2027 Prior Authorization Criteria

Updated 10/15/2026

ACTIMMUNE

Products Affected

- Actimmune

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ADALIMUMAB

Products Affected

- adalimumab-aaty mg/0.4 mL, 40 mg/0.8 mL
- adalimumab-aaty(CF) Al Crohns
- adalimumab-adbm subcutaneous pen injector kit
- adalimumab-adbm subcutaneous syringe kit 40

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER 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	
Age Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AIMOVIG

Products Affected

- Aimovig Autoinjector

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

AKEEGA

Products Affected

- Akeega

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ALECENSA

Products Affected

- Alecensa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Pediatric diffuse high grade glioma- less than or equal to 21 years old, All others- 18 years and older
Prescriber Restrictions	
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.
Off Label Uses	Anaplastic large cell lymphoma, Erdheim Chester disease, Inflammatory Myofibroblastic Tumor, Large B-Cell Lymphoma, Pediatric Diffuse High Grade Glioma

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

ALOSETRON

Products Affected

- alosetron

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

ALPHA 1 PROTEINASE INHIBITORS

Products Affected

- Prolastin-C intravenous solution

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

ALUNBRIG

Products Affected

- Alunbrig

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	ALK status
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Required Medical Information	Diagnosis
Age Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

ANTIFUNGALS (IV) - VORICONAZOLE

Products Affected

- voriconazole intravenous recon soln

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

ARCALYST

Products Affected

- Arcalyst

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

ARIKAYCE

Products Affected

- Arikayce

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

ARMODAFINIL

Products Affected

- armodafinil

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
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	
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	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AUGTYRO

Products Affected

- Augtyro

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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
Prerequisite Therapy Required	No

AUSTEDO

Products Affected

- Austedo
- 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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

AVMAPKI-FAKZYNJA

Products Affected

- Avmapki-Fakzynja

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

AVTOZMA SC

Products Affected

- Avtozma Autoinjector
- Avtozma subcutaneous

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

AYVAKIT

Products Affected

- Ayvakit

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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.
Off Label Uses	Breast cancer, cholangiocarcinoma, glioma, head and neck cancer, Pancreatic adenocarcinoma, non-small cell lung cancer

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

BENLYSTA

Products Affected

- Benlysta subcutaneous

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

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	
Indications	All FDA-approved Indications.
Off Label Uses	
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	
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BEXAROTENE (ORAL)

Products Affected

- bexarotene

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

BEXAROTENE (TOPICAL)

Products Affected

- bexarotene

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
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

BOSENTAN

Products Affected

- bosentan oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
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
- Bosulif oral tablet 100 mg, 500 mg
- bosutinib oral tablet 400 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	ALL - 15 years and older. Myeloid/lymphoid neoplasms w eosinophilia- 18 years and older
Prescriber Restrictions	
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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

BRUKINSA

Products Affected

- Brukinsa oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	
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 if the patient has tried Calquence or Imbruvica. Mantle Cell Lymphoma - approve if patient meets (A or B): A. meets both of the following (i and ii): i. has tried Calquence or Imbruvica, AND ii. ONE of the following (1, 2, or 3): 1) tried at least one other line of systemic regimen, or 2) is not a candidate for a Chemotherapy regimen, or 3) will use this medication in combination with rituximab, OR B. 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 prior anti-CD20 monoclonal anti-body-based systemic regimen. Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma - approve. Hairy Cell Leukemia - approve if the patient has progressive disease after relapsed or refractory therapy and has tried Imbruvica. 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

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

C1 ESTERASE INHIBITORS

Products Affected

- Haegarda

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

CABOMETYX

Products Affected

- Cabometyx

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

CALQUENCE

Products Affected

- Calquence (acalabrutinib mal)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
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.
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

CAPRELSA

Products Affected

- Caprelsa

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

CAYSTON

Products Affected

- Cayston

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CHEMET

Products Affected

- Chemet

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

CINACALCET

Products Affected

- cinacalcet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

COMETRIQ

Products Affected

- Cometriq

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

COPIKTRA

Products Affected

- Copiktra

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	18 years and older
Prescriber Restrictions	
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 (2 Pens)
- Cosentyx subcutaneous syringe 75 mg/0.5 mL
- Cosentyx UnoReady Pen

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

COTELLIC

Products Affected

- Cotellic

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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
Prerequisite Therapy Required	Yes

CRESEMBA (ORAL)

Products Affected

- Cresemba oral

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

CYSTEAMINE (OPHTHALMIC)

Products Affected

- Cystaran

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
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	
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	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DALFAMPRIDINE

Products Affected

- dalfampridine

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DAURISMO

Products Affected

- Daurismo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, medications that will be used in combination, comorbidities
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DEFERASIROX

Products Affected

- deferasirox oral tablet
- deferasirox oral tablet, dispersible

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Serum ferritin level
Age Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DENOSUMAB (NON-OSTEOPOROSIS)

Products Affected

- Bomyntra
- Osenvelt

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

DIACOMIT

Products Affected

- Diacomit

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

DIMETHYL FUMARATE

Products Affected

- dimethyl fumarate

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

DRONABINOL

Products Affected

- dronabinol oral capsule

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DUPIXENT

Products Affected

- Dupixent Pen
- Dupixent Syringe subcutaneous syringe 200 mg/1.14 mL, 300 mg/2 mL

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

EMGALITY

Products Affected

- Emgality Pen
- Emgality Syringe subcutaneous syringe 120 mg/mL

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

ENBREL

Products Affected

- Enbrel Mini
- Enbrel subcutaneous solution
- Enbrel subcutaneous syringe
- Enbrel SureClick

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

ENDARI

Products Affected

- glutamine (sickle cell)

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ENSACOVE

Products Affected

- Ensacove

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	NON-SMALL CELL LUNG CANCER- approve.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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 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.

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

EPIDIOLEX

Products Affected

- Epidiolex

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

EPOETIN ALFA

Products Affected

- Retacrit

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

ERIVEDGE

Products Affected

- Erivedge

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
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

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

ERLOTINIB

Products Affected

- erlotinib

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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
Prerequisite Therapy Required	Yes

EVEROLIMUS

Products Affected

- everolimus (antineoplastic)
- Yulithira

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Coverage Duration	Authorization will be for 1 year.

PA Criteria	Criteria Details
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. 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.

PA Criteria	Criteria Details
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

FASENRA

Products Affected

- Fasenra
- Fasenra Pen

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

FILSPARI

Products Affected

- Filspari

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FINTEPLA

Products Affected

- Fintepla

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

FIRMAGON

Products Affected

- Firmagon kit w diluent syringe

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a 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. Patients new to therapy, are required to try Eligard prior to approval of Firmagon.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FLUCYTOSINE

Products Affected

- flucytosine

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Peritonitis: 1 month, Candida: 6 weeks, Cryptococcus: 3 months
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Fungal peritoneal dialysis-associated peritonitis
Part B Prerequisite	No
Prerequisite Therapy Required	No

FOTIVDA

Products Affected

- Fotivda

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

FRUZAQLA

Products Affected

- Fruzaqla

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	
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

FULPHILA

Products Affected

- Fulphila

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

GABAPENTINOID - GABAPENTIN

Products Affected

- gabapentin oral tablet extended release 24 hr
  300 mg, 600 mg

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

GAVRETO

Products Affected

- Gavreto

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	NSCLC-18 years and older. thyroid cancer-12 years and older
Prescriber Restrictions	
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	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
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	
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
- Glatopa

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

GLUCAGON-LIKE PEPTIDE-1 AGONISTS - DULAGLUTIDE

Products Affected

- Trulicity

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

GLUCAGON-LIKE PEPTIDE-1 AGONISTS - LIRAGLUTIDE

Products Affected

- liraglutide

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

GLUCAGON-LIKE PEPTIDE-1 AGONISTS - SEMAGLUTIDE

Products Affected

- Ozempic
- Rybelsus

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

GLUCAGON-LIKE PEPTIDE-1 AGONISTS - TIRZEPATIDE

Products Affected

- Mounjaro

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

GOMEKLI

Products Affected

- Gomekli

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	2 years and older
Prescriber Restrictions	
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	
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	
Required Medical Information	Diagnosis
Age Restrictions	
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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

HERNEXEOS

Products Affected

- Hernexeos

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

HIGH RISK MEDICATIONS - ANTIDEPRESSANTS - CLOMIPRAMINE

Products Affected

- clomipramine

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

HIGH RISK MEDICATIONS - ANTIPARKINSONIAN AGENTS - BENZTROPINE

Products Affected

- benztropine oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For all medically accepted indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. Please note that this risk assessment should include the concomitant use of other anticholinergic medications at the same time as the requested medication. For Extrapyramidal Symptoms (EPS): the patient has tried and experienced an inadequate treatment response, intolerance, or has a contraindication to the non-HRM alternative drug amantadine. For Parkinson's Disease: the patient has tried and experienced an inadequate treatment response, intolerance, or has a contraindication to at least TWO of the following non-HRM alternative drugs: 1) amantadine, 2) a levodopa containing medication (e.g. carbidopa/levodopa), 3) pramipexole, 4) ropinirole, or 5) a MAO-B inhibitor (e.g. rasagiline, selegiline).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

HIGH RISK MEDICATIONS - ANTISPASMODICS - DICYCLOMINE

Products Affected

- dicyclomine oral capsule
- dicyclomine oral solution
- dicyclomine oral tablet 20 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	For all medically accepted indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. Please note that this risk assessment should include the concomitant use of other anticholinergic medications at the same time as the requested medication.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

HIGH RISK MEDICATIONS - BARBITURATES - PHENOBARBITAL

Products Affected

- phenobarbital

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for use in sedation/insomnia.
Required Medical Information	Diagnosis
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For all medically accepted indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. For the treatment of Epilepsy/Seizures, approve only if the patient is currently taking phenobarbital.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

HIGH RISK MEDICATIONS - BENZODIAZEPINES - ALPRAZOLAM

Products Affected

- alprazolam oral tablet

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

HIGH RISK MEDICATIONS - BENZODIAZEPINES - CLORAZEPATE

Products Affected

- clorazepate dipotassium

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

HIGH RISK MEDICATIONS - BENZODIAZEPINES - DIAZEPAM

Products Affected

- Diazepam Intensol
- diazepam oral solution 5 mg/5 mL (1 mg/mL)
- diazepam oral tablet

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

HIGH RISK MEDICATIONS - BENZODIAZEPINES - LORAZEPAM

Products Affected

- Lorazepam Intensol
- lorazepam oral tablet

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

HIGH RISK MEDICATIONS - BENZODIAZEPINES - TEMAZEPAM

Products Affected

- temazepam oral capsule 15 mg, 30 mg, 7.5 mg

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

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES - CYPROHEPTADINE

Products Affected

- cyproheptadine oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	For all covered indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. Please note that this risk assessment should include the concomitant use of other anticholinergic medications at the same time as the requested medication. For Allergic Rhinitis: the patient has tried and experienced an inadequate treatment response or intolerance to at least TWO of the following non-HRM alternative drugs: 1) azelastine nasal/eye, 2) desloratadine, 3) flunisolide nasal, 4) fluticasone nasal, 5) levocetirizine, 6) mometasone nasal, or 7) olopatadine nasal.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Pruritus, spasticity due to spinal cord injury
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES - HYDROXYZINE

Products Affected

- hydroxyzine HCl oral tablet
- hydroxyzine pamoate oral capsule 25 mg, 50 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	For all medically accepted indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. Please note that this risk assessment should include the concomitant use of other anticholinergic medications at the same time as the requested medication. For Allergic Rhinitis: the patient has tried and experienced an inadequate treatment response or intolerance to at least TWO of the following non-HRM alternative drugs: 1) azelastine nasal/eye, 2) desloratadine, 3) flunisolide nasal, 4) fluticasone nasal, 5) levocetirizine, 6) mometasone nasal, or 7) olopatadine nasal. For Anxiety: the patient has tried and experienced an inadequate treatment response, intolerance, or has a contraindication to at least TWO of the following alternative drugs: 1) a selective serotonin reuptake inhibitor (SSRI) (e.g. sertraline, escitalopram), 2) a serotonin-norepinephrine reuptake inhibitor (SNRI) (e.g. duloxetine, venlafaxine), or 3) buspirone.
Indications	All Medically-accepted Indications.
Off Label Uses	

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

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES - MECLIZINE

Products Affected

- meclizine oral tablet 12.5 mg, 25 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	For all medically accepted indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. Please note that this risk assessment should include the concomitant use of other anticholinergic medications at the same time as the requested medication.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES - PROMETHAZINE

Products Affected

- promethazine oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	For all medically accepted indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. Please note that this risk assessment should include the concomitant use of other anticholinergic medications at the same time as the requested medication. For Allergic Rhinitis: the patient has tried and experienced an inadequate treatment response or intolerance to at least TWO of the following non-HRM alternative drugs: 1) azelastine nasal/eye, 2) desloratadine, 3) flunisolide nasal, 4) fluticasone nasal, 5) levocetirizine, 6) mometasone nasal, or 7) olopatadine nasal. For the treatment of Nausea and Vomiting, approve if the patient has tried at least one other prescription oral anti-emetic agent (e.g. ondansetron, granisetron, aprepitant).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

HIGH RISK MEDICATIONS - SKELETAL MUSCLE RELAXANTS - CYCLOBENZAPRINE

Products Affected

- cyclobenzaprine oral tablet 10 mg, 5 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	For all medically accepted indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. Please note that this risk assessment should include the concomitant use of other anticholinergic medications at the same time as the requested medication.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

HYRNUO

Products Affected

- Hyrnuo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

IBTROZI

Products Affected

- Ibtrozi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ICATIBANT

Products Affected

- icatibant

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

ICLUSIG

Products Affected

- Iclusig

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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
Prerequisite Therapy Required	Yes

IDHIFA

Products Affected

- Idhifa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	IDH2-mutation status
Age Restrictions	18 years and older
Prescriber Restrictions	
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

IMATINIB

Products Affected

- imatinib
- Imkeldi

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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

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

IMPAVIDO

Products Affected

- Impavido

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
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

INCRELEX

Products Affected

- Increlex

PA Criteria	Criteria Details
Exclusion Criteria	Pediatric patients with closed epiphyses
Required Medical Information	For growth failure due to severe primary insulin like growth factor 1 (IGF 1) deficiency: the patient must meet all of the following (1, 2, AND 3): 1) height is three (3) or more standard deviations (SD) below the mean for children of the same age and gender, and 2) basal insulin-like growth factor-1 level three or more standard deviations below the mean for children of the same age and gender, and 3) a provocative growth hormone stimulation test demonstrates a normal or elevated growth hormone level. For growth failure due to growth hormone (GH) gene deletion: the patient must have documentation of neutralizing antibodies to growth hormone. Continuation of therapy: the patient is experiencing improvement.
Age Restrictions	2 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

INGREZZA

Products Affected

- Ingrezza
- Ingrezza Initiation Pk(tardiv)

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

INLURIYO

Products Affected

- Inluriyo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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.
Off Label Uses	Recurrent breast cancer

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

INLYTA

Products Affected

- Inlyta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
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	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

IVERMECTIN (ORAL)

Products Affected

- ivermectin oral

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

IVIG

Products Affected

- Gamunex-C injection solution 1 gram/10 mL (10 %)

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

IWILFIN

Products Affected

- Iwilfin

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JAKAFI

Products Affected

- Jakafi
- Jakafi XR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
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	
Coverage Duration	1 year

PA Criteria	Criteria Details
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 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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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, capsules, and oral solution), rituximab, bendamustine, cyclophosphamide, dexamethasone, bortezomib, Kyprolis (carfilzomib intravenous infusion), or Ninlaro (ixazomib capsule) .

PA Criteria	Criteria Details
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

JIDEYTRO

Products Affected

- Jideytro

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

JYNARQUE

Products Affected

- tolvaptan (polycys kidney dis) oral tablet

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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KETOCONAZOLE

Products Affected

- ketoconazole oral

PA Criteria	Criteria Details
Exclusion Criteria	Acute or chronic liver disease. Concurrent use with drugs that are contraindicated with ketoconazole tablets: dofetilide, quinidine, pimozide, cisapride, methadone, disopyramide, dronedarone, ranolazine, ergot alkaloids, irinotecan, lurasidone, oral midazolam, alprazolam, triazolam, felodipine, nisoldipine, tolvaptan, eplerenone, lovastatin, simvastatin, or colchicine.
Required Medical Information	The potential benefits outweigh the risks of treatment with oral ketoconazole. For systemic fungal infections, the patient has any of the following diagnoses: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis. For Cushing's syndrome: the requested drug is being prescribed for a patient who cannot tolerate surgery or where surgery has not been curative.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Cushing's syndrome, Castration-resistant prostate cancer: 12 months. All others: 6 months
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Cushing's syndrome, Castration-resistant prostate cancer, Cutaneous leishmaniasis
Part B Prerequisite	No
Prerequisite Therapy Required	No

KISQALI

Products Affected

- Kisqali

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

KOMZIFTI

Products Affected

- Komzifti

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KORLYM

Products Affected

- mifepristone oral tablet 300 mg

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

KOSELUGO

Products Affected

- Koselugo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
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	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
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 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

LAPATINIB

Products Affected

- lapatinib

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

LAZCLUZE

Products Affected

- Lazcluze

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LEDIPASVIR/SOFOSBUVIR

Products Affected

- ledipasvir-sofosbuvir

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other direct acting antivirals, excluding ribavirin
Required Medical Information	Diagnosis
Age Restrictions	3 years or older
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
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

LENALIDOMIDE

Products Affected

- lenalidomide

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (except Kaposi Sarcoma, Castleman Disease, Primary CNS Lymphoma)
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year.

PA Criteria	Criteria Details
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-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.

PA Criteria	Criteria Details
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

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

LEQEMBI IQLIK

Products Affected

- Leqembi Iqlik subcutaneous auto-injector 360 mg/1.8 mL

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

LEUKINE

Products Affected

- Leukine injection recon soln

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
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

LIDOCAINE PATCH

Products Affected

- lidocaine topical adhesive patch,medicated 5 %
- Lidocan III
- Tridacaine II

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months
Other Criteria	
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

LIFYORLI

Products Affected

- Lifyorli

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LIVTENCITY

Products Affected

- Livtencity

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

LONG ACTING OPIOIDS - METHADONE

Products Affected

- methadone oral solution
- methadone oral tablet

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

LONG ACTING OPIOIDS - MORPHINE

Products Affected

- morphine oral tablet extended release

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

LONSURF

Products Affected

- Lonsurf

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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

LORBRENA

Products Affected

- Lorbrena

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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.
Off Label Uses	Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma, Small Bowel Adenocarcinoma, Appendiceal cancer

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

LUPRON DEPOT

Products Affected

- Lupron Depot

PA Criteria	Criteria Details
Exclusion Criteria	
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.

PA Criteria	Criteria Details
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 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

LYNPARZA

Products Affected

- Lynparza

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
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 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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MEGESTROL

Products Affected

- megestrol oral suspension 400 mg/10 mL (40 mg/mL), 625 mg/5 mL (125 mg/mL)

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for weight gain for cosmetic reasons.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEKINIST

Products Affected

- Mekinist

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year.

PA Criteria	Criteria Details
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 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	
Required Medical Information	Diagnosis, BRAF V600 status, concomitant medications
Age Restrictions	18 years and older
Prescriber Restrictions	
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 - MEMANTINE

Products Affected

- memantine oral capsule,sprinkle,ER 24hr
- memantine oral solution
- memantine oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Indication for which memantine is being prescribed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	This Prior Authorization requirement only applies to patients 26 years of age or younger
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

MODAFINIL

Products Affected

- modafinil

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
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	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NAYZILAM

Products Affected

- Nayzilam

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, other medications used at the same time
Age Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NERLYNX

Products Affected

- Nerlynx

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Stage of cancer, HER2 status, previous or current medications tried
Age Restrictions	18 years and older
Prescriber Restrictions	
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: 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.

PA Criteria	Criteria Details
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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

NILOTINIB

Products Affected

- Danziten
- nilotinib HCl

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older, ALL - 15 years and older
Prescriber Restrictions	
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
Prerequisite Therapy Required	Yes

NINLARO

Products Affected

- Ninlaro

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
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
Prerequisite Therapy Required	Yes

NINTEDANIB

Products Affected

- nintedanib
- Ofev

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER 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	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NIVESTYM

Products Affected

- Nivestym

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

NON-INJECTABLE TESTOSTERONE PRODUCTS - TESTOSTERONE

Products Affected

- 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)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
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)-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.

PA Criteria	Criteria Details
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	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NUCALA

Products Affected

- Nucala

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

NUEDEXTA

Products Affected

- Nuedexta

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

NUPLAZID

Products Affected

- Nuplazid

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

NURTEC

Products Affected

- Nurtec ODT

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

OCTREOTIDE INJECTABLE

Products Affected

- octreotide acetate injection solution

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

ODOMZO

Products Affected

- Odomzo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	BCC - Must not have had disease progression while on Erivedge (vismodegib).
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OJEMDA

Products Affected

- Ojemda

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	6 months of age and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OJJAARA

Products Affected

- Ojjaara

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	
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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

ORGOVYX

Products Affected

- Orgovyx

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

ORSERDU

Products Affected

- Orserdu

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

PANRETIN

Products Affected

- Panretin

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PEMAZYRE

Products Affected

- Pemazyre

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PENICILLAMINE

Products Affected

- penicillamine oral tablet

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

PHENYLBUTYRATE - PHENYLBUTYRATE

Products Affected

- sodium phenylbutyrate

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PHEOCHROMOCYTOMA - METYROSINE

Products Affected

- metyrosine

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER 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	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
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	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PHOSPHODIESTERASE-5 INHIBITORS - SILDENAFIL

Products Affected

- sildenafil (pulm.hypertension) oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use With Guanylate Cyclase Stimulators.
Required Medical Information	Diagnosis, right heart cath results
Age Restrictions	
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

- tadalafil (pulm. hypertension)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use With Guanylate Cyclase Stimulators.
Required Medical Information	Diagnosis, right heart cath results
Age Restrictions	
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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PIRFENIDONE

Products Affected

- pirfenidone oral tablet 267 mg, 801 mg

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

POMALYST

Products Affected

- pomalidomide
- Pomalyst

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Kaposi Sarcoma/MM/Systemic light chain amyloidosis-18 years and older
Prescriber Restrictions	
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	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PRALUENT

Products Affected

- Praluent Pen

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

PREVYMIS

Products Affected

- Prevymis oral tablet

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

PROMACTA

Products Affected

- eltrombopag olamine

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

PYRIMETHAMINE

Products Affected

- pyrimethamine

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
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	
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	
Required Medical Information	Diagnosis, other therapies tried
Age Restrictions	18 years and older
Prescriber Restrictions	
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

QUININE SULFATE

Products Affected

- quinine sulfate

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For babesiosis: the requested drug is prescribed in combination with clindamycin
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	2 months
Other Criteria	Chloroquine-sensitive Plasmodium falciparum malaria: Failure, contraindication, or intolerance to chloroquine or hydroxychloroquine.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Babesiosis, Uncomplicated Plasmodium vivax malaria
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RETEVMO

Products Affected

- Retevmo oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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	
Required Medical Information	Diagnosis, lab values, genetic tests (as specified in the Other Criteria field)
Age Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REVUFORJ

Products Affected

- Revuforj

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZDIFFRA

Products Affected

- Rezdiffra

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

REZLIDHIA

Products Affected

- Rezlidhia

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RINVOQ

Products Affected

- Rinvoq

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER 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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ROMVIMZA

Products Affected

- Romvimza

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ROZLYTREK

Products Affected

- Rozlytrek

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

RYDAPT

Products Affected

- Rydapt

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For AML, FLT3 status
Age Restrictions	18 years and older
Prescriber Restrictions	
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

SAPROPTERIN

Products Affected

- sapropterin oral powder in packet 100 mg

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	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SCEMBLIX

Products Affected

- Scemblix

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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
Prerequisite Therapy Required	Yes

SIGNIFOR

Products Affected

- Signifor

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER 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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SKYRIZI

Products Affected

- Skyrizi subcutaneous

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

SOFOSBUVIR/VELPATASVIR

Products Affected

- sofosbuvir-velpatasvir

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other direct acting antivirals, excluding ribavirin.
Required Medical Information	Diagnosis
Age Restrictions	3 years or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No
Prerequisite Therapy Required	No

SOMAVERT

Products Affected

- Somavert

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

SORAFENIB

Products Affected

- sorafenib

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
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 for all diagnoses: Part B before Part D Step Therapy applies only to beneficiaries enrolled in an MA-PD plan

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

SPRYCEL

Products Affected

- dasatinib

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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

SUNITINIB

Products Affected

- sunitinib malate

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

TABRECTA

Products Affected

- Tabrecta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAFINLAR

Products Affected

- Tafinlar

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year.

PA Criteria	Criteria Details
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 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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

TALZENNA

Products Affected

- Talzenna

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

TARPEYO

Products Affected

- Tarpeyo

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

TAZAROTENE

Products Affected

- tazarotene topical cream 0.1 %
- tazarotene topical gel
- Trilitas

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

TEPMETKO

Products Affected

- Tepmetko

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

TETRABENAZINE

Products Affected

- tetrabenazine

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

THALOMID

Products Affected

- Thalomid oral capsule 100 mg, 50 mg

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

TIBSOVO

Products Affected

- Tibsovo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, IDH1 Status
Age Restrictions	All diagnoses (except chondrosarcoma)-18 years and older
Prescriber Restrictions	
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

TOBRAMYCIN (NEBULIZATION)

Products Affected

- tobramycin in 0.225 % NaCl

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
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	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOPICAL AGENTS FOR ATOPIC DERMATITIS - CRISABOROLE

Products Affected

- Eucrisa

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

TOPICAL RETINOID PRODUCTS - TRETINOIN

Products Affected

- tretinoin

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for cosmetic use.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOPIRAMATE

Products Affected

- topiramate oral solution

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for weight loss or smoking cessation.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

TREMFYA SC

Products Affected

- Tremfya One-Press
- Tremfya Pen Induction Pk(2pen)
- Tremfya Pen subcutaneous pen injector 200 mg/2 mL
- Tremfya subcutaneous syringe

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

TRIENTINE

Products Affected

- trientine oral capsule 250 mg

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

TRIKAFTA

Products Affected

- Trikafta

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

TRUQAP

Products Affected

- Truqap

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

TUKYSA

Products Affected

- Tukysa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
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 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

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

TURALIO

Products Affected

- Turalio

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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 SC

Products Affected

- Tyenne Autoinjector
- Tyenne subcutaneous

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

UCERIS

Products Affected

- budesonide oral tablet,delayed and ext.release

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	2 months
Other Criteria	The patient has experienced an inadequate treatment response or intolerance to a 4 week trial of an aminosalicylate (e.g. sulfasalazine, mesalamine)
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

USTEKINUMAB SC

Products Affected

- Steqeyma subcutaneous
- ustekinumab-ttwe subcutaneous

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

VALCHLOR

Products Affected

- Valchlor

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Cutaneous lymphoma-18 years and older
Prescriber Restrictions	
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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

VANFLYTA

Products Affected

- Vanflyta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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

VELSIPITY

Products Affected

- Velsipity

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs) or with other potent immunosuppressants.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist (initial therapy only)
Coverage Duration	Approve through end of plan year
Other Criteria	Ulcerative colitis, initial therapy-approve if the patient has had a trial of TWO of the following: a preferred adalimumab product, a preferred ustekinumab product, Skyrizi, a preferred infliximab product, Rinvoq. A trial of a non-preferred infliximab product, a non-preferred ustekinumab, Tremfya, Simponi SC, Entyvio IV/SC, Omvoh IV/SC, or a Non-Preferred adalimumab product will also count. Ulcerative colitis, continuation-approve if the patient has had a response.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VENCLEXTA

Products Affected

- Venclexta
- Venclexta Starting Pack

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapy
Age Restrictions	18 years and older (all diagnoses except ALL)
Prescriber Restrictions	
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

VERSACLOZ

Products Affected

- Versacloz

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Patient must meet both (1 AND 2): 1) meets either (A or B): A) the patient has prior therapy or intolerance to generic clozapine tablets, or B) the patient has difficulty swallowing solid oral dosage forms, AND 2) For treatment-resistant schizophrenia (failed to respond adequately to standard antipsychotic treatment) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least two other antipsychotic medications (e.g. aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, Caplyta, Cobenfy, Rexulti, Secuado, Vraylar).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VERZENIO

Products Affected

- Verzenio

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

VIGABATRIN

Products Affected

- vigabatrin
- Vigadrone

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

VITRAKVI

Products Affected

- Vitrakvi

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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

VIZIMPRO

Products Affected

- Vizimpro

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

VONJO

Products Affected

- Vonjo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VORICONAZOLE (ORAL)

Products Affected

- voriconazole oral

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

VOSEVI

Products Affected

- Vosevi

PA Criteria	Criteria Details
Exclusion Criteria	
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	Member has an inadequate response, contraindication, or intolerance to sofosbuvir/velpatasvir (Epclusa) or ledipasvir/sofosbuvir (Harvoni), when clinically appropriate per current AASLD/IDSA guidance. 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

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

VOWST

Products Affected

- Vowst

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	No

WEGOVY

Products Affected

- Wegovy

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

WELIREG

Products Affected

- Welireg

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

WINREVAIR

Products Affected

- Winrevair

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

XALKORI

Products Affected

- Xalkori

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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.
Off Label Uses	NSCLC with high level MET amplification or MET Exon 14 skipping mutation, Histiocytic neoplasms, melanoma, cutaneous.

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

XDEMVY

Products Affected

- Xdemvy

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

XELJANZ

Products Affected

- tofacitinib

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

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

XERMELO

Products Affected

- Xermelo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapy, concomitant therapy
Age Restrictions	
Prescriber Restrictions	
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XIFAXAN

Products Affected

- Xifaxan

PA Criteria	Criteria Details
Exclusion Criteria	
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

PA Criteria	Criteria Details
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) 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

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

XOSPATA

Products Affected

- Xospata

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, FLT3-mutation status
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
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 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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis for which Xtandi is being used.
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year.

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

ZEJULA

Products Affected

- Zejula

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
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	
Required Medical Information	BRAFV600 mutation status required.
Age Restrictions	All diagnoses (except CNS cancer)-18 years and older
Prescriber Restrictions	
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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

ZOLINZA

Products Affected

- Zolinza

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Classic Hodgkin Lymphoma-18 years and older
Prescriber Restrictions	
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

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for weight loss or smoking cessation.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZTALMY

Products Affected

- Ztalmy

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

ZURZUVAE

Products Affected

- Zurzuvae

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

ZYKADIA

Products Affected

- Zykadia

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
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	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	UNDER CMS REVIEW
Prerequisite Therapy Required	UNDER CMS REVIEW

ZYTIGA

Products Affected

- abiraterone oral tablet 250 mg
- Abirtega

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year.

PA Criteria	Criteria Details
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 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

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes