

2027 Prior Authorization Criteria

MedMutual Advantage® HMO, HMO-POS and PPO Plans

Updated 10/2026

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C7581-MCA R6/26

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 pathogenic variant 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 pathogenic variant linked to severe, malignant osteopetrosis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ACYCLOVIR (TOPICAL)

Products Affected

- *acyclovir topical ointment*

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

ADALIMUMAB

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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
Prerequisite Therapy Required	No

ADSTILADRIN

Products Affected

- ADSTILADRIN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a urologist or an oncologist
Coverage Duration	1 year
Other Criteria	Non-Muscle Invasive Bladder Cancer, approve initial therapy if the patient meets (A and B): A) patient has high-risk, Bacillus Calmette-Guerin (BCG)-unresponsive disease, and B) the patient has carcinoma in situ (CIS) OR the patient has Ta/T1 papillary tumors without CIS. Non-Muscle Invasive Bladder Cancer, continuation of therapy - approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AIMOVIG

Products Affected

- AIMOVIG AUTOINJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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, metastatic castration-resistant or metastatic castration-sensitive- Approve if the patient meets the following (A, B, and C): A)Patient has a BReast CAncer (BRCA) mutation, AND B) The medication is used in combination with prednisone, AND C) 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
Prerequisite Therapy Required	Yes

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
Prerequisite Therapy Required	No

ALECENSA

Products Affected

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Pediatric diffuse high grade glioma- less than or equal to 21 years old, All others- 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	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. 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. Pediatric diffuse high grade glioma- approve if (A and B): A) ALK-positive disease, and B) either (i or ii): i) medication is used as adjuvant treatment AND tumor is not diffuse midline glioma, H3 K27-altered or pontine location, or ii) medication is used for recurrent or progressive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Anaplastic large cell lymphoma, Erdheim Chester disease, Inflammatory Myofibroblastic Tumor, Large B-Cell Lymphoma, Pediatric Diffuse High Grade Glioma
Part B Prerequisite	No
Prerequisite Therapy Required	No

ALOSETRON

Products Affected

- *alosetron*

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

ALPHA 1 PROTEINASE INHIBITORS

Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

ALUNBRIG

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	ALK status
Age Restrictions	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, Ensacove or Lorbrena 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
Prerequisite Therapy Required	Yes

AMBRISENTAN

Products Affected

- *ambrisentan*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	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
Prerequisite Therapy Required	No

ANKTIVA

Products Affected

- ANKTIVA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	1 year
Other Criteria	NON-MUSCLE INVASIVE BLADDER CANCER-all of (i, ii, iii): i) Patient has high risk Bacillus Calmette-Guerin (BCG) unresponsive disease, AND ii) Patient has carcinoma in situ or has Ta/T1 papillary tumors without carcinoma in situ (CIS), AND iii) Medication is used in combination with BCG.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ANTIFUNGALS (IV) - FLUCONAZOLE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

ANTIFUNGALS (IV) - VORICONAZOLE

Products Affected

- *voriconazole intravenous recon soln*
- *voriconazole-hpbcd*

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

ARCALYST

Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

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	1 year
Other Criteria	Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD)-approve. Excessive daytime sleepiness associated with obstructive sleep apnea-approve. Excessive daytime sleepiness associated with Narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ASPARLAS

Products Affected

- ASPARLAS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 month to 21 years
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

AUBAGIO

Products Affected

- *teriflunomide*

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

AUGTYRO

Products Affected

- AUGTYRO ORAL CAPSULE 160 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	NSCLC - 18 and older, Solid tumors - 12 and older, Pediatric Diffuse High-Grade Glioma-less than 18
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. Note: If the patient has non-small cell lung cancer with neurotrophic receptor tyrosine kinase (NTRK) gene fusion, see Solid Tumors indication. 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. Pediatric Diffuse High-Grade Gliomas - approve if tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the medication is used 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 Gliomas
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

AUSTEDO

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

AVMAPKI-FAKZYNJA

Products Affected

- AVMAPKI-FAKZYNJA

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

AVONEX

Products Affected

- AVONEX INTRAMUSCULAR PEN INJECTOR KIT
- AVONEX INTRAMUSCULAR SYRINGE KIT

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

AVTOZMA IV

Products Affected

- AVTOZMA INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic Disease-Modifying Antirheumatic Drug (DMARD) or targeted synthetic DMARD. Exclude for indication of COVID-19 treatment in hospitalized patients (ie, non-D use).
Required Medical Information	Diagnosis
Age Restrictions	(Initial therapy only): GCA/RA-18 years and older. PJIA/SJIA-2 years and older.
Prescriber Restrictions	RA, SJIA, PJIA, GCA - Prescribed by or in consultation with a rheumatologist (initial therapy).
Coverage Duration	Approve through end of plan year
Other Criteria	RA initial - approve if the patient meets one of the following (A or B): A) patient has tried ONE of the following drugs in the past: Enbrel, a preferred adalimumab product, Rinvoq or tofacitinib/XR (Note: if the patient does not meet this requirement, previous trial(s) with Cimzia, Kevzara, infliximab, golimumab SC/IV, Orencia or a non-preferred adalimumab product will also count.). OR B) patient has heart failure or a previously treated lymphoproliferative disorder. PJIA, initial-approve if the patient meets one of the following (A or B): A) patient has tried ONE of the following drugs in the past: Enbrel, Rinvoq, tofacitinib or a preferred adalimumab product. (Note: if the patient does not meet this requirement, a previous trial with the drug Kevzara, infliximab, Orencia or a non-preferred adalimumab product will be counted), OR B) patient has heart failure or a previously treated lymphoproliferative disorder. Systemic-onset JIA, approve. Giant cell arteritis, initial-approve if the patient has tried or is currently taking a systemic corticosteroid or corticosteroid is contraindicated. Cont tx, RA/PJIA/SJIA/GCA - approve if the pt had a response as determined by the prescriber. Cytokine release syndrome associated with chimeric antigen receptor (CAR) T-Cell therapy-approve. Please Note: preferred adalimumab products include Hadlima, Simlandi.
Indications	All FDA-approved Indications.

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

AVTOZMA SC

Products Affected

- AVTOZMA AUTOINJECTOR
- AVTOZMA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic oral small molecule drug.
Required Medical Information	Diagnosis
Age Restrictions	(Initial therapy only): GCA/RA/Lung disease-18 years and older. PJIA/SJIA-2 years and older.
Prescriber Restrictions	RA, SJIA, PJIA, GCA - Prescribed by or in consultation with a rheumatologist (initial therapy). Interstitial lung disease w/systemic sclerosis-pulmonologist or rheumatologist (initial therapy)
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA) [A or B): A) tried one of the following: Enbrel, preferred adalimumab product (see Example 1), Rinvoq or tofacitinib/XR (Note: trials with the following will also count: Cimzia, infliximab, Kevzara, golimumab SC/IV, non-preferred adalimumab product, Orencia), or B) heart failure or a previously treated lymphoproliferative disorder. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) [A or B]: A) tried one of the following: Enbrel, Rinvoq, tofacitinib, preferred adalimumab product. (Note: trials with Kevzara, infliximab, Orencia or a non-preferred adalimumab product will also count), or B) heart failure or a previously treated lymphoproliferative disorder. SYSTEMIC-ONSET JIA (SJIA): Approve. GIANT CELL ARTERITIS: tried or is currently taking a systemic CS or CS is contraindicated. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS (A and B): A) elevated acute phase reactants and B) diagnosis confirmed by high-resolution computed tomography. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. Example 1: preferred adalimumab products include Hadlima, Simlandi.
Indications	All FDA-approved Indications.

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

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), 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
Prerequisite Therapy Required	Yes

BALVERSA

Products Affected

- BALVERSA

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	Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 genomic alterations AND the medication is used for subsequent therapy. Pancreatic adenocarcinoma- approve if (A, B, and C): A) patient has a fibroblast growth factor receptor (FGFR) genetic alterations, and B) locally advanced, recurrent or metastatic disease, and C) medication is used for subsequent therapy. NSCLC- approve if patient has metastatic disease and FGFR mutation or gene fusions. Breast cancer-Approve if the patient has Stage IV (M1) disease, the medication is used for subsequent therapy, and fibroblast growth factor receptors 1-3 (FGFR1-3) mutation or gene fusions. Cholangiocarcinoma-Approve if the patient has unresectable, gross residual, or metastatic disease, tumor has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements and the medication is used for subsequent therapy. Glioma-Approve if the patient has recurrent or progressive disease and has fibroblast growth factor receptor (FGFR) alterations. Head and neck cancer-Approve if (A, B and C): A) patient has recurrent unresectable, or metastatic disease, and B) the medication is used for subsequent therapy, and C) has fibroblast growth factor receptor (FGFR) mutation or gene fusion positive.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Breast cancer, cholangiocarcinoma, glioma, head and neck cancer, Pancreatic adenocarcinoma, non-small cell lung cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BENLYSTA

Products Affected

- BENLYSTA

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

BENLYSTA IV

Products Affected

- BENLYSTA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Biologics or Lupkynis
Required Medical Information	Diagnosis
Age Restrictions	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	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 at least one of the following: antinuclear antibodies (ANA), anti-double-stranded DNA (anti-dsDNA) antibodies, or anti-Smith (anti-Sm) antibodies AND Benlysta is being used concurrently with at least one other standard therapy for SLE (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
Prerequisite Therapy Required	Yes

BESREMI

Products Affected

- BESREMI
- BESREMI PEN

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

BETASERON/EXTAVIA

Products Affected

- BETASERON SUBCUTANEOUS KIT

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

BEXAROTENE (TOPICAL)

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	Cutaneous T-Cell lymphoma-approve if pt has cutaneous manifestations/lesions. 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	Primary Cutaneous B-Cell Lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

BIZENGRI

Products Affected

- BIZENGRI

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	CHOLANGIOCARCINOMA- Both (A and B): A) has advanced, unresectable, or metastatic disease and B) the disease is neuregulin 1 (NRG1) gene fusion positive. NON-SMALL CELL LUNG CANCER-All of (A, B and C): A) Patient has advanced, unresectable, or metastatic disease, AND B) The disease is neuregulin 1 (NRG1) gene fusion positive, AND C) Patient has tried at least one systemic regimen. Note: Examples of a systemic regimen include one or more of the following drugs: carboplatin, cisplatin, or programmed cell death protein 1 (PD)-1 or PD-ligand 1 (PD-L1) blockers. PANCREATIC ADENOCARCINOMA-All of (A, B and C): A) Patient has locally advanced, recurrent, or metastatic disease, AND B) The disease is neuregulin 1 (NRG1) gene fusion positive, AND C) Patient has tried at least one systemic regimen. Note: Examples of systemic regimen include one or more of the following drugs: fluorouracil, leucovorin, irinotecan, oxaliplatin, gemcitabine, paclitaxel, capecitabine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

BLENREP

Products Affected

- BLENREP

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Approve if (A, B and C): A) the patient has tried at least two prior systemic lines of therapy and B) has received at least one drug from each of the following drug classes- proteasome inhibitor, [ex: bortezomib, Kyprolis (carfilzomib intravenous infusion), and Ninlaro (ixazomib capsules)] and immunomodulatory drug [ex: lenalidomide, Pomalyst (pomalidomide capsules), and Thalomid (thalidomide capsules], and C) will be used in combination with bortezomib and dexamethasone.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BONIVA INJECTION

Products Affected

- *ibandronate intravenous*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other medications for Osteoporosis
Required Medical Information	Diagnosis, test results
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Treatment of postmenopausal osteoporosis, must meet (A and B): A) pt meets ONE of the following 1. T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip, and/or one-third radius (wrist) 2. has had osteoporotic fracture or fragility fracture, 3. pt has low bone mass [for example: T-score (current or at any time in the past) between 1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or one-third radius (wrist)] and the physician determines the patient is at high risk for fracture AND B) pt meets one of the following: has had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing and significant loss of bone mineral density (BMD), lack of BMD increase), had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy, or experienced intolerability to an oral bisphosphonate (e.g., severe GI-related adverse effects) OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid) OR the patient has had an osteoporotic fracture or a fragility fracture OR pt has very low T-score less than -3.0.

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

BOSENTAN

Products Affected

- *bosentan oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	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)
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BOSULIF

Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 500 MG
- *bosutinib oral tablet 100 mg, 400 mg, 500 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	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	CML-approve if the patient has Ph-positive or BCR::ABL1-positive CML. For Ph-positive ALL-approve if pt has tried at least one other tyrosine kinase inhibitor for Ph+ ALL. 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
Prerequisite Therapy Required	Yes

BRAFTOVI

Products Affected

- BRAFTOVI

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

BRIUMVI

Products Affected

- BRIUMVI

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use 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	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS.
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

BRIVARACETAM

Products Affected

- *brivaracetam intravenous*
- *brivaracetam oral solution*
- *brivaracetam oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 month 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
Prerequisite Therapy Required	No

BRUKINSA

Products Affected

- BRUKINSA ORAL TABLET

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). CLL/SLL - approve. Mantle Cell Lymphoma-approve if patient meets one of (A, B, C or D): A) tried at least one systemic regimen, or B) is not a candidate for a chemotherapy regimen, or C) will use this medication in combination with rituximab, or D) patient has TP53 mutation and this medication is used as induction therapy in combination with Venclexta (venetoclax tablets) and Gazyva (obinutuzumab intravenous infusion). 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. Primary Central Nervous System Lymphoma - approve if pt has tried at least one systemic regimen and the medication is used in combination with autologous stem cell reinfusion.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Hairy Cell Leukemia, Primary Central Nervous System Lymphoma
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

C1 ESTERASE INHIBITORS

Products Affected

- CINRYZE

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

CABLIVI

Products Affected

- CABLIVI INJECTION KIT

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

CABOMETYX

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

CALQUENCE

Products Affected

- 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 chemotherapy 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 Macroglobulinamia/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, Kyprolis [carfilzomib intravenous infusion], or Ninlaro [ixazomib capsule], fludarabine, or cladribine)
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Marginal zone lymphoma.

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

CAMZYOS

Products Affected

- CAMZYOS

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

CAPRELSA

Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	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
Prerequisite Therapy Required	No

CARGLUMIC ACID

Products Affected

- *carglumic acid*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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 Pseudomonas aeruginosa in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CEPROTIN

Products Affected

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

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

CIMERLI

Products Affected

- CIMERLI

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with another intravitreal vascular endothelial growth factor inhibitor (except Susvimo [ranibizumab intravitreal injection via ocular implant])
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Administered by or under the supervision of an ophthalmologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Retinopathy of prematurity
Part B Prerequisite	No
Prerequisite Therapy Required	No

CINACALCET

Products Affected

- *cinacalcet*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Hypercalcemia d/t parathyroid CA-prescr/consult w/onco or endo.Hypercalcemia w/primary hyperparathyroidism-prescr/consult w/nephro or endo. Hyperparathyroidism in post-renal transplant-prescr/consult w/transplant physician/nephro/endo.
Coverage Duration	12 months
Other Criteria	Hypercalcemia due to parathyroid carcinoma-approve. Hypercalcemia in patients with primary hyperparathyroidism-approve if the patient has failed or is unable to undergo a parathyroidectomy due to a contraindication. Secondary Hyperparathyroidism in patients with chronic kidney disease on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundles payment benefit). Hyperparathyroidism in Post-Renal Transplant Patients-approve if the baseline (prior to starting cinacalcet therapy) calcium and intact parathyroid hormone (iPTH) levels are above the normal range, as defined by the laboratory reference values.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	hyperparathyroidism in post-renal transplant patients
Part B Prerequisite	No
Prerequisite Therapy Required	No

CLOBAZAM

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

CLOMIPHENE

Products Affected

- *clomid*
- *clomiphene citrate*
- *milophene*

PA Criteria	Criteria Details
Exclusion Criteria	Use in patients for infertility
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Woman (a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Male hypogonadism
Part B Prerequisite	No
Prerequisite Therapy Required	No

COLUMVI

Products Affected

- COLUMVI

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 or hematologist
Coverage Duration	1 year
Other Criteria	Diffuse large B-cell lymphoma-approve if the patient has received one or more lines of systemic therapy and the patient has or will receive pretreatment with obinutuzmab intravenous infusion before the first dose of Columvi. Note: Examples of diffuse large B-cell lymphoma (DLBCL) include DLBCL not otherwise specified, high-grade B-cell lymphoma, and DLBCL arising from indolent lymphoma. Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and DHA (dexamethasone, cytarabine) plus platinum (carboplatin, cisplatin, or oxaliplatin) plus/minus rituximab. Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma-approve if the patient has received one or more lines of systemic therapy and the patient has or will receive pretreatment with obinutuzmab intravenous infusion before the first dose of Columvi. Note: HIV-related B-cell lymphomas includes HIV-related diffuse large B-cell lymphoma (DLBCL), primary effusion lymphoma, and human herpes virus-8 (HHV8) positive DLBCL or for HIV-related plasmablastic lymphoma. Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and R-EPOCH (rituximab, etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin). Post-transplant lymphoproliferative disorders- approve if the patient has received one or more lines of systemic therapy and the patient has or will receive pretreatment with obinutuzmab intravenous infusion

PA Criteria	Criteria Details
	before the first dose of Columvi. Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and RCEPP (rituximab, cyclophosphamide, etoposide, prednisone, procarbazine). Burkitt Lymphoma - approve if the medication is used as subsequent therapy, and in combination with Polivy (polatuzumab intravenous infusion), and as a bridge for allogeneic hematopoietic cell transplant. Chronic lymphocytic leukemia/small lymphocytic lymphoma - approve if patient has Richter transformation. Mantle Cell Lymphoma - approve if patient has received at least one covalent Bruton tyrosine kinase inhibitor.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma. Post-transplant lymphoproliferative disorders, Burkitt Lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma, Mantle Cell Lymphoma.
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

COMETRIQ

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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 at least one Bruton tyrosine kinase inhibitor (examples: ibrutinib, zanubrutinib, acalabrutinib, pirtobrutinib) and at least one B-cell lymphoma 2 inhibitor (example: venetoclax). 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
Prerequisite Therapy Required	Yes

COSENTYX

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

COSENTYX IV

Products Affected

- COSENTYX INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs)
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	PsA initial - Prescribed by or in consultation with a dermatologist or rheumatologist. AS/Non-radio Axial Spondy-Prescribed by or in consultation with a rheumatologist.
Coverage Duration	Approve through end of plan year
Other Criteria	Non-Radiographic Axial Spondyloarthritis, initial therapy- approve if pt has objective signs of inflammation defined as (a or b): a) C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory or b) sacroiliitis reported on magnetic resonance imaging. For continuation of therapy for all covered indications - approve if the pt has benefit from the medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

COTELLIC

Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf AND patient has BRAF V600 mutation positive disease. 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) circumscribed ganglioglioma/neuroglioma/glioneuronal tumor OR ii. Recurrent or progressive disease for one of the following conditions (a, b or c): a) high grade glioma, b) circumscribed glioma OR c) Glioblastoma, OR iii. Melanoma with brain metastases AND medication will 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 OR ii. Patient has Erdheim Chester disease OR iii. Patient has Rosai-Dorfman disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central Nervous System Cancer
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

CRESEMBA (ORAL)

Products Affected

- CRESEMBA ORAL

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 Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CRYSVITA

Products Affected

- CRYSVITA

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

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

CYSTEAMINE (OPHTHALMIC)

Products Affected

- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases
Coverage Duration	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
Prerequisite Therapy Required	No

CYSTEAMINE (ORAL)

Products Affected

- CYSTAGON

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Cystagon and Procysbi
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	1 year
Other Criteria	Cystinosis, nephropathic-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming biallelic pathogenic or likely pathogenic variants in the CTNS gene OR white blood cell cystine concentration above the upper limit of the normal reference range for the reporting laboratory.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	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	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
Prerequisite Therapy Required	No

DATROWAY

Products Affected

- DATROWAY

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	BREAST CANCER - All of (A, B and C): A) Unresectable or metastatic disease, AND B) Human epidermal growth factor receptor 2 (HER2)-negative (immunohistochemistry [IHC] 0, IHC 1+, or IHC 2+/in situ hybridization [ISH]-negative) disease, AND C) meets one (i or ii): i) has hormone receptor (HR)-negative disease (Note: This is triple-negative disease) and is not a candidate for programmed death receptor-1 (PD-1)/programmed death ligand-1 (PD-L1) inhibitor therapy, OR ii) meets all (a, b, c, and d): a) has hormone receptor (HR) positive disease AND b) has received prior endocrine-based therapy, Note: Examples of endocrine therapy are tamoxifen, anastrozole, letrozole, exemestane, AND c) has received prior chemotherapy for unresectable or metastatic disease. Note: Examples are paclitaxel, doxorubicin, liposomal doxorubicin, gemcitabine, capecitabine, vinorelbine, Halaven (eribulin intravenous infusion), cyclophosphamide, docetaxel AND d) not a candidate for Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion) therapy. Non-Small Cell Lung Cancer- meets ALL (A, B, and C): A) locally advanced or metastatic disease AND B) EGFR-mutated disease AND C) meets BOTH (i and ii): i. tried at least one prior EGFR-directed therapy AND ii. tried platinum-based chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

DAURISMO

Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, 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
Prerequisite Therapy Required	Yes

DECNUPAZ

Products Affected

- DECNUPAZ

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 or hematologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DEFERASIROX

Products Affected

- *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 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
Prerequisite Therapy Required	No

DEFERIPRONE

Products Affected

- *deferiprone*

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
Prerequisite Therapy Required	No

DENOSUMAB (NON-OSTEOPOROSIS)

Products Affected

- BOMYNTRA
- WYOST

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

DIABETIC SUPPLY - ALCOHOL PADS

Products Affected

- *alcohol pads*
- DROPSAFE ALCOHOL PREP PADS

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

DIABETIC SUPPLY - GAUZE PADS

Products Affected

- GAUZE PADS 2 X 2

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

DIABETIC SUPPLY - NEEDLES

Products Affected

- NOVO PEN NEEDLE
- BD PEN NEEDLE
- EMBECTA PEN NEEDLE

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

DIABETIC SUPPLY - SYRINGES

Products Affected

- EMBECTA INSULIN SYRINGE
- BD INSULIN SYRINGE

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

DIACOMIT

Products Affected

- DIACOMIT

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

DICLOFENAC (TOPICAL)

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	Authorization will be for 12 mos.
Other Criteria	Patients requesting Diclofenac 2% solution pump must have a trial of generic diclofenac 1.5% topical solution.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DIMETHYL FUMARATE

Products Affected

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

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

DOPTELET

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

DRONABINOL

Products Affected

- *dronabinol oral capsule*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DROXIDOPA

Products Affected

- *droxidopa*

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
Prerequisite Therapy Required	Yes

DUAL OREXIN RECEPTOR ANTAGONIST - SUVOREXANT

Products Affected

- BELSOMRA

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	Treatment of insomnia, characterized by difficulties with sleep onset and /or sleep maintenance-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DUPIXENT

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

ELAHERE

Products Affected

- ELAHERE

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	Ovarian, Fallopian Tube, or Primary Peritoneal Cancer-approve if the patient has folate receptor alpha positive disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ELAPRASE

Products Affected

- ELAPRASE

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant Use of Elaprase with Avlayah (tividenofusp alfa-eknm).
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
Prerequisite Therapy Required	No

ELREXFIO

Products Affected

- ELREXFIO

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	Multiple myeloma-approve if per FDA approved labeling the patient has tried at least four systemic regimens and among the previous regimens tried, the patient has received at least one drug from each of the following classes: proteasome inhibitor, an immunomodulatory drug and an anti-CD38 monoclonal antibody.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EMGALITY

Products Affected

- EMGALITY PEN
- EMGALITY SUBCUTANEOUS SYRINGE 120 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

EMRELIS

Products Affected

- EMRELIS

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	NON-SMALL CELL LUNG CANCER- ALL of the following (A, B, C and D): A. Patient has locally advanced or metastatic, non-squamous disease, AND B. Tumor has high c-Met protein overexpression, defined as a greater than or equal to 50 percent of tumor cells with strong [3+] staining, AND C. Patient has received at least one prior systemic therapy. Note: Examples are cisplatin, carboplatin, pemetrexed, Keytruda (pembrolizumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Imfinzi (durvalumab intravenous infusion), Libtayo (cemiplimab-rwlc intravenous infusion) AND D. Tumor is epidermal growth factor receptor (EGFR) wildtype.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ENBREL

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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
Prerequisite Therapy Required	No

ENSACOVE

Products Affected

- ENSACOVE

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

ENTYVIO

Products Affected

- ENTYVIO

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) used for an Inflammatory Condition
Required Medical Information	N/A
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	CD/UC initial - Prescribed by or in consultation with a gastroenterologist. GVHD initial - prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: ULCERATIVE COLITIS: approve if the patient has had a trial of TWO of the following: a preferred adalimumab product, a preferred infliximab product, a preferred ustekinumab product, Rinvoq, Skyrizi, Tremfya (a trial of a non-preferred adalimumab, infliximab or ustekinumab product will also count). CROHN'S DISEASE: approve if the patient has had a trial of TWO of the following: a preferred adalimumab product, a preferred infliximab product, a preferred ustekinumab product, Rinvoq, Skyrizi, Tremfya (a trial of a non-preferred adalimumab, infliximab or ustekinumab product will also count). GRAFT VERSUS HOST DISEASE: approve if (A and B): A) pt has acute GVHD, and B) pt has tried at least one systemic medication for GVHD (examples: corticosteroids, cyclosporine, tacrolimus, mycophenolate mofetil, Jakafi (ruxolitinib), an etanercept product, an infliximab product). CONTINUATION THERAPY, UC/CD: approve if the patient has already been started on Entyvio IV or SC and has had a response to therapy. CONTINUATION THERAPY, GVHD: approve if the patient has already been started on Entyvio IV and has had a response to therapy. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab products include Remicade, infliximab IV (brand name

PA Criteria	Criteria Details
	product), Zymfentra. Preferred ustekinumab products include Otulfi, Pyzchiva (NDCs beginning with 61314-), Yesintek.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Graft versus host disease (GVHD)
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ENTYVIO PEN

Products Affected

- ENTYVIO PEN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) used for an Inflammatory Condition
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist (initial)
Coverage Duration	Approve through end of plan year
Other Criteria	Ulcerative Colitis, initial therapy with Entyvio SC: approve if the patient meets (A and B): (A) the patient is currently receiving Entyvio intravenous or will receive induction dosing with Entyvio intravenous within 2 months of initiating therapy with Entyvio subcutaneous, (B) patient meets (i or ii): (i): the patient has had a trial of TWO of the following: a preferred ustekinumab product, Skyrizi, Tremfya, Rinvoq, a preferred infliximab product, or a preferred adalimumab product. Trials of a Non-Preferred infliximab product, Simponi SC, a non-preferred ustekinumab or a Non-Preferred adalimumab product will also count. OR (ii) the patient has already started on Entyvio IV or is currently undergoing induction therapy with Entyvio IV. Ulcerative colitis, continuation of therapy with Entyvio SC: approve if the patient has had a response to therapy. Crohn's Disease, initial therapy with Entyvio SC: approve if the patient meets (A and B): (A) the patient is currently receiving Entyvio intravenous or will receive induction dosing with Entyvio intravenous within 2 months of initiating therapy with Entyvio subcutaneous, (B) patient meets (i or ii): (i): the patient has had a trial of TWO of the following: a preferred adalimumab product, a preferred infliximab, a preferred ustekinumab product, Skyrizi, Tremfya or Rinvoq. Trials of a Non-Preferred infliximab product, a non-preferred ustekinumab or a Non-Preferred adalimumab product will also count. OR (ii) the patient has already started on Entyvio IV or is currently

PA Criteria	Criteria Details
	undergoing induction therapy with Entyvio IV. Crohn's disease, continuation of therapy with Entyvio SC: approve if the patient has had a response to therapy. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab products include Remicade, infliximab IV (brand name product), Zymfentra. Preferred ustekinumab products include Otulfi, Pyzchiva (NDCs beginning with 61314-), Yesintek.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EPIDIOLEX

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

EPKINLY

Products Affected

- EPKINLY

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 or hematologist
Coverage Duration	1 year
Other Criteria	Diffuse large B-cell lymphoma - approve if the patient has received one or more lines of systemic therapy. Classic follicular lyphoma - approve if pt has received one or more lines of systemic therapy. Human immunodeficiency virus (HIV)-Related B-Cell Lymphoma - approve if the patient has received one or more lines of systemic therapy. Note: HIV-related B-cell lymphomas includes HIV-related diffuse large B-cell lymphoma (DLBCL), primary effusion lymphoma, and human herpes virus-8 (HHV8) positive DLBCL. Post-transplant lymphoproliferative disorders - approve if the patient has received one or more lines of systemic therapy. Chronic lymphocytic leukemia/small lymphocytic lymphoma - approve if the patient has Richter transformation.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Human immunodeficiency virus (HIV)-Related B-Cell Lymphoma. Post-transplant lymphoproliferative disorders, chronic lymphocytic leukemia/small lymphocytic lymphoma.
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

EPOETIN ALFA

Products Affected

- PROCRIT
- RETACRIT

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

ERIVEDGE

Products Affected

- ERIVEDGE

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	Basal cell carcinoma, locally advanced-approve if (A, B, C, or D): A) Erivedge will be used in combination with radiation therapy OR B) pt has recurrent BCC following surgery or radiation therapy OR C) pt is not a candidate for radiation therapy or surgery, OR D) Erivedge will be used as neoadjuvant therapy before surgery. 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 regimen and the patient has a mutation of the sonic hedgehog (SHH) pathway. Basal cell carcinoma, metastatic (this includes primary or recurrent nodal metastases and distant metastases)-approve. Diffuse Basal Cell Carcinoma Formation, including basal cell nevus syndrome (Gorlin syndrome) or other genetic forms of multiple basal cell carcinoma - approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central nervous System Cancer, diffuse basal cell carcinoma formation
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ERLEADA

Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

ERLOTINIB

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Advanced or Metastatic NSCLC, approve if the patient has EGFR mutation positive non-small cell lung cancer. 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 meets (A, B, and C): A) has stage IV or relapsed non-clear cell histology RCC and B) has advanced papillary disease including hereditary leiomyomatosis and renal cell carcinoma (HLRCC)-associated renal cell carcinoma and C) 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

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

EVEROLIMUS

Products Affected

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

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	Breast Cancer-approve if pt meets ALL the following (A, B, C, D, E, and F):A)pt has recurrent or metastatic,HR+ disease AND B)pt has HER2-negative breast cancer AND C)pt has tried at least 1 prior endocrine therapy AND D)pt meets 1 of the following conditions (i or ii):i.pt is a postmenopausal woman or man OR ii.pt is pre/perimenopausal woman AND is receiving ovarian suppression/ablation with a GnRH agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND E)pt meets 1 of the following conditions (i or ii): i.Everolimus will be used in combo with exemestane and pt meets 1 of the following:pt is male and is receiving a GnRH analog or pt is a woman or ii. Everolimus will be used in combo with fulvestrant or tamoxifen AND F)pt 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, pt has tried 1 prior systemic therapy (e.g., Inlyta, Votrient, Sutent, Cabometyx, Nexavar).TSC Associated SEGA-approve if pt requires therapeutic intervention but cannot be curatively resected. Thymomas and Thymic Carcinomas-approve if pt has tried chemotherapy or cannot tolerate chemotherapy.TSC associated renal angiomyolipoma -approve. WM/LPL - pt has tried at least one systemic regimen. Thyroid Carcinoma, differentiated-approve if pt is refractory to radioactive iodine therapy.

PA Criteria	Criteria Details
	Endometrial Carcinoma-approve if everolimus will be used in combo with letrozole. GIST-approve if pt has tried 2 of the following drugs: Sutent, Sprycel, Stivarga, Ayvakit, Qinlock 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-approve if pt has perivascular epithloid cell tumors (PE Coma) or recurrent angiomyolipoma/lymphangioleiomyomatosis. Classic hodgkin lymphoma-approve if pt has relapsed or refractory disease AND not a candidate for high-dose therapy and autologous stem cell rescue. Histiocytic neoplasm-approve if pt has Erdheim-Chester disease or, Rosai-Dorfman disease or Langerhans cell histiocytosis. Patient must also have PIK3CA mutation. Meningioma-(A, B and C): A) approve if pt has recurrent or progressive disease AND B) pt has surgically inaccessible disease and radiation therapy is not possible AND C) medication will be used in combination with a somatostatin analogue or bevacizumab. Uterine Sarcoma-approve if the patient has advanced, recurrent, metastatic, or inoperable disease, AND has a perivascular epithelioid cell tumor (PEComa), AND has tried at least one systemic regimen. Note: Examples of systemic regimen include doxorubicin, docetaxel, gemcitabine, ifosfamide, dacarbazine.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	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
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FABRAZYME

Products Affected

- FABRAZYME

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Galafold (migalastat oral capsules) or Elfabrio (pegunigalsidase alfa intravenous infusion).
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient alpha-galactosidase A activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating a pathogenic variant in the galactosidase alpha (GLA) gene.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

FILSPARI

Products Affected

- FILSPARI

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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
Prerequisite Therapy Required	No

FINTEPLA

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

FIRMAGON

Products Affected

- FIRMAGON KIT W DILUENT SYRINGE

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
Coverage Duration	1 year
Other Criteria	Patients new to therapy, are required to try Eligard prior to approval of Firmagon.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FOTIVDA

Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

FRUZAQLA

Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years of age 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: Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, Note: Examples of fluoropyrimidine agents include 5-fluorouracil (5-FU) and capecitabine.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Appendiceal cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FYARRO

Products Affected

- FYARRO

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	Perivascular Epithelioid Cell Tumor (PEComa), Malignant-approve if the patient has locally advanced unresectable disease or metastatic disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

GATTEX

Products Affected

- GATTEX 30-VIAL
- GATTEX ONE-VIAL

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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 either (i or ii) i) pt has papillary or follicular thyroid carcinoma and the disease is radioactive iodine-refractory or ii) pt has oncocytic (formerly Hurthle cell) carcinoma. Anaplastic thyroid cancer or Medullary Thyroid Cancer- pt has unresectable, recurrent, or metastatic disease AND pt has disease positive for RET pathogenic variant.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Medullary Thyroid Cancer, Anaplastic Thyroid Cancer
Part B Prerequisite	No
Prerequisite Therapy Required	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 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 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
Prerequisite Therapy Required	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
Prerequisite Therapy Required	Yes

GLATIRAMER

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple sclerosis
Required Medical Information	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
Prerequisite Therapy Required	No

GLUCAGON-LIKE PEPTIDE-1 AGONISTS - DULAGLUTIDE

Products Affected

- TRULICITY

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

GLUCAGON-LIKE PEPTIDE-1 AGONISTS - SEMAGLUTIDE

Products Affected

- OZEMPIC ORAL
- OZEMPIC SUBCUTANEOUS
- RYBELSUS

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
Prerequisite Therapy Required	No

GLUCAGON-LIKE PEPTIDE-1 AGONISTS - TIRZEPATIDE

Products Affected

- MOUNJARO

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
Prerequisite Therapy Required	No

GNRH AGONIST IMPLANTS - GOSERELIN ACETATE

Products Affected

- ZOLADEX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Endometriosis-18 years and older
Prescriber Restrictions	Prostate cancer/Breast cancer/Head and Neck/Ovarian/Uterine-prescr by or in consult with oncologist. Endometriosis/abnormal uterine bleeding-prescr by or in consult with an OB-GYN or a health care practitioner who specializes in the treatment of women's health. Gender Dysphoria-prescr by or in consult with an endocrinologist or a physician who specializes in the treatment of transgender patients. Preservation of Ovarian Function/Fertility-prescr by or in consult with OB-GYN or oncologist
Coverage Duration	Abnormal uterine bleeding-2 months, Endometriosis-6 months, all other dx-1 year
Other Criteria	Abnormal uterine bleeding-Zoladex 3.6mg is used as an endometrial-thinning agent prior to endometrial ablation.Endometriosis-approve Zoladex 3.6 mg. Prostate cancer-approve Zoladex 3.6 mg and/or 10.8 mg. Head and Neck Cancer - Salivary Gland Tumors: approve if patient has recurrent, unresectable, or metastatic disease AND has androgen receptor-positive disease. Gender Dysphoric/Gender-Incongruent Persons, Persons Undergoing Gender Reassignment- Approve. Preservation of Ovarian Function/Fertility in Patients Undergoing Chemotherapy-Approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Zoladex 3.6mg only: head and neck cancer - salivary gland tumors, Ovarian Cancer including Fallopian Tube Cancer and Primary Peritoneal Cancer, and Uterine Cancer. Zoladex 3.6mg or 10.8mg: Gender Dysphoria, Preservation of Ovarian Function/Fertility in Patients Undergoing Chemotherapy

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

GOMEKLI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NEUROFIBROMATOSIS TYPE 1- patient has or had symptomatic plexiform neurofibromas prior to starting Gomekli and the tumor is not amenable to complete resection.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

GONADOTROPIN-RELEASING HORMONE AGONISTS - ONCOLOGY

Products Affected

- ELIGARD
- ELIGARD (3 MONTH)
- ELIGARD (4 MONTH)
- ELIGARD (6 MONTH)
- *leuprolide subcutaneous kit*

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, breast cancer- 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), breast cancer (Eligard only)
Part B Prerequisite	No
Prerequisite Therapy Required	No

GROWTH HORMONES

Products Affected

- OMNITROPE

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

HERNEXEOS

Products Affected

- HERNEXEOS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NON-SMALL CELL LUNG CANCER-BOTH (A and B): A) Unresectable or metastatic disease, AND B) Human epidermal growth factor receptor 2 (HER2) [ERBB2] activating mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

HIGH RISK MEDICATIONS - ANTIPARKINSON AGENTS

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 covered indications, approve if the prescriber confirms he/she has assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and he/she would still like to initiate/continue therapy. Please note that this risk assessment should include the concomitant use of other anticholinergic drugs at the same time as the requested medication.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

HIGH RISK MEDICATIONS - BENZODIAZEPINES - CLORAZEPATE

Products Affected

- *clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg*

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	6 months
Other Criteria	All medically accepted indications, approve if the physician has assessed risk versus benefit in using the 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
Prerequisite Therapy Required	No

HIGH RISK MEDICATIONS - BENZODIAZEPINES - DIAZEPAM

Products Affected

- *diazepam injection*
- *diazepam intensol*
- *diazepam oral concentrate*
- *diazepam oral solution*
- *diazepam oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	Procedure-related sedation = 1mo. All other conditions = 6 months.
Other Criteria	All medically accepted indications, approve if the physician has assessed risk versus benefit in using the 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
Prerequisite Therapy Required	No

HIGH RISK MEDICATIONS - BENZODIAZEPINES - LORAZEPAM

Products Affected

- *lorazepam injection*
- *lorazepam intensol*
- *lorazepam oral concentrate*
- *lorazepam oral tablet 0.5 mg, 1 mg, 2 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES - HYDROXYZINE

Products Affected

- *hydroxyzine hcl oral tablet*

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 the treatment of anxiety, approve if the patient has tried at least two other FDA-approved products. Additionally for all covered indications, the prescriber must confirm that he/she has 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. Please note that this risk assessment should include the concomitant use of other anticholinergic drugs at the same time as the requested medication.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES - PROMETHAZINE

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 the treatment of emesis, approve if the patient has tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant).Additionally for all covered indications, the prescriber must confirm that he/she has 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. Please note that this risk assessment should include the concomitant use of other anticholinergic drugs at the same time as the requested medication.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

HIGH RISK MEDICATIONS - SKELETAL MUSCLE RELAXANTS - CYCLOBENZAPRINE

Products Affected

- *cyclobenzaprine oral tablet 10 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 6 months.
Other Criteria	For all covered indications, approve if the prescriber confirms he/she 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. Please note that this risk assessment should include the concomitant use of other anticholinergic drugs at the same time as the requested medication.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

HYRNUO

Products Affected

- HYRNUO

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 (A, B AND C): A. Locally advanced or metastatic disease, AND B. Human epidermal growth factor receptor 2 (HER2) [ERBB2] activating mutations, AND C. Received at least one prior systemic therapy. Note: Examples include checkpoint inhibitors such as Keytruda (pembrolizumab intravenous infusion), Libtayo (cemiplimab-rwlc intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), or Imjudo (tremelimumab-actl intravenous infusion) in combination with chemotherapy (e.g., carboplatin, cisplatin, pemetrexed, paclitaxel, albumin-bound paclitaxel, bevacizumab), chemotherapy alone (e.g., docetaxel, gemcitabine, etoposide, vinorelbine, other chemotherapy noted above).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IBRANCE

Products Affected

- IBRANCE ORAL CAPSULE 125 MG
- IBRANCE ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

IBTROZI

Products Affected

- IBTROZI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NON-SMALL CELL LUNG CANCER-locally advanced or metastatic disease and ROS1-positive non-small cell lung cancer.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ICATIBANT

Products Affected

- *icatibant*
- *sajazir*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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	All indications except ALL - 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 ABL-class translocation: approve if the patient meets (1, 2 or 3): 1) will use in combination with chemotherapy, or 2) ALL is T315I-positive, or 3) pt tried at least one other tyrosine kinase inhibitor (examples: imatinib or dasatinib). Chronic myeloid leukemia, Philadelphia chromosome positive or BCR::ABL1-positive-approve if patient meets (1, 2 or 3): 1) CML is T315I-positive, or 2) pt tried at least one other tyrosine kinase inhibitor (examples: imatinib, dasatinib, nilotinib), or 3) pt has accelerated-phase or blast-phase CML and no other tyrosine kinase inhibitor is indicated. GIST - approve if the patient tried all of the following therapies first to align with NCCN recommendations which include: Imatinib, AND Sunitinib, 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

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

ICOTYDE

Products Affected

- ICOTYDE

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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. Myelodysplastic Syndrome - approve if patient has isocitrate dehydrogenase-2 (IDH2) mutation-positive disease AND has tried at least one prior therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myelodysplastic Syndrome
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ILARIS

Products Affected

- ILARIS (PF)

PA Criteria	Criteria Details
Exclusion Criteria	When used in combination with concurrent biologic therapy (e.g.TNF antagonists, etanercept, adalimumab, certolizumab pegol, golimumab, infliximab), anakinra, or rilonacept.
Required Medical Information	N/A
Age Restrictions	CAPS-4 years of age and older (initial). SJIA/HIDS/MKD/FMF/TRAPS-2 years of age and older (initial). Still's disease-18 years and older (initial) Note-patients less than 18 should be referred to criteria for systemic juvenil idiopathic arthritis. Acute gout flare-18 years of age and older
Prescriber Restrictions	CAPS initial- Prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist. SJIA/Still's disease (initial), Acute gout flare (initial/cont)- prescribed by or in consultation with a rheumatologist. FMF initial - rheumatologist, nephrologist, geneticist, gastroenterologist, oncologist, hematologist. HIDS/MKD/TRAPS initial - rheumatologist, nephrologist, geneticist, oncologist, hematologist.
Coverage Duration	Acute gout flare-6 mos, all other diagnoses-6 months initial, 1 year cont.
Other Criteria	For renewal of CAPS/SJIA/FMF/HIDS/MKD/TRAPS/Still's - After pt had been started on Ilaris, approve if the pt had a response to therapy as determined by prescribing physician. SJIA, initial therapy - approve. Adult Onset Still's Disease-Initial-approve. Acute gout flare- approve if (i and ii): (i) pt has intolerance, contraindication, or lack of response to NSAIDs and colchicine for the treatment of acute gout flares OR pt is unable to be retreated with a repeat course of corticosteroids (oral or injectable) for acute gout flare, and (ii) patient is receiving or will be taking concomitant urate lowering medication for prevention of gout unless contraindicated (ex: allopurinol, febuxostat, probenecid). FMF, initial-approve if pt has tried colchicine, unless contraindicated and will be taking Ilaris in combination with colchicine, unless colchicine is contraindicated or not tolerated, AND prior to starting Ilaris, the patient meets BOTH of the

PA Criteria	Criteria Details
	following (a and b): a) C-reactive protein level is greater than or equal to 10 mg/L OR elevated to at least two times the upper limit of normal AND b) pt has a history of at least one flare per month despite use of colchicine, OR was hospitalized for a severe flare. HIDS/MKD, initial-approve if prior to starting Ilaris, the patient meets BOTH of the following (a and b): a) C-reactive protein level is greater than or equal to 10 mg/L OR elevated to at least two times the upper limit of normal AND b) Pt has a history of at least three febrile acute flares within the previous 6-month period OR was hospitalized for a severe flare. TRAPS, initial-approve if prior to starting Ilaris, the patient meets BOTH of the following (a and b): a) C-reactive protein level is greater than or equal to 10 mg/L OR elevated to at least two times the upper limit of normal AND b) Pt has a history of at least six flares per year OR was hospitalized for a severe flare.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IMATINIB

Products Affected

- *imatinib oral tablet 100 mg, 400 mg*
- 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	1year
Other Criteria	For ALL-approve for Ph-positive or ABL-class translocation ALL. CML - approve for Ph-positive or BCR::ABL1-mutation positive CML. Systemic Mastocytosis-Approve if the disease is KIT D816V mutation negative or unknown. Kaposi's Sarcoma-approve if (A or B): A) the patient has tried at least one regimen AND has relapsed or refractory disease OR B) has Kaposi sarcoma-associated herpesvirus (KSHV)-associated inflammatory cytokine syndrome. Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT)-patient has tried Turalio or Romvimza or according to the prescriber, the patient cannot take Turalio or Romvimza. 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-PDGFRA or PDGFRB rearrangement. Approve Imkeldi if the patient has had a trial of imatinib tablets (brand or generic) dispersed in a glass of water or apple juice (per product labeling).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Chordoma, desmoid tumors (aggressive fibromatosis), metastatic or unresectable cutaneous melanoma with activating kit mutation, Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor, myeloid/lymphoid neoplasms with eosinophilia, GVHD, chronic.
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IMBRUVICA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

IMDELLTRA

Products Affected

- IMDELLTRA

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. SMALL CELL LUNG CANCER-patient meets both (A and B): A) has primary progressive, relapsed or refractory extensive stage disease or has brain metastases and B) 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
Prerequisite Therapy Required	Yes

IMJUDO

Products Affected

- IMJUDO

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	HCC, Esophageal/Esophagogastric Junction Ca, Gastric Ca-30 days, NSCLC-6 months
Other Criteria	HCC-approve if the medication is used in combination with Imfinzi (durvalumab intravenous infusion) and the patient meets (A or B): A) Meets either (i or ii): i) has liver-confined unresectable disease and is deemed ineligible for transplant or (ii) has extrahepatic or metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy or B) Imjudo will be used as subsequent therapy. Non-Small Cell Lung Cancer, recurrent, advanced or metastatic -approve if patient meets ALL of (A, B and C): A) tumor is negative for the following actionable biomarkers: epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase (ALK), RET, and ROS1, and B) medication is used in combination with Imfinzi, and C) pt meets (i, ii, iii or iv): i) medication is used as first-line therapy and tumor is positive for one of: EGFR exon 20 mutation, ERBB2 (HER2) mutation or NRG1 gene fusion, ii) medication is used as first-line or subsequent therapy and tumor is positive for one of: BRAF V600E mutation, NTRK1/2/3 gene fusion, or MET exon 14 skipping mutation, iii) medication is used as subsequent therapy and tumor is EGFR S768I, L861Q, and/or G719X mutation positive, or iv) medication is used as first-line therapy and tumor has no actionable mutations (Note: The tumor does NOT have the following mutations: EGFR exon 19 deletion, EGFR exon 21 L858R, EGFR S768I, EGFR L861Q, EGFR G719X, EGFR exon 20 insertion, ALK rearrangement, ROS1 rearrangement, BRAF V600E, NTRK 1/2/3 gene

PA Criteria	Criteria Details
	fusion, METex14 skipping, RET rearrangement, ERBB2 (HER2), and NRG1 gene fusion.). Esophageal and Esophagogastric Junction Cancers-approve if pt has adenocarcinoma tumor AND has microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) disease AND Imjudo is used as neoadjuvant therapy AND Imjudo is used in combination with Imfinzi (durvalumab intravenous infusion). Gastric cancer-approve if pt has locoregional disease AND has MSI-H or dMMR disease AND Imjudo is used as neoadjuvant therapy AND Imjudo is used in combination with Imfinzi.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Esophageal and Esophagogastric Junction Cancers, Gastric Cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IMPAVIDO

Products Affected

- IMPAVIDO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious diseases specialist
Coverage Duration	1 month
Other Criteria	Ameba related infections: approve if the patient is being treated for an infection due to one of the following: Acanthameoba, Balamuthia mandrillaris, or Naegleria fowleri. Note: Examples of ameba related infections are Acanthamoeba keratitis, granulomatous amebic encephalitis (GAE), and primary amebic meningoencephalitis (PAM).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ameba related infections
Part B Prerequisite	No
Prerequisite Therapy Required	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
Prerequisite Therapy Required	Yes

INGREZZA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- *testosterone cypionate*
- *testosterone enanthate*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, lab results
Age Restrictions	Delayed puberty or induction of puberty in males-14 years and older, 12 years and older (testosterone cypionate)
Prescriber Restrictions	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.
Coverage Duration	Delayed puberty or induction of puberty in males-6 months, all others-12 months
Other Criteria	Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. Delayed puberty or induction of puberty in males - Approve testosterone enanthate or testosterone cypionate. Breast cancer in females-approve testosterone enanthate. Male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Female is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression. Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-

PA Criteria	Criteria Details
	Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-approve.Note: For a patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).
Part B Prerequisite	No
Prerequisite Therapy Required	No

INLEXZO

Products Affected

- INLEXZO

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 or urologist
Coverage Duration	1 year
Other Criteria	NON-MUSCLE INVASIVE BLADDER CANCER-patient has carcinoma in situ (CIS) and Bacillus Calmette-Guerin (BCG)-unresponsive disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

INLURIYO

Products Affected

- INLURIYO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	BREAST CANCER-All of (A, B, C, D, E and F): A) Recurrent, advanced or metastatic disease, AND B) Hormone receptor-positive (HR+) disease (example: estrogen receptor (ER)-positive), AND C) Human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) meets one (i or ii): i) Estrogen receptor 1 gene (ESR1)-mutated disease or ii) medication will be used in combination with Verzenio (abemaciclib tablets), AND E) Tried at least one endocrine therapy, Note: Examples of endocrine therapy include fulvestrant, anastrozole, exemestane, letrozole, and tamoxifen. AND F) ONE of the following (i or ii): i. Patient is a postmenopausal woman or man [See note 1], OR ii. Patient is a pre/perimenopausal woman [See note 1] and meets ONE of the following (a or b): a) Receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), and Zoladex (goserelin acetate subcutaneous injection). OR b) Patient has had surgical bilateral oophorectomy or ovarian irradiation. Note 1- a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression, 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, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Recurrent breast cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

INLYTA

Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	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 the patient meets (i or ii): i) Patient meets both (a and b): a) Has papillary or follicular thyroid carcinoma AND b) the disease is refractory to radioactive iodine therapy OR ii) has oncocytic (formulary Hurthle cell) carcinoma. Soft tissue sarcoma-approve if the patient has alveolar soft part sarcoma and the medication will be used in combination with Keytruda. Thymic carcinoma - Approve if the patient has tried at least one chemotherapy regimen and the medication will be used in combination with Bavencio (aveluman intravenous infusion).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma, Soft tissue sarcoma, thymic carcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

INQOVI

Products Affected

- INQOVI

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

INREBIC

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has higher-risk disease. Myeloid/Lymphoid Neoplasms with Eosinophilia-approve if the tumor has a JAK2 rearrangement and has tried Jakafi (ruxolitinib tablets). Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid/Lymphoid Neoplasms with Eosinophilia, accelerated or blast phase myeloproliferative neoplasm
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ITOVEBI

Products Affected

- ITOVEBI ORAL TABLET 3 MG, 9 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	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 male, OR ii. Patient meets BOTH of the following (a and b): a. Patient is a pre/perimenopausal female, AND b. Patient is receiving a gonadotropin-releasing hormone (GnRH) agonist OR had surgical bilateral oophorectomy or ovarian irradiation, 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 meets (i or ii): i) has disease progression while on adjuvant endocrine therapy or ii) had disease recurrence within 12 months after completing adjuvant endocrine therapy, Note: Examples of endocrine therapy 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

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

IVERMECTIN (ORAL)

Products Affected

- *ivermectin oral tablet 3 mg, 6 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

IVIG

Products Affected

- GAMUNEX-C

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

IWILFIN

Products Affected

- IWILFIN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	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
Prerequisite Therapy Required	Yes

JAKAFI

Products Affected

- JAKAFI
- JAKAFI XR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	ALL-1 to 21 years of age, GVHD-12 and older, MF/PV/accelerated or blast phase MPN/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 or the disease has a EPOR rearrangement, SH2B3 alterations, or IL7R insertion/deletion. 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 (A or B): A) peripheral T-cell lymphoma or B) meets (i and ii): i) pt has T-cell prolymphocytic leukemia, T-cell large granular lymphocytic leukemia, hepatosplenic T-cell lymphoma, or breast implant-associated anaplastic large cell lymphoma and ii) pt has tried at least one systemic regimen. Accelerated or blast phase myeloproliferative

PA Criteria	Criteria Details
	neoplasm-approve if pt has at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Acute lymphoblastic leukemia, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2), essential thrombocythemia, myeloid/lymphoid neoplasms, T-Cell lymphoma, accelerated or blast phase myeloproliferative neoplasm
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JAYPIRCA

Products Affected

- JAYPIRCA ORAL TABLET 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	Mantle cell lymphoma-approve if the patient has tried at least one systemic chemotherapy regimen or patient is not a candidate for a chemotherapy regimen, 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, cytarabine, carboplatin, cisplastin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, 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 tried at least one Bruton tyrosine kinase (BTK) inhibitor. Examples of BTK inhibitor include: Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules). Richter's Transformation - pt currently receiving or has tried at least one chemotherapy regimen. Marginal Zone Lymphoma - approve if pt has tried at least one Bruton tyrosine kinase inhibitor. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma - approve if pt has tried at least one systemic regimen. Note: Examples of a systemic regimen contain one or more of the following products: Brukinsa (zanubrutinib capsules), Imbruvica (ibrutinib tablets,

PA Criteria	Criteria Details
	capsules, and oral solution), rituximab, bendamustine, cyclophosphamide, dexamethasone, bortezomib, Kyprolis (carfilzomib intravenous infusion), or Ninlaro (ixazomib capsule) .
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Richter's Transformation to Diffuse Large B-Cell Lymphoma, Marginal Zone Lymphoma, Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JEMPERLI

Products Affected

- JEMPERLI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Endometrial cancer (see note)-approve if the patient has recurrent, advanced or metastatic disease. Mismatch repair deficient (dMMR) or microsatellite instability high (MSI-H) Solid tumors-approve. Small Bowel Adenocarcinoma (see note)-approve if the patient has polymerase epsilon/delta (POLE/POLD1) mutation positive disease with ultra-hypermutated phenotype (tumor mutation burden greater than 50 mutations/megabase) and has advanced or metastatic disease. Colon, Rectal, or Appendiceal Cancer (see note)- approve if patient has polymerase epsilon/delta (POLE/POLD1) mutation positive disease with ultra-hypermutated phenotype (tumor mutation burden greater than 50 mutations/megabase) AND is being used for neoadjuvant therapy or advanced or metastatic disease. Anal carcinoma- approve if pt meets one (A or B): A) pt has locally recurrent or progressive disease and medication is administered before proceeding to abdominoperineal resection, or B) pt has metastatic disease. Note: If the tumor is Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors, see MSI-H or dMMR Solid Tumors criteria.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Small Bowel Adenocarcinoma, Colon, Rectal or Appendiceal Cancer, Anal carcinoma

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

JIDEYTRO

Products Affected

- JIDEYTRO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

JYNARQUE

Products Affected

- *tolvaptan (polycys kidney dis)*

PA Criteria	Criteria Details
Exclusion Criteria	Patient is currently receiving another tolvaptan product
Required Medical Information	Diagnosis, renal function
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	1 year (initial and continuation)
Other Criteria	Approve if the patient has rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD) (e.g., reduced or declining renal function, high or increasing total kidney volume [height adjusted]),according to the prescriber AND at baseline, patient's estimated glomerular filtration rate is at least 25 mL/min/1.73 m2 AND patient is not on renal replacement therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

KADCYLA

Products Affected

- KADCYLA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Breast Cancer-Recurrent/metastatic-1 yr, Breast Cancer-Adjuvant tx-approve 1 yr total, other-1yr
Other Criteria	Breast Cancer-approve if the patient has human epidermal growth factor receptor 2 (HER2)-positive disease and the patient is using for recurrent or metastatic breast cancer OR if using for adjuvant therapy. NSCLC-approve if pt meets (A, B and C): A) the disease has activating human epidermal growth factor receptor 2 (HER2) [ERBB2] mutations and B) the patient has recurrent, advanced, or metastatic disease and C) pt has tried at least one prior systemic therapy. Salivary gland tumor-approve if the patient has recurrent, unresectable, or metastatic disease and the patient has human epidermal growth factor receptor 2 (HER2)-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-small cell lung cancer (NSCLC), salivary gland tumor
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

KALYDECO

Products Affected

- KALYDECO

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

KANUMA

Products Affected

- KANUMA

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

KERENDIA

Products Affected

- KERENDIA

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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
Prerequisite Therapy Required	No

KEVZARA

Products Affected

- KEVZARA SUBCUTANEOUS PEN INJECTOR
- KEVZARA SUBCUTANEOUS SYRINGE 200 MG/1.14 ML

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

KEYTRUDA

Products Affected

- KEYTRUDA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Melanoma, bone cancer - 12 and older, Glioma - less than 18 years, all others- 18 and older (except Merkel cell, MSI-H/dMMR tumors, large B-cell lymph, TMB-H, Classic Hodgkin Lymphoma)
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	adrenal gland tumor, anal carcinoma, bone cancer, extranodal NK/T-Cell Lymphoma, nasal type, Gestational trophoblastic neoplasia, mycosis fungoides/Sezary syndrome, primary cutaneous anaplastic large cell lymphoma, small cell lung cancer, soft tissue sarcoma, thymic carcinoma, vulvar cancer, pediatric diffuse high grade glioma, Kaposi sarcoma, small bowel adenocarcinoma (without MSI-H or dMMR), thyroid carcinoma (without MSI-H or dMMR), vaginal cancer, chronic lymphocytic leukemia/small lymphocytic leukemia, penile cancer
Part B Prerequisite	No
Prerequisite Therapy Required	No

KEYTRUDA QLEX

Products Affected

- KEYTRUDA QLEX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Merkel cell carcinoma/TMB-H cancer, melanoma, bone cancer - 12 and older. All others - 18 and older (except MSI-H/dMMR solid tumors), pediatric diffuse high-grade glioma - less than 18 years
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Thymic carcinoma, anal carcinoma, appendiceal cancers, bone cancer, gestational trophoblastic neoplasia, pediatric diffuse high-grade glioma, penile cancer, small bowel adenocarcinoma, soft tissue sarcoma, vaginal cancer, vulvar cancer
Part B Prerequisite	No
Prerequisite Therapy Required	No

KINERET

Products Affected

- KINERET

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

KISQALI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

KOMZIFTI

Products Affected

- KOMZIFTI

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-relapsed or refractory disease and disease is positive for a susceptible nucleophosmin 1 (NPM1) mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

KORLYM

Products Affected

- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome
Coverage Duration	1 year
Other Criteria	Endogenous Cushing's Syndrome-Approve if mifepristone is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance AND pt meets (i, ii or iii): i) patient is not a candidate for surgery or surgery has not been curative, or (ii) patient is awaiting surgery for endogenous Cushing's Syndrome or (iii) patient is awaiting therapeutic response after radiotherapy for endogenous Cushing's Syndrome.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	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	Neurofibromatosis Type 1-approve if the tumor is not amenable to complete resection and prior to starting Koselugo, the patient has symptomatic plexiform neurofibromas. Circumscribed Glioma-approve if (A and B): A) the patient has recurrent or progressive disease AND B) one of (i, ii, or iii): i) the tumor is BRAF fusion positive OR ii) BRAF V600E activating mutation positive OR iii) patient has neurofibromatosis type 1 mutated glioma. Langerhans Cell Histiocytosis- approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Circumscribed Glioma, Langerhans Cell Histiocytosis
Part B Prerequisite	No
Prerequisite Therapy Required	No

KRAZATI

Products Affected

- KRAZATI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-approve if (A and B): A) the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC AND B) patient meets either (i or ii): i) has been previously treated with at least one systemic regimen [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.] or ii) patient has brain metastases. Colon, Rectal, Appendiceal 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. 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

PA Criteria	Criteria Details
	or metastatic disease and previously treated with at least one 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, appendiceal cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LANREOTIDE

Products Affected

- *lanreotide subcutaneous syringe 120 mg/0.5 ml*
- SOMATULINE DEPOT SUBCUTANEOUS SYRINGE 60 MG/0.2 ML, 90 MG/0.3 ML

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 or oncologist. 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/Sellar tumor-prescribed by or in consultation with an endo/onc/neuro.
Coverage Duration	1 year
Other Criteria	Acromegaly-approve if the patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., iii., or iv: 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) or iv. there are signs of tumor growth on imaging. 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/Pheochromocytoma/paraganglioma-approve. Sellar Tumor-Approve if patient has a thyroid-stimulating hormone (TSH) - secreting tumor.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Pheochromocytoma/paraganglioma, Sellar tumor
Part B Prerequisite	No
Prerequisite Therapy Required	No

LAPATINIB

Products Affected

- *lapatinib*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

LAZCLUZE

Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NON-SMALL CELL LUNG CANCER-ALL of the following (A, B and C): 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LENALIDOMIDE

Products Affected

- *lenalidomide*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (except Kaposi Sarcoma, Castleman Disease, Primary CNS Lymphoma)
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	B-cell Lymphoma-Follicular lymphoma-approve if (A, B or C): A) the patient is using lenalidomide in combination with rituximab or B) using in combination with Gazyva (obinutuzumab intravenous infusion), or C) pt has tried at least one prior therapy. B-cell Lymphoma-MCL-approve -if the patient is using lenalidomide in combination with rituximab or has tried at least one other regimen. B-cell Lymphoma-MZL-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one other 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]), OR 4) meets (i, ii and iii): i) pt has myelodysplastic syndrome/myeloproliferative neoplasm overlap neoplasm, and ii) has SF3B1 mutation, and iii) pt has thrombocytosis . B-cell-lymphoma (other) [examples: diffuse large B-cell lymphoma, high grade B-cell lymphoma, post-transplant lymphoproliferative disorders, HIV-related B-cell lymphoma]-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia with presence of del(5q) and will use this in combination with prednisone. Primary CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease, or is not a candidate for high-

PA Criteria	Criteria Details
	dose MTX, or had intolerance to high-dose MTX. Hodgkin lymphoma, classic-approve if (A and B): A) pt has relapsed or refractory disease, and B) pt is not a candidate for high-dose therapy and autologous stem cell rescue. Castleman disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi Sarcoma-approve if the patient has tried at least one medication or has Kaposi sarcoma-associated herpesvirus (KSHV)-associated inflammatory cytokine syndrome. Systemic light chain amyloidosis-approve if lenalidomide is used in combination with dexamethasone. Histiocytic neoplasms-approve if (A or B): A) the patient has Langerhans cell histiocytosis with either (i or ii): i) single-system multifocal skin disease or ii) relapsed or refractory disease, or B) pt has Rosai-Dorfman disease. T-Cell lymphoma- approve if (A, B or C): A) pt has peripheral T-cell lymphoma, or B) pt has T-cell leukemia/lymphoma and has tried at least one other regimen, or C) pt has hepatosplenic T-cell lymphoma and has tried at least two other regimens. Chronic lymphocytic leukemia/Small lymphocytic leukemia- approve if (A, B and C): A) relapsed or refractory disease, and B) tried at least one Bruton-tyrosine kinase inhibitor, and C) tried at least one B-cell lymphoma (BCL)2 inhibitor. POEMS Syndrome- approve if used in combination with dexamethasone. Mycosis Fungoides/Sezary Syndrome-pt has relapsed or refractory disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Systemic Amyloidosis Light Chain, B-Cell Lymphoma (other), Myelofibrosis, Castleman Disease, Hodgkin lymphoma (Classic), T-Cell Lymphoma, Primary Central nervous system Lymphoma, Kaposi sarcoma, histiocytic neoplasms, Chronic Lymphocytic Leukemia, Small Lymphocytic Leukemia, POEMS syndrome, Mycosis Fungoides/Sezary Syndrome.
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LENVIMA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

LEQEMBI IQLIK

Products Affected

- LEQEMBI IQLIK

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

LEUKINE

Products Affected

- LEUKINE INJECTION RECON SOLN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	AML if prescribed by or in consultation with an oncologist or hematologist, PBPC/BMT - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation, Radiation syndrome-prescribed by or in consultation with physician with expertise in treating acute radiation syndrome. Neuroblastoma-prescribed by or in consultation with an oncologist.
Coverage Duration	Radiation Syndrome/BMT - 1 mo, AML/Neuroblastoma-6 months, PBPC-14 days
Other Criteria	Neuroblastoma-approve if the patient is receiving Leukine in a regimen that recommends administration in combination with a granulocyte-macrophage colony stimulating factor (examples: dinutuximab or naxitamab).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Neuroblastoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LIBTAYO

Products Affected

- LIBTAYO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous surgeries or radiation. Anal Carcinoma-meets both of the following (A and B): A) locally recurrent, metastatic, or progressive disease AND B) meets ONE (i, ii, or iii): i. The medication is used in combination with chemotherapy OR ii. The medication is administered before proceeding to abdominoperineal resection OR iii. The medication is used for subsequent therapy. Colon, Rectal, and appendiceal Cancer-meets ALL of the following (A and B): A) Disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) OR polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutational burden greater than 50 mutations/megabase) AND B) Patient meets ONE of the following (i or ii): i. locally unresectable, advanced, recurrent, metastatic, or medically inoperable disease OR ii. medication is used for neoadjuvant therapy. Small Bowel Adenocarcinoma-meets ALL of the following (A and B): A) Disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) or is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutational burden greater than 50 mutations/megabase) AND B) meets ONE (i or ii): i. has locally unresectable or medically inoperable disease OR ii. advanced or metastatic disease.
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	CSCC-approve if the patient meets one of the following (i, ii, or iii): (i): pt has locally advanced, recurrent, or metastatic disease and is not a candidate for curative surgery or curative radiation or (ii): pt has very-high risk, locally advanced, unresectable, in-transit metastasis, or regional disease and this medication will be used as neoadjuvant therapy, or (iii): pt has

PA Criteria	Criteria Details
	disease that is at a high or very-high risk for recurrence, and this medication will be used as adjuvant therapy [Note: High or very-high risk for disease recurrence is defined as nodal features (extracapsular extension with largest node at least 20 mm in diameter or at least 3 involved nodes) or non-nodal features (in-transit metastases, T4 lesion [with bone invasion], perineural invasion, or locally recurrent tumor with at least 1 addition risk feature)]. Basal Cell Carcinoma-approve if the patient has locally advanced, nodal or metastatic disease. NSCLC (recurrent, advanced or metastatic disease)-approve if the tumor is negative for the following actionable biomarkers: epidermal growth factor receptor (EGRF) exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase (ALK), RET, and ROS1 and meets one of the following (i, ii, iii, or iv): (i): medication is used for first-line or continuation maintenance therapy AND tumor has no actionable mutations, or (ii): medication will be used first line AND the tumor is positive for one of EGFR exon 20 mutation or ERBB2 (HER2) mutation, or NRG1 gene fusion, or (iii): medication will be used as first-line or subsequent therapy AND the tumor is positive for one of BRAF V600E mutation or NTRK1/2/3 gene fusion or MET exon 14 skipping mutation, or (iv): medication will be used as subsequent therapy AND the tumor is positive for one of EGFR S768I, L861Q, and/or G719X mutation. Cervical cancer-approve if pt has local or regional recurrence or distant metastic disease AND this medication is used as subsequent therapy. Vulvar cancer- approve if pt has advanced, recurrent, or metastatic disease AND this medication is used as subsequent therapy. Vaginal cancer-approve if pt meets (A and B): A) meets (i or ii): i) local or regional recurrence, or ii) distant metastatic disease, and B) used as subsequent therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Cervical cancer, vulvar cancer, vaginal cancer, anal carcinoma, colon/rectal/appendiceal cancer, small bowel adenocarcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LIDOCAINE PATCH

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Diabetic neuropathic pain, chronic back pain
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIDOCAINE/COMBINATION TOPICAL (NON-PATCH) - LIDOCAINE

Products Affected

- *lidocaine topical ointment*

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 Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIDOCAINE/COMBINATION TOPICAL (NON-PATCH) - LIDOCAINE/PRILOCAINE

Products Affected

- *lidocaine-prilocaine topical cream*

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 Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIFYORLI

Products Affected

- LIFYORLI ORAL CAPSULE 125 MG/DAY(100 MG X1-25MG X1), 125 MG/DAY(100 MG X1-25MG X3), 125 MG/DAY(100 MG X1-25MG X9), 150 MG/DAY(100 MG X1-25MG X2), 150 MG/DAY(100 MG X1-25MG X3), 150 MG/DAY(100 MG X1-25MG X9)

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	OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER-patient has platinum-resistant disease, has tried at least one systemic regimen that includes bevacizumab and requested medication will be used in combination with nab-paclitaxel. Note: Examples of a systemic regimen include one or more of the following agents: carboplatin, cisplatin, docetaxel, doxorubicin, gemcitabine, nab-paclitaxel, oxaliplatin, or paclitaxel.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LIVDELZI

Products Affected

- LIVDELZI

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Iqirvo
Required Medical Information	Diagnosis
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 THERAPY: PRIMARY BILIARY CHOLANGITIS/CIRRHOSIS-All of (A and B): A): Diagnosis confirmed by TWO of the following i, ii, or iii: i) Alkaline phosphatase is elevated above the upper limit of normal, ii) positive anti-mitochondrial antibodies or other primary biliary cholangitis-specific auto-antibodies, including sp100 or gp210, if anti-mitochondrial antibodies are negative or iii) histologic evidence of primary biliary cholangitis from a liver biopsy, B): Receiving ursodiol therapy and had inadequate response or was unable to tolerate ursodiol therapy. Note: examples of ursodiol therapy include ursodiol generic tablets and capsules, Urso 250, Urso Forte, and Actigall. CONTINUATION THERAPY: PRIMARY BILIARY CHOLANGITIS/CIRRHOSIS- patient has demonstrated a response to therapy. Note: Examples of a response to therapy are improved biochemical markers of primary biliary cholangitis (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT]).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

LIVTENCITY

Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

LONG ACTING OPIOIDS - HYDROMORPHONE

Products Affected

- *hydromorphone oral tablet extended release 24 hr*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

LONG ACTING OPIOIDS - METHADONE

Products Affected

- *methadone intensol*
- *methadone oral concentrate*
- *methadone oral solution 10 mg/5 ml, 5 mg/5 ml*
- *methadone oral tablet 10 mg, 5 mg*
- *methadose oral concentrate*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

LONG ACTING OPIOIDS - MORPHINE

Products Affected

- *morphine oral tablet extended release*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

LONSURF

Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Colon, rectal or appendiceal cancer- approve if patients meets (A and B): A) advanced or metastatic disease, AND B) has previously been treated with ALL of the following per labeling: fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. Gastric or Gastroesophageal Junction Adenocarcinoma, approve if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Appendiceal cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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. Anal carcinoma-approve if patient meets (A and B): A) locally recurrent, progressive, or metastatic disease and B) meets (i, ii, or iii): i) medication is used in combination with chemotherapy or ii) medication is administered before proceeding to abdominoperineal resection, or iii) medication is used as subsequent therapy. Small bowel adenocarcinoma- approve if patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation positive disease with ultra-hypermutated phenotype (tumor mutation burden greater than 50 mutations/megabase). Colon and Rectal and appendiceal Cancer-Approve if the patients meets (A and B): A) ONE of the following (i or ii): i. the disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) OR ii. is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden greater than 50 mutations/megabase) AND B) ONE of the following (i or ii): i. locally unresectable, advanced, recurrent, metastatic, or medically inoperable disease OR ii. if the medication is used for neoadjuvant therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Anal carcinoma, small bowel adenocarcinoma, colon/rectal and appendiceal cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LORBRENA

Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Pediatric Diffuse High-Grade Glioma- less than 18 years old, All others (except ALCL)- 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 (i or ii): i) advanced, recurrent, or metastatic disease or ii) tumor is inoperable. NSCLC - Approve if the patient has ALK-positive advanced or metastatic NSCLC. NSCLC-ROS1 Rearrangement-Positive, advanced or metastatic NSCLC-approve if the patient has tried at least one of crizotinib, repotrectinib, taletrectinib or entrectinib. 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. Anaplastic large cell lymphoma (ALCL): approve if (A, B and C): A) pt has ALK-positive disease, B) pt has relapsed or refractory disease, and C) medication will be used as subsequent therapy.
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 IIMT), Large B-Cell Lymphoma, Pediatric Diffuse High-Grade Glioma, anaplastic large cell lymphoma (ALCL)

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

LUMAKRAS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	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, AND meets one (A or B): A) has been previously treated with at least one systemic regimen or B) patient has brain metastases. Ampullary adenocarcinoma - approve if pt has KRAS G12C-mutated disease AND this is used as subsequent therapy. Colon, rectal, or Appendiceal cancer - approve if pt meets all (A, B, C and D): A) advanced or metastatic disease, and B) KRAS G12C mutation-positive disease, and C) used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion) or patient is unable to tolerate combination therapy, and D) previously received a chemotherapy regimen. Pancreatic Adenocarcinoma- approve if patient has KRAS G12C-mutated disease 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. Small bowel adenocarcinoma- approve if pt meets all of (A, B and C): A) has advanced or metastatic disease, and B) has KRAS G12C mutation-positive disease, and C) medication will be used as subsequent therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma, Small Bowel Adenocarcinoma, Appendiceal cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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
Prerequisite Therapy Required	No

LUNSUMIO

Products Affected

- LUNSUMIO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consulation with an oncologist
Coverage Duration	1 year
Other Criteria	Follicular Lymphoma-approve if the patient has received at least two lines of systemic therapy. Note: Examples of systemic therapy for follicular lymphoma include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) plus rituximab or Gazyva (obinutuzumab intravenous infusion), CVP (cyclophosphamide, vincristine, prednisone) plus rituximab or Gazyva, lenalidomide plus rituximab with or without Epkinly (epcoritamab-bysp subcutaneous injection) or Monjuvi (tafasitamab-cxix intravenous infusion), bendamustine plus Gazyva or rituximab, or Tazverik (tazemetostat tablets). B-Cell Lymphoma (examples: diffuse large B-cell lymphoma, high-grade B-cell lymphoma, HIV-related B-cell lymphomas, post-transplant lymphoproliferative disorders)- approve if patient has received at least one line of systemic therapy and will be used in combination with Polivy. Note: Examples of systemic therapy for B-Cell lymphoma include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and Pola-R-CHP (Polivy [polatuzumab vedotin-piiq intravenous infusion], rituximab, cyclophosphamide, doxorubicin, prednisone).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	B-Cell Lymphoma

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

LUNSUMIO VELO

Products Affected

- LUNSUMIO VELO

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	FOLLICULAR LYMPHOMA-patient has received at least two lines of systemic therapy. Note: Examples of systemic therapy include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) plus rituximab or Gazyva (obinutuzumab intravenous infusion), CVP (cyclophosphamide, vincristine, prednisone) plus rituximab or Gazyva, lenalidomide plus rituximab with or without Epkinly (epcoritamab-bysp subcutaneous injection) or Monjuvi (tafasitamab-cxix intravenous infusion), bendamustine plus Gazyva or rituximab, or Tazverik (tazemetostat tablets). MANTLE CELL LYMPHOMA- all of (A and B): A. Tried at least one covalent Bruton tyrosine kinase inhibitor, Note: Examples of a covalent Bruton tyrosine kinase inhibitors include Brukinsa (zanubrutinib capsules and tablets), Calquence (acalabrutinib tablets), and Imbruvica (ibrutinib capsules, oral suspension, and tablets). AND B. Medication will be used in combination with Polivy (polatuzumab vedotin-piiq intravenous infusion) .
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Mantle cell lymphoma
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

LUPRON DEPOT

Products Affected

- LUPRON DEPOT

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 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 disorders including premenstrual syndrome and premenstrual dysphoric disorder, prophylaxis or treatment of uterine bleeding or menstrual

PA Criteria	Criteria Details
	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
Prerequisite Therapy Required	Yes

LYNOZYFIC

Products Affected

- LYNOZYFIC

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 or hematologist
Coverage Duration	1 year
Other Criteria	MULTIPLE MYELOMA-all of the following (A and B): A) Tried at least four systemic regimens, AND B) Among the previous regimens tried, the patient has received at least one drug from each of the following classes (i, ii, and iii): i. Proteasome inhibitor, Note: Examples include bortezomib, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules) AND ii. Immunomodulatory drug, Note: Examples include lenalidomide, pomalidomide, Thalomid (thalidomide capsules) AND iii. Anti-CD38 monoclonal antibody, Note: Examples include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), or Sarclisa (isatuximab-irfc intravenous infusion).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LYNPARZA

Products Affected

- LYNPARZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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 BRCA mutation-positive disease 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, 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 (i or ii): i) germline BRCA mutation-positive breast cancer or ii) germline PALB2 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 patient meets either (i or ii): i) the

PA Criteria	Criteria Details
	patient has homologous recombination repair (HRR) gene-mutated disease, 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 at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Uterine Leiomyosarcoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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, gross residual, or metastatic disease, tumor has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements 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
Prerequisite Therapy Required	Yes

MAVYRET

Products Affected

- MAVYRET ORAL PELLETS IN PACKET
- MAVYRET ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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)*
- *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
Prerequisite Therapy Required	No

MEKINIST

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Melanoma (not including uveal melanoma)- must be used in patients with BRAF V600 mutation or BRAF fusion-positive, 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. Uveal melanoma - approve if metastatic or unresectable disease. For NSCLC - approve if (A, B and C): A) recurrent, advanced or metastatic disease and B) pt has BRAF V600 Mutation and C) pt will use in combination with Tafinlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafinlar 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 (a or b): a) low-grade serous carcinoma or b) the patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafinlar. Glioma-patient meets (A and B): A) has BRAF V600 mutation positive or BRAF fusion-positive disease and B) meets (i or ii): i) the medication will be used in combination with Tafinlar or ii) pt has circumscribed glioma. Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis or Erdheim Chester disease or Rosai-Dorfman disease. Solid Tumors [Note: Examples of solid tumors are: biliary tract cancer, brain metastases

PA Criteria	Criteria Details
	due to melanoma, differentiated thyroid carcinoma, gastrointestinal stromal tumors, gastric cancer, esophageal and esophagogastric junction cancers, salivary gland tumors, pancreatic adenocarcinoma, neuroendocrine tumors, occult primary, ampullary adenocarcinoma, small bowel adenocarcinoma]- Approve if the patient meets the following (A and B): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafinlar (dabrafenib capsules). 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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Histiocytic Neoplasm, Hairy Cell Leukemia, Epithelioid Hemangioendothelioma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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	Authorization will be for 1 year.
Other Criteria	Melanoma - approve if the patient meets (A and B): A) has unresectable, advanced or metastatic melanoma AND B) meets (i or ii): i) has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi or ii) has NRAS mutation AND has tried at least one immune checkpoint inhibitor therapy. Histiocytic neoplasm-approve if the patient has Langerhans cell histiocytosis. NSCLC-approve if pt has BRAF V600E mutation-positive recurrent, advanced or 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, NRAS-mutated unresectable, advanced or metastatic melanoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MEMANTINE - DONEPEZIL/MEMANTINE

Products Affected

- *memantine-donepezil*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

MEMANTINE - MEMANTINE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Indication for which memantine is being prescribed.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with mild to moderate vascular dementia.
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEPSEVII

Products Affected

- MEPSEVII

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

METHYLERGONOVINE

Products Affected

- *methylergonovine oral*

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

MODAFINIL

Products Affected

- *modafinil oral tablet 100 mg, 200 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	Excessive daytime sleepiness associated with narcolepsy/idiopathic hypersomnia-prescribed by or in consultation with a sleep specialist physician or neurologist
Coverage Duration	1 year
Other Criteria	Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD)-approve. 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-approve. Excessive daytime sleepiness associated with Narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Idiopathic hypersomnia - approve if the pt has been evaluated using polysomnography and a multiple sleep latency test and the results are congruent with a diagnosis of idiopathic hypersomnia.
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, idiopathic hypersomnia
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MODEYSO

Products Affected

- MODEYSO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	HIGH-GRADE GLIOMA (Note: Examples of high-grade glioma include World Health Organization (WHO) Grade 3 or 4 gliomas, such as diffuse midline glioma or glioblastoma)-all the following (A, B and C): A) Histone 3 (H3) K27M mutation, AND B) Recurrent or progressive disease, AND C) Received at one least prior therapy. Note: Examples of prior therapy include radiation, temozolomide, procarbazine, lomustine, or vincristine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MONJUVI

Products Affected

- MONJUVI

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	Diffuse large B-Cell Lymphoma - Approve if the patient has been treated with at least one prior chemotherapy regimen and the medication will be used in combination with lenalidomide. B-cell lymphoma-Approve if the patient has been treated with at least one prior chemotherapy regimen and the medication will be used in combination with lenalidomide. Follicular lymphoma - approve if pt meets (A and B): A) pt has been treated with at least one prior systemic regimen and B) medication will be used in combination with lenalidomide and rituximab.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	B-Cell Lymphoma (Examples include high-grade B-cell lymphoma, HIV-related B-cell lymphoma, post-transplant lymphoproliferative disorders, histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma)
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MYFEMBREE

Products Affected

- MYFEMBREE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, test results (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	Fibroids-Prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health
Coverage Duration	24 months of total therapy between Myfembree or Oriahnn
Other Criteria	Uterine Fibroids (Leiomyomas)-approve if the patient is premenopausal (before menopause) and is experiencing heavy menstrual bleeding associated with the uterine fibroids, the uterine fibroids have been confirmed by a pelvic ultrasound, including transvaginal ultrasonography or sonohysterography, hysteroscopy, or magnetic resonance imaging. Endometriosis-approve if the patient is premenopausal and patient has previously tried one of the following (i or ii): i. A contraceptive (e.g., combination oral contraceptives, levnorgestrel-releasing intrauterine systems, a depo-medroxyprogesterone injection), unless contraindicated OR ii. An oral progesterone (e.g., norethindrone tablets), unless contraindicated.Note: An exception to this requirement can be made if the patient has previously used a gonadotropin-releasing hormone agonist (e.g., Lupron Depot [leuprolide depot suspenion]) or Orilissa (elagolix tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

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
Prerequisite Therapy Required	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
Prerequisite Therapy Required	Yes

NEMLUVIO

Products Affected

- NEMLUVIO

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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	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 HER2 positive disease-approve if the patient has HER-2 positive breast cancer, and patient meets (i or ii): i) Nerlynx will be used in combination with capecitabine and the patient has tried at least two prior anti-HER2 based regimens OR ii) the medication is used in combination with one of the following: capecitabine, paclitaxel, or Kadcyla (ado-traztuzumab emtansine intravenous infusion) and the patient has brain metastases. Breast Cancer, Recurrent or Metastatic HER2 Negative Disease: Approve if pt meets (A, B, C and D): A) has HER2-negative breast cancer AND B) cancer has a HER2-activating mutation AND C) meets (i or ii): i) Pt is a postmenopausal female or a male OR ii) pre/perimenopausal female and meets (a or b): a) receiving ovarian suppression/ovarian ablation with a gonadotropin-releasing hormone (GnRH) agonist OR b) has had surgical bilateral oophorectomy or ovarian irradiation AND D) meets (i or ii): i) meets (a and b): a) has hormone receptor (HR)-positive disease AND b) has tried at least one CDK4/6 inhibitor therapy OR ii) has (HR)-negative disease. Cervical Cancer:

PA Criteria	Criteria Details
	Approve if patient meets (A, B and C): A) HER2-mutant disease AND B) recurrent or metastatic disease AND C) tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Breast Cancer - Recurrent or Metastatic HER2 Negative Disease, Cervical Cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NEXLETOL

Products Affected

- NEXLETOL

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

NILOTINIB

Products Affected

- DANZITEN
- *nilotinib hcl oral capsule 150 mg, 200 mg, 50 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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-approve. CML, philadelphia chromosome positive or BCR::ABL1-mutation positive or chronic myeloid leukemia- approve. For GIST, approve if the patient has tried two of the following: imatinib, sunitinib, regorafinib 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 Romvimza or cannot take Turalio or Romvimza, 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

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

NILUTAMIDE

Products Affected

- *nilutamide*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Prostate cancer-approve if nilutamide is used in beneficiaries who have had surgical castration or in combination with a luteinizing hormone-releasing hormone (LHRH) agonist.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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 - approve if (A, B, C or D): A) this medication will be used in combination with lenalidomide or cyclophosphamide and dexamethasone, OR B) pt had received at least ONE prior regimen for multiple myeloma OR C) this medication will be used following hematopoietic stem cell transplantation or D) the patient is not a candidate for bortezomib or Kyprolis (carfilzomib intravenous infusion) and is also not a transplant candidate. 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

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

NINTEDANIB

Products Affected

- *nintedanib*
- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

NITISINONE

Products Affected

- *nitisinone*

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

NIVESTYM

Products Affected

- NIVESTYM

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

NON-INJECTABLE TESTOSTERONE PRODUCTS - TESTOSTERONE

Products Affected

- *testosterone transdermal gel*
- *testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1 %), 20.25 mg/1.25 gram (1.62 %)*
- *testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram)*
- *testosterone transdermal solution in metered pump w/app*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.
Coverage Duration	1 year
Other Criteria	Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-

PA Criteria	Criteria Details
	approve.Note: For a patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).
Part B Prerequisite	No
Prerequisite Therapy Required	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 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
Prerequisite Therapy Required	Yes

NUCALA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

NUEDEXTA

Products Affected

- *dextromethorphan-quinidine*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

NUPLAZID

Products Affected

- NUPLAZID

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

NURTEC

Products Affected

- NURTEC ODT

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

NYVEPRIA

Products Affected

- NYVEPRIA

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

OCTREOTIDE INJECTABLE

Products Affected

- *octreotide acetate*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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 or 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.) Diffuse Basal Cell Carcinoma Formation, including basal cell nevus syndrome (Gorlin syndrome) or other genetic forms of multiple basal cell carcinoma - approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Metastatic BCC, diffuse basal cell carcinoma formation
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

OGSIVEO

Products Affected

- OGSIVEO ORAL TABLET 100 MG, 150 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Desmoid tumors (aggressive fibromatosis)-approve if the patient has progressing desmoid tumors and if the patient requires systemic treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

OJEMDA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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
Prerequisite Therapy Required	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 (A, B or C): A) higher-risk disease, or B) lower-risk disease and has one disease-related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis), or C) myelofibrosis-associated anemia. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease- related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis). Myeloid or Lymphoid Neoplasms - Approve if patient has eosinophilia, has tried Jakafi (ruxolitinib tablets), and the tumor has a Janus Associated Kinase 2 (JAK2) rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Accelerated or blast phase myeloproliferative neoplasm, myeloid or lymphoid neoplasms
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ONUREG

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

OPDIVO

Products Affected

- OPDIVO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	colon/rectal/melanoma-12 years and older, pediatric diffuse high-grade glioma/pediatric hodgkin lymphoma-less than 18 years old, All other (except gestational trophoblastic)-18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	anal carcinoma, cervical carcinoma, endometrial carcinoma, extranodal NK/T-Cell Lymphoma, gestational trophoblastic neoplasia, merkel cell carcinoma, neuroendocrine tumors, small bowel adenocarcinoma, small cell lung cancer, vulvar cancer, ampullary adenocarcinoma, bone cancer, pediatric diffuse high-grade gliomas, Kaposi sarcoma, primary mediastinal large B-cell lymphoma, biliary tract cancers, soft tissue sarcoma, chronic lymphocytic leukemia/small lyphocytic lymphoma, pancreatic cancer, squamous cell skin carcinoma, thyroid carcinoma, vaginal cancer
Part B Prerequisite	No
Prerequisite Therapy Required	No

OPDIVO QVANTIG

Products Affected

- OPDIVO QVANTIG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (all diagnoses except gestational trophoblastic neoplasia)
Prescriber Restrictions	Prescribed by or on consultation with an oncologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	appendiceal cancer, ampullary adenocarcinoma, anal carcinoma, biliary tract cancers, bone cancer, cervical cancer, chronic lymphocytic leukemia/small lymphocytic lymphoma, endometrial carcinoma, gestational trophoblastic neoplasia, Kaposi sarcoma, merkel cell carcinoma, mesothelioma, neuroendocrine tumors, small bowel adenocarcinoma, small cell lung cancer, squamous cell skin carcinoma, thyroid carcinoma, vaginal cancer, vulvar cancer
Part B Prerequisite	No
Prerequisite Therapy Required	No

OPDUALAG

Products Affected

- OPDUALAG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Melanoma-approve if the patient is greater than or equal to 40 kg and either (i or ii): (i) the patient has unresectable or metastatic disease or (ii) medication is used as neoadjuvant therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

OPSUMIT

Products Affected

- *macitentan*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	PAH WHO group, right heart catheterization results
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 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
Prerequisite Therapy Required	No

ORENITRAM

Products Affected

- ORENITRAM MONTH 1 TITRATION KT
- ORENITRAM MONTH 2 TITRATION KT
- ORENITRAM MONTH 3 TITRATION KT
- ORENITRAM ORAL TABLET EXTENDED RELEASE 0.125 MG, 0.25 MG, 1 MG, 2.5 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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
Prerequisite Therapy Required	No

ORKAMBI

Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

ORSERDU

Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

OTEZLA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

PADCEV

Products Affected

- PADCEV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	BLADDER CANCER - Approve if the patient meets one (A or B): A) has muscle invasive bladder cancer and meets both (i and ii): i. the medication is used in combination with Keytruda (pembrolizumab intravenous infusion) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph intravenous infusion) and ii. the medication is used as neoadjuvant or adjuvant therapy OR B) has locally advanced or metastatic disease and meets one (i or ii): i. the medication is used as first-line in combination with Keytruda (pembrolizumab intravenous infusion) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph intravenous infusion) or ii. the medication is used as subsequent therapy. HEAD AND NECK CANCERS - Approve if patient meets both (A and B): A) has non-nasopharyngeal disease AND B) has progressed on or after platinum therapy and a programmed death receptor 1 (PD-1)/ programmed death-ligand 1 (PD-L1) inhibitor.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	head and neck cancers
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

PANRETIN

Products Affected

- PANRETIN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist, oncologist, or infectious disease specialist
Coverage Duration	1 year
Other Criteria	Kaposi Sarcoma-approve if the patient is not receiving systemic therapy for Kaposi Sarcoma.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PAVBLU

Products Affected

- PAVBLU

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with another intravitreal vascular endothelial growth factor inhibitor
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Administered by or under the supervision of an ophthalmologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	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, gross residual, or metastatic disease and the tumor has a fibroblast growth factor receptor 2 (FGFR2) gene fusion or other rearrangement 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PENICILLAMINE

Products Affected

- *penicillamine oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

PHENYLBUTYRATE - PHENYLBUTYRATE

Products Affected

- *sodium phenylbutyrate*

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 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
Prerequisite Therapy Required	No

PHEOCHROMOCYTOMA - METYROSINE

Products Affected

- *metyrosine*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

PHOSPHATE BINDERS AND SIMILAR AGENTS - CALCIUM ACETATE

Products Affected

- *calcium acetate(phosphat bind)*

PA Criteria	Criteria Details
Exclusion Criteria	Patients on dialysis [non-D use].
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PHOSPHATE BINDERS AND SIMILAR AGENTS - SEVELAMER

Products Affected

- *sevelamer carbonate oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	Patients on dialysis [non-D use].
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PHOSPHODIESTERASE-5 INHIBITORS - SILDENAFIL

Products Affected

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

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), are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Raynaud's Phenomenon-approve if the patient has tried one calcium channel blocker or if use of a calcium channel blocker is contraindicated. Clinical criteria incorporated into the quantity limit edits requires confirmation that the indication is PAH or Raynaud's prior to reviewing for quantity exception.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Raynaud's Phenomenon
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PHOSPHODIESTERASE-5 INHIBITORS - TADALAFIL

Products Affected

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

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), are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Raynaud's Phenomenon-approve if the patient has tried one calcium channel blocker or if use of a calcium channel blocker is contraindicated.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Raynaud's Phenomenon
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PIQRAY

Products Affected

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

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

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

PIRFENIDONE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

POLIVY

Products Affected

- POLIVY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	6 months
Other Criteria	Diffuse large B-cell lymphoma-Approve if the patient has International Prognostic Index score of greater than or equal to 2 and will use Polivy as first line therapy OR the patient has been treated with at least one prior chemotherapy regimen. Note: Diffuse large B-cell lymphoma includes histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma. B-Cell Lymphoma (Examples include HIV-related B-cell lymphoma and post-transplant lymphoproliferative disorders) - approve if the patient has an International Prognostic Index score of at least 2 or has been treated with at least one prior chemotherapy regimen. High-Grade B-Cell Lymphoma - Approve. Burkitt Lymphoma - approve if the medication is used as subsequent therapy, and in combination with Columvi (glotitamab intravenous infusion), and as a bridge for allogeneic hematopoietic cell transplant. Mantle Cell Lymphoma - approve if patient has received at least one covalent Bruton tyrosine kinase inhibitor and the medication will be used in combination with Lunsumio Velo (mosunetuzumab-axgb subcutaneous injection).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	B-Cell Lymphoma, Burkitt Lymphoma, Mantle Cell Lymphoma
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

POMALYST

Products Affected

- *pomalidomide*
- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Kaposi Sarcoma/MM/Systemic light chain amyloidosis-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Primary CNS Lymphoma-approve if the patient has relapsed or refractory disease or is not a candidate for high-dose MTX or had intolerance to high-dose MTX. Kaposi Sarcoma-Approve if the patient meets one of the following (i or ii): i. tried at least one other medication OR ii. has Kaposi sarcoma-associated herpesvirus (KSHV)-associated inflammatory cytokine syndrome. MM-approve if the patient has tried at least one other regimen. Systemic light chain amyloidosis- approve if this is used in combination with dexamethasone and pt tried at least one other regimen. In addition, patients new to therapy requesting brand name Pomalyst must have a trial of pomalidomide prior to approval of brand.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Systemic Light Chain Amyloidosis, Primary Central Nervous System (CNS) Lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

POSACONAZOLE (ORAL)

Products Affected

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

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

POTELIGEO

Products Affected

- POTELIGEO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Mycosis fungoides/Sezary-prescribed by, or in consultation with an oncologist or dermatologist. ATLL-prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Mycosis Fungoides/Sezary Syndrome-Approve. ATLL- approve if pt meets (A and B): A) pt has chronic high risk, acute, or lymphoma subtypes, and B) medication is used as second-line or subsequent therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Adults with T-cell leukemia/lymphoma (ATLL)
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PREVYMIS

Products Affected

- PREVYMIS INTRAVENOUS
- PREVYMIS ORAL TABLET 240 MG, 480 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

PROMACTA

Products Affected

- *eltrombopag olamine*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

PYRIMETHAMINE

Products Affected

- *pyrimethamine*

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 infectious disease specialist or a physician specializing in the treatment of human immunodeficiency virus (HIV) infection
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis, chronic maintenance and prophylaxis of cystoisosporiasis, chronic maintenance and prophylaxis of Pneumocystis pneumonia
Part B Prerequisite	No
Prerequisite Therapy Required	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, AND the patient meets one of the following criteria (i or ii): i. Patient has tried sunitinib and regorafenib tablets, OR ii. 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
Prerequisite Therapy Required	Yes

RADICAVA ORS

Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT SUSP

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

RECLAST

Products Affected

- *zoledronic acid-mannitol-water intravenous piggyback 5 mg/100 ml*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Medications for Osteoporosis (e.g., other bisphosphonates, Evenity, Prolia, Forteo/Bonsity, Tymlos, calcitonin nasal spray)
Required Medical Information	Tx of osteoporosis in post menopausal patient, must meet ONE of the following: pt had an inadequate response after 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had an osteoporotic fracture or fragility fracture while receiving therapy or pt experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects), OR pt cannot take oral bisphosphonate because pt cannot swallow or has difficulty swallowing or pt cannot remain in upright position post oral bisphos adminor pt has pre-existing GI medical condition (eg, pt with esophageal lesions/ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has had an osteoporotic fracture or a fragility fracture OR pt has tried IV bisphosphonate (ibandronate or zoledronic acid) OR pt has very low T-score less than -3.0.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Paget's 1 month. Others 12 months.
Other Criteria	Tx of osteo in men (a man defined as an individual with biological traits of man, regardless of the individual's gender identity/gender expression), must meet ONE of the following: pt had inadequate response after 12 mo (eg,ongoing and sign loss of BMD, lack of BMD increase) or pt had osteo fracture or fragility fracture while receiving therapy or pt experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because pt cannot swallow or has difficulty swallowing or pt cannot remain in upright position post oral bisphos admin or pt has pre-existing GI condition (eg, pt with esophageal lesions/ulcers, or abnormal of

PA Criteria	Criteria Details
	the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt had an osteo fracture or a fragility fracture OR pt has tried IV Reclast (zoledronic acid). Prevent or tx of GIO, approve if: pt is initiating or cont therapy with systemic glucocorticoids, AND had an inadequate response after 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had an osteo fracture or fragility fracture while on therapy or pt experienced intol (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because pt cannot swallow or has difficulty swallowing or pt cannot remain in an upright position post oral bisphos administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), or has tried Reclast OR patient had an osteo fracture or a fragility fracture. Tx of Paget's disease, approve if pt has elevations in serum alkaline phos of two times higher than the upper limit of the age-specific normal reference range, OR pt is symptomatic (eg,bone pain, hearing loss, osteoarthritis), OR pt is at risk for complications from their disease (eg,immobilization, bone deformity, fractures, nerve compression syndrome). Prevent of PMO - meets 1 of the following had inadequate response after trial duration of 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had osteo fracture or fragility fracture while receiving therapy or patient experienced intol (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphos admin or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions/ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried Reclast or the patient has had an osteo fracture or fragility fracture.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

REMICADE

Products Affected

- INFLIXIMAB
- REMICADE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medication, previous medications tried
Age Restrictions	CD/UC/Behcet's/GVHD/JIA/UV - Pts aged 6 years or more (initial therapy). AS/PsA/RA/HS/PG/Sarcoidosis/Scleritis, sterile corneal ulceration/Still's/PP-18 years and older (initial therapy)
Prescriber Restrictions	All dx-initial therapy only-Prescribed by or in consult w/RA/AS/Still's/JIA/JRA-rheumatol.Plaque Psor/Pyoderma gangrenosum/HS-dermatol.Psoriatic Arthritis-rheumatol or dermatol.CD/UC-gastroenterol.Uveitis/scleritis, sterile corneal ulceration-ophthalmol.GVHD-transplant center, oncol, or hematol.Behcet's-rheumatol, dermatol,ophthalmol, gastroenterol, or neurol.Sarcoidosis-pulmonol, ophthalmol, or dermatol, cardio/neuro.
Coverage Duration	Init:GVHD1mo,PG4mo,Scler6mo,Other3mo.Cont:GVHD3mo,Other1yr
Other Criteria	INITIAL THERAPY: RHEUMATOID ARTHRITIS: tried one conventional synthetic DMARD for at least 3 months (e.g., MTX, leflunomide, hydroxychloroquine, sulfasalazine. 3-month trial of a biologic also counts). CROHN'S DISEASE: approve. ULCERATIVE COLITIS: approve. BEHCET'S (A or B): A) tried one conventional therapy (e.g., systemic CS, immunosuppressants such as AZA, MTX, mycophenolate, CSA, tacrolimus, chlorambucil, cyclophosphamide, interferon alfa. TNF inhibitor also counts.) or B) ophthalmic manifestations. STILL'S DISEASE (A and B): A) tried one CS and B) tried one DMARD for at least 2 months or intolerant (e.g., MTX. Trial of a biologic also counts.) UVEITIS: tried periocular, intraocular or systemic CS or immunosuppressive (e.g., MTX, mycophenolate, CSA. Trial of a biologic also counts.) SARCOIDOSIS (A and B): A) tried one CS and B) tried one immunosuppressant (e.g., MTX, AZA, leflunomide, mycophenolate, hydroxychloroquine, chloroquine.) PYODERMA GANGRENOSUM (A or B): A) tried one systemic CS or B)

PA Criteria	Criteria Details
	tried one immunosuppressant for at least 2 months or intolerant (e.g., mycophenolate, CSA). HIDRADENITIS SUPPURATIVA: Tried one other therapy (e.g., intralesional or oral CS, systemic antibiotics, isotretinoin). GRAFT VS HOST DISEASE: Tried one conventional systemic treatment (e.g., CS, antithymocyte globulin, CSA, tacrolimus, mycophenolate.) JUVENILE IDIOPATHIC ARTHRITIS: (A or B): A) tried one systemic medication (e.g., MTX, sulfasalazine, leflunomide, NSAID. Trial of a biologic also counts.) or B) has aggressive disease. PLAQUE PSORIASIS (A or B): A) tried at least one traditional systemic agent (e.g., MTX, cyclosporine (CSA), acitretin, PUVA) for at least 3 months, unless intolerant (Trial of a biologic will also count) or B) contraindication to MTX. SCLERITIS/STERILE CORNEAL ULCERATION: tried one other therapy for this condition (e.g., oral non-steroidal anti-inflammatory drugs (NSAIDs), oral, topical (ophthalmic), or intravenous corticosteroids, MTX, CSA, or other immunosuppressants). CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Behcet's disease (BD). Still's disease (SD). Uveitis (UV). Pyoderma gangrenosum (PG). Hidradenitis suppurativa (HS). Graft-versus-host disease (GVHD). Juvenile Idiopathic Arthritis (JIA)/JRA, Sarcoidosis, Scleritis/ sterile corneal ulceration
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

REMODULIN

Products Affected

- *treprostinil sodium*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Oral or Inhaled Prostacyclin Agents Used for Pulmonary Hypertension.
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	PAH WHO Group 1, prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation).
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Pulmonary Arterial Hypertension (PAH) [World Health Organization (WHO) Group 1], Initial Therapy-Approve if the patient meets all of the following criteria (i, ii, iii, and iv): i. Patient has a diagnosis of WHO Group 1 PAH, AND ii. Patient meets the following criteria (a and b): a) Patient has had a right heart catheterization, AND b) Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH, AND iii. Patient meets ONE of the following criteria (a or b): a) Patient is intermediate-high risk or high risk OR b) Patient is low-risk or intermediate-low risk and has tried or is currently receiving at least one agent for PAH from the following different categories (either alone or in combination) for at least 60 days: PDE5 inhibitors or endothelin receptor antagonists or Adempas (riociguat tablets) or Winrevair (sotatercept-csrk subcutaneous injection) or prostacyclin inhibitors AND iv. Patient with idiopathic PAH must meet ONE of the following criteria (a, b, c, d, or e): a) Patient meets both of the following criteria [(1) and (2)]: (1) the patient has had an acute response to vasodilator testing that occurred during the right heart catheterization, AND (2) Patient has tried one calcium channel blocker (CCB) therapy, OR b) According to the prescriber, the patient did not have an acute response to vasodilator testing, OR c) the patient cannot undergo a vasodilator test, OR d) Patient cannot take CCB therapy, OR e) Patient has tried one CCB. Continuation-Approve

PA Criteria	Criteria Details
	if the patient meets ALL of the following conditions (a and b): a) Patient has a diagnosis of WHO Group 1 PAH, AND b) Patient meets the following criteria [(1) and (2)]: (1) Patient has had a right heart catheterization, AND (2) Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

REPATHA

Products Affected

- REPATHA
- REPATHA SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

RETEVMO

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Medullary Thyroid Cancer/Thyroid Cancer/Solid tumors-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, ii or iii: i. patient has anaplastic thyroid cancer OR ii. the disease requires treatment with systemic therapy and patient has medullary thyroid cancer or iii. the disease requires treatment with systemic therapy and the disease is radioactive iodine-refractory if radioactive iodine is appropriate. 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

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

REVCOVI

Products Affected

- REVCOVI

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

REVUFORJ

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	ACUTE LEUKEMIA-patient has relapsed or refractory disease and either (i or ii): i) acute myeloid leukemia and either (a or b): a) the disease is positive for a lysine methyltransferase 2A (KMT2A) gene translocation or rearrangement or b) the disease is positive for a susceptible nucleophosmin 1 (NPM1) mutation, OR ii) acute lymphoblastic leukemia and disease is positive for a lysine methyltransferase 2A (KMT2A) gene translocation or rearrangement.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZDIFFRA

Products Affected

- REZDIFFRA

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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 isocitrate dehydrogenase-1 (IDH1) mutation positive disease and meets (A or B): A) relapsed or refractory disease OR B) meets all (i, ii, and iii): i) not a candidate for intensive induction therapy and ii) not a candidate for azacitidine, decitabine, or Venclexta (venetoclax tablets) and iii) not a candidate for Tibsovo (ivosidenib tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZUROCK

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial therapy)
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Graft-versus-host disease, initial-approve if the patient has chronic graft-versus-host disease and has tried at least two systemic medications (examples: Jakafi [ruxolitinib], Niktimvo [axatilimab-csfr], ibrutinib) for chronic graft-versus-host disease. Graft-versus-host disease, continuation-approve it patient has demonstrated a beneficial clinical response.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RILUZOLE

Products Affected

- *riluzole*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

RINVOQ

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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
Prerequisite Therapy Required	Yes

ROFLUMILAST (ORAL)

Products Affected

- *roflumilast*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

ROMVIMZA

Products Affected

- ROMVIMZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	TENOSYNOVIAL GIANT CELL TUMOR (PIGMENTED VILLONODULAR SYNOVITIS)-tumor is not amenable to improvement with surgery.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ROZLYTREK

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	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 patient's 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
Prerequisite Therapy Required	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 (A, B and C): A) the patient is in complete or partial response after a platinum-based chemotherapy regimen, and B) meets (i or ii): i) the patient is in complete or partial response to first-line primary treatment or ii) patient has recurrent disease and has a BRCA mutation, and C) for new starts, the patient has tried the preferred product Lynparza, unless the prescriber indicates that Lynparza is inappropriate for the patient's specific clinical situation. 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 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) for new starts, the patient has tried one of the preferred products, Lynparza or Talzenna, unless the prescriber indicates that both Lynparza and Talzenna are inappropriate for the patient's specific clinical situation. 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 at least one systemic regimen.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Uterine Leiomyosarcoma, Pancreatic Adenocarcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RUFINAMIDE

Products Affected

- *rufinamide*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

RUXIENCE

Products Affected

- RUXIENCE

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

RYBREVANT

Products Affected

- RYBREVANT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - approve if pt has locally advanced or metastatic disease AND either (A, B or C): (A) the pt has epidermal growth factor receptor (EGFR) exon 20 insertion mutations, or B) EGFR exon 19 deletion, or C) EGFR exon 21 L858R mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

RYBREVANT FASPRO

Products Affected

- RYBREVANT FASPRO

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. NON-SMALL CELL LUNG CANCER-locally advanced or metastatic disease and ONE of the following: epidermal growth factor receptor (EGFR) exon 20 insertion mutations, EGFR exon 19 deletions, or EGFR exon 21 L858R substitution mutations.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	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. Myeloid or lymphoid Neopasms with eosinophilia-approve if the patient has an FGFR1 rearrangement or has an FLT3 rearrangement. systemic mastoytosis-indolent- pt has symptomatic disease and has tried at least one systemic regimen. systemic mastocytosis-smoldering - pt has tried at least one systemic regimen. Systemic Mastocytosis - KIT D816V-Negative-Approve if the pt meets both (A and B): A) has advanced systemic mastocytosis AND B) does not have alternative KIT mutations in exons 8-11.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid or lymphoid Neopasms with eosinophilia, indolent systemic mastocytosis, smoldering systemic mastocytosis, systemic mastocytosis - KIT D816V-negative
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RYTELO

Products Affected

- RYTELO

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 a hematologist or oncologist (initial)
Coverage Duration	1 year
Other Criteria	INITIAL THERAPY: MYELODYSPLASTIC SYNDROME-All of (i, ii, iii and iv): i.Very low- to intermediate risk myelodysplastic syndrome (MDS), Note: MDS risk category is determined using the International Prognostic Scoring System (IPSS). AND, ii. Patient does not have a confirmed mutation with deletion 5q [del(5q)], AND iii. Patient has symptomatic anemia AND, iv. Rytelo will NOT be used in combination with an ESA.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

SANDOSTATIN LAR

Products Affected

- *octreotide,microspheres*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous treatments/therapies
Age Restrictions	N/A
Prescriber Restrictions	Acromegaly-prescr/consult w/endocrinologist. All neuroendocrine tumors-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist or neurosurgeon. Merkel cell/Thymoma/Thymic carcinoma-prescr/consult w/oncologist. Diarrhea assoc w chemo-presc/consult oncologist/gastro. Small bowel bleed/angiodysplasia-presc/consult gastroenterologist.
Coverage Duration	Enterocutaneous fistula/diarrhea chemo - 3 months, small bowel bleed - 6 mos, all others - 1 year
Other Criteria	Acromegaly-approve if the patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Diarrhea assoc w chemo (A and B): A) grade 3 or 4 diarrhea [Examples: more than 6 bowel movements above baseline per day, colitis symptoms, interference with activities of daily living, hemodynamic instability, hospitalization, serious complications (eg, ischemic bowel, perforation, toxic mega-colon), or other colitis-related life-threatening conditions] and B) patient has tried at least one antimotility medication. Merkel cell carcinoma (A and B): A) patient has regional or distant metastatic disease and B) has contraindications to or has progressed on a programmed death-ligand 1 (PD-L1) or programmed death-1 (PD-1) inhibitor. Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including

PA Criteria	Criteria Details
	glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas)-approve. Small bowel bleeds/ angiodysplasia related bleeding: pt has chronic, recurrent gastrointestinal bleeds lasting greater than or equal to 3 months.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pheochromocytoma/paraganglioma, Meningioma, Thymoma and thymic carcinoma, enterocutaneous fistulas, diarrhea associated with chemotherapy, Merkel cell carcinoma, small bowel bleeds/angiodysplasia related bleeding
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SAPROPTERIN

Products Affected

- *sapropterin*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Palynziq at a stable maintenance dose (concurrent use during Palynziq dose titration is permitted). Concurrent use with sepiapterin (Sephience).
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
Prerequisite Therapy Required	No

SARCLISA

Products Affected

- SARCLISA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Multiple myeloma-approve if pt meets (A, B, or C): A) the requested medication will be used as primary therapy in combination with (i or ii): i) lenalidomide and dexamethasone with or without bortezomib, or ii) Kyprolis (carfilzomib intravenous infusion), lenalidomide, and dexamethasone, or B) the requested medication will be used in combination with pomalidomide and dexamethasone and the patient has tried at least TWO prior regimens for multiple myeloma and a proteasome inhibitor was a component of at least one previous regimen and lenalidomide was a component of at least one previous regimen, or C) medication will be used in combination with Kyprolis and dexamethasone and pt has tried at least one prior regimen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SCEMBLIX

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Chronic Myeloid Leukemia (CML)-approve if the patient meets the following (A and B): A) Patient has Philadelphia chromosome-positive or BCR::ABL1-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. Note: Examples of tyrosine kinase inhibitors include imatinib, Bosulif (bosutinib tablets), Iclusig (ponatinib tablets), dasatinib, and nilotinib capsules. Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has an ABL1 rearrangement. Acute lymphoblastic leukemia (ALL)- approve if the pt has Philadelphia chromosome-positive ALL and this medication will be used in combination with dasatinib.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid/Lymphoid Neoplasms with Eosinophilia, Acute Lymphoblastic Leukemia (ALL)
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

SIGNIFOR

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

SIRTURO

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	Patients weighing less than 8 kg
Required Medical Information	Diagnosis, concomitant therapy
Age Restrictions	Patients 2 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with an infectious diseases specialist or pulmonologist
Coverage Duration	6 months
Other Criteria	Tuberculosis (Pulmonary) -Approve if the patient has 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
Prerequisite Therapy Required	Yes

SKYRIZI

Products Affected

- SKYRIZI SUBCUTANEOUS PEN INJECTOR
- SKYRIZI SUBCUTANEOUS SYRINGE 150 MG/ML, 55 MG/0.37 ML
- SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR 180 MG/1.2 ML (150 MG/ML), 360 MG/2.4 ML (150 MG/ML)

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

SKYRIZI IV

Products Affected

- SKYRIZI INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis, Previous medication use
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	Approve for 3 doses
Other Criteria	Crohn's Disease- approve if this medication will be used as induction therapy. Ulcerative colitis- approve if this medication will be used as induction therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

SOMAVERT

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

SORAFENIB

Products Affected

- *sorafenib*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	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, sunitinib, ripretinib or regorafenib. Differentiated thyroid carcinoma (DTC), approve if the patient meets (A or B): A) has papillary or follicular thyroid carcinoma and the disease is refractory to radioactive iodine treatment or B) has oncocytic (formerly Hurthle cell) carcinoma. 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

PA Criteria	Criteria Details
	for all diagnoses: 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	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
Prerequisite Therapy Required	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	Diagnosis
Age Restrictions	MDD w acute suicidal ideation or behavior: 18 years and older. TRD, initial therapy only: 18 years and older
Prescriber Restrictions	MDD w acute suicidal ideation or behavior: Prescribed by a psychiatrist or mental health provider. TRD, intial only: Prescribed by a psychiatrist or mental health provider
Coverage Duration	MDD w/Acute Suicidal Ideation or Behavior - 2 mo, TRD - 6 mo (init), 1 yr (cont)
Other Criteria	Major Depressive Disorder with Acute Suicidal Ideation or Behavior: approve if the patient has major depressive disorder that is considered to be severe, AND if the patient is concomitantly receiving at least one oral antidepressant, AND the patient has no history of psychosis or has a history of psychosis but the prescriber believes that the benefits of Spravato outweigh the risks. Treatment-Resistant Depression, initial: approve if the 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 and each antidepressant was used at therapeutic dosages for at least 6 weeks in the current episode of depression, AND the patient has no history of psychosis or has a history of psychosis but the prescriber believes that the benefits of Spravato outweigh the risks, AND patient's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP). Treatment-Resistant Depression, continuation: approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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

SPRYCEL

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis 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 or BCR::ABL1-positive CML. For ALL, patient must have Ph-positive ALL or ABL-class translocation. For Bone Cancer-approve if patient has chondrosarcoma or chordoma. GIST - approve if the patient has tried 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
Prerequisite Therapy Required	Yes

STIVARGA

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For GIST, (A or B): A) patient has previously been treated with (i and ii): i) imatinib and ii) (a or b): a) sunitinib, or b) is intolerant to sunitinib and has tried Quinlock (ripretinib tablets), OR B) medication is used for succinate dehydrogenase (SDH)-deficient disease. 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 borderline/malignant phyllodes tumor of the breast, epithelioid hemangioendothelioma, 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 or mesencymal chondrosarcoma. Colon, Rectal or Appendiceal cancer-approve if the patient has advanced or metastatic disease, and has been previously treated with a fluoropyrimidine, oxaliplatin, and irinotecan. Uterine sarcoma- (A and B): A) pt has recurrent, advanced, inoperable, or metastatic disease, and B) tried at least one systemic regimen. Biliary Tract Cancers- Approve if the patient has tried at least one systemic therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Soft tissue Sarcoma, Bone Cancer, Appendiceal cancer, Uterine sarcoma, Biliary tract cancers

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

SUCRAID

Products Affected

- SUCRAID

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

SUNITINIB

Products Affected

- *sunitinib malate*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

SYMDEKO

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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 pt has (i or ii): i) mesenchymal-epithelial transition (MET) exon 14 skipping mutations or ii) high-level MET amplification.
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
Prerequisite Therapy Required	No

TADALAFIL

Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Treatment of erectile dysfunction (ED)
Required Medical Information	Indication for which tadalafil is being prescribed.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 mos.
Other Criteria	Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed as once daily dosing, to treat the signs and symptoms of BPH and not for the treatment of erectile dysfunction (ED).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAFINLAR

Products Affected

- TAFINLAR ORAL CAPSULE
- TAFINLAR ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Glioma- approve if pt has BRAF V600 mutation-positive disease and this medication will be taken with Mekinist (trametinib). 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. NSCLC-approve if pt has recurrent, advanced, or metastatic disease AND BRAF V600 mutation-positive disease. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafinlar will be taken in combination with Mekinist, AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or oncocytic) AND recurrent or metastatic disease AND the patient has BRAF-positive disease. Histiocytic neoplasm-approve if (A and B): A) patient has Langerhans cell histiocytosis or Erdheim Chester disease AND B) patient has BRAF V600-mutation positive disease. Solid tumors [examples: biliary tract cancer, brain metastases due to melanoma, ovarian/fallopian tube/primary peritoneal cancer, gastrointestinal stromal tumors, gastric cancer, esophageal and esophagogastric junction cancers, salivary gland tumors, occult primary, pancreatic adenocarcinoma, neuroendocrine tumors, ampullary adenocarcinoma, small bowel adenocarcinoma]-approve if BRAF V600 mutation-positive disease AND medication will be taken in combination

PA Criteria	Criteria Details
	with Mekinist (trametinib). 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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Histiocytic neoplasm, hairy cell leukemia
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TAGRISSO

Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

TALVEY

Products Affected

- TALVEY

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	Multiple myeloma-approve if per FDA approved labeling the patient has tried at least four systemic regimens and among the previous regimens tried, the patient has received at least one drug from each of the following classes: proteasome inhibitor, an immunomodulatory drug and an anti-CD38 monoclonal antibody.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TALZENNA

Products Affected

- TALZENNA

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

TARPEYO

Products Affected

- TARPEYO

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

TAZAROTENE

Products Affected

- *tazarotene topical cream*
- *tazarotene topical gel*
- *trilitas*

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
Prerequisite Therapy Required	No

TECVAYLI

Products Affected

- TECVAYLI

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	Multiple Myeloma-approve if the patient meets one (A, B, or C): A) has tried at least four systemic regimens which must include at least one drug from each of the following classes: proteasome inhibitor, immunomodulatory drug and Anti-CD38 monoclonal antibody OR B) tried lenalidomide and at least one proteasome inhibitor and the medication will be used in combination with Darzalex (daratumumab intravenous infusion) or Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection) OR C) tried at least three prior lines of therapy and the medication will be used in combination with Talvey (talquetamab-tgvs subcutaneous injection).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TEPMETKO

Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NSCLC-approve if the patient has advanced or metastatic disease and pt has (i or ii): i) mesenchymal-epithelial transition (MET) exon 14 skipping mutations or ii) high-level MET amplification.
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
Prerequisite Therapy Required	No

TERIPARATIDE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

TETRABENAZINE

Products Affected

- *tetrabenazine oral tablet 12.5 mg, 25 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

TEVIMBRA

Products Affected

- TEVIMBRA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. Hepatocellular carcinoma-approve if (A or B): A) meets (i or ii): i) pt has liver-confined, unresectable disease and is deemed ineligible for transplant, or ii) pt has extrahepatic/metastatic disease and are deemed ineligible for resection, transplant, or locoregional therapy, or B) medication is being used for subsequent-line therapy. Nasopharyngeal carcinoma-approve if (A and B): A) pt has recurrent, unresectable, oligometastatic, or metastatic disease, and B) meets (i or ii): i) used in combination with cisplatin and gemcitabine or ii) used as subsequent treatment. Small bowel adenocarcinoma-approve if either (A or B): A) deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or B) polymerase epsilon/delta (POLE/POLD1) mutation positive disease with ultra-hypermutated phenotype (Ultra-hypermutated phenotype is defined as tumor mutational burden greater than 50 mutations/megabase).
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	ESOPHAGEAL and ESOPHAGOGASTRIC JUNCTION CANCERS-All of (A, B and C): A. Unresectable locally advanced, recurrent, or metastatic disease, AND B. Meets (i or ii): i) pt has esophageal squamous cell carcinoma with (a or b): a) tumor expression for programmed death-ligand 1 (PD-L1) has a combined positive score (CPS) greater than or equal to 1 and is used in combination with chemotherapy, or b) medication is used for subsequent therapy or ii) pt has esophageal adenocarcinoma that is HER2 overexpression negative and tumor expression for PD-L1 has a CPS greater than or equal to 1, AND C. NO tumor progression while on a checkpoint inhibitor. Note: Examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous

PA Criteria	Criteria Details
	infusion). Gastric or gastroesophageal junction adenocarcinoma- approve if (A, B and C): A) unresectable locally advanced, recurrent or metastatic human epidermal growth factor receptor 2 (HER2)-negative disease, B) tumor expression for programmed death-ligand 1 (PD-L1) has combined positive score (CPS) greater than or equal to 1 percent, C) used in combination with platinum and fluoropyrimidine-based chemotherapy. Anal carcinoma- meets (A or B): A) locally recurrent, progressive disease and administered before proceeding to abdominoperineal resection, or B) metastatic disease and used as subsequent therapy. CLL/SLL-approve if (A and B): A) patient has histologic Richter transformation, and B) is used in combination with Brukinsa (zanubrutinib capsules). Colon, rectal or appendiceal cancer-approve if pt meets (A and B): A) meets (i or ii): i) pt has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease, or ii) disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (Ultra-hypermutated phenotype is defined as tumor mutational burden greater than 50 mutations/megabase), and B) pt has advanced or metastatic disease. Classic Hodgkin Lymphoma-approve if refractory or relapsed disease and medication is used with GEMOX (gemcitabine and oxaliplatin). Endometrial carcinoma-approve if (A and B): A) recurrent or metastatic disease, and B) pt has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anal carcinoma, Chronic lymphocytic leukemia/small lymphocytic lymphoma, hepatocellular carcinoma, nasopharyngeal carcinoma, small bowel adenocarcinoma, colon/rectal/appendiceal cancer, Classic Hodgkin Lymphoma, endometrial carcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

THALOMID

Products Affected

- THALOMID ORAL CAPSULE 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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. 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 isocitrate dehydrogenase-1 (IDH1) mutation-positive disease AND not a candidate for Voranigo (vorasidenib tablets) AND has oligodendroglioma, high-grade glioma, or astrocytoma. Myelodysplastic Syndrome-approve if patient has isocitrate dehydrogenase-1 (IDH1) mutation-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chondrosarcoma, Central nervous system cancer
Part B Prerequisite	Yes
Prerequisite Therapy Required	Yes

TIVDAK

Products Affected

- TIVDAK

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	Cervical cancer-approve if (A and B): A) pt has recurrent or metastatic disease and B) the patient has tried at least one chemotherapy agent. Vaginal cancer- approve if (A and B): A) pt has recurrent or metastatic disease and B) the patient has tried at least one chemotherapy agent.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Vaginal cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TOBRAMYCIN (NEBULIZATION)

Products Affected

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

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

TOLVAPTAN

Products Affected

- *tolvaptan*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Jynarque.
Required Medical Information	Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 30 days 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
Prerequisite Therapy Required	No

TOPICAL AGENTS FOR ATOPIC DERMATITIS - CRISABOROLE

Products Affected

- EUCRISA

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 Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOPICAL AGENTS FOR ATOPIC DERMATITIS - PIMECROLIMUS

Products Affected

- *pimecrolimus*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
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
Prerequisite Therapy Required	Yes

TOPICAL AGENTS FOR ATOPIC DERMATITIS - TACROLIMUS

Products Affected

- *tacrolimus topical*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
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
Prerequisite Therapy Required	Yes

TOPICAL RETINOID PRODUCTS - TRETINOIN

Products Affected

- *tretinoin topical cream*
- *tretinoin topical topical gel 0.01 %*

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	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOPIRAMATE

Products Affected

- *topiramate oral capsule, sprinkle 15 mg, 25 mg*
- *topiramate oral solution*
- *topiramate oral tablet*

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	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRANSDERMAL FENTANYL

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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	Prostate cancer: Prescribed by or in consultation with a oncologist or urologist. Head and neck cancer - salivary gland tumors, breast cancer: Prescribed by or in consultation with a oncologist.
Coverage Duration	1 year
Other Criteria	Prostate cancer: Patients new to therapy, are required to try Eligard prior to approval of Trelstar. Head and neck cancer - salivary gland tumors: approve if patient 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, breast cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TREMFYA IV

Products Affected

- TREMFYA INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic oral small molecule drug.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	3 doses for induction
Other Criteria	ULCERATIVE COLITIS-Approve if the medication will be used as induction therapy. CROHN'S DISEASE (CD): Approve if the medication will be used as induction therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TREMFYA SC

Products Affected

- TREMFYA ONE-PRESS
- TREMFYA PEN
- TREMFYA PEN INDUCTION PK(2PEN)
- TREMFYA SUBCUTANEOUS SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

TREPROSTINIL INHALATION POWDER

Products Affected

- YUTREPIA INHALATION CAPSULE, W/INHALATION DEVICE 106 MCG, 26.5 MCG, 53 MCG, 79.5 MCG

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

TRIENTINE

Products Affected

- *trientine oral capsule 250 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

TRIKAFTA

Products Affected

- TRIKAFTA ORAL GRANULES IN PACKET, SEQUENTIAL
- TRIKAFTA ORAL TABLETS, SEQUENTIAL

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

TRODELVY

Products Affected

- TRODELVY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Breast Cancer-approve if the patient has recurrent or metastatic, human epidermal growth factor receptor (HER2) negative breast cancer and patient meets (a or b): a) patient has hormone receptor (HR) negative disease (Note: this is triple-negative disease), OR b) patient has HR positive disease, has tried endocrine therapy, has tried a cyclin-dependent kinase(CDK) 4/6 inhibitor, has tried at least two systemic chemotherapy regimens (one of which was tried in the metastatic setting), and patient is not a candidate for Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion) therapy . Urothelial Cancer-approve if the patient has locally advanced or metastatic urothelial cancer AND has tried at least one systemic chemotherapy AND has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Urothelial cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

TUKYSA

Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast Cancer - HER2-positive disease-approve if the patient has recurrent or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, Tukysa is used in combination with trastuzumab and capecitabine, and meets one (A or B): A) has received at least one prior anti-HER2-based regimen in the metastatic setting or B) has brain metastases. 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)-overexpressed or HER2-amplified disease [This includes pts that are immunohistochemistry (IHC) 3+, IHC 2+/in situ hybridization (ISH)+, or HER2 overexpressed/amplified as detected by next-generation sequencing (NGS)], AND Pt has RAS wild-type disease (this includes KRAS wild-type and NRAS wild-type) and has BRAF wild type disease. Biliary tract cancer- approve if the patient meets all of (a, b, c, and d): a) unresectable or metastatic disease, b) HER2 positive disease [This includes patients that are immunohistochemistry (IHC) 3+, in situ hybridization (ISH)+, or next-generation sequencing (NGS)+], c) tried at least one systemic regimen, d) will use in combination with trastuzumab. Appendiceal cancer- approve if patient has human epidermal growth factor receptor 2 (HER2)-positive disease, has not previously been treated with a HER2 antagonist, RAS wild-type disease, BRAF wild type disease, and the medication is used in combination with

PA Criteria	Criteria Details
	trastuzumab. Breast Cancer- HER2-negative disease-approve if pt meets all (A, B, C, D and E): A) has recurrent or metastatic disease, B) human epidermal growth factor receptor 2 (HER2)-negative breast cancer, C) the cancer has a HER2-activating mutation (Examples of HER2-activating mutations include: L755S, D769H/Y, V777L, or exon 20 insertion), D) meets one (i or ii): i) pt is a postmenopausal female or a male or ii) pt is pre/perimenopausal and meets one (a or b): a) receiving ovarian suppression/ovarian ablation with a gonadotropin-releasing hormone (GnRH) agonist or b) has had surgical bilateral oophorectomy or ovarian irradiation AND E) meets one (i or ii): i) has hormone receptor (HR)-positive (i.e., estrogen receptor [ER] or progesterone receptor [PR] positive) disease and has tried at least one cyclin dependent kinase (CDK) 4/6 inhibitor therapy or ii) has hormone receptor (HR)-negative (i.e., estrogen receptor [ER] or progesterone receptor [PR] negative) disease. Small bowel adenocarcinoma-approve if pt has human epidermal growth factor receptor 2 (HER2)-overexpressed or HER2-amplified disease, RAS wild-type disease (This includes KRAS wild-type and NRAS wild-type disease), BRAF wild type disease, and the medication is used in combination with trastuzumab.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Appendiceal cancer, Biliary tract cancer, Breast cancer-HER2-negative disease, Small bowel adenocarcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TURALIO

Products Affected

- TURALIO

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
Prerequisite Therapy Required	No

TYENNE IV

Products Affected

- TYENNE INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic Disease-Modifying Antirheumatic Drug (DMARD) or targeted synthetic DMARD. Exclude for indication of COVID-19 treatment in hospitalized patients (ie, non-D use).
Required Medical Information	Diagnosis
Age Restrictions	(Initial therapy only): GCA/RA-18 years and older. PJIA/SJIA-2 years and older.
Prescriber Restrictions	RA, SJIA, PJIA, GCA - Prescribed by or in consultation with a rheumatologist (initial therapy).
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY- RHEUMATOID ARTHRITIS (RA) [A OR B]: A) Try ONE of the following: Enbrel, a preferred adalimumab product, Rinvoq or tofacitinib/XR. (Note: previous trial(s) with the following drugs: Cimzia, infliximab, Simponi (IV/SC), Kevzara, Orencia or another non-preferred adalimumab product will also count.) OR B) Patient has heart failure or a previously treated lymphoproliferative disorder. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) [A OR B]: A) Try ONE of the following: Enbrel, Rinvoq, tofacitinib, a preferred adalimumab product, (Note: a trial with infliximab, Kevzara, Orencia or another non-preferred adalimumab product will also count.) OR B) Patient has heart failure or a previously treated lymphoproliferative disorder. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): Approve. GIANT CELL ARTERITIS: tried or is currently taking a systemic corticosteroid or corticosteroid is contraindicated. CYTOKINE RELEASE SYNDROME ASSOCIATED WITH CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY-approve. Please Note: preferred adalimumab products include Hadlima, Simlandi. CONTINUATION THERAPY-RA, PJIA, SJIA, GCA:patient has responded to therapy.
Indications	All FDA-approved Indications.

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

TYENNE SC

Products Affected

- TYENNE AUTOINJECTOR
- TYENNE SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

UNLOXCYT

Products Affected

- UNLOXCYT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or on consultation with an oncologist
Coverage Duration	1 year
Other Criteria	CUTANEOUS SQUAMOUS CELL CARCINOMA - Patient has locally advanced or metastatic disease and is not a candidate for curative surgery or curative radiation therapy. COLON AND RECTAL CANCER - Approve if disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) or polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (defined as tumor mutational burden greater than 50 mutations/megabase). SMALL BOWEL ADENOCARCINOMA - Approve if pt has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (defined as tumor mutational burden greater than 50 mutations/megabase).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Colon and rectal cancer, small bowel adenocarcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

UPTRAVI

Products Affected

- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLETS,DOSE PACK

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

USTEKINUMAB IV

Products Affected

- OTULFI INTRAVENOUS
- PYZCHIVA INTRAVENOUS
- YESINTEK INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis
Age Restrictions	UC-18 years and older, CD-2 years and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	Approve a single dose
Other Criteria	INDUCTION THERAPY for USTEKINUMAB IV: UC: approve. Crohn's Disease: approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

USTEKINUMAB SC

Products Affected

- OTULFI SUBCUTANEOUS SOLUTION
- OTULFI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- PYZCHIVA SUBCUTANEOUS SOLUTION
- PYZCHIVA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- YESINTEK SUBCUTANEOUS SOLUTION
- YESINTEK SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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. 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	Langerhans Cell Histiocytosis
Part B Prerequisite	No
Prerequisite Therapy Required	No

VALTOCO

Products Affected

- VALTOCO

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

VANCOMYCIN

Products Affected

- *vancomycin oral capsule 125 mg, 250 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	2 weeks
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	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. Myeloid or lymphoid neoplasms: approve if patient has eosinophilia and the tumor has FLT3 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid or lymphoid neoplasms
Part B Prerequisite	No
Prerequisite Therapy Required	No

VENCLEXTA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy
Age Restrictions	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
Prerequisite Therapy Required	Yes

VEPPANU

Products Affected

- VEPPANU

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. Recurrent or metastatic disease, AND B. Hormone receptor-positive (HR +) disease, AND C. Human epidermal growth factor receptor 2 (HER2)-negative disease, AND D. Estrogen receptor 1 gene (ESR1)-mutated disease, AND E. Tried at least one endocrine therapy Note: Examples of endocrine therapy include fulvestrant, anastrozole, exemestane, letrozole, and tamoxifen., AND F. Meets ONE of the following (i or ii): i. Patient is a man or postmenopausal woman, OR ii. Patient is a pre/perimenopausal woman and meets ONE of the following (a or b): a. Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), and Zoladex (goserelin acetate subcutaneous injection) OR b.Patient has had surgical bilateral oophorectomy or ovarian irradiation. Note-a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression, 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

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

VERZENIO

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

VIGABATRIN

Products Affected

- *vigabatrin*
- *vigadrone*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

VIMIZIM

Products Affected

- VIMIZIM

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient N-acetylgalactosamine-6-sulfatase activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating biallelic pathogenic or likely pathogenic N-acetylgalactosamine-6-sulfatase gene variants.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VITRAKVI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, NTRK gene fusion status
Age Restrictions	Pediatric Diffuse High-Grade Glioma- less than or equal to 21 years old
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. Pediatric diffuse high grade glioma - approve if (A and B): A) tumor is positive for NTRK gene fusion and B) meets (i or ii): i) medication is used as adjuvant therapy or ii) medication is used 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
Prerequisite Therapy Required	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) meets (i and ii): i) the patient has a platelet count of less than 50 x 109 /L (less than 50,000/mcL) and (ii): meets (a or b): a) has higher-risk disease or b) has lower-risk disease and at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis) OR (B) Patient has a platelet count of greater than or equal to 50 x 109 /L (greater than or equal to 50,000/mcL) and has higher-risk disease and has at least one disease-related symptom, OR (C) patient has myelofibrosis-associated anemia. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease- related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis). Myeloid or Lymphoid Neoplasms - Approve if patient has eosinophilia, has tried Jakafi (ruxolitinib tablets), and the tumor has a Janus Associated Kinase 2 (JAK2) rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Accelerated or blast phase myeloproliferative neoplasm, myeloid or lymphoid neoplasms

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

VORANIGO

Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	N/A
Coverage Duration	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 or greater oligodendroglioma OR Grade 2 or greater 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
Prerequisite Therapy Required	No

VORICONAZOLE (ORAL)

Products Affected

- *voriconazole oral*

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 Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	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
Prerequisite Therapy Required	No

VOTRIENT

Products Affected

- *pazopanib oral tablet 200 mg*
- PAZOPANIB ORAL TABLET 400 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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 (or will start a bowel prep the day before and at least 8 hours prior to taking the first dose), 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
Prerequisite Therapy Required	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	GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA (all of A, B, C, and D): A. Unresectable locally advanced, recurrent, metastatic disease, or palliative therapy, AND B. Tumor is claudin 18.2 positive, 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 in combination with fluoropyrimidine- and platinum-containing chemotherapy. Note: Examples of fluoropyrimidines include 5-fluorouracil and capecitabine. Examples of platinum chemotherapy agents include oxaliplatin. Esophageal adenocarcinoma- all of (A, B, C, and D): A. unresectable locally advanced, recurrent, metastatic disease, or palliative therapy, AND B. tumor is is claudin 18.2 positive, AND C. tumor is human epidermal growth factor receptor 2 (HER2)-negative, and D. used in combination with fluoropyrimidine- and platinum-containing chemotherapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Esophageal adenocarcinoma
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

VYVGART

Products Affected

- VYVGART
- VYVGART HYTRULO

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

WEGOVY

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

WELIREG

Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

WINREVAIR

Products Affected

- WINREVAIR

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

XALKORI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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 (meets A or B): A) has anaplastic lymphoma kinase (ALK)-positive disease, and patients new to therapy must have a trial of Alecensa, Ensacove or Lorbrena prior to approval of Xalkori or B) has ROS1 rearrangement positive disease. 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
Prerequisite Therapy Required	Yes

XDEMVY

Products Affected

- XDEMVY

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

XELJANZ

Products Affected

- *tofacitinib oral solution*
- *tofacitinib oral tablet*
- *tofacitinib oral tablet extended release 24 hr*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a Targeted Synthetic DMARD for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil].
Required Medical Information	Diagnosis
Age Restrictions	AS/RA/UC-18 years and older (initial therapy), JIA/JRA/PsA-2 years and older (initial therapy)
Prescriber Restrictions	RA, JIA/JRA/AS prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist. (all apply to initial therapy only)
Coverage Duration	Approve through end of plan year
Other Criteria	RA initial-approve tofacitinib/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. PsA initial, approve tofacitinib immediate release tablets or oral solution (patients 2 years and older) or tofacitinib XR tablets (patients 18 years and older) if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. UC-Approve tofacitinib/XR tablets if the patient has had a 3 month trial of at least ONE tumor necrosis factor inhibitor for ulcerative colitis or was unable to tolerate a 3-month trial. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthropathy/active sacroiliac arthritis]-initial-approve tofacitinib immediate release tablets or solution if the patient meets the following: patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial.

PA Criteria	Criteria Details
	AS-approve tofacitinib/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. Continuation Therapy - Patient must have responded, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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 short-acting octreotide or long-acting somatostatin analog (SSA) therapy (eg, Somatuline Depot [lanreotide for injection]) AND 2) while on short-acting octreotide or 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 short-acting octreotide or a long-acting SSA therapy. Continuation therapy - approve if the patient is continuing to take Xermelo concomitantly with short-acting octreotide or a long-acting SSA therapy for carcinoid syndrome diarrhea.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XIAFLEX

Products Affected

- XIAFLEX

PA Criteria	Criteria Details
Exclusion Criteria	Retreatment for Peyronie's Disease (i.e., treatment beyond eight injections).
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-approve if (A, B, C and D): A) pt has at least one palpable cord in the affected hand, and B) pt has contracture of a metacarpophalangeal or proximal interphalangeal joint that is associated with the palpable cord, and C) at baseline (prior to initial injection of Xiaflex), the contracture measures at least 20 degrees AND D) 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-approve if (A, B and C): A) pt has at least one palpable plaque in the penis, and B) 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 ii) in a patient who has received prior treatment with Xiaflex, the patient has a penile curvature deformity of at least 15 degrees AND C) 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

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

XIFAXAN

Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Traveler's diarrhea - 12 years of age or older. Hepatic encephalopathy, irritable bowel syndrome with diarrhea - 18 years of age or older.
Prescriber Restrictions	Pouchitis - prescribed by or in consultation with a gastroenterologist
Coverage Duration	Enceph-6 mo, IBS w/diarrhea-14 days, TD-3 days, intest bact overgrowth-14 days, Pouchitis - 1 year
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 if pt has not received a treatment course with the requested medication for IBS-D in the previous 1 year or has received a treatment course for IBS-D in the previous 1 year and meets all (A, B and C): A) pt responded to treatment AND B) experiencing a recurrence of IBS-D symptoms after a Xifaxan treatment-free interval AND C) has received less than 3 treatment courses in the previous 1 year. 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)

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

XOLAIR

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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 disease is FLT3-mutation positive. Lymphoid, Myeloid Neoplasms-approve if the patient has eosinophilia and the disease is FLT3-mutation positive.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Lymphoid/Myeloid Neoplasms
Part B Prerequisite	No
Prerequisite Therapy Required	No

XPOVIO

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, 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 two prior regimens for multiple myeloma AND b) The medication will be taken in combination with Pomalyst (pomalidomide) 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 bortezomib, Darzalex (daratumumb infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Kyprolis (carfilzomib intravenous infusion). Note: Examples of prior regimens include Darzalex (daratumumab intravenous infusion)/bortezomib/lenalidomide/dexamethasone, bortezomib/lenalidomide/dexamethasone, Kyprolis (carfilzomib infusion)/lenalidomide/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

PA Criteria	Criteria Details
	includes patients with histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma)-approve if the patient has tried at least two prior therapies. B-Cell lymphoma-approve if (A and B): A) pt has high-grade B-cell lymphoma or HIV-related B-cell lymphoma or post-transplant lymphoproliferative disorders and B) has tried at least two prior therapies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Treatment of multiple myeloma in combination with daratumumb or pomalidomide, B-cell lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XTANDI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis 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] 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. In addition, patients new to therapy are required to try abiraterone (a trial of brand name Zytiga or Yonsa would also count), unless the patient has a contraindication or severe intolerance (e.g., difficulty achieving blood glucose control in patients with diabetes, psychiatric reactions) to low-dose systemic corticosteroids (e.g., prednisone) according to the prescriber.Prostate cancer-castration-resistant [Non-metastatic]- 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-

PA Criteria	Criteria Details
	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
Prerequisite Therapy Required	Yes

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 - narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Patients requesting sodium oxybate who are 18 years or older-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil. Patients less than 18 years old requesting sodium oxybate-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextramphetamine) or modafinil. 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
Prerequisite Therapy Required	Yes

ZEJULA

Products Affected

- ZEJULA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	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 new to therapy they must have a trial of Lynparza prior to approval of Zejula. Patients who have had a complete or partial response to first-line platinum based chemotherapy and do not have BRCA altered disease are not required to try Lynparza. Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried at least one systemic regimen. In addition, patients new to therapy must have a trial of Lynparza prior to approval of Zejula. Prostate Cancer, Metastatic, Castration-Resistant - Approve if pt meets all (A, B, C, and D): A) has a BRCA mutation, AND B) Zejula is used in combination with abiraterone, AND C) Zejula is used in combination with prednisone or methylprednisolone, AND D) Zejula is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or pt has had a bilateral orchiectomy. Prostate Cancer, Metastatic, Castration-Sensitive - Approve if pt meets all (A, B, C, and D): A) has a BRCA2 mutation, AND B) Zejula is used in combination with abiraterone, AND C) Zejula is used in combination with prednisone or methylprednisolone, AND D) Zejula is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or pt has had a bilateral orchiectomy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Uterine Leiomyosarcoma, Prostate Cancer Metastatic Castration-Resistant and Castration-Sensitive
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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	Melanoma, patient must have BRAFV600 mutation for approval AND have unresectable, advanced or metastatic melanoma. HCL - meets (A or B): A) must have tried at least one other systemic therapy for hairy cell leukemia OR B) meets (i and ii): i) is unable to tolerate purine analogs and ii) Zelboraf will be used in combination with rituximab or Gazyva (obinutuzumab intravenous infusion). 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 (A, B and C): A) the patient has BRAF V600 mutation-positive disease AND B) 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) Circumscribed ganglioglioma/neuroglioma/glioneuronal tumor OR d) pediatric diffuse high-grade glioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b or c): a) high grade glioma b) circumscribed glioma OR c) Glioblastoma OR iii. Melanoma with brain metastases AND C) the medication with be taken in combination with Cotellic (cobimetinib tablets). Histiocytic Neoplasm-approve if the patient has Langerhans cell histiocytosis AND the patient has BRAF V600-mutation positive disease.
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
Prerequisite Therapy Required	Yes

ZENBEXUS

Products Affected

- ZENBEXUS

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

ZEPOSIA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	MS-Concurrent use with other disease-modifying agents used for multiple sclerosis. UC- Concurrent Use with a Biologic or with a Targeted Synthetic Disease-modifying Antirheumatic Drug (DMARD) for Ulcerative Colitis
Required Medical Information	Diagnosis
Age Restrictions	UC-18 years and older
Prescriber Restrictions	MS-Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. UC-Prescribed by or in consultation with a gastroenterologist
Coverage Duration	MS-1 year, UC initial, 6 months, cont-1 year
Other Criteria	MS-approve. Ulcerative Colitis, initial-approve if the patient has tried TWO of the following: a preferred adalimumab product, a preferred ustekinumab product, a preferred infliximab product, Rinvoq, Skyrizi, Tremfya. Note-a trial of Simponi SC, Entyvio IV/SC, Omvoh IV/SC, a non-preferred adalimumab product, a non-preferred ustekinumab product or a non-preferred infliximab would also count). Cont tx-approve if the patient has been established on Zeposia. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab products include Remicade, infliximab IV (brand name product), Zymfentra. Preferred ustekinumab products include Otulfi, Pyzchiva (NDCs beginning with 61314-), Yesintek.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

ZEPZELCA

Products Affected

- ZEPZELCA

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	Small cell lung cancer-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	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	BILIARY TRACT CANCER - (A, B, and C): A) Patient has unresectable, resected gross residual, or metastatic disease, AND B) The tumor is human epidermal growth factor receptor 2 (HER2) positive with immunohistochemistry score of 3+ (IHC3+), AND C) the medication is used for subsequent therapy. GASTROESOPHAGEAL ADENOCARCINOMA - Approve if patient meets ALL (A, B and C): A) has unresectable locally advanced or metastatic disease AND B) the tumor is human epidermal growth factor receptor 2 (HER2) positive AND C) the medication is used in combination with fluoropyrimidine- and platinum-containing chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZOLINZA

Products Affected

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Classic Hodgkin Lymphoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve. Classic Hodgkin Lymphoma- tried at least three systemic regimens AND used in combination with pembrolizumab.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Classic Hodgkin Lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZONISAMIDE

Products Affected

- 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	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	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 variant in the CDKL5 gene.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZURZUVAE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

ZYDELIG

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	CLL/SLL-approve if the patient has tried at least one Bruton tyrosine kinase inhibitor (examples: ibrutinib, zanubrutinib, acalabrutinib, pirtobrutinib) and at least one B-cell lymphoma 2 inhibitor (example: venetoclax).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	small lymphocytic lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZYKADIA

Products Affected

- ZYKADIA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	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, Ensacove or Lorbrena prior to approval of Zykadia. 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. Erdheim-Chester disease. Peripheral T-Cell Lymphoma.
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZYMFENTRA

Products Affected

- ZYMFENTRA

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

ZYNLONTA

Products Affected

- ZYNLONTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	B-Cell Lymphoma, HIV-Related B-Cell Lymphoma and post-transplant lymphoproliferative disorder-approve if the patient has tried at least two systemic regimens.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	HIV-related B-Cell Lymphoma, Post-transplant lymphoproliferative disorders
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZYNYZ

Products Affected

- ZYNYZ

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Merkel Cell Carcinoma-approve if (A, B, C or D): A) pt has primary or recurrent locally advanced disease, if according to the prescriber curative surgery and curative radiation therapy are not feasible, or B) pt has primary or recurrent regional disease, if according to the prescriber curative surgery and curative radiation therapy are not feasible, or C) pt has metastatic disease, or D) pt has in-transit disease. Anal carcinoma- approve if (A and B): A) pt has locally recurrent, progressive, or metastatic disease and, B) meets (i, ii, or iii): i) medication is used in combination with chemotherapy, or ii) the medication is used as subsequent therapy, or iii) medication is administered before proceeding to abdominoperineal resection. Colon, rectal or appendiceal cancer- approve if (A and B): A) meets one of (i, ii or iii): i) locally unresectable or medically inoperable disease, or ii) advanced, recurrent, or metastatic disease, or iii) medication is used as neoadjuvant therapy, and B) meets (i or ii): i) pt has a deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or ii) pt has polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype. Small bowel adenocarcinoma- approve if (A and B): A) meets (i, ii, or iii): i) pt has has locally unresectable or medically inoperable disease or ii) pt has advanced or metastatic disease or iii) medication is used as neoadjuvant therapy, and B) meets (i or ii): i) pt has a deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or ii) pt has polymerase epsilon/delta (POLE/POLD1) mutation with ultra-

PA Criteria	Criteria Details
	hypermutated phenotype. Endometrial Carcinoma - Approve if patient has recurrent or metastatic disease and microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	colon/rectal/appendiceal cancer, small bowel adenocarcinoma, endometrial carcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZYTIGA

Products Affected

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

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	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

PA Criteria	Criteria Details
	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).
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
Prerequisite Therapy Required	Yes

PART B VERSUS PART D

Products Affected

- *acetylcysteine*
- *acyclovir sodium intravenous solution*
- *albuterol sulfate inhalation solution for nebulization 0.63 mg/3 ml, 1.25 mg/3 ml, 2.5 mg /3 ml (0.083 %), 2.5 mg/0.5 ml*
- *amphotericin b*
- *amphotericin b liposome*
- *aprepitant*
- *arformoterol*
- *azathioprine oral tablet 50 mg*
- *azathioprine sodium*
- *bleomycin*
- BLINCYTO INTRAVENOUS KIT
- *budesonide inhalation suspension for nebulization 0.25 mg/2 ml, 0.5 mg/2 ml, 1 mg/2 ml*
- *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)
- *cromolyn inhalation*
- *cyclophosphamide oral capsule*
- CYCLOPHOSPHAMIDE ORAL TABLET 50 MG
- *cyclosporine modified*
- *cyclosporine oral capsule*
- *cytarabine*
- *cytarabine (pf)*
- *deferoxamine*
- *dobutamine*
- *dobutamine in d5w intravenous parenteral solution 1,000 mg/250 ml (4,000 mcg/ml), 250 mg/250 ml (1 mg/ml), 500 mg/250 ml (2,000 mcg/ml)*
- *dopamine in 5 % dextrose*
- *dopamine intravenous solution*
- *doxorubicin*
- ENGERIX-B (PF)
- ENGERIX-B PEDIATRIC (PF)
- ENVARSUS XR
- *everolimus (immunosuppressive)*
- FAVLYXA
- *floxuridine*
- *fluorouracil intravenous*
- *formoterol fumarate*
- *ganciclovir sodium*
- *gengraf oral capsule*
- *granisetron hcl oral*
- HEPLISAV-B (PF)
- IMOVAX RABIES VACCINE (PF)
- *intralipid intravenous emulsion 20 %*
- *ipratropium bromide inhalation solution*
- *ipratropium-albuterol*
- JYLAMVO
- JYNNEOS (PF)
- LIORESAL
- *methotrexate sodium oral*
- *methylprednisolone oral tablet*
- *milrinone*
- *milrinone in 5 % dextrose*
- *mycophenolate mofetil*
- *mycophenolate mofetil (hcl)*
- *mycophenolate sodium*
- MYHIBBIN
- NULOJIX
- *ondansetron hcl oral solution*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet,disintegrating 4 mg, 8 mg*
- *pentamidine inhalation*
- PLENAMINE
- *premasol 10 %*
- PROGRAF INTRAVENOUS
- PROGRAF ORAL GRANULES IN PACKET
- PULMOZYME
- RABAVERT (PF)
- RECOMBIVAX HB (PF)
- SIMULECT
- *sirolimus*
- *tacrolimus oral capsule*
- *travasol 10 %*

- TROPHAMINE 10 %
- VARUBI
- *veletri*
- *vinblastine*
- *vincristine*
- XEMBIFY

Details

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

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