent use with ICS. CRSwNP (all of A, B, and C): A) received Dupixent for at least 6 months, B) responding positively to therapy, and C) concurrent use with intranasal CS. EoE (A and B): A) received Dupixent for at least 6 months and B) reduction in intraepithelial eosinophil count, decreased dysphagia/pain upon swallowing, or reduced frequency/severity of food impaction. PRURIGO NODULARIS (A and B): A) received Dupixent for at least 6 months and B) reduction in nodular lesion count, pruritus, or nodular lesion size.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ELAPRASE

Products Affected

- ELAPRASE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has laboratory test demonstrating deficient iduronate-2-sulfatase activity in leukocytes, fibroblasts, serum or plasma OR a molecular genetic test demonstrating iduronate-2-sulfatase gene variant.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ENBREL

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologic therapy or targeted synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried.
Age Restrictions	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. Behcet's disease,prescribed by or in consult w/ rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist.
Coverage Duration	End of the plan year
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 or JAK inhibitor for RA/PsA 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 for at least 3 months (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID), biologic or JAK inhibitor) 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

PA Criteria	Criteria Details
	systemic corticosteroid, immunosuppressives or other biologic therapy. GVHD, approve. Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. Continuation-approve if the patient has had a response as determined by the prescriber.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Graft versus host disease (GVHD), Uveitis, Behcet's disease
Part B Prerequisite	No

ENDARI

Products Affected

- *glutamine (sickle cell)*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty
Age Restrictions	Greater than or equal to 5 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, a physician who specializes in sickle cell disease (e.g., a hematologist)
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EPIDIOLEX

Products Affected

- EPIDIOLEX

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

EPOETIN ALFA

Products Affected

- PROCRIT
- RETACRIT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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-1yr, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr
Other Criteria	<p>Anemia in a pt with Chronic Kidney Disease (CKD) not on dialysis- for initial therapy, approve if hemoglobin (Hb) is less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children, or for continuation of therapy in a pt currently on an erythropoiesis-stimulating agent (ESA) approve if Hb is less than or equal to 12 g/dL. Anemia in a pt with cancer due to chemotherapy- approve if pt is currently receiving myelosuppressive chemo as a non-curative treatment and (for initial therapy) Hb is less than 10.0 g/dL or (if currently on ESA) Hb is less than or equal to 12.0 g/dL. Anemia in HIV with zidovudine- for initial therapy, approve if Hb is less than 10.0 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA, approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - Approve if Hb is less than or equal to 13, AND surgery is elective, nonvascular and non-cardiac AND pt is unwilling or unable to donate autologous blood prior to surgery. MDS- for initial therapy, approve if Hb is less than 10 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA approve if Hb is 12.0 g/dL or less. Myelofibrosis- for Initial therapy approve if patient has a Hb less than 10 or serum erythropoietin less than or equal to 500 mU/mL, or for continuation of therapy in pt currently on ESA hemoglobin is less than or equal to 12g/dL. Anemia in patients with chronic renal failure on dialysis -</p>

PA Criteria	Criteria Details
	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
Part B Prerequisite	No

ERIVEDGE

Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	BCC (La or Met) - must not have had disease progression while on Odomzo.
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Basal cell carcinoma, locally advanced-approve. Central nervous system cancer (this includes brain and spinal cord tumors)-approve if the patient has medulloblastoma, the patient has tried at least one chemotherapy agent and according to the prescriber, the patient has a mutation of the sonic hedgehog pathway. Basal cell carcinoma, metastatic (this includes primary or recurrent nodal metastases and distant metastases)-approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central nervous System Cancer
Part B Prerequisite	No

ERLEADA

Products Affected

- ERLEADA

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	Prostate cancer-non-metastatic, castration resistant and prostate cancer-metastatic, castration sensitive-approve if the requested medication will be used in combination with a gonadotropin-releasing hormone (GnRH) analog [for example: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ERLOTINIB

Products Affected

- *erlotinib*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	Advanced or Metastatic NSCLC, approve if the patient has EGFR mutation positive non-small cell lung cancer as detected by an approved test. Note-Examples of EGFR mutation-positive non-small cell lung cancer include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. RCC, approve if the patient has recurrent or advanced non-clear cell histology RCC or if the patient had hereditary leiomyomatosis and renal cell carcinoma and erlotinib will be used in combination with bevacizumab. Bone cancer-approve if the patient has chordoma and has tried at least one previous therapy. Pancreatic cancer-approve if the medication is used in combination with gemcitabine and if the patient has locally advanced, metastatic or recurrent disease. Vulvar cancer-approve if the patient has advanced, recurrent or metastatic disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Renal Cell Carcinoma, vulvar cancer and Bone Cancer-Chordoma.
Part B Prerequisite	No

EVEROLIMUS

Products Affected

- AFINITOR
- AFINITOR DISPERZ
- *everolimus (antineoplastic)*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer-HER2 status, hormone receptor (HR) status.
Age Restrictions	All dx except TSC associated SEGA, renal angiomyolipoma or partial onset seizures-18 years and older.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	<p>Breast Cancer-pt meets the following (A,B,C,D,E, and F):A)recurrent or metastatic,HR+ disease AND B)HER2-negative breast cancer AND C)tried at least 1 prior endocrine therapy AND D)meets 1 of the following conditions (i or ii):i.postmenopausal woman or man OR ii.pre/perimenopausal woman AND receiving ovarian suppression/ablation with GnRH agonist, or had surgical bilateral oophorectomy or ovarian irradiation AND E)meets 1 of the following conditions (i or ii): i.Everolimus used in combo w/exemestane and meets 1 of the following:male and receiving a GnRH analog or woman or ii.Everolimus will be used in combo with fulvestrant or tamoxifen AND F)has not had disease progression while on everolimus.RCC, relapsed or Stage IV disease-approve if using for non-clear cell disease or if using for clear cell disease, has tried 1 prior systemic therapy(e.g., Inlyta, Votrient, Sutent, Cabometyx, Nexavar).TSC Associated SEGA-requires therapeutic intervention but cannot be curatively resected.Thymomas and Thymic Carcinomas-has tried chemo or cannot tolerate chemo.TSC associated renal angiomyolipoma-approve.WM/LPL-has progressive or relapsed disease or if has not responded to primary therapy.Thyroid Carcinoma, differentiated-refractory to radioactive iodine therapy.Endometrial Carcinoma- Everolimus will be used in combo with letrozole.GIST-has tried 2 of the following drugs: Sutent, Sprycel, Stivarga, Ayvakit, Qinlock</p>

PA Criteria	Criteria Details
	<p>or imatinib AND there is confirmation that everolimus will be used in combo with 1 of these drugs (Sutent, Stivarga, or imatinib) in the treatment of GIST. TSC-associated partial-onset seizures-approve.NET tumors of the pancreas, GI Tract, Lung and Thymus (carcinoid tumors)-approve. Soft tissue sarcoma-has perivascular epitheloid cell tumors (PE Coma) or recurrent angiomyolipoma/lymphangioliomyomatosis.Classic hodgkin lymphoma-has relapsed or refractory disease AND has tried at least three prior lines of chemotherapy.Histiocytic neoplasm-has Erdheim-Chester disease or, Rosai-Dorfman disease or Langerhans cell histiocytosis.Pt must also have PIK3CA mutation. Meningioma-has recurrent or progressive disease AND has surgically inaccessible disease and radiation therapy is not possible AND medication will be used in combination with a somatostatin analogue. Uterine Sarcoma-has advanced, recurrent, metastatic, or inoperable disease, AND has perivascular epithelioid cell tumor (PEComa), AND has tried at least 1 systemic regimen.Note: Examples of include doxorubicin, docetaxel, gemcitabine, ifosfamide, dacarbazine. For all covered diagnoses, if the request is for brand Afinitor-pt is required to have tried generic everolimus tablets AND cannot use the generic product due to formulation diff in the inactive ingredient(s) between Brand and generic product which would result in a significant allergy or serious adverse reaction.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	<p>neuroendocrine tumors of the thymus (Carcinoid tumors). Soft tissue sarcoma, classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Thymomas and Thymic carcinomas, Differentiated Thyroid Carcinoma, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST), men with breast cancer, Pre-peri-menopausal women with breast cancer, Histiocytic Neoplasm, uterine sarcoma, meningioma</p>
Part B Prerequisite	No

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

FARYDAK

Products Affected

- FARYDAK

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

FASENRA

Products Affected

- FASENRA
- FASENRA PEN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy.
Required Medical Information	Diagnosis
Age Restrictions	Asthma: 6 years of age and older, EGPA: 18 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
Coverage Duration	Asthma: 6 months initial, 12 months continuation. EGPA: 8 months initial, 12 months continuation.
Other Criteria	<p>INITIAL THERAPY: ASTHMA (all of A, B, and C): A) blood eosinophil greater than or equal to 150 cells per microliter within previous 6 weeks or within 6 weeks prior to Fasentra or another monoclonal antibody, B) used an inhaled corticosteroid (ICS) in combination with at least one additional asthma controller/maintenance medication, and C) uncontrolled asthma prior to any asthma monoclonal antibody as defined by one of the following (a, b, c, d, or e): a) one or more exacerbations requiring a systemic CS in the past year, b) one or more exacerbations requiring hospital/urgent care/emergency department visit in the past year, c) FEV1 less than 80 percent predicted or less than 90 percent predicted for patients less than 18, d) FEV1/FVC less than 0.80, or e) worsened asthma with systemic CS taper. EGPA: (all of A, B, and C): A) active disease, and B) currently on systemic CS for at least 4 weeks, and C) blood eosinophil greater than or equal to 150 cells per microliter within previous 4 weeks or prior to treatment with any monoclonal antibody that may alter eosinophil levels.</p> <p>CONTINUATION THERAPY: ASTHMA (A and B): A) patient has responded to therapy (e.g., decrease in any of the following: asthma exacerbations, asthma symptoms, hospitalizations, emergency department/urgent care visits, physician visits, requirement for oral corticosteroid therapy) and B) continues to receive therapy with an ICS.</p>

PA Criteria	Criteria Details
	EGPA: patient has responded to therapy (e.g. reduced rate of relapse, CS dose reduction, reduced eosinophil levels).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FINGOLIMOD

Products Affected

- *fingolimod*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of fingolimod with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	10 years and older
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FINTEPLA

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Dravet Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex, Clobazam or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. Lennox-Gastaut Syndrome, initial-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Lennox-Gastaut Syndrome, continuation-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FORTEO

Products Affected

- FORTEO

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	High risk for fracture-2 yrs, Not high risk-approve a max of 2 yrs of therapy (total)/lifetime.
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 hypogonadal 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
Part B Prerequisite	No

FOTIVDA

Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Renal Cell Carcinoma (RCC)-approve if the patient has relapsed or Stage IV disease and has tried at least two other systemic regimens. Note: Examples of systemic regimens for renal cell carcinoma include axitinib tablets, axitinib + pembrolizumab injection, cabozantinib tablets, cabozantinib + nivolumab injection, sunitinib malate capsules, pazopanib tablets, sorafenib tablets, and lenvatinib capsules + everolimus.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FRUZAQLA

Products Affected

- FRUZAQLA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Colon cancer, rectal cancer, or appendiceal cancer-Approve if the patient meets the following (A and B): A.Patient has advanced or metastatic disease, AND B.Patient has previously been treated with the following (i, ii, and iii): i.Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, Note: Examples of fluoropyrimidine agents include 5-fluorouracil (5-FU) and capecitabine. AND ii.An anti-vascular endothelial growth factor (VEGF) agent, Note: Examples of anti-VEGF agents include bevacizumab. AND iii. If the tumor is RAS wild-type (KRAS wild-type and NRAS wild-type) [that is, the tumor or metastases are KRAS and NRAS mutation negative], the patient meets ONE of the following (a or b): a.According to the prescriber, anti-epidermal growth factor receptor (EGFR) therapy is NOT medically appropriate, OR b. The patient has received an anti-EGFR therapy. Note: Examples of anti-EGFR therapy includes Erbitux (cetuximab intravenous infusion) and Vectibix (panitumumab intravenous infusion).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Appendiceal cancer
Part B Prerequisite	No

GATTEX

Products Affected

- GATTEX 30-VIAL
- GATTEX ONE-VIAL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	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 improvement.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GAVRETO

Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	NSCLC-18 years and older, thyroid cancer-12 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NSCLC-approve if the patient has advanced, recurrent, or metastatic disease and rearranged during transfection (RET) fusion-positive disease detected by an Food and Drug Administration (FDA) approved test. Differentiated Thyroid Cancer- pt has unresectable, recurrent, or metastatic disease AND pt has RET fusion-positive or RET-mutation-positive disease AND disease requires treatment with systemic therapy AND the disease is radioactive iodine-refractory. Anaplastic thyroid cancer or Medullary Thyroid Cancer- pt has unresectable, recurrent, or metastatic disease AND pt has RET fusion-positive or RET-mutation-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Medullary Thyroid Cancer, Anaplastic Thyroid Cancer
Part B Prerequisite	No

GEFITINIB

Products Affected

- *gefitinib*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NSCLC-approve if the patient has advanced or metastatic disease and the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	NSCLC with EGFR L861Q, G719X, or S768I mutations.
Part B Prerequisite	No

GILENYA

Products Affected

- GILENYA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Gilenya with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	10 years and older
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Cont tx - approve if the patient has been established on Gilenya.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GILOTRIF

Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For NSCLC - EGFR exon deletions or mutations or if NSCLC is squamous cell type
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	NSCLC EGFR pos - For the treatment of advanced or metastatic non small cell lung cancer (NSCLC)-approve if the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: examples of sensitizing EGFR mutation-positive NSCLC include the following mutations : exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. NSCLC metastatic squamous cell must have disease progression after treatment with platinum based chemotherapy. Head and neck cancer-approve if the patient has non-nasopharyngeal head and neck cancer and the patient has disease progression on or after platinum based chemotherapy. (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan)
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Head and neck cancer
Part B Prerequisite	Yes

GLATIRAMER

Products Affected

- *glatiramer*
- *glatopa*

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

GLP-1 AGONISTS

Products Affected

- | | |
|---|------------------------------------|
| • BYDUREON BCISE | MG/3 ML), 1 MG/DOSE (4 MG/3 ML), 2 |
| • <i>liraglutide</i> | MG/DOSE (8 MG/3 ML) |
| • MOUNJARO | • RYBELSUS |
| • OZEMPIC SUBCUTANEOUS PEN
INJECTOR 0.25 MG OR 0.5 MG (2 | • TRULICITY |
| | • VICTOZA 2-PAK |
| | • VICTOZA 3-PAK |

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

GONADOTROPIN-RELEASING HORMONE AGONISTS - ONCOLOGY

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prostate cancer- prescribed by or in consultation with an oncologist or urologist. Head and neck-salivary gland tumors- prescribed by or in consultation with an oncologist.
Coverage Duration	1 year
Other Criteria	Head and neck cancer-salivary gland tumor- approve if pt has recurrent, unresectable, or metastatic disease AND androgen receptor-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Head and neck cancer- salivary gland tumors (Eligard only)
Part B Prerequisite	No

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 less than 10ng/mL OR had at least 1 GH test less than 10ng/mL 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 less than 10ng/mL 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 less than 10ng/mL 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 multiple pituitary deficiencies and pt has 3 or more pituitary hormone deficiencies or pt has had one GH test less than 10ng/mL 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, Noonan (initial), Prader Willi (initial for child/adult and cont tx in adults), SHOX (initial), SGA (initial) - prescribed by or in consultation with an endocrinologist. CKD (initial) endocrinologist or nephrologist.
Coverage Duration	ISS - 6 mos initial, 12 months cont tx, SBS-1 month, 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 childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage,

PA Criteria	Criteria Details
	<p>AND 3. meets one of the following - A. has known perinatal insults or congenital or genetic defects or structural hypothalamic pituitary defects, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, IGF1 less than 84 mcg/L (Esoterix RIA), AND other causes of low serum IGF-1 have been excluded, C. Neg response to ONE preferred GH stim test (insulin peak response less than or equal to 5 mcg/L, Glucagon peak less than or equal to 3 mcg/L (BMI is less than or equal to 25), less than or equal to 3 and BMI is greater than or equal to 25 and less than or equal to 30 with a high pretest probability of GH deficiency, less than or equal to 1 and BMI is greater than or equal to 25 and less than or equal to 30 with a low pretest probability of GH deficiency or less than or equal to 1 mcg/L (BMI is greater than 30), if insulin and glucagon contraindicated then Arginine 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.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	SBS
Part B Prerequisite	No

HAEGARDA

Products Affected

- HAEGARDA

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

HETLIOZ

Products Affected

- HETLIOZ
- *tasimelteon*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Non-24-patient is totally blind with no perception of light
Age Restrictions	Non-24-18 years or older (initial and continuation), SMS-3 years and older
Prescriber Restrictions	prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders (initial and continuation)
Coverage Duration	6 mos initial, 12 mos cont
Other Criteria	Initial - patient is totally blind with no perception of light, dx of Non-24 is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy plus evaluation of sleep logs. Cont - Approve if patient is totally blind with no perception of light and pt has achieved adequate results with tasimelteon therapy according to the prescribing physician (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep). Nighttime sleep disturbances in Smith-Magenis SYndrome (SMS)-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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
Part B Prerequisite	No

HIGH RISK MEDICATIONS - CARISOPRODOL

Products Affected

- *carisoprodol*

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 anticholinergic medications, the physician 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
Part B Prerequisite	No

HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

Products Affected

- *cyclobenzaprine oral tablet*

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
Part B Prerequisite	No

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

Products Affected

- *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 hydroxyzine hydrochloride, authorize use without a previous drug trial for all FDA-approved indications other than anxiety. 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
Part B Prerequisite	No

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
Part B Prerequisite	No

HRM - ANTIDEMENTIA AGENTS

Products Affected

- *ergoloid*

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, AND the physician has documented that the patient has tried and failed two (2) safer formulary alternatives or provided clinical rationale why two safer formulary alternatives are not appropriate for the patient.
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	The patient has tried two of the following: donepezil, galantamine and rivastigmine. 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
Part B Prerequisite	No

HRM - BUTALBITAL COMBINATIONS

Products Affected

- *ascomp with codeine*
- *butalbital-acetaminop-caf-cod*
- *butalbital-acetaminophen oral tablet*
- *butalbital-acetaminophen-caff*
- *butalbital-aspirin-caffeine oral capsule*
- *tencon*

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, AND the physician has documented that the patient has tried and failed two (2) safer formulary alternatives or provided clinical rationale why two safer formulary alternatives are not appropriate for the patient.
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	The patient has tried two of the following: naproxen sodium and ibuprofen. 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
Part B Prerequisite	No

HRM - GLYBURIDE

Products Affected

- *glyburide*
- *glyburide micronized*

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, AND the physician has documented that the patient has tried and failed glipizide or provided clinical rationale as to why that safer formulary alternative is not appropriate for the patient.
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	The patient has tried glipizide. 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
Part B Prerequisite	No

HRM - GLYBURIDE/METFORMIN

Products Affected

- *glyburide-metformin*

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, AND the physician has documented that the patient has tried and failed glipizide-metformin or provided clinical rationale why that safer formulary alternative is not appropriate for the patient.
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	The patient has tried glipizide-metformin. 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
Part B Prerequisite	No

HRM - SKELETAL MUSCLE RELAXANTS

Products Affected

- *chlorzoxazone oral tablet 500 mg*
- *metaxalone*
- *methocarbamol oral tablet 500 mg, 750 mg*
- *orphenadrine citrate oral*

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 anticholinergic medications, the physician 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	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. For patients concurrently taking multiple anticholinergic medications, the physician has assessed this risk as well.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HRM - TRIHEXYPHENIDYL

Products Affected

- *trihexyphenidyl*

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 anticholinergic medications, the physician 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	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. For patients concurrently taking multiple anticholinergic medications, the physician has assessed this risk as well.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HUMIRA

Products Affected

- HUMIRA PEN (PREFERRED NDCS STARTING WITH 00074)
- HUMIRA SUBCUTANEOUS SYRINGE KIT 40 MG/0.8 ML (PREFERRED NDCS STARTING WITH 00074)
- HUMIRA(CF) (PREFERRED NDCS STARTING WITH 00074)
- HUMIRA(CF) PEN (PREFERRED NDCS STARTING WITH 00074)
- HUMIRA(CF) PEN CROHNS-UC-HS (PREFERRED NDCS STARTING WITH 00074)
- HUMIRA(CF) PEN PEDIATRIC UC (PREFERRED NDCS STARTING WITH 00074)
- HUMIRA(CF) PEN PSOR-UV-ADOL HS (PREFERRED NDCS STARTING WITH 00074)
- YUFLYMA(CF)
- YUFLYMA(CF) AI CROHN'S-UC-HS
- YUFLYMA(CF) AUTOINJECTOR

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	End of the plan year
Other Criteria	RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor 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 for at least 3 months (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID), biologic or JAK inhibitor) OR patient

PA Criteria	Criteria Details
	<p>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. CD initial, approve if the patient has tried or is currently taking corticosteroids or patient has tried one other agent for CD for at least 3 months. UC initial, approve if the patient has had a trial of one systemic agent for at least 3 months (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, biologic, JAK inhibitor or a corticosteroid such as prednisone or methylprednisolone). 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.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IBRANCE

Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Breast cancer - approve recurrent or metastatic, hormone receptor positive (HR+) [i.e., estrogen receptor positive- {ER+} and/or progesterone receptor positive {PR+}] disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and Ibrance will be used in combination with anastrozole, exemestane, or letrozole 2, pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonists, or has had surgical bilateral oophorectomy, or ovarian irradiation AND meets one of the following conditions: Ibrance will be used in combination with anastrozole, exemestane, or letrozole or Ibrance will be used in combination with fulvestrant 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Ibrance will be used in combination with anastrozole, exemestane or letrozole or Ibrance will be used in combination with fulvestrant 4. Pt is postmenopausal and Ibrance will be used in combination with fulvestrant. In addition, patients new to therapy must have a trial of Kisqali, Kisqali Femara Co-Pack or Verzenio prior to approval of Ibrance, unless patient will be using Ibrance with Itovebi. Liposarcoma-approve if the patient has well-differentiated/dedifferentiated liposarcoma (WD-DDLS).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Liposarcoma
Part B Prerequisite	No

ICATIBANT

Products Affected

- *icatibant*
- *sajazir*

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

ICLUSIG

Products Affected

- ICLUSIG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Acute lymphoblastic leukemia, Philadelphia chromosome positive or chronic myeloid leukemia-approve. GIST - approve if the patient tried all of the following therapies first to align with NCCN recommendations which include: Imatinib or Ayvakit (avapritinib tablets), AND Sunitinib or Sprycel (dasatinib tablets), AND Stivarga (regorafenib tablets), AND Qinlock (ripretinib tablets). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has ABL1 rearrangement or FGFR1 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia
Part B Prerequisite	No

IDHIFA

Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	IDH2-mutation status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	AML - approve if the patient is IDH2-mutation status positive as detected by an approved test
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IMATINIB

Products Affected

- *imatinib*
- IMKELDI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
Age Restrictions	ASM, DFSP, HES, MDS/MPD/Myeloid/Lymphoid Neoplasms/Kaposi Sarcoma/Cutaneous Melanoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For ALL/CML, must have Ph-positive for approval of imatinib. Kaposi's Sarcoma-approve if the patient has tried at least one regimen AND has relapsed or refractory disease. Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT)-patient has tried Turalio or according to the prescriber, the patient cannot take Turalio. Myelodysplastic/myeloproliferative disease-approve if the condition is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements.Graft versus host disease, chronic-approve if the patient has tried at least one conventional systemic treatment (e.g., imbruvica). Cutaneous melanoma-approve if the patient has an activating KIT mutation, metastatic or unresectable melanoma, and has tried at least one systemic regimen. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement or an FIP1L1-PDGFR or PDGFRB rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chordoma, desmoid tumors (aggressive fibromatosis), cKit positive metastatic or unresectable cutaneous melanoma, Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor, myeloid/lymphoid neoplasms with eosinophilia, GVHD, chronic.

PA Criteria	Criteria Details
Part B Prerequisite	No

IMBRUVICA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	GVHD-1 year and older, other-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	CLL- Approve. GVHD-Approve if the patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], imatinib, low-dose methotrexate, sirolimus, mycophenolate mofetil, Jakafi [ruxolitinib tablets]). B-cell lymphoma-approve if the patient has tried at least one systemic regimen (e.g., cisplatin, cytarabine, rituximab, oxaliplatin, gemcitabine, ifosfamide, carboplatin, etoposide, or rituximab). Central nervous system Lymphoma (primary)- approve if the patient is not a candidate for or is intolerant to high-dose methotrexate OR has tried at least one therapy (e.g., methotrexate, rituximab, vincristine, procarbazine, cytarabine, thiotepa, carmustine, intrathecal methotrexate, cytarabine, or rituximab). Hairy Cell Leukemia - approve if the patient has tried at least two systemic regimens (cladribine, Nipent [pentostatin injection], rituximab, or Pegasys [peginterferon alfa-2a subcutaneous injection]).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma
Part B Prerequisite	No

IMDELLTRA

Products Affected

- IMDELLTRA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. SMALL CELL LUNG CANCER-patient has relapsed or refractory extensive stage disease and has previously received platinum-based chemotherapy. Note: Examples of platinum medications include cisplatin and carboplatin.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INBRIJA

Products Affected

- INBRIJA INHALATION CAPSULE, W/INHALATION DEVICE

PA Criteria	Criteria Details
Exclusion Criteria	Asthma, COPD, other chronic underlying lung disease
Required Medical Information	Diagnosis, medications that will be used in combination
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Approve if the patient is currently taking carbidopa-levodopa and is experiencing off episodes.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INCRELEX

Products Affected

- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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
Part B Prerequisite	No

INFLECTRA

Products Affected

- INFLECTRA

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 suppurativa-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, cardio, neuro, 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 mo
Other Criteria	RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor 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 for at least 3 months (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID), biologic or JAK inhibitor 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

PA Criteria	Criteria Details
	<p>systemic corticosteroid, immunosuppressives or other biologic therapy. GVHD, approve. CD initial, approve if the patient has tried or is currently taking corticosteroids or patient has tried one other agent for CD. UC initial, approve if the patient has had a trial of one systemic agent for at least 3 months (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, biologic, JAK inhibitor or a corticosteroid such as prednisone or methylprednisolone). HS initial, tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Behcet's initial, patient has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa) or at least one tumor necrosis factor for Behcet's disease OR has ophthalmic manifestations. Still's Disease initial, tried CS AND 1 conventional synthetic DMARD (eg, MTX) for 2 mos, or was intolerant. Prev trial of one biologic other than requested drug or biosimilar of the requested drug also counts. Sarcoidosis initial, tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide. Pyoderma gangrenosum (PG) initial, tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos or was intolerant to one of these agents. Continuation-approve if the patient has had a response as determined by the prescriber.</p>
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
Part B Prerequisite	No

INFLIXIMAB

Products Affected

- AVSOLA
- RENFLEXIS

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 suppurativa-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, cardio, neuro, 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 mo
Other Criteria	RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor 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 for at least 3 months (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID), biologic or JAK inhibitor 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

PA Criteria	Criteria Details
	<p>systemic corticosteroid, immunosuppressives or other biologic therapy. GVHD, approve. CD initial, approve if the patient has tried or is currently taking corticosteroids or patient has tried one other agent for CD. UC initial, approve if the patient has had a trial of one systemic agent for at least 3 months (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, biologic, JAK inhibitor or a corticosteroid such as prednisone or methylprednisolone). HS initial, tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Behcet's initial, patient has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa) or at least one tumor necrosis factor for Behcet's disease OR has ophthalmic manifestations. Still's Disease initial, tried CS AND 1 conventional synthetic DMARD (eg, MTX) for 2 mos, or was intolerant. Prev trial of one biologic other than requested drug or biosimilar of the requested drug also counts. Sarcoidosis initial, tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide. Pyoderma gangrenosum (PG) initial, tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos or was intolerant to one of these agents. Continuation-approve if the patient has had a response as determined by the prescriber.</p>
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
Part B Prerequisite	No

INGREZZA

Products Affected

- INGREZZA
- INGREZZA INITIATION PK(TARDIV)
- INGREZZA SPRINKLE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	TD-Prescribed by or in consultation with a neurologist or psychiatrist. Chorea HD - prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Chorea associated with Huntington's Disease- approve if diagnosis is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INLYTA

Products Affected

- INLYTA

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 1 year.
Other Criteria	Advanced Renal cell carcinoma-approve. Differentiated thyroid cancer, approve if patient is refractory to radioactive iodine therapy. Soft tissue sarcoma-approve if the patient has alveolar soft part sarcoma and the medication will be used in combination with Keytruda (pembrolizumab).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma, Soft tissue sarcoma
Part B Prerequisite	No

INQOVI

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myelodysplastic Syndrome/Myeloproliferative Neoplasm Overlap Neoplasms
Part B Prerequisite	No

INREBIC

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has intermediate-2 or high-risk disease. Myeloid/Lymphoid Neoplasms with Eosinophilia-approve if the tumor has a JAK2 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid/Lymphoid Neoplasms with Eosinophilia
Part B Prerequisite	No

INTRAROSA

Products Affected

- INTRAROSA

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
Part B Prerequisite	No

ITOVEBI

Products Affected

- ITOVEBI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	BREAST CANCER (all of A, B, C, D, E and F): A. Patient meets ONE of the following (i or ii): i. Patient is a postmenopausal female, OR ii. Patient meets BOTH of the following (a and b): a. Patient is a pre/perimenopausal female or a male, AND b. Patient is receiving a gonadotropin-releasing hormone (GnRH) agonist, Note: Examples of a GnRH agonist include leuprolide acetate, leuprolide acetate intramuscular injection, triptorelin pamoate intramuscular injection, goserelin acetate subcutaneous injection. AND B. Patient has locally advanced or metastatic hormone receptor (HR)-positive disease, AND C. Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D. Patient has PIK3CA-mutated breast cancer as detected by an approved test, AND E. Patient has disease recurrence on or after completing adjuvant endocrine therapy, Note: Examples include tamoxifen, anastrozole, letrozole, exemestane, toremifene. AND F. The medication will be used in combination with palbociclib capsules/tablets and fulvestrant injection.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IVERMECTIN

Products Affected

- *ivermectin oral*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	Pediculosis-approve if the patient has infection caused by pediculus humanus capitis (head lice), pediculus humanus corporis (body lice), or has pediculosis pubis caused by phthirus pubis (pubic lice). Scabies-approve if the patient has classic scabies, treatment resistant scabies, is unable to tolerate topical treatment, has crusted scabies or is using ivermectin tablets for prevention and/or control of scabies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ascariasis, Enterobiasis (pinworm infection), Hookworm-related cutaneous larva migrans, Mansonella ozzardi infection, Mansonella streptocerca infection, Pediculosis, Scabies. Trichuriasis, Wucheria bancrofti infection
Part B Prerequisite	No

IWILFIN

Products Affected

- IWILFIN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Neuroblastoma-Approve if the patient meets the following (A, B and C): A) Patient has high-risk disease, AND B) The medication is being used to reduce the risk of relapse, AND C) Patient has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy. Note:Examples of anti-GD2 immunotherapy includes Unituxin (dinutuximab intravenous infusion).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

JAKAFI

Products Affected

- JAKAFI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	ALL-less than 21 years of age, GVHD-12 and older, MF/PV/CMML-2/essential thrombo/myeloid/lymphoid neoplasm/T-cell Lymphoma-18 and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For polycythemia vera patients must have tried hydroxyurea or peginterferon alfa-2a or Besremi (ropeginterferon alfa-2b-njft subcutaneous injection). ALL-approve if the mutation/pathway is Janus associated kinase (JAK)-related. GVHD, chronic-approve if the patient has tried one conventional systemic treatment for graft versus host disease (for example: prednisone, ibrutinib capsules/tablets). GVHD, acute-approve if the patient has tried one systemic corticosteroid. Atypical chronic myeloid leukemia-approve if the patient has a CSF3R mutation or a janus associated kinase 2 (JAK2) mutation. Chronic monomyelocytic leukemia-2 (CMML-2)-approve if the patient is also receiving a hypomethylating agent. Essential thrombocythemia-approve if the patient has tried hydroxyurea, peginterferon alfa-2a or anagrelide. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the tumor has a janus associated kinase 2 (JAK2) rearrangement. T-Cell Lymphoma - approve if pt has T-cell prolymphocytic leukemia or T-cell large granular lymphocytic leukemia AND pt has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Acute lymphoblastic leukemia, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2), essential thrombocythemia, myeloid/lymphoid neoplasms, T-Cell lymphoma
Part B Prerequisite	No

JAYPIRCA

Products Affected

- JAYPIRCA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	<p>Mantle cell lymphoma-approve if the patient has tried at least one systemic regimen or patient is not a candidate for a systemic regimen (i.e., an elderly patient who is frail), AND the patient has tried one Bruton tyrosine kinase inhibitor (BTK) for mantle cell lymphoma. Note: Examples of a systemic regimen contain one or more of the following products: rituximab, dexamethasone, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, Velcade (bortezomib intravenous or subcutaneous injection), lenalidomide, gemcitabine, and Venclexta (venetoclax tablets). Note: Examples of BTK inhibitors indicated for mantle cell lymphoma include Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib capsules), and Imbruvica (ibrutinib capsules, tablets, and oral suspension). CLL/SLL-patient meets (A or B): A) patient has resistance or intolerance to Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules) or B) patient has relapsed or refractory disease and has tried a Bruton tyrosine kinase (BTK) inhibitor and Venclexta (venetoclax tablet)-based regimen. Examples of BTK inhibitor include: Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules). Richter's Transformation to DLBCL- pt has tried at least one chemotherapy regimen or is not a candidate for a chemotherapy</p>

PA Criteria	Criteria Details
	regimen. Marginal Zone Lymphoma - approve if pt has tried at least one Bruton tyrosine kinase inhibitor.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Richter's Transformation to Diffuse Large B-Cell Lymphoma, Marginal Zone Lymphoma
Part B Prerequisite	No

JYLAMVO

Products Affected

- JYLAMVO

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
Part B Prerequisite	No

KALYDECO

Products Affected

- KALYDECO ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with Orkambi, Trikafta or Symdeko
Required Medical Information	N/A
Age Restrictions	1 month 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 meet A, B, and C: A) pt must have one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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
Part B Prerequisite	No

KESIMPTA

Products Affected

- KESIMPTA PEN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis
Coverage Duration	Authorization will be for 1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KISQALI

Products Affected

- KISQALI
- KISQALI FEMARA CO-PACK ORAL TABLET 400 MG/DAY(200 MG X 2)-2.5 MG, 600 MG/DAY(200 MG X 3)-2.5 MG

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	1 year
Other Criteria	Breast cancer - approve for hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative early (stage II or III), recurrent, or metastatic breast cancer [for early breast cancer must be adjuvant treatment and high risk of recurrence] when the pt meets ONE of the following 1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Kisqali will be used in combination with anastrozole, exemestane, or letrozole 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Kisqali with be used in combination with anastrozole, exemestane or letrozole. 4. Patient is postmenopausal, pre/perimenopausal (patient receiving ovarian suppression/ablation with a GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man, and Kisqali (not Co-Pack) will be used in combination with fulvestrant. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane or letrozole. Endometrial cancer - approve if pt meets all of (A,

PA Criteria	Criteria Details
	B and C): A) pt has recurrent or metastatic disease, and B) has estrogen receptor (ER)-positive tumors, and C) if request is for Kisqali (not Co-Pack), Kisqali will be used in combination with letrozole.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Endometrial cancer
Part B Prerequisite	No

KORLYM

Products Affected

- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior surgeries
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome.
Coverage Duration	Endogenous Cushing's Synd-1 yr. 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 mifepristone is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance.
Indications	All FDA-approved Indications, 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
Part B Prerequisite	No

KOSELUGO

Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Neurofibromatosis Type 1-approve if prior to starting Koselugo, the patient has symptomatic, inoperable plexiform neurofibromas and if the patient is 2 to 18 years old OR if the patient is 19 years or older if the patient started on therapy with Koselugo prior to becoming 19. Circumscribed Glioma-approve if the patient has recurrent, refractory or progressive disease AND the tumor is BRAF fusion positive OR BRAF V600E activating mutation positive OR patient has neurofibromatosis type 1 mutated glioma AND this medication will be used as a single agent AND the patient is 3-21 years of age OR is greater 21 and has been previously started on therapy with Koselugo prior to becoming 21 years of age. Langerhans Cell Histiocytosis- approve if the patient meets the following criteria (A and B):</p> <p>A) Patient meets one of the following (i, ii, iii, or iv): i. Patient meets both of the following (a and b): a) Patient has multisystem Langerhans cell histiocytosis, AND b) Patient has symptomatic disease or impending organ dysfunction, OR ii. Patient has single system lung Langerhans cell histiocytosis, OR iii. Patient meets all of the following (a, b, and c): a) Patient has single system bone disease, AND b) Patient has not responded to treatment with a bisphosphonate, AND c) Patient has more than 2 bone lesions, OR iv. Patient has central nervous system disease, AND B) The medication is used as a single agent.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Circumscribed Glioma, Langerhans Cell Histiocytosis
Part B Prerequisite	No

KRAZATI

Products Affected

- KRAZATI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an approved test AND has been previously treated with at least one systemic regimen. Note: Examples of systemic regimens include those containing one or more of the following products: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Alimta (pemetrexed intravenous infusion), Yervoy (ipilimumab intravenous infusion), Abraxane (albumin-bound paclitaxel intravenous infusion), bevacizumab, cisplatin, carboplatin, docetaxel, gemcitabine, paclitaxel, vinorelbine. Colon or Rectal Cancer-approve if pt has unresectable, advanced, or metastatic disease AND pt has KRAS G12C mutation-positive disease AND medication is prescribed as part of a combination regimen or the patient is unable to tolerate combination therapy AND pt has has previously received a chemotherapy regimen for colon or rectal cancer. Ampullary adenocarcinoma-approve if (A, B and C): A) metastatic disease, B) KRAS G12C mutation-positive disease, and C) will be used as subsequent therapy. Biliary tract cancer-approve if (A, B and C): A) unresectable or metastatic disease, B) KRAS G12C mutation-positive disease, and C) previously treated with at least one systemic regimen. Pancreatic adenocarcinoma- approve if (A and B): A) KRAS G12C mutation-positive disease, and B) either (i or ii): (i) locally advanced or metastatic disease and previously treated with at least one</p>

PA Criteria	Criteria Details
	systemic regimen, or (ii) recurrent disease after resection. Small bowel adenocarcinoma- approve if (A, B and C): A) advanced or metastatic disease, B) KRAS G12C mutation-positive disease, and C) will be used as subsequent therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ampullary adenocarcinoma, biliary tract cancer, pancreatic adenocarcinoma, small bowel adenocarcinoma
Part B Prerequisite	No

LAPATINIB

Products Affected

- *lapatinib*
- TYKERB

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which lapatinib is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	HER2-positive recurrent or metastatic breast cancer, approve if lapatinib will be used in combination with capecitabine OR trastuzumab and the patient has tried at least two prior anti-HER2 based regimens OR the medication will be used in combination with an aromatase inhibitor and the patient has HR+ disease and the patient is a postmenopausal woman or the patient is premenopausal or perimenopausal woman and is receiving ovarian suppression/ablation with a GnRH agonist, surgical bilateral oophorectomy or ovarian irradiation OR the patient is a man and is receiving a GnRH analog. Colon or rectal cancer-approve if the patient has unresectable advanced or metastatic disease that is human epidermal receptor 2 (HER2) amplified and with wild-type RAS and BRAF disease and the patient has tried at least one chemotherapy regimen or is not a candidate for intensive therapy and the medication is used in combination with trastuzumab (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan) and the patient has not been previously treated with a HER2-inhibitor. Bone Cancer-approve if the patient has recurrent chordoma and if the patient has epidermal growth-factor receptor (EGFR)-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Bone cancer-chordoma, colon or rectal cancer, breast cancer in pre/perimenopausal women and men

PA Criteria	Criteria Details
Part B Prerequisite	Yes

LAZCLUZE

Products Affected

- LAZCLUZE

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	NON-SMALL CELL LUNG CANCER-ALL of the following (A, B, C, and D): A. Locally advanced or metastatic disease, AND B. Epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test, AND C. Used in combination with Rybrevant, AND D. Used as first-line treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LENALIDOMIDE

Products Affected

- *lenalidomide*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and previous therapies or drug regimens tried.
Age Restrictions	18 years and older (except Kaposi's Sarcoma, Castleman's Disease, CNS Lymphoma)
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	Follicular lymphoma-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one prior therapy. MCL-approve -if the patient is using lenalidomide in combination with rituximab or has tried at least two other therapies or therapeutic regimens. MZL-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one other therapy or therapeutic regimen. Multiple myeloma-approve. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). B-cell-lymphoma (other)-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve. CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease. Hodgkin lymphoma, classical-approve if the patient has tried at least three other I222 regimens. Castleman's disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease. Systemic light chain amyloidosis-approve if lenalidomide is used in combination with dexamethasone. Histiocytic

PA Criteria	Criteria Details
	neoplasms-approve if the patient has Langerhans cell histiocytosis with single-system multifocal skin disease or Rosai-Dorfman disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical), Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma, Central nervous system lymphoma, Kaposi's sarcoma, histiocytic neoplasm.
Part B Prerequisite	No

LENVIMA

Products Affected

- LENVIMA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	<p>DTC - must be refractory to radioactive iodine treatment for approval.</p> <p>RCC, advanced disease- approve if the pt meets i or ii: i. Lenvima is being used in combination with pembrolizumab OR ii. Lenvima is used in combination with everolimus and the patient meets a or b - a. Patient has clear cell histology and patient has tried one antiangiogenic therapy or b. patient has non-clear cell histology. New starts for all RCC must have tried Cabometyx. MTC-approve if the patient has tried at least one systemic therapy. Endometrial Carcinoma-Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has advanced endometrial carcinoma that mismatch repair proficient (pMMR) or is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) AND B) The medication is used in combination with Keytruda (pembrolizumab for intravenous injection) AND C)the disease has progressed on at least one prior systemic therapy AND D) The patient is not a candidate for curative surgery or radiation. Thymic carcinoma-approve if the patient has tried at least one chemotherapy regimen. New starts for Hepacocellular Carnicoma: For first line systemic therapy, sorafenib must be tried first. For subsequent-line system therapy if disease progression, Cabometyx must be tried first. Melanoma - approve if the patient has unresectable or metastatic melanoma AND the medication will be used in combination with Keytruda (pembrolizumab intravenous injection) AND the patient has disease progression on anti-programmed</p>

PA Criteria	Criteria Details
	death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1)-based therapy. Anaplastic thyroid carcinoma-approve if the medication is used in combination with Keytruda (pembrolizumab intravenous infusion).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Medullary Thyroid Carcinoma (MTC), thymic carcinoma, Melanoma, Anaplastic thyroid carcinoma
Part B Prerequisite	No

LIBERVANT

Products Affected

- LIBERVANT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 to 5 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
Part B Prerequisite	No

LIVTENCITY

Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with ganciclovir or valganciclovir
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, infectious diseases specialist, oncologist, or a physician affiliated with a transplant center.
Coverage Duration	2 months
Other Criteria	Cytomegalovirus Infection, Treatment-approve if the patient meets the following criteria (A, B, and C): A) Patient weighs greater than or equal to 35 kg, AND B) Patient is post-transplant, AND Note: This includes patients who are post hematopoietic stem cell transplant or solid organ transplant. C) Patient has cytomegalovirus infection/disease that is refractory to treatment with at least one of the following: cidofovir, foscarnet, ganciclovir, or valganciclovir or patient has a significant intolerance to ganciclovir or valganciclovir.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LONSURF

Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Gastric or Gastroesophageal Junction Adenocarcinoma, approve if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma. Colon and rectal cancer-approve per labeling if the patient has been previously treated with a fluopyrimidine, oxaliplatin, irinotecan and if the patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type) they must also try Erbitux or Vectibix.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LOQTORZI

Products Affected

- LOQTORZI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Nasopharyngeal carcinoma-approve if the patient has recurrent, unresectable, oligometastatic, or metastatic disease AND the patient meets ONE of the following (i or ii): i. Patient meets BOTH of the following (a and b): a) Loqtorzi is used for first-line treatment AND b) Loqtorzi is used in combination with cisplatin and gemcitabine, OR ii. Patient meets both of the following (a and b): a) Loqtorzi is used for subsequent treatment AND b) Loqtorzi is used as a single agent.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LORBRENA

Products Affected

- LORBRENA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, ALK status, ROS1 status, previous therapies
Age Restrictions	Pediatric Diffuse High-Grade Glioma- less than 18 years old, All others- 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Erdheim Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has IMT with ALK translocation. NSCLC - Approve if the patient has ALK-positive advanced or metastatic NSCLC, as detected by an approved test. In addition, patients new to therapy must also have a trial of Alecensa prior to approval of Lorbrena. NSCLC-ROS1 Rearrangement-Positive, advanced or metastatic NSCLC-approve if the patient has tried at least one of crizotinib, entrectinib or ceritinib. Large B-Cell Lymphoma- approve if ALK-positive disease and disease is relapsed or refractory. Pediatric Diffuse High-Grade Glioma- approve if ALK-positive disease and (i or ii): i) used as adjuvant therapy, or ii) used for recurrent or progressive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-small cell lung cancer (NSCLC)-ROS1 Rearrangement-Positive, Erdheim Chester Disease, Inflammatory Myofibroblastic Tumor (IMT), Large B-Cell Lymphoma, Pediatric Diffuse High-Grade Glioma
Part B Prerequisite	No

LUMAKRAS

Products Affected

- LUMAKRAS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test AND has been previously treated with at least one systemic regimen. Ampullary adenocarcinoma - approve if pt has KRAS G12C-mutated disease as determined by an approved test AND this is used as subsequent therapy. Colon or rectal cancer - approve if pt meets all (A, B, C and D): A) unresectable, advanced, or metastatic disease, and B) KRAS G12C mutation-positive disease, and C) medication is prescribed as part of a combination regimen for colon or rectal cancer [Ex: Lumakras plus cetuximab or panitumumab] or patient is unable to tolerate combination therapy, and D) previously received a chemotherapy regimen for colon or rectal cancer. Pancreatic Adenocarcinoma- approve if patient has KRAS G12C-mutated disease, as determined by an approved test AND either (i or ii): (i) patient has locally advanced or metastatic disease and has been previously treated with at least one systemic regimen OR (ii) patient has recurrent disease after resection.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma, Colon or Rectal Cancer

PA Criteria	Criteria Details
Part B Prerequisite	No

LUMIZYME

Products Affected

- LUMIZYME

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

LUPRON DEPOT

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Premenstrual disorders - 18 years and older
Prescriber Restrictions	Prostate cancer-prescribed by/consultation with oncologist or urologist. Other cancer diagnosis- prescribed by/consultation with an oncologist. Gender dysphoria/reassignment- prescribed by/consultation with endocrinologist or physician who specializes in treatment of transgender patients
Coverage Duration	uterine leiomyomata - 3 months, abnormal uterine bleeding - 6 months, all others - 12 months
Other Criteria	Endometriosis-approve if the pt has tried one of the following, unless contraindicated: a contraceptive, an oral progesterone or depo-medroxyprogesterone injection. An exception can be made if the pt has previously tried a gonadotropin-releasing hormone [GnRH] agonist (e.g. Lupron Depot) or antagonist (e.g. Orilissa). Head and neck cancer-salivary gland tumor- approve if pt has recurrent, unresectable, or metastatic disease AND androgen receptor-positive disease. Premenstrual disorders including PMS and PMDD- approve if pt has severe refractory premenstrual symptoms AND pt has tried an SSRI or combined oral contraceptive. Prostate cancer - for patients new to therapy requesting Lupron Depot 7.5mg, patients are required to try Orgovyx or Eligard prior to approval.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	abnormal uterine bleeding, breast cancer, gender dysphoria/gender reassignment, head and neck cancer-salivary gland tumors, ovarian cancer including fallopian tube and primary peritoneal cancers, premenstrual

PA Criteria	Criteria Details
	disorders including premenstrual syndrome and premenstrual dysphoric disorder, prophylaxis or treatment of uterine bleeding or menstrual suppression in pts with hematologic malignancy or undergoing cancer treatment or prior to bone marrow or stem cell transplant, uterine cancer
Part B Prerequisite	No

LYNPARZA

Products Affected

- LYNPARZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if the patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND The patient is in complete or partial response to at least one platinum-based chemotherapy regimen (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Ovarian, fallopian tube, or primary peritoneal cancer-maintenance, combination therapy-approve if the medication is used in combination with bevacizumab, the patient has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and the patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast cancer, adjuvant-approve if the patient has germline BRCA mutation-positive, HER2-negative breast cancer and the patient has tried neoadjuvant or adjuvant therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has recurrent or metastatic disease and has germline BRCA mutation-positive breast cancer. Pancreatic Cancer-maintenance therapy-approve if the patient has a germline BRCA mutation-positive metastatic disease and the disease has not progressed on at least 16 weeks of treatment with a first-line platinum-based chemotherapy regimen. Prostate cancer-castration resistant-approve if the patient has metastatic disease, the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or the pateint has had a bilateral orchiectomy, and the

PA Criteria	Criteria Details
	<p>patient meets either (i or ii): i) the patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test and the patient has been previously treated with at least one androgen receptor directed therapy or ii) the patient has a BRCA mutation and the medication is used in combination with abiraterone plus one of prednisone or prednisolone. Uterine Leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Uterine Leiomyosarcoma
Part B Prerequisite	No

LYTGOBI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease, tumor has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements as detected by an approved test and if the patient has been previously treated with at least one systemic regimen. Note: Examples of systemic regimens include gemcitabine + cisplatin, 5-fluorouracil + oxaliplatin or cisplatin, capecitabine + cisplatin or oxaliplatin, gemcitabine + Abraxane (albumin-bound paclitaxel) or capecitabine or oxaliplatin, and gemcitabine + cisplatin + Abraxane.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MAVYRET

Products Affected

- MAVYRET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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
Part B Prerequisite	No

MEGESTROL

Products Affected

- *megestrol oral suspension 400 mg/10 ml (10 ml), 400 mg/10 ml (40 mg/ml), 625 mg/5 ml (125 mg/ml), 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
Part B Prerequisite	No

MEKINIST

Products Affected

- MEKINIST

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Mekinist is being used. For melanoma, thyroid cancer and NSCLC must have documentation of BRAF V600 mutations
Age Restrictions	1 year and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Melanoma must be used in patients with BRAF V600 mutation, and patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC requires BRAF V600E Mutation and use in combination with Tafenlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafenlar, unless intolerant AND the patient has BRAF V600-positive disease. Ovarian/fallopian tube/primary peritoneal cancer-approve if the patient has recurrent disease and the medication is used for low-grade serous carcinoma or the patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafenlar. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafenlar. Central Nervous System Cancer-approve if the medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c or d): a) glioma OR b) Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma or d) Oligodendroglioma OR iii. Melanoma with brain

PA Criteria	Criteria Details
	<p>metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Tafinlar (dabrafenib). Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR patient has Erdheim Chester disease or Rosai-Dorfman disease. Metastatic or Solid Tumors-Approve if the patient meets the following (A, B, and C): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafinlar (dabrafenib capsules), AND C) Patient has no satisfactory alternative treatment options. Hairy Cell Leukemia, approve if pt has not previously been treated with a BRAF inhibitor therapy and this will be used for relapsed/refractory disease and will be taken in combination with Tafinlar.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Histiocytic Neoplasm, Hairy Cell Leukemia
Part B Prerequisite	No

MEKTOVI

Products Affected

- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRAF V600 status, concomitant medications
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi. Histiocytic neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following (i, ii, or iii): i. multisystem disease OR, ii. pulmonary disease or, iii. central nervous system lesions. NSCLC-approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Braftovi (encorafenib capsules).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Histiocytic Neoplasms
Part B Prerequisite	No

MODAFINIL

Products Affected

- *modafinil*
- PROVIGIL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	Excessive daytime sleepiness associated with narcolepsy-prescribed by or in consultation with a sleep specialist physician or neurologist
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD) - approve if the patient is working at least 5 overnight shifts per month. 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.
Part B Prerequisite	No

MRESVIA

Products Affected

- MRESVIA (PF)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	60 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	The patient has not already received an RSV vaccine
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NAGLAZYME

Products Affected

- NAGLAZYME

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient N-acetylgalactosamine 4-sulfatase (arylsulfatase B) activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating biallelic pathogenic or likely pathogenic arylsulfatase B gene variants.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NAYZILAM

Products Affected

- NAYZILAM

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

NERLYNX

Products Affected

- NERLYNX

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

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 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
Part B Prerequisite	No

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 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
Part B Prerequisite	No

NINLARO

Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	MM - be used in combination with dexamethasone and lenalidomide or cyclophosphamide OR pt had received at least ONE previous therapy for multiple myeloma OR the agent will be used following autologous stem cell transplantation (ASCT). Systemic light chain amyloidosis-approve if the patient has tried at least one other regimen for this condition. Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma-approve if used in combination with a rituximab product and dexamethasone (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with systemic light chain amyloidosis, Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma, Multiple myeloma after previous treatment (either monotherapy or in combination other than lenalidomide/dexamethasone) or stem cell transplant
Part B Prerequisite	Yes

NIVESTYM

Products Affected

- NIVESTYM

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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-hematologist. HIV/AIDS neutropenia-infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
Coverage Duration	chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,ALL,BMT,Radiation-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)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), 2)patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, or HIV infection), 3)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, or 4)patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia

PA Criteria	Criteria Details
	[absolute neutrophil count less than 100 cells/mm ³], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Acute lymphocytic leukemia (ALL), Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome)
Part B Prerequisite	No

NMDA RECEPTOR ANTAGONIST

Products Affected

- *memantine oral capsule, sprinkle, er 24hr*
- *memantine oral solution*
- *memantine oral tablet*
- MEMANTINE ORAL TABLETS, DOSE PACK
- NAMENDA TITRATION PAK
- NAMZARIC

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
Part B Prerequisite	No

NUBEQA

Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (See Note 1) or if the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration sensitive-approve if (A and B): A) the medication is used in combination with docetaxel or patient has completed docetaxel therapy, and B) the medication will be used in combination with a GnRH analog (See Note 1) or if the patient had a bilateral orchiectomy. Note 1: examples of GnRH analogs are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NUCALA

Products Affected

- NUCALA SUBCUTANEOUS AUTO-INJECTOR
- NUCALA SUBCUTANEOUS SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy
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/polyps-6 months, EGPA/HES-8 months. 12 months continuation.
Other Criteria	Asthma initial - must have blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks (or prior to tx with Nucala or another monoclonal antibody therapy that may lower blood eosinophil levels) AND has received combo tx w/inhaled corticosteroid AND at least 1 additional asthma controller/maintenance med (Examples: LAMA, LABA, leukotriene receptor antagonist, monoclonal antibody) AND pt's asthma cont to be uncontrolled, or was uncontrolled prior to starting Nucala or another monoclonal antibody therapy for asthma as defined by 1 of following-pt experi 2 or more asthma exacer req tx w/systemic corticosteroids in prev yr, pt experienced 1 or more asthma exacer requiring hospitalization, urgent care visit or ED visit in the prev yr, pt has a FEV1 less than 80 percent predicted, Pt has FEV1/FVC less than 0.80, or Pt's asthma worsens upon taper of oral (systemic) corticosteroid therapy. Cont-pt responded to Nucala tx as determined by the prescribing physician AND Pt cont to receive tx with an inhaled corticosteroid. EGPA initial-approve if pt has active, non-severe disease, has/had a blood eosinophil level of greater than or equal to 150 cells per microliter within

PA Criteria	Criteria Details
	<p>the previous 6 wks or prior to any monoclonal antibody that may lower blood eosinophil levels. Cont-pt responded to Nucala tx as determined by the prescribing physician.HES initial-pt has had hypereosinophilic synd for greater than or equal to 6 months AND has FIP1L1-PDGFRalpha-negative dis AND pt does NOT have identifiable non-hematologic secondary cause of hypereosinophilic synd AND prior to initiating tx with monoclonal antibody that may lower blood eosinophil levels, pt has/had a blood eosinophil level of greater than or equal to 1,000 cells per microliter. Cont-approve if the patient has responded to Nucala tx. Nasal polyps, initial-approve if pt meets ALL of the following criteria(A, B, C and D):A) pt has chronic rhinosinusitis w/nasal polyposis as evidenced by direct examination, endoscopy, or sinus CT scan AND B)pt experienced 2 or more of the following sympt for at least 6 months:nasal congest/obstruct/discharge, and/or reduction/loss of smell AND C)pt meets BOTH of the following (a and b): a)Pt has received tx with intranasal corticosteroid AND b)Pt will continue to receive tx with intranasal corticosteroid concomitantly with Nucala AND D)pt meets 1 of the following (a, b or c): a)Pt has received at least 1 course of tx with a systemic corticosteroid for 5 days or more within the previous 2 years, OR b)Pt has a contraindication to systemic corticosteroid tx, OR c)Pt had prior surgery for nasal polyps.Cont-approve if the pt has received at least 6 months of therapy, continues to receive tx with an intranasal corticosteroid and has responded to tx.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NUEDEXTA

Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NUPLAZID

Products Affected

- NUPLAZID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NURTEC

Products Affected

- NURTEC ODT

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention if Nurtec ODT is being taking for the preventive treatment of episodic migraine.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Migraine, Acute treatment (initial and continuation)-approve. Preventive treatment of episodic migraine (initial)-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). Preventive treatment of episodic migraine (continuation) - 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 the patient has had a significant clinical benefit from the medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OCALIVA

Products Affected

- OCALIVA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Prescriber specialty, lab values, prior medications used for diagnosis and length of trials
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial)
Coverage Duration	6 months initial, 1 year cont.
Other Criteria	Initial treatment of PBC-Patient must meet both 1 and 2-1. Patient has a diagnosis of PBC as defined by TWO of the following:a)Alkaline phosphatase (ALP) elevated above the upper limit of normal as defined by normal laboratory reference values b)Positive anti-mitochondrial antibodies (AMAs) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative c)Histologic evidence of primary biliary cholangitis (PBC) from a liver biopsy 2. Patient meets ONE of the following: a) Patient has been receiving ursodiol therapy for greater than or equal to 1 year and has had an inadequate response. b) Patient is unable to tolerate ursodiol therapy. Cont tx - approve if the patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT] levels)). Patients new to therapy and continuing therapy must not have cirrhosis or must have compensated cirrhosis without evidence of portal hypertension.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OCREVUS

Products Affected

- OCREVUS
- OCREVUS ZUNOVO

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	For relapsing remitting disease new starts - patient must have tried and failed two other MS therapies
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OCTREOTIDE INJECTABLE

Products Affected

- *octreotide acetate*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Acromegaly-prescr/consult w/endocrinologist. NETs-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist, neurosurg/thymoma/thymic carcinoma-presc/consult with oncologist
Coverage Duration	Enterocutaneous fistula - 3 months, all others - 1 year
Other Criteria	ACROMEGALY (A or B): A) inadequate response to surgery and/or radiotherapy or patient not an appropriate candidate or B) patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) and has pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Meningioma, thymoma and thymic carcinoma, pheochromocytoma and paraganglioma, enterocutaneous fistulas
Part B Prerequisite	No

ODOMZO

Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	BCC - Must not have had disease progression while on Erivedge (vismodegib).
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Locally advanced BCC approve if the BCC has recurred following surgery/radiation therapy or if the patient is not a candidate for surgery AND the patient is not a candidate for radiation therapy, according to the prescribing physician. Metastatic BCC - approve, if the disease is limited to nodal metastases. (Note-This includes primary or recurrent nodal metastases. A patient with distant metastasis does not meet this requirement.)
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Metastatic BCC
Part B Prerequisite	No

OFEV

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	IPF-Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis-prescribed by or in consultation with a pulmonologist or rheumatologist.
Coverage Duration	1 year
Other Criteria	IDIOPATHIC PULMONARY FIBROSIS (IPF) [A and B]: A) diagnosis confirmed by presence of usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) or surgical lung biopsy and B) forced vital capacity (FVC) greater than or equal to 40 percent of the predicted value. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS (A and B): A) diagnosis confirmed by HRCT and B) FVC greater than or equal to 40 percent of the predicted value. CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE (all of A, B and C): A) FVC greater than or equal to 45 percent of the predicted value, B) fibrosing lung disease impacting more than 10 percent of lung volume on HRCT, and C) clinical signs of progression.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OGSIVEO

Products Affected

- OGSIVEO

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	Desmoid tumors (aggressive fibromatosis)-approve if the patient has progressing desmoid tumors, the desmoid tumors are not amenable to surgery or radiotherapy and if the patient requires systemic treatment. Note: Progressing desmoid tumors are defined as greater than or equal to 20 percent progression within 12 months
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OJEMDA

Products Affected

- OJEMDA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	6 months of age and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	PEDIATRIC LOW GRADE GLIOMA-patient has relapsed or refractory disease and the tumor is positive for one of the following: BRAF fusion, BRAF rearrangement or BRAF V600 mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OJJAARA

Products Affected

- OJJAARA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Myelofibrosis-approve if the patient has intermediate-risk or high-risk disease and (a or b): a) the patient has anemia, defined as hemoglobin less than 10g/dL and has symptomatic splenomegaly and/or constitutional symptoms, or b) the patient has platelet count greater than or equal to 50x10 ⁹ /L.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ONUREG

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML - Approve if the medication is used for post-remission maintenance therapy AND allogeneic hematopoietic stem cell transplant is not planned. Peripheral T-cell lymphoma - all of (A, B, and C): A) relapsed or refractory disease, and B) pt has one of the following (i, ii or iii): i) angioimmunoblastic T-cell lymphoma, or ii) nodal peripheral T-cell lymphoma with T-follicular helper (TFH) phenotype, or iii) follicular T-cell lymphoma, and C) medication is used as a single agent.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Peripheral T-cell lymphoma
Part B Prerequisite	No

OPSUMIT

Products Affected

- OPSUMIT

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

ORENCIA EGWP

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	End of the plan year
Other Criteria	RA, approve if the patient has tried one of the following: Enbrel, a preferred adalimumab product, Rinvoq, Xeljanz. PsA, approve if the patient meets one of the following (i or ii): i. patient is 2 to 5 years of age OR ii. patient is 6 years of age or older and has tried one of the following: Enbrel, a preferred adalimumab product, Rinvoq, Skyrizi, Xeljanz. JIA/JRA, approve if the patient has tried one of the following: Enbrel, a preferred adalimumab product, or Xeljanz. Continuation- approve if the patient has had a response as determined by the prescriber. Please Note: preferred adalimumab products include Humira (NDCs starting with - 00074), adalimumab-aaty and Yuflyma.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORENITRAM

Products Affected

- ORENITRAM
- ORENITRAM MONTH 1 TITRATION KT
- ORENITRAM MONTH 2 TITRATION KT
- ORENITRAM MONTH 3 TITRATION KT

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Inhaled or Parenteral Prostacyclin Agents Used for Pulmonary Hypertension.
Required Medical Information	Diagnosis, results of right heart cath
Age Restrictions	N/A
Prescriber Restrictions	PAH must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	1 year
Other Criteria	For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORGOVYX

Products Affected

- ORGOVYX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Prostate Cancer-approve
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORKAMBI

Products Affected

- ORKAMBI

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with Kalydeco, Trikafta or Symdeko.
Required Medical Information	N/A
Age Restrictions	1 year 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 - Approve if the pt mees A, B and C: A) pt has two copies of the F508del mutation in the CTFR gene, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORSERDU

Products Affected

- ORSERDU

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast cancer in postmenopausal women or Men-approve if the patient meets the following criteria (A, B, C, D, and E): A) Patient has recurrent or metastatic disease, AND B) Patient has estrogen receptor positive (ER+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has estrogen receptor 1 gene (ESR1)-mutated disease, AND E) Patient has tried at least one endocrine therapy. Note: Examples of endocrine therapy include fulvestrant, anastrozole, exemestane, letrozole, and tamoxifen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OSPHENA

Products Affected

- OSPHENA

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
Part B Prerequisite	No

OTEZLA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARD).
Required Medical Information	Diagnosis, previous drugs tried
Age Restrictions	PP- 6 years and older (initial), All other dx - 18 years and older (initial)
Prescriber Restrictions	All dx, initial only-PsA - Prescribed by or in consultation with a dermatologist or rheumatologist. PP - prescribed by or in consultation with a dermatologist. Behcet's-prescribed by or in consultation with a dermatologist or rheumatologist
Coverage Duration	End of the plan year
Other Criteria	PP, approve if the patient meets (A or B): A) has tried one of the following: traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA), TNF, JAK or biologic or B) patient has mild to moderate disease and the patient requires systemic therapy. PsA, approve if the patient has tried one of the following: traditional systemic agent (eg, MTX, cyclosporine, PUVA), TNF, JAK or biologic. Behcet's-patient has oral ulcers or other mucocutaneous involvement AND patient has tried one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, CSA, chlorambucil, cyclophosphamide] or interferon alfa) or a tumor necrosis factor. PsA/PP/Behcet's cont - pt has received 4 months of therapy and had a response, as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OXERVATE

Products Affected

- OXERVATE

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

PEGASYS

Products Affected

- PEGASYS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
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
Part B Prerequisite	No

PEMAZYRE

Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease and the tumor has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test AND the patient has been previously treated with at least one systemic therapy regimen. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the cancer has fibroblast growth factor receptor 1 (FGFR1) rearrangement, as detected by an approved test and the cancer is in chronic phase or blast phase.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PHENYL BUTYRATE

Products Affected

- *sodium phenylbutyrate*

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

PHEOCHROMOCYTOMA

Products Affected

- *metyrosine*

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

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Products Affected

- *alyq*
- *sildenafil (pulm.hypertension) oral tablet*
- *tadalafil (pulm. hypertension)*
- TADLIQ

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use With Guanylate Cyclase Stimulators.
Required Medical Information	Diagnosis, right heart cath results
Age Restrictions	N/A
Prescriber Restrictions	For PAH, if prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets require confirmation that the indication is PAH (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PIQRAY

Products Affected

- PIQRAY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast Cancer. Approve if the patient meets the following criteria (A, B, C, D, E and F): A) The patient is a postmenopausal female, male or pre/perimenopausal and is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene or fulvestrant) AND F) Piqray will be used in combination with fulvestrant injection.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PIRFENIDONE

Products Affected

- *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
Part B Prerequisite	No

POMALYST

Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Kaposi Sarcoma/MM-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	CNS Lymphoma-approve if the patient has relapsed or refractory disease. Kaposi Sarcoma-Approve if the patient meets one of the following (i or ii): i. patient is Human Immunodeficiency Virus (HIV)-negative OR ii. patient meets both of the following (a and b): a) The patient is Human Immunodeficiency Virus (HIV)-positive AND b) The patient continues to receive highly active antiretroviral therapy (HAART). MM-approve if the patient has received at least one other Revlimid (lenalidomide tablets)-containing regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Systemic Light Chain Amyloidosis, Central Nervous System (CNS) Lymphoma
Part B Prerequisite	No

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, prescribed by, or after consultation with, a hematologist (initial therapy). Hep C, 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). Post-transplant, prescribed by or in consult with a hematologist, oncologist or stem cell transplant specialist physician (initial)
Coverage Duration	Imm Thrombo/MDS init-3mo,cont 1yr,AA-init-4mo,cont-1yr,Thrombo/HepC-1yr,Transplant-init 3mo,cont 6mo
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 (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Nplate, Tavalisse, Doptelet, rituximab) 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 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 microliter) AND tried one immunosuppressant therapy (e.g., cyclosporine) 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

PA Criteria	Criteria Details
	<p>patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and is at an increased risk for bleeding. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Thrombocytopenia post-allogeneic transplantation, initial - approve if, according to the prescriber, the patient has poor graft function AND has a platelet count less than 50,000/mcL. Cont- patient demonstrated a beneficial clinical response.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	<p>Thrombocytopenia in Myelodysplastic Syndrome (MDS), Thrombocytopenia in a patient post-allogeneic transplantation</p>
Part B Prerequisite	No

PYRIMETHAMINE

Products Affected

- *pyrimethamine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Patient's immune status (Toxoplasma gondii Encephalitis, chronic maintenance and prophylaxis, primary)
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
Part B Prerequisite	No

PYRUKYND

Products Affected

- PYRUKYND

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a hematologist (initial and continuation)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	<p>Initial therapy-Approve if the patient has the presence of at least two variant/mutant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene [documentation required] and at least one of the variant/mutant alleles was a missense variant [documentation required] AND the patient has a current hemoglobin level less than or equal to 10g/dL or patient is currently receiving red blood cell transfusions regularly, defined as at least six transfusion within the last year.</p> <p>Continuation of therapy-Approve if the patient has the presence of at least two variant/mutant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene [documentation required] and at least one of the variant/mutant alleles was a missense variant [documentation required] AND the patient has experienced a benefit from therapy, defined as increase in or maintenance of hemoglobin levels, or improvement in or maintenance of hemolysis laboratory parameters, OR decrease in or maintenance of transfusion requirements.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

QINLOCK

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Gastrointestinal stromal tumor (GIST)-approve if the patient has tried imatinib or avapritinib tablets, AND the patient meets one of the following criteria (i, ii, or iii): i. Patient has tried sunitinib and regorafenib tablets, OR ii. Patient has tried dasatinib tablets, OR iii. Patient is intolerant of sunitinib. Melanoma, cutaneous-approve if the patient has metastatic or unresectable disease, AND the patient has an activating KIT mutation, AND the patient has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Melanoma, cutaneous
Part B Prerequisite	No

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.
Part B Prerequisite	No

RADICAVA IV

Products Affected

- EDARAVONE
- RADICAVA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS (initial and continuation).
Coverage Duration	Initial, 6 months. Continuation, 6 months.
Other Criteria	ALS, initial therapy-approve if the patient meets ALL of the following criteria: 1. According to the prescribing physician, the patient has a definite or probable diagnosis of ALS, based on the application of the El Escorial or the revised Airlie house diagnostic criteria 2. The patient has a score of two points or more on each item of the ALS Functional Rating Scale-Revised (ALSFRS-R) [ie, has retained most or all activities of daily living], AND 3. The patient has a percent predicted FVC greater than or equal to 80% (ie, has normal respiratory function), AND 4. The Patient has been diagnosed with ALS for less than or equal to 2 years 5. Patient has received or is currently receiving riluzole tablets. Note-a trial of Tiglutik or Exservan would also count. ALS, continuation therapy: approve if, according to the prescribing physician, the patient continues to benefit from therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REBIF

Products Affected

- REBIF (WITH ALBUMIN)
- REBIF TITRATION PACK
- REBIF REBIDOSE

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

RELISTOR

Products Affected

- RELISTOR SUBCUTANEOUS SOLUTION
- RELISTOR SUBCUTANEOUS SYRINGE

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

REMICADE

Products Affected

- REMICADE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Biologic DMARD or Targeted Synthetic.
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 suppurativa-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, cardio, neuro, or derm
Coverage Duration	GVHD intl-1 mo, cont-3 mo.Pyoderma Gangrenosum-intl 4 mo, cont 1 yr.all others-intl 3 mo, cont-12 m
Other Criteria	RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor 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 for at least 3 months (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID), biologic or JAK inhibitor 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

PA Criteria	Criteria Details
	<p>systemic corticosteroid, immunosuppressives or other biologic therapy. GVHD, approve. CD initial, approve if the patient has tried or is currently taking corticosteroids or patient has tried one other agent for CD. UC initial, approve if the patient has had a trial of one systemic agent for at least 3 months (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, biologic, JAK inhibitor or a corticosteroid such as prednisone or methylprednisolone). HS initial, tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Behcet's initial, patient has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa) or at least one tumor necrosis factor for Behcet's disease OR has ophthalmic manifestations. Still's Disease initial, tried CS AND 1 conventional synthetic DMARD (eg, MTX) for 2 mos, or was intolerant. Prev trial of one biologic other than requested drug or biosimilar of the requested drug also counts. Sarcoidosis initial, tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide. Pyoderma gangrenosum (PG) initial, tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos or was intolerant to one of these agents. Continuation-approve if the patient has had a response as determined by the prescriber.</p>
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
Part B Prerequisite	No

REPATHA

Products Affected

- REPATHA PUSHTRONEX
- REPATHA SURECLICK
- REPATHA SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Leqvio or Praluent.
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	ASCVD/Primary Hyperlipidemia - 18 yo and older, HoFH/HeFH - 10 yo and older.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	<p>Hyperlipidemia with HeFH - approve if: 1) diagnosis of HeFH AND 2) tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) and LDL remains 70 mg/dL or higher unless pt is statin intolerant defined by experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the symptoms resolved upon discontinuation.</p> <p>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, CAD, PAD, undergone a coronary or other arterial revascularization procedure, AND 2) tried ONE high intensity statin (defined above) and LDL remains 55 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 400 mg/dL (prior to treatment), OR c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such as Repatha or Juxtapid), OR d) has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) tried ONE high intensity statin (defined above) for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above).</p>

PA Criteria	Criteria Details
	Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)- approve if all of the following are met: 1) coronary artery calcium or calcification (CAC) score 300 Agatston units or higher, AND 2) the patient has tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RETEVMO

Products Affected

- RETEVMO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Medullary Thyroid Cancer/Thyroid Cancer/Solid tumors-2 years and older, all others 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has recurrent, advanced or metastatic disease AND the tumor is RET fusion-positive. Thyroid cancer-approve if the patient has rearranged during transfection (RET) fusion positive or RET mutation positive disease or RET pathogenic variant AND the patient meets i or ii: i. patient has anaplastic thyroid cancer OR ii. the disease requires treatment with systemic therapy and patient has medullary thyroid cancer or the disease is radioactive iodine-refractory. Solid tumors-approve if the patient has recurrent, advanced or metastatic disease and the tumor is rearranged during transfection (RET) fusion-positive. Histiocytic neoplasm-approve if the patient has a rearranged during transfection (RET) fusion and has Langerhans cell histiocytosis or Erdheim Chester disease or Rosai-Dorfman disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anaplastic thyroid carcinoma, histiocytic neoplasm
Part B Prerequisite	No

REVLIMID

Products Affected

- REVLIMID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and previous therapies or drug regimens tried.
Age Restrictions	18 years and older (except Kaposi's Sarcoma, Castleman's Disease, CNS Lymphoma)
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Follicular lymphoma-approve if the patient is using lenalidomide (brand or generic) in combination with rituximab or has tried at least one prior therapy. MCL-approve if the patient is using lenalidomide (brand or generic) in combination with rituximab or has tried at least two other therapies or therapeutic regimens. MZL-approve if the patient is using lenalidomide (brand or generic) in combination with rituximab or has tried at least one other therapy or therapeutic regimen. Multiple myeloma-approve. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). B-Cell-Lymphoma (other)-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia and the pt has serum erythropoietin levels greater than or equal to 500 mU/mL or according to the prescriber the patient has anemia, has serum erythropoietin levels less than 500 mU/mL and patient has experienced no response or loss of response to erythropoietic stimulating agents. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve if the pt has tried at least one other therapy or regimen. CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease. Hodgkin lymphoma, classical-

PA Criteria	Criteria Details
	<p>approve if the patient has tried at least three other regimens. Castleman's disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease. Systemic light chain amyloidosis-approve if lenalidomide (brand or generic) is used in combination with dexamethasone.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	<p>Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical), Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma, Central nervous system lymphoma, Kaposi's sarcoma.</p>
Part B Prerequisite	No

REVUFORJ

Products Affected

- REVUFORJ

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 year and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	ACUTE LEUKEMIA-patient has relapsed or refractory disease and the disease is positive for a lysine methyltransferase 2A (KMT2A) gene translocation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REZDIFFRA

Products Affected

- REZDIFFRA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist (initial/continuation)
Coverage Duration	1 year
Other Criteria	<p>INITIAL THERAPY: METABOLIC-DYSFUNCTION ASSOCIATED STEATOHEPATITIS (MASH)/NON-ALCOHOLIC STEATOHEPATITIS (NASH) WITH MODERATE-ADVANCED LIVER FIBROSIS: All of (i, ii, and iii): i) Diagnosed by (a or b): a) Liver biopsy performed within 3 years preceding treatment with Rezdiffra showing non-alcoholic fatty liver disease activity score of greater than or equal to 4 with a score of greater than 1 in ALL of the following: steatosis, ballooning and lobular inflammation, or b) One of the following within 3 months preceding treatment with Rezdiffra (1, 2 or 3): 1) Elastography (e.g. vibration-controlled transient elastography (e.g., FibroScan), transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, shear wave elastography) or 2) Computed tomography or 3) Magnetic resonance imaging, and ii) stage F2 or F3 fibrosis prior to Rezdiffra and iii) This will be used in combination with appropriate diet and exercise therapy (prescriber attestation the patient has received counseling on diet and exercise). CONTINUATION THERAPY (on therapy less than 1 year or restarting, review as initial therapy): MASH/NASH: All of (i, ii, and iii): i) completed greater than or equal to 1 year of therapy and has not had worsening of fibrosis or MASH/NASH, and ii) has not progressed to stage F4 (cirrhosis) and iii) This will be used in combination with appropriate diet and exercise therapy (prescriber attestation the patient has received counseling on diet and exercise).</p>

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

REZLIDHIA

Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Acute myeloid leukemia-approve if the patient has relapsed or refractory disease and the patient has isocitrate dehydrogenase-1 (IDH1) mutation positive disease as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REZUROK

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Graft-versus-host disease-approve if the patient has chronic graft-versus-host disease and has tried at least two conventional systemic treatments (e.g., ibrutinib, cyclosporine) for chronic graft-versus-host disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	PsA/JIA - 2 years and older (initial therapy), RA/UC/AS/CD/nr-axSpA-18 years and older (initial therapy), AD-12 years and older (initial therapy)
Prescriber Restrictions	RA/AS/Non-Radiographic Spondy/JIA, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. AD-prescr/consult with allergist, immunologist or derm. UC/CD-prescribed by or in consultation with a gastroenterologist. (all apply to initial therapy only)
Coverage Duration	End of the plan year
Other Criteria	RA/PsA/UC/AS/CD/JIA initial - patient has tried a TNF blocker for at least 3 months. AD - patient has tried at one systemic agent for at least 3 months. Examples of traditional systemic therapies include azathioprine, cyclosporine, and mycophenolate mofetil. A patient who has already tried Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection) is not required to step back and try a traditional systemic agent for atopic dermatitis. Non-Radiographic Axial Spondyloarthritis-approve if the patient has objective signs of inflammation defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroiliitis reported on MRI and patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3- month trial. Continuation-approve if the patient has had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

RINVOQ LQ

Products Affected

- RINVOQ LQ

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic DMARD, other potent immunosuppressants, other janus kinase inhibitors, or a biologic immunomodulator.
Required Medical Information	Diagnosis
Age Restrictions	PsA-2 years and older (initial therapy)
Prescriber Restrictions	JIA-prescribed by or in consultation with a rheumatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or a dermatologist (initial therapy)
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: JUVENILE IDIOPATHIC ARTHRITIS (JIA)/ PSORIATIC ARTHRITIS (PsA) - 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial. CONTINUATION THERAPY: ALL INDICATIONS - patient responded to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ROFLUMILAST (ORAL)

Products Affected

- DALIRESP
- *roflumilast*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD), medications tried.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	COPD, approve in patients who meet all of the following conditions: Patients has severe COPD or very severe COPD, AND Patient has a history of exacerbations, AND Patient has tried a medication from two of the three following drug categories: long-acting beta2-agonist (LABA) [eg, salmeterol, indacaterol], long-acting muscarinic antagonist (LAMA) [eg, tiotropium], inhaled corticosteroid (eg, fluticasone).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ROMIDEPSIN

Products Affected

- *romidepsin intravenous recon soln*
- ROMIDEPSIN INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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
Part B Prerequisite	No

ROZLYTREK

Products Affected

- ROZLYTREK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	NSCLC-18 years and older, Solid Tumors-1 month and older, Pediatric Diffuse High-Grade Glioma-less than 18 years old
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Solid Tumors-Approve if the patients tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic OR surgical resection of tumor will likely result in severe morbidity. Non-Small Cell Lung Cancer-Approve if the patient has ROS1-positive metastatic disease and the mutation was detected by an approved test. Pediatric Diffuse High-Grade Glioma- approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the medication is used either as adjuvant therapy or for recurrent or progressive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pediatric Diffuse High-Grade Glioma
Part B Prerequisite	No

RUBRACA

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Rubraca is being used. BRCA-mutation (germline or somatic) status. Other medications tried for the diagnosis provided
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-Approve if the patient is in complete or partial response after a platinum-based chemotherapy regimen and the patient is in complete or partial response to first-line primary treatment or if the patient has recurrent disease and has a BRCA mutation. Castration-Resistant Prostate Cancer - Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND B) The patient meets one of the following criteria (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy AND C) The patient has been previously treated with at least one androgen receptor-directed therapy AND D) The patient meets one of the following criteria (i or ii): i. The patient has been previously treated with at least one taxane-based chemotherapy OR ii. The patient is not a candidate or is intolerant to taxane-based chemotherapy. Pancreatic adenocarcinoma-approve if pt has a BRCA mutation or PALB2 mutation AND pt has tried platinum-based chemotherapy AND has not had disease progression following the most recent platinum-based chemotherapy. Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Uterine Leiomyosarcoma, Pancreatic Adenocarcinoma
Part B Prerequisite	No

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
Part B Prerequisite	No

RYDAPT

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For AML, FLT3 status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML-approve if the patient is FLT3-mutation positive as detected by an approved test. Myeloid or lymphoid Neoplasms with eosinophilia-approve if the patient has an FGFR1 rearrangement or has an FLT3 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid or lymphoid Neoplasms with eosinophilia
Part B Prerequisite	No

SABRIL

Products Affected

- *vigabatin*
 - *vigadrone*
- VIGAFYDE

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
Part B Prerequisite	No

SANDOSTATIN

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Acromegaly-prescr/consult w/endocrinologist. NETs-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist, neurosurg/thymoma/thymic carcinoma-presc/consult with oncologist
Coverage Duration	Enterocutaneous fistula - 3 months, all others -1 year
Other Criteria	Acromegaly-approve if patient meets ONE of the following (i, ii, or iii): i. Patient has had an inadequate response to surgery and/or radiotherapy OR ii. Patient is NOT an appropriate candidate for surgery and/or radiotherapy OR iii. Patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) AND Patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Meningioma, thymoma and thymic carcinoma, pheochromocytoma and paraganglioma, enterocutaneous fistulas
Part B Prerequisite	No

SAPROPTERIN

Products Affected

- *javygtor*
- *sapropterin*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Palynziq
Required Medical Information	Diagnosis, Phe concentration
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy)
Coverage Duration	Initial-12 weeks, Continuation-1 year
Other Criteria	Initial - approve. Continuation (Note-if the patient has received less than 12 weeks of therapy or is restarting therapy with sapropterin should be reviewed under initial therapy) - approve if the patient has had a response to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SCSEMBLIX

Products Affected

- SCSEMBLIX

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	Chronic Myeloid Leukemia (CML)-approve if the patient meets the following (A and B): A) Patient has Philadelphia chromosome-positive chronic myeloid leukemia, AND B) Patient meets one of the following (i, ii or iii): i. Patient has newly diagnosed disease, OR ii. The chronic myeloid leukemia is T315I-positive, OR iii. Patient has tried at least one other tyrosine kinase inhibitor indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia. Note: Examples of tyrosine kinase inhibitors include imatinib tablets, Bosulif (bosutinib tablets), Iclusig (ponatinib tablets), Sprycel (dasatinib tablets), and Tassigna (nilotinib capsules). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has an ABL1 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid/Lymphoid Neoplasms with Eosinophilia
Part B Prerequisite	No

SIGNIFOR

Products Affected

- SIGNIFOR

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

SIMPONI

Products Affected

- SIMPONI
- SIMPONI ARIA

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	UC-18 years and older (initial therapy)
Prescriber Restrictions	All dx-initial only-RA/Ankylosing spondylitis, prescribed by or in consultation with a rheumatologist. Psoriatic arthritis, prescribed by or in consultation with a rheumatologist or dermatologist. UC-prescribed by or in consultation with a gastroenterologist
Coverage Duration	End of the plan year
Other Criteria	AS, approve if the patient has tried two of the following: TNF, JAK or biologic. RA, approve if the patient has tried two of the following: TNF, JAK or biologic. PsA, approve if the patient has tried two of the following: TNF, JAK or biologic. UC, approve if the patient has tried two of the following: TNF, JAK or biologic. Continuation-approve if the patient has had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SIRTURO

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	Patients weighing less than 15 kg
Required Medical Information	Diagnosis, concomitant therapy
Age Restrictions	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) -Approve if the patient has multidrug-resistant tuberculosis or Mycobacterium tuberculosis resistant to at least rifampin and isoniazid, and the requested medication is prescribed as part of a combination regimen with other anti-tuberculosis agents
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SKYRIZI

Products Affected

- SKYRIZI INTRAVENOUS
- SKYRIZI SUBCUTANEOUS PEN INJECTOR
- SKYRIZI SUBCUTANEOUS SYRINGE 150 MG/ML
- 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	PP/UC-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 (initial therapy). CD/UC, prescribed by or in consultation with a gastroenterologist (initial therapy).
Coverage Duration	End of the plan year
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 - peripheral disease, patient has tried one conventional synthetic DMARD for at least 3 months, unless intolerant. (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor are not required to step back and try a conventional synthetic DMARD) 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 or JAK inhibitor are not required to step back and try a conventional synthetic DMARD or NSAID). CD initial, approve if the patient has tried or is currently taking corticosteroids, or patient has tried one other agent for at least 3 months. UC initial - meets ONE of the following (a or b): a) Patient has had a trial of one systemic agent for at

PA Criteria	Criteria Details
	<p>least 3 months (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, biologic, JAK inhibitor or a corticosteroid such as prednisone or methylprednisolone). OR b) Patient meets BOTH of the following [(1) and (2)]: (1)Patient has pouchitis, AND (2)Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema. Continuation-approve if the patient has had a response as determined by the prescriber.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SOMATULINE

Products Affected

- SOMATULINE DEPOT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous treatments/therapies
Age Restrictions	N/A
Prescriber Restrictions	Acromegaly-prescribed by or in consultation with an endocrinologist. Carcinoid syndrome-prescribed by or in consultation with an oncologist, endocrinologist or gastroenterologist. All neuroendocrine tumors-prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescribed by or in consultation with an endo/onc/neuro.
Coverage Duration	1 year
Other Criteria	Acromegaly-approve if the patient has a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas)-approve. Carcinoid Syndrome-approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pheochromocytoma/paraganglioma, Neuroendocrine tumors of the gastrointestinal tract, lung, thymus (carcinoid tumor) and pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas)

PA Criteria	Criteria Details
Part B Prerequisite	No

SOMAVERT

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapy, concomitant therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	1 year
Other Criteria	ACROMEGALY (A or B): A) inadequate response to surgery and/or radiotherapy or patient not an appropriate candidate or B) patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) and has pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SORAFENIB

Products Affected

- NEXAVAR
- *sorafenib*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	<p>Bone cancer, approve if the patient has recurrent chordoma or has osteosarcoma and has tried one standard chemotherapy regimen. GIST, approve if the patient has tried TWO of the following: imatinib mesylate, avapritinib, sunitinib, dasatinib, ripretinib or regorafenib. Differentiated (ie, papillary, follicular, oncocytic) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. Medullary thyroid carcinoma, approve if the patient has tried at least one systemic therapy. AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test and the medication is used in combination with azacitidine or decitabine or patient has had an allogeneic stem cell transplant and is in remission. Renal cell carcinoma (RCC)-approve if the patient has relapsed or advanced clear cell histology and the patient has tried at least one systemic therapy (e.g., Inlyta, Votrient, Sutent Cabometyx). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and sorafenib is used in combination with topotecan. HCC-approve if the patient has unresectable or metastatic disease. Soft tissue sarcoma-approve if the patient has angiosarcoma or desmoid tumors (aggressive fibromatosis) or solitary fibrous tumor/hemangiopericytoma. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement. Please note for all diagnoses: Part B before Part D Step Therapy applies only to beneficiaries enrolled in an MA-PD plan</p>

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Bone cancer, Soft tissue sarcoma, gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, ovarian, fallopian tube, primary peritoneal cancer, myeloid/lymphoid neoplasms with eosinophilia
Part B Prerequisite	Yes

SPRAVATO

Products Affected

- SPRAVATO NASAL SPRAY, NON-AEROSOL 56 MG (28 MG X 2), 84 MG (28 MG X 3)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	Psychiatrist
Coverage Duration	MDD with Acute Suicidal Ideation or Behavior: 2 mo. Treatment-Resistant Depression: 6 mo
Other Criteria	Major Depressive Disorder with Acute Suicidal Ideation or Behavior-approve if the patient meets the following criteria (A, B and C): A) Patient has major depressive disorder that is considered to be severe, according to the prescriber, AND B) Patient is concomitantly receiving at least one oral antidepressant (Note: Antidepressants may include, but are not limited to, selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), mirtazapine, and bupropion), AND C) Patient has one of the following (i or ii): i. No history of psychosis, OR ii. History of psychosis and the prescriber believes that the benefits of Spravato outweigh the risks. Treatment-Resistant Depression-approve if the patient meets the following criteria (A, B, C and D): A) Patient meets both of the following (i and ii): i. Patient has demonstrated nonresponse (less than or equal to 25 percent improvement in depression symptoms or scores) to at least two different antidepressants, each from a different pharmacologic class, according to the prescriber (Note: Different pharmacologic classes of antidepressants include selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), bupropion, mirtazapine, etc.) AND ii. Each antidepressant was used at therapeutic dosages for at least 6 weeks in the current episode of depression, according

PA Criteria	Criteria Details
	to the prescriber, AND C) Patient is concomitantly receiving at least one oral antidepressant, AND D) Patient has one of the following (i or ii): i. No history of psychosis, OR ii. History of psychosis and the prescriber believes that the benefits of Spravato outweigh the risks, AND E) The patient history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP), according to the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SPRYCEL

Products Affected

- *dasatinib*
- SPRYCEL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which dasatinib is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For melanoma, cutaneous- KIT mutation and previous therapies.
Age Restrictions	GIST/bone cancer/ melanoma, cutaneous-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	For CML, patient must have Ph-positive CML. For ALL, patient must have Ph-positive ALL. For Bone Cancer-approve if patient has chondrosarcoma or chordoma. GIST - approve if the patient has tried imatinib or avapritinib. For melanoma, cutaneous - approve if patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	GIST, bone cancer, melanoma cutaneous
Part B Prerequisite	No

STELARA

Products Affected

- STELARA SUBCUTANEOUS

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/PsA-6 years and older (initial therapy).
Prescriber Restrictions	PP-Prescr/consult w/derm (initial therapy).PsA-prescr/consult w/rheum or derm (initial therapy).CD/UC-prescr/consult w/gastro (initial therapy).
Coverage Duration	End of the plan year
Other Criteria	PsA initial, approve if the patient meets one of the following (i or ii): i. patient is 6 to 17 years of age OR ii. patient is 18 years of age or older and has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor for PsA 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 has tried or is currently taking corticosteroids, or patient has tried one other agent for at least 3 months. UC initial, approve if the patient has had a trial of one systemic agent for at least 3 months (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, biologic, JAK inhibitor or a corticosteroid such as prednisone or methylprednisolone) or if the patient has pouchitis and has tried an antibiotic, probiotic, corticosteroid enema or mesalamine enema.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

STIVARGA

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Stivarga is being used. Prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For GIST, patient must have previously been treated with imatinib or Ayvakit and sunitinib or Sprycel. For HCC, patient must have previously been treated with at least one systemic regimen. Soft tissue sarcoma, advanced or metastatic disease-approve if the patient has non-adipocytic sarcoma, angiosarcoma, or pleomorphic rhabdomyosarcoma. Bone Cancer-approve if the patient has relapsed/refractory or metastatic disease AND the patient has tried one systemic chemotherapy regimen AND pt has Ewing sarcoma or osteosarcoma. Colon and Rectal cancer/Appendiceal cancer-approve if the patient has advanced or metastatic disease, has been previously treated with a fluoropyrimidine, oxaliplatin, irinotecan and if the patient meets one of the following (i or ii): i. patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type), the patient has tried Erbitux or Vectibix or the patient's tumor did not originate on the left side of the colon (from the splenic fixture to rectum) or ii. the patient's tumor or metastases has a RAS mutation (either KRAS mutation or NRAS mutation). Glioblastoma-approve if the patient has recurrent or progressive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Soft tissue Sarcoma, Bone Cancer, Glioblastoma, Appendiceal cancer

PA Criteria	Criteria Details
Part B Prerequisite	No

SUCRAID

Products Affected

- SUCRAID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, gastroenterologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of congenital diarrheal disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient meets the following criteria (A and B): A) The diagnosis is established by one of the following (i or ii): i. Patient has endoscopic biopsy of the small bowel with disaccharidase levels consistent with congenital sucrose-isomaltase deficiency as evidenced by ALL of the following (a, b, c, and d): a) Decreased (usually absent) sucrase (normal reference: greater than 25 U/g protein), b) Decreased to normal isomaltase (palatinase) [normal reference: greater than 5 U/g protein], c) Decreased maltase (normal reference: greater than 100 U/g protein), d) Decreased to normal lactase (normal reference: greater than 15 U/g protein) OR ii. Patient has a molecular genetic test demonstrating homozygous or compound heterozygous pathogenic or likely pathogenic sucrase-isomaltase gene variant AND B) Patient has symptomatic congenital sucrose-isomaltase deficiency (e.g., diarrhea, bloating, abdominal cramping).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SUNITINIB

Products Affected

- *sunitinib malate*
- SUTENT

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	1 year
Other Criteria	Gastrointestinal stromal tumors (GIST), approve if the patient has tried imatinib or Ayvakit or if the patient has succinate dehydrogenase (SDH)-deficient GIST. Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Medullary thyroid carcinoma, approve if the patient has tried at least one systemic therapy. Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried at least one systemic chemotherapy. Renal Cell Carcinoma (RCC)- approve if the patient has relapsed or advanced disease. Neuroendocrine tumors of the pancreas-approve for advanced or metastatic disease. Pheochromocytoma/paraganglioma-approve if the patient has unresectable or metastatic disease. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), differentiated (ie, papillary, follicular, and oncocytic carcinoma) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma, pheochromocytoma/paraganglioma, myeloid/lymphoid neoplasms with eosinophilia, GIST-unresectable succinate dehydrogenase (SDH)-deficient GIST, or use after avapritinib.

PA Criteria	Criteria Details
Part B Prerequisite	No

SYMDEKO

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	Patients with unknown CFTR gene mutations, Combination therapy with Orkambi, Kalydeco or Trikafta
Required Medical Information	Diagnosis, specific CFTR gene mutations
Age Restrictions	Six years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF - Approve if the pt mees A, B and C: A) pt has at least one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic or patient has TWO copies of the F508 del mutation, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SYMLIN

Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

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

TABRECTA

Products Affected

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has advanced or metastatic disease AND the tumor is positive for a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping or high-level MET amplification, as detected by an approved test.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-small cell lung cancer with high-level MET amplification.
Part B Prerequisite	No

TAFAMIDIS

Products Affected

- VYNDAMAX
- VYNDAQEL

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

TAFINLAR

Products Affected

- TAFINLAR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Tafinlar is being used. BRAF V600 mutations
Age Restrictions	1 year and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	<p>Melanoma with BRAF V600 mutation AND patient has unresectable, advanced (including Stage III or Stage IV disease) or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC, must have BRAF V600E mutation. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafinlar will be taken in combination with Mekinist, unless intolerant AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or Hurthle cell) AND the patient has disease that is refractory to radioactive iodine therapy AND the patient has BRAF-positive disease. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Mekinist. Central Nervous System Cancer-approve if the medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c, or d): a) glioma OR b) Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma OR d)Oligodendroglioma OR iii. Melanoma with brain metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets).</p>

PA Criteria	Criteria Details
	<p>Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR patient has Erdheim Chester disease AND patient has BRAF V600-mutation positive disease. Metastatic or solid tumors-approve if BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets) AND patient has no satisfactory alternative treatment options. Hairy Cell Leukemia, approve if pt has not previously been treated with a BRAF inhibitor therapy and this will be used for relapsed/refractory disease and will be taken in combination with Mekinist.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Differentiated Thyroid Cancer, Biliary tract cancer, central nervous system cancer, histiocytic neoplasm, Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, hairy cell leukemia
Part B Prerequisite	No

TAGRISSO

Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>NSCLC-EGFR Mutation Positive (other than EGFR T790M-Positive Mutation)- approve if the patient has advanced or metastatic disease, has EGFR mutation-positive NSCLC as detected by an approved test. Note-examples of EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. NSCLC-EGFR T790M mutation positive-approve if the patient has advanced or metastatic EGFR T790M mutation-positive NSCLC as detected by an approved test and has progressed on treatment with at least one of the EGFR tyrosine kinase inhibitors. NSCLC- Post resection-approve if the patient has completely resected disease and has received previous adjuvant chemotherapy or if the patient is ineligible to receive platinum based chemotherapy and the patient has EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test. NSCLC- Unresectable Stage III - approve if the patient has locally advanced, unresectable (stage III) disease AND EGFR exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an approved test AND not had disease progression during or following platinum-based chemoradiation therapy. (Note: Patients could have received concurrent or sequential chemoradiation therapy.)</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

TALZENNA

Products Affected

- TALZENNA

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	Recurrent or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive disease. Prostate cancer - approve if the patient has metastatic castration resistant prostate cancer, AND is using this medication concurrently with a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy AND the patient has homologous recombination repair (HRR) gene-mutated disease [Note: HRR gene mutations include ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C] AND the medication is used in combination with Xtandi (enzalutamide capsules and tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TARGRETIN TOPICAL

Products Affected

- *bexarotene*
- TARGRETIN TOPICAL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	Adult T-Cell Leukemia/Lymphoma- approve if the patient has chronic/smoldering subtype and this medication is used as first-line therapy. Primary cutaneous B-Cell lymphoma-approve if used as skin-directed therapy for either (a or b): a) primary cutaneous marginal zone lymphoma or b) follicle center lymphoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Adult T-Cell Leukemia/Lymphoma, Primary Cutaneous B-Cell Lymphoma
Part B Prerequisite	No

TASIGNA

Products Affected

- TASIGNA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Tasigna is being used. For indication of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For indication of gastrointestinal stromal tumor (GIST) and melanoma, cutaneous, prior therapies tried. For melanoma, cutaneous, KIT mutation status.
Age Restrictions	GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older, ALL - 15 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Acute lymphoblastic leukemia, philadelphia chromosome positive or chronic myeloid leukemia- approve. For GIST, approve if the patient has tried two of the following: imatinib, avapritinib, sunitinib, dasatinib, regorafenib or ripretinib. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement. Pigmented villonodular synovitis/tenosynovial giant cell tumor-approve if the patient has tried Turalio or cannot take Turalio, according to the prescriber. For melanoma, cutaneous - approve if the patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST), Pigmented villonodular synovitis/tenosynovial giant cell tumor, Myeloid/Lymphoid neoplasms with Eosinophilia, melanoma cutaneous.
Part B Prerequisite	No

TAZAROTENE

Products Affected

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

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

TAZVERIK

Products Affected

- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Epithelioid Sarcoma-16 years and older, Follicular Lymphoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Epithelioid Sarcoma-approve if the patient has metastatic or locally advanced disease and the patient is not eligible for complete resection. Follicular Lymphoma-approve if the patient has relapsed or refractory disease and there are no appropriate alternative therapies or the patient has tried at least two prior systemic therapies.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TEPMETKO

Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NSCLC-approve if the patient has advanced or metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutations or patient has high-level MET amplification, as detected by an approved test.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-small cell lung cancer with high-level MET amplification.
Part B Prerequisite	No

TERIPARATIDE

Products Affected

- *teriparatide subcutaneous pen injector 20 mcg/dose (600mcg/2.4ml)*
- TERIPARATIDE SUBCUTANEOUS PEN INJECTOR 20 MCG/DOSE (620MCG/2.48ML)

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications for osteoporosis
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	High risk for fracture-2 yrs, Not high risk-approve a max of 2 yrs of therapy (total)/lifetime.
Other Criteria	<p>INITIAL THERAPY: Postmenopausal Osteoporosis (PMO) Treatment, Increase Bone Mass in Men (see Note 1 below) with Primary or Hypogonadal Osteoporosis, and Treatment of Glucocorticosteroid-Induced Osteoporosis (GIO): (one of A, B, C, D or E): A) tried one oral bisphosphonate or cannot take due to swallowing difficulties or inability to remain upright after administration, B) pre-existing gastrointestinal condition (e.g., esophageal lesions/ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), C) tried an IV bisphosphonate (PMO-ibandronate or zoledronic acid, all other diagnoses-zoledronic acid), D) severe renal impairment (creatinine clearance [CrCL] less than 35 mL/min) or chronic kidney disease (CKD), or E) patient had an osteoporotic fracture or fragility fracture at any time in the past.</p> <p>CONTINUATION THERAPY: ALL INDICATIONS: if the patient has taken teriparatide for two years, approve if the patient is at high risk for fracture. Examples of high risk for fracture include a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, and very low bone mineral density. Note 1: a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.</p>
Indications	All FDA-approved Indications.

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

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.
Part B Prerequisite	No

THALOMID

Products Affected

- THALOMID ORAL CAPSULE 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	MM, myelofibrosis, histiocytic neoplasms-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
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, dapsons, acitretin [Soriatane]). Myelofibrosis, approve if according to the prescriber the patient has anemia and has serum erythropoietin levels greater than or equal to 500 mU/mL or if the patient has serum erythropoietin level less than 500 mU/mL and experienced no response or loss of response to erythropoietic stimulating agents. Prurigo nodularis, approve. Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried at least two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and has relapsed or refractory disease. Castleman's disease-approve if the patient has multicentric Castleman's disease and is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). Histiocytic neoplasms-approve if pt has Langerhans cell histiocytosis with single-system multifocal skin disease or Rosai-Dorfman cutaneous disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi's Sarcoma, Castleman's Disease, histiocytic neoplasms.
Part B Prerequisite	No

TIBSOVO

Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, IDH1 Status
Age Restrictions	All diagnoses (except chondrosarcoma)-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML- approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive, as detected by an approved test. Cholangiocarcinoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive and has been previously treated with at least one chemotherapy regimen (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan). Chondrosarcoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. Central nervous system cancer-approve if the patient has recurrent or progressive disease, AND patient has World Health Organization (WHO) grade 2 or 3 oligodendroglioma, OR Patient has WHO grade 2 astrocytoma. Myelodysplastic Syndrome-approve if patient has isocitrate dehydrogenase-1 (IDH1) mutation-positive disease AND relapsed or refractory disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chondrosarcoma, Central nervous system cancer
Part B Prerequisite	Yes

TOLVAPTAN

Products Affected

- SAMSCA ORAL TABLET 15 MG
- *tolvaptan*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Jynarque.
Required Medical Information	Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 30 days for initial therapy, 3 months for continuation of therapy
Other Criteria	Hyponatremia, initial therapy (including new starts, patients on therapy for less than 30 days, and patients restarting therapy) - Pt must meet ONE of the following: 1. serum sodium less than 125 mEq/L at baseline, OR 2. marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on tolvaptan and has received less than 30 days of therapy. Hyponatremia, continuation of therapy for patients established on therapy for at least 30 days - approve if the serum sodium level has increased from baseline (prior to initiating the requested drug) OR if the patient experienced improvement in at least one symptom, such as nausea, vomiting, headache, lethargy, or confusion.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TOPICAL AGENTS FOR ATOPIC DERMATITIS

Products Affected

- ELIDEL
- *pimecrolimus*
- *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
Part B Prerequisite	No

TOPICAL RETINOID PRODUCTS

Products Affected

- *tretinoin*
- *tretinoin microspheres*

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

TOPIRAMATE/ZONISAMIDE

Products Affected

- EPRONTIA
- TOPAMAX
- *topiramate oral capsule, sprinkle 15 mg, 25 mg*
- *topiramate oral capsule, extended release 24hr*
- *topiramate oral tablet*
- TROKENDI XR
- 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
Part B Prerequisite	No

TRANSMUCOSAL FENTANYL DRUGS

Products Affected

- *fentanyl citrate buccal lozenge on a handle 1,200 mcg, 200 mcg*

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

TRELSTAR

Products Affected

- TRELSTAR INTRAMUSCULAR
SUSPENSION FOR RECONSTITUTION

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 oncologist or urologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TREMFYA

Products Affected

- TREMFYA
- TREMFYA PEN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis
Age Restrictions	PP/UC- 18 years of age and older (initial therapy)
Prescriber Restrictions	PP-Prescribed by or in consultation with a dermatologist (initial therapy only). PsA-prescribed by or in consultation with a dermatologist or rheumatologist (initial therapy). UC-prescribed by or in consultation with a gastroenterologist (initial therapy).
Coverage Duration	Approve through end of plan year
Other Criteria	PP, intial therapy - approve if the pt 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: a biologic that is not a biosimilar of the requested product will also count) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. ULCERATIVE COLITIS- pt will receive 3 induction doses with Tremfya IV within 3 months of initiating Tremfya SC AND (A or B): A) tried a systemic therapy (e.g., 6-MP, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a CS) or B) has pouchitis and tried therapy with an antibiotic, probiotic, CS enema, or mesalamine (Rowasa) enema. PP/PsA/UC continuation of therapy - approve it the pt is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TRIENTINE

Products Affected

- CUVRIOR
- *trientine oral capsule 250 mg*

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

PA Criteria	Criteria Details
Part B Prerequisite	No

TRIKAFTA

Products Affected

- TRIKAFTA

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	2 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF - Approve if the pt meets A, B and C: A) pt has at least one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TRUQAP

Products Affected

- TRUQAP

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast Cancer-Approve if the patient meets the following (A, B, C, D and E): A) Patient has locally advanced or metastatic disease, AND B) Patient has hormone receptor positive (HR+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has at least one phosphatidylinositol 3-kinase (PIK3CA), serine/threonine protein kinase (AKT1), or phosphatase and tensin homolog (PTEN)-alteration, AND E) Patient meets one of the following (i or ii): i. Patient has had progression with at least one endocrine-based regimen in the metastatic setting (Note: Examples of endocrine therapy include anastrozole, exemestane, and letrozole.) and has had progression with at least one cyclin-dependent kinase (CDK) 4/6 inhibitor in the metastatic setting (Note: Examples of CDK4/6 inhibitor include: Ibrance (palbociclib tablets or capsules), Verzenio (abemaciclib tablets), Kisqali (ribociclib tablets), Kisqali Femara Co-Pack (ribociclib and letrozole tablets) OR ii. Patient has recurrence on or within 12 months of completing adjuvant endocrine therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TUKYSA

Products Affected

- TUKYSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast Cancer-approve if the patient has recurrent or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti-HER2-based regimen in the metastatic setting and Tukysa is used in combination with trastuzumab and capecitabine. Colon/Rectal Cancer-approve if the requested medication is used in combination with trastuzumab, patient has unresectable or metastatic disease, human epidermal growth factor receptor 2 (HER2)-amplified disease, AND Patient's tumor or metastases are wild-type RAS (KRAS wild-type and NRAS wild-type). Biliary tract cancer- approve if the patient meets all of (a, b, c, and d): a) unresectable or metastatic disease, b) HER2 positive disease, c) tried at least one systemic regimen, d) will use in combination with trastuzumab.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Biliary tract cancer
Part B Prerequisite	No

TURALIO

Products Affected

- TURALIO ORAL CAPSULE 125 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
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
Part B Prerequisite	No

TYMLOS

Products Affected

- TYMLOS

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, calcitonin nasal spray [Fortical], Forteo), Evenity, except calcium and Vitamin D. Previous use of Tymlos for a combined total no greater than 2 years duration during a patient's lifetime.
Required Medical Information	Previous medications tried, renal function
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 2 years of total therapy over a patient's lifetime
Other Criteria	Postmenopausal Osteoporosis (PMO) Treatment and Osteoporosis Treatment in Men (see Note 1 below) [one of A, B, C, D, or E]: A) tried one oral bisphosphonate or cannot take due to swallowing difficulties or inability to remain upright after administration, B) pre-existing gastrointestinal condition (e.g., esophageal lesions/ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), C) tried an IV bisphosphonate (PMO-ibandronate or zoledronic acid, osteoporosis in men- zoledronic acid), D) severe renal impairment (creatinine clearance [CrCL] less than 35 mL/min) or chronic kidney disease (CKD), or E) patient had an osteoporotic fracture or fragility fracture at any time in the past. Note 1: a man 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
Part B Prerequisite	No

TYSABRI

Products Affected

- TYSABRI

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of other disease-modifying agents used for MS. Concurrent use with immunosuppressants (eg, 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) in Crohn's disease (CD) patient
Required Medical Information	Diagnosis
Age Restrictions	18 and older (initial and continuation)
Prescriber Restrictions	MS: prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of MS. (initial and continuation) CD: prescribed by, or in consultation with, a gastroenterologist (initial and continuation)
Coverage Duration	MS-Authorization will be for 1 year.CD, initial-6 mo. CD, cont therapy-1 year.
Other Criteria	Adults with a relapsing form of MS-initial. Patient has had an inadequate response to, or is unable to tolerate, one disease modifying agent used for MS: (eg, interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron, Extavia), glatiramer acetate (Copaxone/Glatopa), Plegridy, fingolimod (Gilenya), Tecfidera, Lemtrada, daclizumab (Zinbryta), Aubagio, Mavenclad, Mayzent, Vumerity, Lemtrada, Ocrevus) OR the patient has highly active or aggressive disease according to the prescribing physician by meeting one of the following-the patient has demonstrated rapidly-advancing deterioration(s) in physical functioning (e.g., loss of mobility/or lower levels of ambulation, severe changes in strength or coordination OR disabling relapse(s) with suboptimal response to systemic corticosteroids OR magnetic resonance imaging (MRI) findings suggest highly-active or aggressive multiple sclerosis (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium lesions) OR manifestation of multiple sclerosis-related cognitive impairment. Adults with CD, initial. Patient has moderately to severely active CD and patient has tried two biologics for CD. CD, continuation therapy. Patient has had a response to Tysabri, as determined by the prescribing physician.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Patients already started on Tysabri for a Covered Use.
Part B Prerequisite	No

TZIELD

Products Affected

- TZIELD

PA Criteria	Criteria Details
Exclusion Criteria	Diagnosis of clinical type 1 diabetes (i.e., Stage 3 type 1 diabetes) or type 2 diabetes
Required Medical Information	Patient meets ALL of the following (A, B, C and D): A) has tested positive for at least TWO of the following type 1 diabetes-related autoantibodies on two separate occasions: anti-glutamic acid decarboxylase 65 (anti-GAD65), anti-islet antigen-2 (anti-IA-2), islet-cell autoantibody (ICA), micro insulin, or anti-zinc transporter 8 (anti-ZnT8). B) Patient meets both of the following (i and ii): i. Patient has taken an oral glucose tolerance test within the preceding 2 months AND ii. The results of the oral glucose tolerance test indicated dysglycemia by meeting at least one of the following (a, b, or c): a) Fasting plasma glucose level greater than or equal to 110 to less than 126 mg/dL OR b) 2-hour postprandial plasma glucose level greater than or equal to 140 to less than 200 mg/dL OR c) Intervening postprandial glucose level at 30, 60, or 90 minutes greater than 200 mg/dL. C) At baseline (prior to the initiation of Tzield), patient does NOT have evidence of hematologic compromise, as defined by meeting the following (i, ii, iii, and iv): i. Lymphocyte count greater than or equal to 1,000 lymphocytes/mcL AND ii. Hemoglobin greater than or equal to 10 g/dL AND iii. Platelet count greater than or equal to 150,000 platelets/mcL AND iv. Absolute neutrophil count greater than or equal to 1,500 neutrophils/mcL AND D) At baseline (prior to the initiation of Tzield), patient does NOT have evidence of hepatic compromise, as defined by meeting the following (i, ii, and iii): i. Alanine aminotransferase (ALT) greater than or equal to 2 times the upper limit of normal (ULN) AND ii. Aspartate aminotransferase (AST) greater than or equal to 2 times the ULN AND iii. Bilirubin greater than or equal to 1.5 times the ULN.
Age Restrictions	8 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	14 days

PA Criteria	Criteria Details
Other Criteria	Patient meets all the following (A, B and C): A) has at least one biological relative with a diagnosis of type 1 diabetes B) According to the prescriber, the patient does NOT have any of the following (i, ii, or iii): i. Laboratory or clinical evidence of acute infection with Epstein-Barr Virus or cytomegalovirus OR ii. Active serious infection OR iii. Chronic active infection (other than localized skin infection) AND C) Patient has NOT received Tzield in the past
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

UPTRAVI

Products Affected

- UPTRAVI ORAL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Inhaled or Parenteral Prostacyclin Agents Used for Pulmonary Hypertension.
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 therapy must meet a) OR b): a) tried one or is currently taking one oral therapy for PAH for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas, OR b) receiving or has received in the past one prostacyclin therapy for PAH (eg, Orenitram, Ventavis, or epoprostenol injection).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VALCHLOR

Products Affected

- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Cutaneous lymphoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
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
Part B Prerequisite	No

VALTOCO

Products Affected

- VALTOCO

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

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
Part B Prerequisite	No

VANFLYTA

Products Affected

- VANFLYTA

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

VENCLEXTA

Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy
Age Restrictions	18 years and older (all diagnoses except ALL)
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML-approve if used in combination with azacitidine, decitabine, or cytarabine. CLL/SLL- approve. ALL- approve if relapsed/refractory disease and will be used in combination with chemotherapy. Hairy cell leukemia- approve if disease resistance to BRAF inhibitor therapy. Mantle Cell Lymphoma- approve if (A or B): A) the patient has tried at least one systemic regimen or B) patient has TP53 mutation and will use this as induction therapy in combination with Brukinsa (zanubrutinib) and Gazyva (obinutuzumab intravenous infusion). MDS- approve if pt meets (A and B): A) pt meets (i or ii): (i) has chronic myelomonocytic leukemia-2 or (ii) has higher risk disease (note: includes international prognostic scoring system (IPSS-R) intermediate-, high-, or very-high risk disease) and B) will use in combination with azacitidine or decitabine. Myeloproliferative neoplasm- approve if pt has accelerated or blast phase disease and will use in combination with azacitidine or decitabine. Multiple Myeloma- approve if the patient has t (11,14) translocation AND has tried at least one systemic regimen for multiple myeloma AND Venclexta will be used in combination with dexamethasone. Systemic light chain amyloidosis-approve if the patient has t (11, 14) translocation and has tried at least one systemic regimen. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Mantle Cell Lymphoma, waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, multiple myeloma, systemic light chain amyloidosis, acute lymphoblastic leukemia, hairy cell leukemia, myelodysplastic syndrome, myeloproliferative neoplasm
Part B Prerequisite	No

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
Part B Prerequisite	No

VERQUVO

Products Affected

- VERQUVO

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	Patient has symptomatic chronic heart failure, an ejection fraction less than 45% and for new starts, has had either a hospitalization for heart failure within the last six months or has needed outpatient IV diuretics within the last three months.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VERZENIO

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Breast Cancer, Early-Approve if pt meets (A,B,C and D): A)Pt has HR+disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt has node-positive disease at high risk of recurrence AND D)Pt meets ONE of the following (i or ii): i.Verzenio will be used in combo w/anastrozole, exemestane, or letrozole AND pt meets one of the following (a,b, or c): a)Pt is a postmenopausal woman, OR b)Pt is a pre/perimenopausal woman and meets one of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, OR 2-Pt has had surgical bilateral oophorectomy or ovarian irradiation, OR c)Pt is a man and pt is receiving a GnRH analog, OR ii.Verzenio will be used in combo with tamoxifen AND pt meets one of the following (a or b): a)Pt is a postmenopausal woman or man OR b)Pt is a pre/perimenopausal woman and meets one of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Patient has had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer-Recurrent or Metastatic in Women-Approve if pt meets (A, B, C and D): A) Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets ONE of the following criteria (i or ii): i.Pt is a postmenopausal woman, OR ii.Pt is a pre/perimenopausal woman and meets one of the following (a or b): a)Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR b)Pt has had surgical bilateral oophorectomy or ovarian irradiation, AND D)Pt meets ONE of the</p>

PA Criteria	Criteria Details
	<p>following criteria (i, ii, or iii): i.Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.pt meets the following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least one prior endocrine therapy, AND c)Pt has tried chemotherapy for metastatic breast cancer.Breast Cancer-Recurrent or Metastatic in Men-Approve if pt meets the following criteria (A,B and C): A)Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets ONE of the following criteria (i, ii, or iii): i.Pt meets BOTH of the following conditions (a and b): a)Pt is receiving a GnRH analog, AND b)Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.Pt meets the following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least one prior endocrine therapy, AND c)Pt has tried chemotherapy for metastatic breast cancer. Endometrial cancer- approve if pt meets all of (A, B, And C): A) pt has recurrent or metastatic disease, and B) pt has estrogen receptor (ER)-positive tumors, and C) pt will be using in combination with letrozole.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Endometrial cancer
Part B Prerequisite	No

VIBERZI

Products Affected

- VIBERZI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of irritable bowel syndrome with diarrhea.
Age Restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	The patient must have a history of failure, contraindication or intolerance to one antidiarrheal drug.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	1 year
Other Criteria	Solid tumors - approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VIZIMPRO

Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, EGFR status, exon deletions or substitutions
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NSCLC-approve if the patient has advanced or metastatic disease, has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VONJO

Products Affected

- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Myelofibrosis (MF), including primary MF, post-polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient meets either (A, B, or C): (A) the patient has a platelet count of less than 50×10^9 /L (less than 50,000/mcL) and meets one of the following criteria (a or b): a) Patient has intermediate-risk or high-risk disease and is not a candidate for transplant, or b) Patient has lower-risk disease OR (B) Patient has a platelet count of greater than or equal to 50×10^9 /L (greater than or equal to 50,000/mcL) and meets all of the following criteria (a and b): a) Patient has high-risk disease, AND b) Patient is not a candidate for transplant OR (C) patient has myelofibrosis-associated anemia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VORANIGO

Products Affected

- VORANIGO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	GLIOMAS-All of (A, B and C): A. Susceptible isocitrate dehydrogenase-1 (IDH1) or IDH2 mutation-positive disease, AND B. Grade 2 oligodendroglioma OR Grade 2 astrocytoma, AND C. Prior surgery, including biopsy, sub-total resection, or gross total resection
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VOSEVI

Products Affected

- VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
Coverage Duration	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No

VOTRIENT

Products Affected

- *pazopanib*

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	1 year
Other Criteria	<p>Soft tissue sarcoma other than GIST-approve if the patient has advanced or metastatic disease and has ONE of the following: alveolar soft part sarcoma, angiosarcoma, desmoid tumors (aggressive fibromatosis, dermatofibrosarcoma protuberans with fibrosarcomatous transformation, non-adipocytic sarcoma or pleomorphic rhabdomyosarcoma.</p> <p>Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Uterine sarcoma, approve if the patient has recurrent or metastatic disease. Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or advanced disease or VonHippel-Lindau disease. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease. GIST - approve if the patient has succinate dehydrogenase (SDH)-deficient GIST OR the patient has tried TWO of the following: Gleevec, Ayvakit, Sutent, Sprycel, Qinlock or Stivarga. Medullary Thyroid Carcinoma, approve if the patient has tried at least one systemic therapy. Bone cancer-approve if the patient has chondrosarcoma and has metastatic widespread disease.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (ie, papillary, follicular, oncocytic carcinoma) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or

PA Criteria	Criteria Details
	Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma, bone cancer.
Part B Prerequisite	No

VOWST

Products Affected

- VOWST

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	30 days
Other Criteria	Prevention of recurrence of clostridioides difficile infection (CDI)-approve if the patient has completed a bowel prep, will not eat or drink for at least 8 hours prior to the first dose and will complete their antibacterial treatment for recurrent CDI 2-4 days before initiating treatment with Vowst and Vowst will not be used for the TREATMENT of CDI.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VUMERITY

Products Affected

- VUMERITY

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

VYLOY

Products Affected

- VYLOY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA (all of A, B, C, D and E): A. Locally advanced unresectable or metastatic disease, AND B. Tumor is claudin 18.2 positive as determined by an approved test, Note: Claudin 18.2 positivity is defined as greater than or equal to 75 percent of tumor cells demonstrating moderate to strong membranous claudin 18.2 immunohistochemical staining. AND C. Tumor is human epidermal growth factor receptor 2 (HER2)-negative, AND D. Used for first-line treatment, AND E. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy. Note: Examples of fluoropyrimidines include 5-fluorouracil and capecitabine. Examples of platinum chemotherapy agents include oxaliplatin.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VYVGART HYTRULO

Products Affected

- VYVGART HYTRULO

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant Use with Another Neonatal Fc Receptor Blocker, a Complement Inhibitor, or a Rituximab Product
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (CIDP: initial only, GMG: initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (CIDP: initial only, GMG: initial and continuation)
Coverage Duration	CIDP initial - 3 months, GMG Initial-6 months, All dx Continuation-1 year
Other Criteria	<p>CIDP, Initial Therapy - approve if diagnosis was supported by electrodiagnostic studies AND pt previously received treatment with an intravenous or subcutaneous immune globulin and had inadequate efficacy or significant intolerance or patient has a contraindication to IV or SC immune globulin. CIDP, Cont therapy - pt has clinically significant improvement in neurologic symptoms. Generalized myasthenia gravis, Initial Therapy-Approve if the patient meets the following criteria (A, B, C and D): A. Patient has confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis, AND B. Patient received or is currently receiving pyridostigmine or has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine, C. Patient has evidence of unresolved symptoms of generalized myasthenia gravis, such as difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility) AND D) patient has myasthenia gravis foundation of america classification of II to IV and myasthenia gravis activities of daily living (MG-ADL) score of greater than or equal to 5. Generalized myasthenia gravis, Continuation Therapy-Approve if patient is continuing to derive benefit from Vyvgart. All treatment cycles should be no more frequent than every 50 days from the start of the previous treatment cycle.</p>
Indications	All FDA-approved Indications.

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

WEGOVY

Products Affected

- WEGOVY

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other glucagon-like peptide-1 (GLP-1) agonists or GLP-1/ glucose-dependent insulintropic polypeptide (GIP) receptor agonists
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	To reduce the risk of major adverse cardiovascular events in a patient with established cardiovascular disease who is either obese or overweight: approve if the patient meets (A, B, C and D): A) at baseline, the patient has body mass index greater than or equal to 27 kg/m ² (refers to baseline prior to Wegovy) AND B) the patient meets one of the following (a, b, or c): a) prior myocardial infarction, b) prior stroke or c) history of symptomatic peripheral arterial disease as evidenced by one of the following: (1) intermittent claudication with ankle-brachial index less than 0.85, (2) peripheral arterial revascularization procedure, or (3) amputation due to atherosclerotic disease AND C) the medication will be used in combination with pharmacotherapy for established cardiovascular disease as deemed appropriate by the prescribing physician AND D) the medication will be used in combination with a reduced calorie diet (e.g. Prescriber attestation that patient has received counseling on diet).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

WELIREG

Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Renal Cell Carcinoma- approve if pt has advanced disease AND has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor AND has tried at least one a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). [Note: Examples of PD-1 inhibitor or PD-L1 inhibitor include: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), and Bavencio (avelumab intravenous infusion). Examples of VEGF-TKI include Cabometyx (cabozantinib tablets), Lenvima (lenvatinib capsules), Inlyta (axitinib tablets), Fotivda (tivozanib capsules), pazopanib, sunitinib, and sorafenib.] 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.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XALKORI

Products Affected

- XALKORI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Anaplastic large cell lymphoma/IMT-patients greater than or equal to 1 year of age. All other diagnoses-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Metastatic non-small cell lung cancer-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease, as detected by an approved test and patients new to therapy must have a trial of Alecensa prior to approval of Xalkori. Metastatic non-small cell lung cancer, approve if the patient has ROS1 rearrangement positive disease, as detected by an approved test. Anaplastic Large Cell Lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Histiocytic neoplasm-approve if the patient has ALK rearrangement/fusion-positive disease and meets one of the following criteria (i, ii, or iii): (i. Patient has Langerhans cell histiocytosis, OR ii. Patient has Erdheim-Chester disease OR iii. Patient has Rosai-Dorfman disease. NSCLC with MET mutation-approve if the patient has high level MET amplification or MET exon 14 skipping mutation. Inflammatory Myofibroblastic Tumor-approve if the patient has ALK positive disease and the patient has advanced, recurrent or metastatic disease or the tumor is inoperable. Melanoma, cutaneous-approve if the patient has ALK fusion disease or ROS1 fusion disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	NSCLC with high level MET amplification or MET Exon 14 skipping mutation, Histiocytic neoplasms, melanoma, cutaneous.
Part B Prerequisite	No

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
Part B Prerequisite	No

XCOPRI

Products Affected

- XCOPRI
- XCOPRI MAINTENANCE PACK
- 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
Part B Prerequisite	No

XDEMVY

Products Affected

- XDEMVY

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

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/AS prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist. (all apply to initial therapy only)
Coverage Duration	End of the plan year
Other Criteria	Initial - Approve if the patient has tried a TNF, JAK or other biologic for at least 3 months. Continuation-approve if the patient has had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XENICAL

Products Affected

- ORLISTAT
- XENICAL

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	For hyperlipidemia, the patient is on a maximally tolerated statin and a secondary cholesterol lowering drug. Patients intolerant to statins as demonstrated by experiencing statin-associated rhabdomyolysis to one statin OR has tried 2 statins (any combination of high or moderate intensity statins) and has experienced skeletal muscle related symptoms on both agents, no concurrent statin use required. Xenical can be approved with a non-D authorization for the indication of weight loss if the EGWP customer has the weight loss buy-up.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XERMELO

Products Affected

- XERMELO

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

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
Part B Prerequisite	No

XIAFLEX

Products Affected

- XIAFLEX

PA Criteria	Criteria Details
Exclusion Criteria	Retreatment (i.e., treatment 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 as part of the current treatment course. Peyronie's Disease-the patient meets ONE of the following (i or ii): i. at baseline (prior to use of Xiaflex), the patient has a penile curvature deformity of at least 30 degrees OR in a patient who has received prior treatment with Xiaflex, the patient has a penile curvature deformity of at least 15 degrees AND the patient has not previously been treated with a complete course (8 injections) of Xiaflex for Peyronie's disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XIFAXAN

Products Affected

- XIFAXAN

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. Traveler's diarrhea - 12 years of age or older.
Prescriber Restrictions	Pouchitis - prescribed by or in consultation with a gastroenterologist
Coverage Duration	HepEnceph-6mo,IBS/diarr-14days,Traveler's diarr-3days,Sm intest bact overgrowth-14days,Pouchitis-1yr
Other Criteria	Hepatic Encephalopathy-approve Xifaxan 550 mg tablets if the patient has previously had overt hepatic encephalopathy and the requested medication will be used concomitantly with lactulose, unless the patient has a contraindication or significant intolerance to treatment with lactulose. Irritable bowel syndrome with diarrhea-approve Xifaxan 550 mg tablets. (For IBS with diarrhea - customers are limited to 3 courses) Travelers Diarrhea-approve Xifaxan 200 mg tablets if the patient is afebrile and does not have blood in the stool. Small intestine bacterial overgrowth-approve Xifaxan 200mg or 550 mg tablets if the diagnosis has been confirmed by a glucose hydrogen breath test, lactulose hydrogen breath test, or small bowel aspiration and culture. Chronic antibiotic-dependent pouchitis-approve Xifaxan 200mg or 550mg tablets if patient meets all of (a, b, c and d): a) recurrent pouchitis (Note: recurrent pouchitis is typically considered history of at least 3 pouchitis episodes within a 12 month period), and b) episodes of pouchitis respond to antibiotic therapy but relapse shortly after antibiotic discontinuation, and c) alternative causes of recurrent pouchitis have been ruled out, and d) has tried long-term antibiotic therapy trials (at least 4 weeks) of BOTH ciprofloxacin and metronidazole for remission maintenance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Small intestine bacterial overgrowth, chronic antibiotic-dependent pouchitis
Part B Prerequisite	No

XOLAIR

Products Affected

- XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy.
Required Medical Information	Diagnosis
Age Restrictions	Moderate to severe persistent asthma-6 years and older. CIU-12 years and older. Polyps-18 years and older. Food Allergy-1 yr and older
Prescriber Restrictions	Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist. Polyps-prescribed by or in consult with an allergist, immunologist, or otolaryngologist. Food allergy- allergist or immunologist
Coverage Duration	asthma/CIU-Initial tx 4 months, Polyps-initial-6 months, continued tx 12 months, Food allergy-1 yr
Other Criteria	<p>MODERATE TO SEVERE PERSISTENT ASTHMA (A, B, C and D): A) baseline IgE greater than or equal to 30 IU/mL, and B) baseline positive skin test or in vitro test for 1 or more perennial or seasonal aeroallergens C) received at least 3 months of combination therapy with an inhaled corticosteroid (ICS) and additional asthma controller/maintenance medication (e.g., LABA, LAMA, leukotriene receptor antagonist, monoclonal antibody) [see Exception 1 below] and D) asthma is uncontrolled or was uncontrolled prior to receiving Xolair or another monoclonal antibody and meets one of the following (a, b, c, d, or e): a) experienced two or more asthma exacerbations requiring systemic CSs in the past year, b) experienced one or more asthma exacerbation requiring hospitalization/urgent care visit/emergency department visit in the past year, c) forced expiratory volume in 1 second (FEV1) less than 80% predicted, d) FEV1/forced vital capacity (FVC) less than 0.80, or e) asthma worsens upon tapering of oral CS. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRwNP) [all of A, B, C, D, and E]: A) diagnosis by direct exam, endoscopy, or sinus CT scan, B) baseline (prior to Xolair or another monoclonal antibody that may lower IgE) IgE at least 30 IU/ml, C)</p>

PA Criteria	Criteria Details
	<p>at least two of the following symptoms for 6 months: nasal congestion, obstruction, discharge, reduction/loss of smell, D) tried intranasal CS and will continue in combination with Xolair, and E) one of the following (a, b, or c): a) had systemic CS at least 5 days in past 2 years, b) contraindication to systemic CS, or c) had nasal polyp surgery. CHRONIC IDIOPATHIC URTICARIA (CIU): urticaria more than 6 weeks prior to treatment with Xolair with symptoms present more than 3 days per week despite daily non-sedating H1-antihistamine therapy. IgE-MEDIATED FOOD ALLERGY (all of A, B, C and D): A) baseline IgE greater than or equal to 30 IU/mL, B) positive skin prick test and positive in vitro test for IgE to one or more foods, C) history of allergic reaction that met all of the following (a, b, and c): a) signs and symptoms of a significant systemic allergic reaction, b) reaction occurred within a short period of time following a known ingestion of the food, and c) prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector, and D) patient has been prescribed an epinephrine auto-injector.</p> <p>CONTINUATION THERAPY: ASTHMA: patient responded to therapy and continues to receive an ICS. CRwNP: patient responded after 6 months of therapy and continues intranasal CS. CIU: patient responded to therapy.</p> <p>Exception 1: an exception to the requirement of 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.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XOSPATA

Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, FLT3-mutation status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML - approve if the patient has relapsed or refractory disease AND the disease is FLT3-mutation positive as detected by an approved test. Lymphoid, Myeloid Neoplasms-approve if the patient has eosinophilia and the disease is FLT3-mutation positive as detected by an approved test.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Lymphoid, Myeloid Neoplasms
Part B Prerequisite	No

XPOVIO

Products Affected

- XPOVIO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Multiple Myeloma-Approve if the patient meets the following (A and B): A) The medication will be taken in combination with dexamethasone AND B) Patient meets one of the following (i, ii, or iii): i. Patient has tried at least four prior regimens for multiple myeloma OR ii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with bortezomib OR iii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with Darzalex (daratumumab infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Pomalyst (pomalidomide capsules). Note: Examples include bortezomib/Revlimid (lenalidomide capsules)/dexamethasone, Kyprolis (carfilzomib infusion)/Revlimid/dexamethasone, Darzalex (daratumumab injection)/bortezomib or Kyprolis/dexamethasone, or other regimens containing a proteasome inhibitor, immunomodulatory drug, and/or anti-CD38 monoclonal antibody. Diffuse large B-cell lymphoma Note:this includes patients with histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma)-approve if the patient has been treated with at least two prior systemic therapies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Treatment of multiple myeloma in combination with daratumumb or pomalidomide
Part B Prerequisite	No

XTANDI

Products Affected

- XTANDI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Xtandi is being used.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Prostate cancer-castration-resistant [Metastatic or Non-metastatic] and Prostate cancer-metastatic, castration sensitive-approve if Xtandi will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog [for example: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy. Prostate cancer- Non-Metastatic, Castration-Sensitive - approve if pt has biochemical recurrence and is at high risk for metastasis. [Note: High-risk biochemical recurrence is defined as prostate-specific antigen (PSA) doubling time less than or equal to 9 months.]
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XYREM

Products Affected

- SODIUM OXYBATE

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Xywav, Wakix or Sunosi
Required Medical Information	Medication history (as described in Other Criteria field)
Age Restrictions	7 years and older
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, 18 years and older - approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). For EDS in patients with narcolepsy, less than 18 years old-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextramphetamine) or modafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZARXIO

Products Affected

- ZARXIO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer/AML, MDS, ALL- oncologist or a hematologist. Cancer patients receiving BMT and PBPC- prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation.Radiation-expertise in acute radiation.SCN, AA - hematologist. HIV/AIDS neutropenia- infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
Coverage Duration	chemo/SCN/AML-6mo.HIV/AIDS-4mo.MDS-3mo.PBPC,Drug induce A/N,ALL,BMT/Radiation-1mo.
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), 2)patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, or HIV infection), 3)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, or 4)patient has received chemotherapy, has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia

PA Criteria	Criteria Details
	[absolute neutrophil count less than 100 cells/mm ³], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Acute lymphocytic leukemia (ALL). Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome).
Part B Prerequisite	No

ZEJULA

Products Affected

- ZEJULA ORAL TABLET

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	1 year
Other Criteria	Ovarian, fallopian tube, or primary peritoneal cancer, maintenance therapy - approve if the patient is in complete or partial response after platinum-based chemotherapy regimen and if the patient is in complete or partial response to first-line primary treatment or if the patient has recurrent disease and a BRCA mutation. Uterine leiomyosarcoma-approve if the patient has BRCA2 altered disease and has tried one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Uterine Leiomyosarcoma, Ovarian, fallopian tube or primary peritoneal cancer-treatment
Part B Prerequisite	No

ZELBORAF

Products Affected

- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	BRAFV600 mutation status required.
Age Restrictions	All diagnoses (except CNS cancer)-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	<p>Melanoma, patient new to therapy must have BRAFV600 mutation for approval AND have unresectable, advanced or metastatic melanoma. HCL - must have tried at least one other systemic therapy for hairy cell leukemia OR is unable to tolerate purine analogs and Zelboraf will be used in combination with Gazyva (obinutuzumab intravenous infusion) as initial therapy. Thyroid Cancer-patient has disease that is refractory to radioactive iodine therapy. Erdheim-Chester disease, in patients with BRAF V600 mutation-approve. Central Nervous System Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, c or d): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma/neuroglioma/glioneuronal tumor OR d) pediatric diffuse high-grade glioma OR ii. Recurrent or progressive disease for one of the following conditions (a or b): a) glioma/circumscribed glioma OR b) Glioblastoma OR iii. Melanoma with brain metastases AND the medication will be taken in combination with Cotellic (cobimetinib tablets). Histiocytic Neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following (i, ii, or iii): i. Multisystem disease OR ii. Pulmonary disease OR iii. Central nervous system lesions AND the patient has BRAF V600-mutation positive disease.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, Differentiated thyroid carcinoma (i.e., papillary, follicular, or oncocytic carcinoma) with BRAF-positive disease, Central Nervous System Cancer, Histiocytic Neoplasm
Part B Prerequisite	No

ZEPBOUND

Products Affected

- ZEPBOUND

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other glucagon-like peptide-1 (GLP-1) agonists or GLP-1/ glucose-dependent insulinotropic polypeptide (GIP) receptor agonists
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial/continuation)
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	<p>Obstructive sleep apnea (OSA), moderate to severe, in a patient with obesity, initial therapy (or on therapy for less than 1 year): approve if the patient meets (A, B, C and D): A) current body mass index greater than or equal to 30 kg/m² AND B) patient had a sleep study in the past year that shows both (a and b): a) diagnosed with moderate-to-severe OSA, and b) apnea-hypoxia index greater than or equal to 15 events per hour AND C) the patient does not have (a or b): a) Central sleep apnea with percent of central apneas/hypoapneas greater than or equal to 50 percent, or b) Cheyne Stokes respiration AND D) the medication will be used in combination with a reduced calorie diet (e.g. prescriber attestation that patient has received counseling on diet).</p> <p>Obstructive sleep apnea (OSA), moderate to severe, in a patient with obesity, continuation of therapy (on therapy at least 1 year): approve if the patient meets (A, B and C): A) body mass index greater than or equal to 30 kg/m² (at baseline, prior to Zepbound), and B) patient meets (a and b): a) patient lost greater than or equal to 10 percent of baseline body weight and b) has stability in OSA signs or symptoms, according to the prescriber, and C) the medication will be used in combination with a reduced calorie diet (e.g. prescriber attestation that patient has received counseling on diet).</p>
Indications	All FDA-approved Indications.

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

ZIEXTENZO

Products Affected

- ZIEXTENZO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer patients receiving chemotherapy -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 meets one of the following: 1) 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), 2) patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, or 3) 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
Part B Prerequisite	No

ZIIHERA

Products Affected

- ZIIHERA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. BILIARY TRACT CANCER - (all of A, B, C, D and E): A. Patient has ONE of the following (i, ii, or iii): i. Gallbladder cancer, OR ii. Intrahepatic cholangiocarcinoma, OR iii. Extrahepatic cholangiocarcinoma, AND B. Patient has unresectable, resected gross residual, or metastatic disease, AND C. The tumor is human epidermal growth factor receptor 2 (HER2) positive with immunohistochemistry score of 3+ (IHC3+) as determined by an approved test, AND D. The medication is used for subsequent therapy, AND E. The medication is used as a single agent.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZOLINZA

Products Affected

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZTALMY

Products Affected

- ZTALMY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years 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 and patient has tried or is concomitantly receiving two other antiepileptic drugs.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZURZUVAE

Products Affected

- ZURZUVAE

PA Criteria	Criteria Details
Exclusion Criteria	Previous treatment with Zurzuvae during the current episode of postpartum depression
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist or an obstetrician-gynecologist
Coverage Duration	14 days
Other Criteria	Postpartum depression-approve if the patient meets the following (A, B and C): A.Patient meets BOTH of the following (i and ii): i. Patient has been diagnosed with severe depression, AND ii. Symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery, AND B. Patient is less than or equal to 12 months postpartum, AND C. Patient is not currently pregnant.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZYDELIG

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be 1 year
Other Criteria	CLL/SLL-approve if the patient has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	small lymphocytic lymphoma
Part B Prerequisite	No

ZYKADIA

Products Affected

- ZYKADIA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Erdheim-Chester Disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. NSCLC, ALK positive-approve if the patient has advanced or metastatic disease that is ALK positive as detected by an approved test and for patients new to therapy must have a trial of Alecensa prior to approval of Zykadia. NSCLC, ROS1 Rearrangement-approve if the patient has advanced or metastatic disease. Peripheral T-Cell Lymphoma- approve if patient has ALK-positive anaplastic large cell lymphoma (ALCL).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Patients with NSCLC with ROS1 Rearrangement. Erdheim-Chester disease. Peripheral T-Cell Lymphoma.
Part B Prerequisite	No

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 Prerequisite	No

ZYTIGA

Products Affected

- *abiraterone*

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 1 year.
Other Criteria	<p>Prostate Cancer-Metastatic, Castration-Resistant (mCRPC)-Approve if abiraterone is being used in combination with prednisone or dexamethasone and the medication is used concurrently used with a gonadotropin-releasing hormone (GnRH) analog (see Note 1) or the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration-sensitive (mCSPC)- approve if the medication is used in combination with prednisone and the medication is concurrently used with a GnRH analog (see Note 1) or the patient has had a bilateral orchiectomy. Prostate Cancer - Regional Risk Group - Approve if the patient meets all of the following criteria (A, B, and C): A) abiraterone is used in combination with prednisone AND B) Patient has regional lymph node metastases and no distant metastases AND C) Patient meets one of the following criteria (i or ii): i. abiraterone with prednisone is used in combination with a GnRH analog (see Note 1) OR ii. Patient has had a bilateral orchiectomy. Prostate cancer-very-high-risk-group-approve if according to the prescriber the patient is in the very-high-risk group, the medication will be used in combination with prednisone, the medication will be used in combination with external beam radiation therapy and the patient meets one of the following criteria (i or ii): i. abiraterone is used in combination with a GnRH analog (see Note 1) OR ii. Patient has had a bilateral orchiectomy. Prostate cancer- radical prostatectomy or post radiation therapy-approve if patient meets (A, B, C and D): A) the medication is used in combination</p>

PA Criteria	Criteria Details
	<p>with prednisone, B) meets (i or ii): i) the patient has prostate specific antigen (PSA) persistence or recurrence following radical prostatectomy or ii) PSA recurrence or positive digital rectal examination (DRE) after radiation therapy, C) patient has pelvic recurrence or positive regional lymph nodes, and D) the medication will be used concurrently with GnRH analog (see Note 1) or the patient has had a bilateral orchiectomy. Salivary Gland Tumors- approve if (A, B and C): A) used in combination with prednisone, B) androgen receptor-positive (AR+) recurrent, unresectable or metastatic tumor, and C) used in combination with a GnRH analog (see Note 1). Note 1: examples of GnRH analogs are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Prostate Cancer-Regional Risk Group, Prostate cancer-very-high-risk group, Prostate cancer- radical prostatectomy or post radiation, Salivary Gland Tumors
Part B Prerequisite	No

PART B VERSUS PART D

Products Affected

- *acetylcysteine*
- *acyclovir sodium intravenous solution*
- ADRIAMYCIN
- *albuterol sulfate inhalation solution for nebulization*
- *amiodarone intravenous solution*
- *aprepitant*
- *arformoterol*
- *arsenic trioxide*
- ASCENIV
- ASTAGRAF XL
- ATGAM
- *azacitidine*
- AZASAN
- *azathioprine*
- *azathioprine sodium*
- BELEODAQ
- *bendamustine intravenous recon soln*
- BENDAMUSTINE INTRAVENOUS SOLUTION
- BENDEKA
- BIVIGAM
- *bleomycin*
- BLINCYTO INTRAVENOUS KIT
- BROVANA
- *budesonide inhalation*
- *busulfan*
- *carboplatin intravenous solution*
- *carmustine intravenous recon soln 100 mg*
- CELLCEPT
- *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)
- CLINISOL SF 15 %
- *clofarabine*
- *cromolyn inhalation*
- *cyclophosphamide intravenous recon soln*
- CYCLOPHOSPHAMIDE INTRAVENOUS SOLUTION
- *cyclophosphamide oral capsule*
- CYCLOPHOSPHAMIDE ORAL TABLET
- *cyclosporine modified*
- *cyclosporine oral capsule*
- *cytarabine*
- *cytarabine (pf)*
- *dacarbazine*
- *dactinomycin*
- *daunorubicin*
- *decitabine*
- *docetaxel*
- *doxorubicin intravenous recon soln 50 mg*
- *doxorubicin intravenous solution*
- *doxorubicin, peg-liposomal*
- *dronabinol*
- EMEND ORAL SUSPENSION FOR RECONSTITUTION
- ENGERIX-B (PF)
- ENGERIX-B PEDIATRIC (PF)
- ENVARSUS XR
- *epirubicin intravenous solution*
- ERBITUX
- ETOPOPHOS
- *etoposide intravenous*
- *everolimus (immunosuppressive)*
- FIRMAGON KIT W DILUENT SYRINGE
- FLEBOGAMMA DIF INTRAVENOUS SOLUTION 5 %
- *floxuridine*
- *fludarabine*
- *fluorouracil intravenous*
- FOLOTYN
- *formoterol fumarate*
- FORMOTEROL FUMARATE-NEBULIZER
- *fulvestrant*
- GAMMAGARD LIQUID
- GAMMAGARD S-D (IGA < 1 MCG/ML)
- GAMMAKED

- GAMMAPLEX (WITH SORBITOL)
- GAMMAPLEX INTRAVENOUS SOLUTION 10 %
- GAMUNEX-C
- *gemcitabine intravenous recon soln*
- *gemcitabine intravenous solution 1 gram/26.3 ml (38 mg/ml), 2 gram/52.6 ml (38 mg/ml), 200 mg/5.26 ml (38 mg/ml)*
- GEMCITABINE INTRAVENOUS SOLUTION 100 MG/ML
- *gengraf*
- *granisetron hcl oral*
- HEPLISAV-B (PF)
- *idarubicin*
- *ifosfamide*
- INFUMORPH P/F
- *intralipid intravenous emulsion 20 %*
- INTRALIPID INTRAVENOUS EMULSION 30 %
- *ipratropium bromide inhalation*
- *ipratropium-albuterol*
- *irinotecan*
- IXEMPRA
- JEVTANA
- KABIVEN
- KYPROLIS
- *levalbuterol hcl*
- MEDROL ORAL TABLET 2 MG
- *melphalan hcl*
- *mesna intravenous*
- *methotrexate sodium (pf)*
- *methotrexate sodium injection*
- *methylprednisolone oral tablet*
- *mitomycin intravenous*
- *mitoxantrone*
- *mycophenolate mofetil*
- *mycophenolate mofetil (hcl)*
- *mycophenolate sodium*
- MYFORTIC
- *nelarabine*
- NEORAL
- NIPENT
- *nitroglycerin intravenous*
- NULOJIX
- NUTRILIPID
- OCTAGAM
- OHTUVAYRE
- ONCASPAR
- *ondansetron hcl oral solution*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet, disintegrating 4 mg, 8 mg*
- *oxaliplatin*
- *paclitaxel*
- PANZYGA
- *pentamidine inhalation*
- PERFOROMIST
- PERIKABIVEN
- PLENAMINE
- *plerixafor*
- PORTRAZZA
- PRALATREXATE
- *prednisolone sodium phosphate oral tablet, disintegrating*
- *premasol 10 %*
- PRIVIGEN
- PROGRAF
- PROSOL 20 %
- PULMICORT
- PULMOZYME
- RAPAMUNE ORAL TABLET 1 MG
- RECOMBIVAX HB (PF)
- RYLAZE
- SIMULECT
- *sirolimus*
- SYLVANT
- *tacrolimus oral capsule*
- TEMODAR INTRAVENOUS
- *temsirolimus*
- TICE BCG
- *tobramycin in 0.225 % nacl*
- *topotecan*
- TPN ELECTROLYTES
- *travasol 10 %*
- TROPHAMINE 10 %
- TYVASO
- TYVASO INSTITUTIONAL START KIT
- TYVASO REFILL KIT
- TYVASO STARTER KIT
- *valrubicin*
- *vinblastine*

- *vincristine*
- *vinorelbine*
- VYXEOS
- XEMBIFY
- YUPELRI
- 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.

Index

A

ABELCET..... 19
abiraterone..... 392, 393
ABRAXANE 20, 21
ABRYSVO (PF) 1
acetylcysteine 394
acitretin 2
ACTHAR 3
ACTHAR SELFJECT..... 3
ACTIMMUNE..... 4
acyclovir sodium intravenous solution ... 394
ADCETRIS 20, 21
ADEMPAS 5
ADRIAMYCIN..... 394
ADSTILADRIN..... 20, 21
ADVOCATE PEN NEEDLE NEEDLE 32
 GAUGE X 5/32..... 76, 77
AFINITOR 96, 97
AFINITOR DISPERZ..... 96, 97
AIMOVIG AUTOINJECTOR..... 6
AJOVY AUTOINJECTOR 7
AJOVY SYRINGE 7
AKEEGA 8
albuterol sulfate inhalation solution for
 nebulization..... 394
alcohol pads 76, 77
ALCOHOL PREP PADS..... 76, 77
ALCOHOL SWABS..... 76, 77
ALCOHOL WIPES 76, 77
ALDURAZYME..... 9
ALECENSA..... 10
ALIQOPA 20, 21
alosetron 11
ALUNBRIG..... 13
alyq..... 235
ambrisentan 14
amikacin injection solution 1,000 mg/4 ml,
 500 mg/2 ml 16, 17
amiodarone intravenous solution 394
amphotericin b 19
amphotericin b liposome..... 19
ampicillin sodium..... 16, 17
ampicillin-sulbactam..... 16, 17
ANKTIVA 15

aprepitant..... 394
ARALAST NP 12
ARANESP (IN POLYSORBATE)
 INJECTION SOLUTION 100 MCG/ML,
 200 MCG/ML, 25 MCG/ML, 40
 MCG/ML, 60 MCG/ML 22
ARANESP (IN POLYSORBATE)
 INJECTION SYRINGE..... 22
ARCALYST 23
AREXVY (PF)..... 24
arformoterol 394
ARIKAYCE..... 25
armodafinil 26
arsenic trioxide..... 394
ASCENIV 394
ascomp with codeine..... 126
ASSURE ID INSULIN SAFETY
 SYRINGE 1 ML 29 GAUGE X 1/2 76, 77
ASTAGRAF XL 394
ATGAM..... 394
AUBAGIO 28
AUGTYRO 29
AUSTEDO 30
AUSTEDO XR 30
AUSTEDO XR TITRATION KT(WK1-4)
 30
AVONEX..... 31
AVSOLA 146, 147
AYVAKIT 32
azacitidine 394
AZASAN 394
azathioprine..... 394
azathioprine sodium 394
azithromycin intravenous..... 16, 17
aztreonam 16, 17

B

BALVERSA 33
BAVENCIO..... 20, 21
BD INSULIN SYRINGE ULTRA-FINE
 SYRINGE 0.5 ML 30 GAUGE X 1/2 . 76,
 77
BD SAFETYGLIDE INSULIN SYRINGE
 SYRINGE 1 ML 29 GAUGE X 1/2 76, 77

BD ULTRA-FINE NANO PEN NEEDLE	76, 77	CARBAGLU.....	51
BD ULTRA-FINE SHORT PEN NEEDLE	76, 77	carboplatin intravenous solution.....	394
BELEODAQ.....	394	CARETOUCH ALCOHOL PREP PAD .	76, 77
bendamustine intravenous recon soln	394	carglumic acid.....	51
BENDAMUSTINE INTRAVENOUS SOLUTION.....	394	carisprodol.....	121
BENDEKA	394	carmustine intravenous recon soln 100 mg	394
BENLYSTA.....	34, 35	casprofungin.....	18
benztropine oral	120	CAYSTON.....	52
BESPONSA	20, 21	CEFEPIME INTRAVENOUS.....	16, 17
BESREMI	36	cefoxitin	16, 17
BETASERON SUBCUTANEOUS KIT ..	37	cefoxitin in dextrose, iso-osm.....	16, 17
bexarotene.....	38, 303	ceftazidime.....	16, 17
BICILLIN L-A.....	16, 17	cefuroxime sodium injection recon soln 750 mg	16, 17
BIVIGAM.....	394	cefuroxime sodium intravenous.....	16, 17
BIZENGRI.....	20, 21	CELLCEPT.....	394
bleomycin.....	394	CEREZYME INTRAVENOUS RECON SOLN 400 UNIT.....	53
BLINCYTO INTRAVENOUS KIT	394	CHEMET	54
BORTEZOMIB INJECTION RECON SOLN 1 MG, 2.5 MG	20, 21	chlorzoxazone oral tablet 500 mg	129
bortezomib injection recon soln 3.5 mg... 21	20, 21	CHORIONIC GONADOTROPIN, HUMAN INTRAMUSCULAR	55
BORUZU	20, 21	CIALIS ORAL TABLET 5 MG.....	56
bosentan	39	CIMZIA POWDER FOR RECONST	57, 58
BOSULIF.....	40	CIMZIA STARTER KIT	57, 58
BOTOX.....	41, 42	CIMZIA SUBCUTANEOUS SYRINGE KIT 400 MG/2 ML (200 MG/ML X 2)	57, 58
BRAFTOVI.....	43	ciprofloxacin in 5 % dextrose	16, 17
BRIUMVI	44	cisplatin intravenous solution	394
BROVANA.....	394	cladribine.....	394
BRUKINSA	45	CLINDAMYCIN IN 0.9 % SOD CHLOR	16, 17
budesonide inhalation	394	CLINDAMYCIN IN 5 % DEXTROSE... 17	16, 17
busulfan.....	394	clindamycin phosphate injection.....	16, 17
butalbital-acetaminop-caf-cod	126	CLINIMIX 5%/D15W SULFITE FREE	394
butalbital-acetaminophen oral tablet.....	126	CLINIMIX 4.25%/D10W SULF FREE .	394
butalbital-acetaminophen-caff	126	CLINIMIX 4.25%/D5W SULFIT FREE	394
butalbital-aspirin-caffeine oral capsule... 126	126	CLINIMIX 5%-D20W(SULFITE-FREE)	394
BYDUREON BCISE	114	CLINIMIX 6%-D5W (SULFITE-FREE)	394
C		CLINIMIX 8%-D10W(SULFITE-FREE)	394
CABOMETYX	46		
CALQUENCE	47		
CALQUENCE (ACALABRUTINIB MAL)	47		
CAMZYOS.....	48, 49		
CAPRELSA	50		

CLINIMIX 8%-D14W(SULFITE-FREE)	
.....	394
CLINISOL SF 15 %.....	394
clobazam	59
clofarabine.....	394
clomid	60
colistin (colistimethate na).....	16, 17
COLUMVI.....	20, 21
COMETRIQ.....	61
COPAXONE SUBCUTANEOUS	
SYRINGE	62
COPIKTRA.....	63
CORLANOR ORAL TABLET	64
COSENTYX	65
COSENTYX (2 SYRINGES).....	65
COSENTYX PEN.....	65
COSENTYX PEN (2 PENS)	65
COSENTYX UNOREADY PEN	65
COTELLIC	66, 67
CRINONE VAGINAL GEL 8 %	68
cromolyn inhalation	394
CURITY ALCOHOL SWABS.....	76, 77
CURITY GAUZE TOPICAL BANDAGE 2	
X 2.....	76, 77
CURITY GAUZE TOPICAL SPONGE 2 X	
2.....	76, 77
CUVRIOR.....	321, 322
cyclobenzaprine oral tablet	122
cyclophosphamide intravenous recon soln	
.....	394
CYCLOPHOSPHAMIDE INTRAVENOUS	
SOLUTION.....	394
cyclophosphamide oral capsule	394
CYCLOPHOSPHAMIDE ORAL TABLET	
.....	394
cyclosporine modified.....	394
cyclosporine oral capsule	394
CYRAMZA.....	20, 21
CYSTARAN	69
cytarabine	394
cytarabine (pf).....	394
D	
dacarbazine	394
dactinomycin.....	394
dalfampridine	70
DALIRESP	263
DANYELZA.....	20, 21
DANZITEN	71
DARZALEX.....	20, 21
DARZALEX FASPRO.....	20, 21
dasatinib	286
daunorubicin	394
DAURISMO	72
decitabine	394
deferasirox oral granules in packet	73
deferasirox oral tablet	73
deferiprone	74
diclofenac sodium topical drops	78
diclofenac sodium topical solution in	
metered-dose pump.....	78
dihydroergotamine nasal.....	79
dimethyl fumarate	80
docetaxel	394
DOPTELET (10 TAB PACK).....	81
DOPTELET (15 TAB PACK).....	81
DOPTELET (30 TAB PACK).....	81
doxorubicin intravenous recon soln 50 mg	
.....	394
doxorubicin intravenous solution.....	394
doxorubicin, peg-liposomal	394
doxy-100	16, 17
doxycycline hyclate intravenous.....	16, 17
dronabinol	394
DROPLET MICRON PEN NEEDLE 76, 77	
DROPLET PEN NEEDLE NEEDLE 30	
GAUGE X 5/16.....	76, 77
DROPSAFE ALCOHOL PREP PADS ... 76,	
77	
DROPSAFE PEN NEEDLE NEEDLE 31	
GAUGE X 3/16.....	76, 77
droxidopa	82
DUAVEE	83
DUPIXENT PEN	84, 85
DUPIXENT SYRINGE SUBCUTANEOUS	
SYRINGE 200 MG/1.14 ML, 300 MG/2	
ML.....	84, 85
E	
EASY COMFORT ALCOHOL PAD. 76, 77	
EASY COMFORT SAFETY PEN	
NEEDLE NEEDLE 31 GAUGE X 3/16	
.....	76, 77

EASY TOUCH ALCOHOL PREP PADS
 76, 77
 EDARAVONE..... 245
 ELAPRASE 86
 ELIDEL..... 315
 ELIGARD 115
 ELIGARD (3 MONTH)..... 115
 ELIGARD (4 MONTH)..... 115
 ELIGARD (6 MONTH)..... 115
 ELREXFIO 20, 21
 ELZONRIS 20, 21
 EMEND ORAL SUSPENSION FOR
 RECONSTITUTION 394
 EMLICITI..... 20, 21
 ENBREL MINI..... 87, 88
 ENBREL SUBCUTANEOUS SOLUTION
 87, 88
 ENBREL SUBCUTANEOUS SYRINGE87,
 88
 ENBREL SURECLICK..... 87, 88
 ENGERIX-B (PF)..... 394
 ENGERIX-B PEDIATRIC (PF) 394
 ENHERTU 20, 21
 ENVARSUS XR..... 394
 EPIDIOLEX..... 90
 epirubicin intravenous solution..... 394
 EPKINLY 20, 21
 EPRONTIA..... 317
 ERBITUX 394
 ergoloid 125
 eribulin 20, 21
 ERIVEDGE..... 93
 ERLEADA 94
 erlotinib 95
 ERYTHROCIN INTRAVENOUS RECON
 SOLN 500 MG..... 16, 17
 erythromycin lactobionate 16, 17
 ETOPOPHOS 394
 etoposide intravenous..... 394
 everolimus (antineoplastic)..... 96, 97
 everolimus (immunosuppressive) 394
 EVOMELA 20, 21
 EXTENCILLINE..... 16, 17
 EYLEA 98
F
 FANAPT 27

FARYDAK 99
 FASENRA 100, 101
 FASENRA PEN..... 100, 101
 fentanyl citrate buccal lozenge on a handle
 1,200 mcg, 200 mcg..... 318
 FERRIPROX..... 74
 FERRIPROX (2 TIMES A DAY) 74
 fingolimod..... 102
 FINTEPLA..... 103
 FIRMAGON KIT W DILUENT SYRINGE
 394
 FLEBOGAMMA DIF INTRAVENOUS
 SOLUTION 5 % 394
 floxuridine..... 394
 fluconazole in nacl (iso-osm)..... 18
 fludarabine 394
 fluorouracil intravenous 394
 FOLOTYN 394
 formoterol fumarate 394
 FORMOTEROL FUMARATE-
 NEBULIZER 394
 FORTEO 104, 105
 FOTIVDA 106
 FRUZAQLA 107
 fulvestrant 394
 FYARRO 20, 21
G
 GAMMAGARD LIQUID..... 394
 GAMMAGARD S-D (IGA < 1 MCG/ML)
 394
 GAMMAKED..... 394
 GAMMAPLEX (WITH SORBITOL) 395
 GAMMAPLEX INTRAVENOUS
 SOLUTION 10 % 395
 GAMUNEX-C 395
 GATTEX 30-VIAL..... 108
 GATTEX ONE-VIAL 108
 GAUZE PAD TOPICAL BANDAGE 2 X 2
 76, 77
 GAVRETO 109
 GAZYVA..... 20, 21
 gefitinib 110
 gemcitabine intravenous recon soln..... 395
 gemcitabine intravenous solution 1
 gram/26.3 ml (38 mg/ml), 2 gram/52.6 ml

(38 mg/ml), 200 mg/5.26 ml (38 mg/ml)
 395
GEMCITABINE INTRAVENOUS
SOLUTION 100 MG/ML 395
 gengraf 395
GENOTROPIN 116, 117
GENOTROPIN MINIQUICK 116, 117
 gentamicin in nacl (iso-osm) intravenous
 piggyback 100 mg/100 ml, 60 mg/50 ml,
 80 mg/100 ml, 80 mg/50 ml..... 16, 17
GENTAMICIN IN NAACL (ISO-OSM)
INTRAVENOUS PIGGYBACK 100
MG/50 ML, 120 MG/100 ML 16, 17
 gentamicin injection solution 40 mg/ml .. 16,
 17
 gentamicin sulfate (ped) (pf)..... 16, 17
GILENYA..... 111
GILOTRIF 112
GLASSIA..... 12
 glatiramer 113
 glatopa..... 113
 glutamine (sickle cell)..... 89
 glyburide 127
 glyburide micronized 127
 glyburide-metformin 128
 granisetron hcl oral 395
H
HAEGARDA 118
HALAVEN 20, 21
HEPLISAV-B (PF) 395
HETLIOZ..... 119
HUMIRA PEN..... 131, 132
HUMIRA SUBCUTANEOUS SYRINGE
KIT 40 MG/0.8 ML 131, 132
HUMIRA(CF)..... 131, 132
HUMIRA(CF) PEN 131, 132
HUMIRA(CF) PEN CROHNS-UC-HS. 131,
 132
HUMIRA(CF) PEN PEDIATRIC UC... 131,
 132
HUMIRA(CF) PEN PSOR-UV-ADOL HS
 131, 132
I
IBRANCE..... 133, 134
 icatibant..... 135
ICLUSIG..... 136

idarubicin 395
IDHIFA 137
 ifosfamide 395
 imatinib 138, 139
IMBRUVICA ORAL CAPSULE..... 140
IMBRUVICA ORAL SUSPENSION.... 140
IMBRUVICA ORAL TABLET 140 MG,
280 MG, 420 MG..... 140
IMDELLTRA 141
IMFINZI 20, 21
IMJUDO 20, 21
IMKELDI..... 138, 139
INBRIJA INHALATION CAPSULE,
W/INHALATION DEVICE 142
INCONTROL PEN NEEDLE NEEDLE 32
GAUGE X 5/32..... 76, 77
INCRELEX..... 143
INFLECTRA..... 144, 145
INFUMORPH P/F 395
INGREZZA..... 148
INGREZZA INITIATION PK(TARDIV)
 148
INGREZZA SPRINKLE 148
INLYTA..... 149
INQOVI 150
INREBIC..... 151
INSULIN SYRINGE-NEEDLE U-100
SYRINGE 0.3 ML 29 GAUGE, 1 ML 29
GAUGE X 1/2..... 76, 77
 intralipid intravenous emulsion 20 % 395
INTRALIPID INTRAVENOUS
EMULSION 30 %..... 395
INTRAROSA..... 152
 ipratropium bromide inhalation 395
 ipratropium-albuterol 395
 irinotecan..... 395
ITOVEBI..... 153
IV PREP WIPES..... 76, 77
 ivabradine..... 64
 ivermectin oral 154
IWILFIN 155
IXEMPRA..... 395
J
JAKAFI..... 156, 157
 javygtor 272
JAYPIRCA 158, 159

JEMPERLI..... 20, 21
JEVTANA..... 395
JYLAMVO 160
K
KABIVEN..... 395
KADCYLA 20, 21
KALYDECO ORAL TABLET 161
KERENDIA 162
KESIMPTA PEN 163
KEYTRUDA..... 20, 21
KIMMTRAK 20, 21
KISQALI..... 164, 165
KISQALI FEMARA CO-PACK ORAL
TABLET 400 MG/DAY(200 MG X 2)-
2.5 MG, 600 MG/DAY(200 MG X 3)-2.5
MG 164, 165
KOSELUGO..... 167, 168
KRAZATI..... 169, 170
KYPROLIS 395
L
lapatinib..... 171, 172
LAZCLUZE..... 173
lenalidomide..... 174, 175
LENVIMA 176, 177
LEUPROLIDE (3 MONTH)..... 186, 187
leuprolide subcutaneous kit..... 186, 187
levabuterol hcl..... 395
levofloxacin in d5w..... 16, 17
levofloxacin intravenous 16, 17
LIBERVANT 178
LIBTAYO 20, 21
lincomycin..... 16, 17
linezolid in dextrose 5%..... 16, 17
LINEZOLID-0.9% SODIUM CHLORIDE
..... 16, 17
liraglutide 114
LIVTENCITY..... 179
LONSURF 180
LOQTORZI..... 181
LORBRENA..... 182
LUMAKRAS 183, 184
LUMIZYME 185
LUNSUMIO 20, 21
LUPRON DEPOT..... 186, 187
LUPRON DEPOT (3 MONTH) 186, 187
LUPRON DEPOT (4 MONTH) 186, 187

LUPRON DEPOT (6 MONTH) 186, 187
LUPRON DEPOT-PED..... 186, 187
LUPRON DEPOT-PED (3 MONTH) ... 186,
187
LYBALVI..... 27
LYNPARZA 188, 189
LYTGOBI ORAL TABLET 12 MG/DAY
(4 MG X 3), 16 MG/DAY (4 MG X 4),
20 MG/DAY (4 MG X 5) 190
M
MARGENZA 20, 21
MAVYRET..... 191
MAXICOMFORT SAFETY PEN NEEDLE
NEEDLE 29 GAUGE X 5/16..... 76, 77
MEDROL ORAL TABLET 2 MG..... 395
megestrol oral suspension 400 mg/10 ml (10
ml), 400 mg/10 ml (40 mg/ml), 625 mg/5
ml (125 mg/ml), 800 mg/20 ml (20 ml)
..... 192
megestrol oral tablet..... 192
MEKINIST 193, 194
MEKTOVI..... 195
melphalan hcl 395
memantine oral capsule,sprinkle,er 24hr 206
memantine oral solution..... 206
memantine oral tablet..... 206
MEMANTINE ORAL TABLETS,DOSE
PACK..... 206
mesna intravenous..... 395
metaxalone 129
methocarbamol oral tablet 500 mg, 750 mg
..... 129
methotrexate sodium (pf)..... 395
methotrexate sodium injection..... 395
methylprednisolone oral tablet..... 395
metro i.v. 16, 17
metronidazole in nacl (iso-os)..... 16, 17
metyrosine..... 234
mifepristone oral tablet 300 mg 166
mitomycin intravenous..... 395
mitoxantrone 395
modafinil 196
MONJUVI..... 20, 21
MOUNJARO 114
MOXIFLOXACIN-SOD.ACE,SUL-
WATER 16, 17

moxifloxacin-sod.chloride(iso).....	16, 17	octreotide acetate	215
MRESVIA (PF)	197	octreotide,microspheres	271
mycophenolate mofetil.....	395	ODOMZO	216
mycophenolate mofetil (hcl).....	395	OFEV	217
mycophenolate sodium	395	OGSIVEO	218
MYFORTIC.....	395	OHTUVAYRE.....	395
MYLOTARG.....	20, 21	OJEMDA	219
N		OJJAARA	220
nafcillin in dextrose iso-osm intravenous		ONCASPAR	395
piggyback 2 gram/100 ml	16, 17	ondansetron hcl oral solution.....	395
nafcillin injection	16, 17	ondansetron hcl oral tablet 4 mg, 8 mg...	395
NAGLAZYME	198	ondansetron oral tablet,disintegrating 4 mg,	
NAMENDA TITRATION PAK.....	206	8 mg	395
NAMZARIC	206	ONIVYDE	20, 21
NAYZILAM	199	ONUREG.....	221
nelarabine.....	395	OPDIVO	20, 21
NEORAL	395	OPDUALAG.....	20, 21
NERLYNX	200	OPSUMIT	222
NEXAVAR.....	282, 283	ORBACTIV	16, 17
NEXLETOL.....	201	ORENCIA.....	223
NEXLIZET	202	ORENCIA CLICKJECT.....	223
NINLARO.....	203	ORENITRAM.....	224
NIPENT	395	ORENITRAM MONTH 1 TITRATION KT	
nitroglycerin intravenous	395	224
NIVESTYM.....	204, 205	ORENITRAM MONTH 2 TITRATION KT	
NORTHERA.....	82	224
NOVAREL INTRAMUSCULAR RECON		ORENITRAM MONTH 3 TITRATION KT	
SOLN 5,000 UNIT.....	55	224
NOVOFINE 32	76, 77	ORGOVYX.....	225
NOVOFINE PLUS	76, 77	ORKAMBI.....	226
NUBEQA	207	ORLISTAT	364
NUCALA SUBCUTANEOUS AUTO-		orphenadrine citrate oral	129
INJECTOR.....	208, 209	ORSERDU	227
NUCALA SUBCUTANEOUS SYRINGE		OSPHENA	228
.....	208, 209	OTEZLA.....	229
NUEDEXTA.....	210	OTEZLA STARTER ORAL	
NULOJIX.....	395	TABLETS,DOSE PACK 10 MG (4)- 20	
NUPLAZID.....	211	MG (51), 10 MG (4)-20 MG (4)-30 MG	
NURTEC ODT	212	(47).....	229
NUTRILIPID	395	oxacillin.....	16, 17
NUZYRA INTRAVENOUS	16, 17	oxaliplatin	395
O		OXERVATE.....	230
OALIVA.....	213	OZEMPIC SUBCUTANEOUS PEN	
OCREVUS.....	214	INJECTOR 0.25 MG OR 0.5 MG (2	
OCREVUS ZUNOVO	214	MG/3 ML), 1 MG/DOSE (4 MG/3 ML),	
OCTAGAM	395	2 MG/DOSE (8 MG/3 ML)	114

P

paclitaxel	395
PACLITAXEL PROTEIN-BOUND ..	20, 21
PADCEV.....	20, 21
paliperidone.....	27
PANZYGA	395
pazopanib	349, 350
PEGASYS.....	231
PEMAZYRE.....	232
pemetrexed disodium intravenous recon soln 1,000 mg, 100 mg, 500 mg	20, 21
PEMETREXED DISODIUM INTRAVENOUS RECON SOLN 750 MG	20, 21
PEN NEEDLE, DIABETIC NEEDLE 29 GAUGE X 1/2.....	76, 77
penicillin g potassium	16, 17
pentamidine inhalation.....	395
PENTIPS PEN NEEDLE.....	76, 77
PERFOROMIST	395
PERIKABIVEN.....	395
PERJETA.....	20, 21
pfizerpen-g	16, 17
phenobarbital.....	124
PHESGO	20, 21
pimecrolimus.....	315
PIQRAY	236
pirfenidone oral tablet 267 mg, 801 mg..	237
PIRFENIDONE ORAL TABLET 534 MG	237
PLENAMINE	395
plerixafor.....	395
POLIVY	20, 21
polymyxin b sulfate.....	16, 17
POMALYST.....	238
PORTRAZZA	395
POTELIGEO.....	20, 21
PRALATREXATE	395
prednisolone sodium phosphate oral tablet, disintegrating.....	395
PREGNYL	55
premasol 10 %.....	395
PRIVIGEN.....	395
PRO COMFORT ALCOHOL PADS .	76, 77
PROCRIT.....	91, 92
PROGRAF	395

PROLASTIN-C INTRAVENOUS

SOLUTION.....	12
PROMACTA	239, 240
promethazine oral.....	123
PROSOL 20 %	395
PROVIGIL.....	196
PULMICORT	395
PULMOZYME	395
PURE COMFORT ALCOHOL PADS76, 77	
pyrimethamine	241
PYRUKYND	242
Q	
QINLOCK.....	243
quinine sulfate.....	244
R	
RADICAVA	245
RAPAMUNE ORAL TABLET 1 MG ...	395
REBIF (WITH ALBUMIN)	246
REBIF REBIDOSE.....	246
REBIF TITRATION PACK	246
RECOMBIVAX HB (PF).....	395
REGRANEX.....	75
RELISTOR SUBCUTANEOUS SOLUTION.....	247
RELISTOR SUBCUTANEOUS SYRINGE	247
REMICADE.....	248, 249
RENFLXIS	146, 147
REPATHA PUSHTRONEX.....	250, 251
REPATHA SURECLICK.....	250, 251
REPATHA SYRINGE.....	250, 251
RETACRIT	91, 92
RETEVMO	252
REVLIMID	253, 254
REVUFORJ	255
REZDIFFRA.....	256, 257
REZLIDHIA	258
REZUROCK.....	259
RINVOQ	260, 261
RINVOQ LQ.....	262
roflumilast	263
romidepsin intravenous recon soln	264
ROMIDEPSIN INTRAVENOUS SOLUTION.....	264
ROZLYTREK.....	265
RUBRACA	266, 267

rufinamide 268
RUXIENCE 20, 21
RYBELSUS 114
RYBREVANT 20, 21
RYDAPT..... 269
RYLAZE..... 395
S
sajazir 135
SAMSCA ORAL TABLET 15 MG 314
SANDOSTATIN LAR DEPOT
 INTRAMUSCULAR
 SUSPENSION,EXTENDED REL
 RECON 271
sapropterin..... 272
SARCLISA 20, 21
SCEMBLIX 273
SIGNIFOR 274
sildenafil (pulm.hypertension) oral tablet 235
SIMPONI 275
SIMPONI ARIA 275
SIMULECT..... 395
sirolimus..... 395
SIRTURO 276
SIVEXTRO INTRAVENOUS 16, 17
SKYRIZI INTRAVENOUS 277, 278
SKYRIZI SUBCUTANEOUS PEN
 INJECTOR..... 277, 278
SKYRIZI SUBCUTANEOUS SYRINGE
 150 MG/ML..... 277, 278
SKYRIZI SUBCUTANEOUS WEARABLE
 INJECTOR..... 277, 278
SODIUM OXYBATE..... 376
sodium phenylbutyrate..... 233
SOMATULINE DEPOT..... 279, 280
SOMAVERT..... 281
sorafenib..... 282, 283
SPRAVATO NASAL SPRAY, NON-
 AEROSOL 56 MG (28 MG X 2), 84 MG
 (28 MG X 3)..... 284, 285
SPRYCEL 286
STELARA SUBCUTANEOUS..... 287, 288
STIVARGA 289, 290
STREPTOMYCIN 16, 17
SUCRAID 291
sulfamethoxazole-trimethoprim intravenous
..... 16, 17

sunitinib malate..... 292, 293
SUTENT 292, 293
SYLVANT 395
SYMDEKO..... 294
SYMLINPEN 120..... 295
SYMLINPEN 60..... 295
SYMPAZAN..... 59
T
TABRECTA 296
tacrolimus oral capsule 395
tacrolimus topical..... 315
tadalafil (pulm. hypertension)..... 235
tadalafil oral tablet 2.5 mg, 5 mg 56
TADLIQ..... 235
TAFINLAR..... 298, 299
TAGRISSO 300, 301
TALVEY..... 20, 21
TALZENNA 302
TARGRETIN TOPICAL 303
TASIGNA 304
tasimelteon 119
tazarotene topical cream 305
tazarotene topical gel 305
tazicef..... 16, 17
TAZORAC TOPICAL CREAM 0.05 % 305
TAZORAC TOPICAL GEL 305
TAZVERIK..... 306
TECENTRIQ 20, 21
TECENTRIQ HYBREZA 20, 21
TECHLITE INSULIN SYRINGE
 SYRINGE 1 ML 30 GAUGE X 1/2 76, 77
TECHLITE INSULN SYR(HALF UNIT)
 SYRINGE 0.3 ML 31 GAUGE X 15/64
..... 76, 77
TECHLITE PEN NEEDLE NEEDLE 29
 GAUGE X 1/2..... 76, 77
TECVAYLI..... 20, 21
TEFLARO..... 16, 17
TEMODAR INTRAVENOUS 395
temsirolimus..... 395
tencon 126
TEPMETKO 307
teriflunomide..... 28
teriparatide subcutaneous pen injector 20
 mcg/dose (600mcg/2.4ml) 308, 309

TERIPARATIDE SUBCUTANEOUS PEN INJECTOR 20 MCG/DOSE (620MCG/2.48ML).....	308, 309	TRUQAP.....	324
tetrabenazine	310	TUKYSA	325
TEVIMBRA.....	20, 21	TURALIO ORAL CAPSULE 125 MG..	326
THALOMID ORAL CAPSULE 100 MG, 50 MG	311, 312	TYKERB.....	171, 172
thiotepa.....	20, 21	TYMLOS	327
TIBSOVO	313	TYSABRI	328, 329
TICE BCG	395	TYVASO	395
tigecycline.....	16, 17	TYVASO INSTITUTIONAL START KIT	395
TIVDAK	20, 21	TYVASO REFILL KIT	395
tobramycin in 0.225 % nacl	395	TYVASO STARTER KIT.....	395
tobramycin sulfate.....	16, 17	TZIELD.....	330, 331
tolvaptan.....	314	U	
TOPAMAX.....	317	UNIFINE PENTIPS MAXFLOW	76, 77
topiramate oral capsule, sprinkle 15 mg, 25 mg	317	UNIFINE PENTIPS NEEDLE 29 GAUGE X 1/2.....	76, 77
topiramate oral capsule,extended release 24hr	317	UNIFINE PENTIPS PLUS	76, 77
topiramate oral tablet	317	UNIFINE PENTIPS PLUS MAXFLOW 76, 77	
topotecan	395	UNITUXIN.....	20, 21
TPN ELECTROLYTES.....	395	UPTRAVI ORAL	332
travasol 10 %.....	395	V	
TRAZIMERA	20, 21	VALCHLOR.....	333
TRELSTAR INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION	319	valrubicin	395
TREMFYA	320	VALTOCO	334
TREMFYA PEN.....	320	vancomycin oral capsule.....	335
tretinoin	316	VANFLYTA.....	336
tretinoin microspheres.....	316	VECTIBIX	20, 21
trientine oral capsule 250 mg.....	321, 322	VENCLEXTA.....	337, 338
trihexyphenidyl	130	VENCLEXTA STARTING PACK	337, 338
TRIKAFTA.....	323	VENTAVIS.....	339
TRIPTODUR	115	VERIFINE PLUS PEN NEEDLE-SHARP	76, 77
TRODELVY	20, 21	VERQUVO	340
TROKENDI XR.....	317	VERZENIO.....	341, 342
TROPHAMINE 10 %	395	VIBERZI.....	343
TRUE COMFORT ALCOHOL PADS ... 77		VICTOZA 2-PAK.....	114
TRUE COMFORT PRO ALCOHOL PADS	76, 77	VICTOZA 3-PAK.....	114
TRUEPLUS INSULIN	76, 77	vigabatrin	270
TRUEPLUS PEN NEEDLE	76, 77	vigadrone.....	270
TRULICITY	114	VIGAFYDE	270
		vinblastine	395
		vincristine.....	396
		vinorelbine	396
		VITRAKVI.....	344
		VIZIMPRO	345

VONJO	346	YONDELIS.....	20, 21
VORANIGO	347	YUFLYMA(CF)	131, 132
voriconazole intravenous	18	YUFLYMA(CF) AI CROHN'S-UC-HS	131, 132
VOSEVI.....	348	YUFLYMA(CF) AUTOINJECTOR	131, 132
VOWST	351	YUPELRI.....	396
VUMERITY	352	Z	
VYLOY.....	353	ZALTRAP.....	396
VYNDAMAX.....	297	ZANOSAR.....	396
VYNDAQEL	297	ZARXIO	377, 378
VYVGART HYTRULO.....	354, 355	ZEJULA ORAL TABLET.....	379
VYXEOS	396	ZELBORAF	380, 381
W		ZEMAIRA	12
WEGOVY.....	356	ZEPBOUND	382, 383
WELIREG.....	357	ZEPZELCA.....	20, 21
X		ZIEXTENZO	384
XALKORI.....	358, 359	ZIIHERA.....	385
XATMEP	360	ZIRABEV	20, 21
XCOPRI.....	361	ZOLADEX.....	396
XCOPRI MAINTENANCE PACK.....	361	zoledronic acid intravenous solution	396
XCOPRI TITRATION PACK.....	361	zoledronic acid-mannitol-water	396
XDEMZY	362	ZOLEDRONIC AC-MANNITOL-0.9NACL	396
XELJANZ.....	363	ZOLINZA	386
XELJANZ XR	363	ZONISADE.....	317
XEMBIFY.....	396	zonisamide	317
XENICAL.....	364	ZORTRESS ORAL TABLET 1 MG.....	396
XERMELO	365	ZTALMY	387
XGEVA.....	366	ZURZUVAE.....	388
XIAFLEX	367	ZYDELIG	389
XIFAXAN.....	368, 369	ZYKADIA	390
XOLAIR	370, 371	ZYNLONTA.....	20, 21
XOSPATA	372	ZYNYZ.....	20, 21
XPOVIO	373, 374	ZYPREXA RELPREVV	391
XTANDI.....	375		
Y			
YERVOY	20, 21		