PENDING CMS REVIEW & APPROVAL

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

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PENDING CMS REVIEW & APPROVAL

ACYCLOVIR (Topical)

Products Affected

- Acyclovir External

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

PENDING CMS REVIEW & APPROVAL

ADALIMUMAB

Products Affected

- Abrilada (2 Pen)
- Abrilada (2 Syringe)
- Hadlima
- Hadlima PushTouch
- Simlandi (1 Pen)
- Simlandi (2 Pen)
- Simlandi (2 Syringe)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
Required Medical Information	Diagnosis
Age Restrictions	Initial therapy only: CD-6 years and older, UC-5 years and older, AS/PsA/RA/PP/ Pyoderma gangrenosum/ sarcoidosis/ scleritis/ sterile corneal ulceration/ non-radiographic axial spondyloarthritis-18 years and older, JIA/UV/Behcet's disease-2 years and older, HS-12 years and older
Prescriber Restrictions	Initial therapy only for all dx, prescribed by or in consultation with one of the following specialists-RA/JIA/JRA/Ankylosing spondylitis/nr-axSpA, rheumatologist. PsA, rheumatologist or dermatologist. PP, dermatologist. UC/ CD, gastroenterologist. HS/pyoderma gangrenosum - dermatologist.UV/scleritis/sterile corneal ulceration-ophthalmologist. Behcet's- rheum, derm, ophthalmol, gastro, neuro. Sarcoidosis, pulm, ophthalmol, derm, cardio, neuro.
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: CROHN'S DISEASE (CD): approve. JUVENILE IDIOPATHIC ARTHRITIS (JIA)/JRA (one of A, B, C, D, or E): A) tried one other systemic therapy (e.g., MTX, sulfasalazine, leflunomide, NSAID), B) tried a biologic (e.g., etanercept, abatacept, infliximab, anakinra, tocilizumab), C) will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide, D) patient has absolute contraindication to MTX, sulfasalazine, or leflunomide, or E) patient has aggressive disease. HIDRADENITIS SUPPURATIVA (HS): tried one other therapy (e.g., intralesional or oral CS, systemic antibiotics,



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PA Criteria	Criteria Details
	isotretinoin). PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent (e.g., MTX, cyclosporine (CSA), acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of a biologic will also count) or B) contraindication to MTX. RHEUMATOID ARTHRITIS (RA): tried one conventional synthetic DMARD for at least 3 months (Note: a 3-month trial of a biologic will also count). ULCERATIVE COLITIS: approve. BEHCET'S DISEASE (A or B): A) tried one conventional therapy (e.g., systemic CS, azathioprine, MTX, CSA, chlorambucil, cyclophosphamide, interferon alfa, or Otezla/Otezla XR [apremilast tablets/extended-release tablets]), or B) has ophthalmic manifestations. SARCOIDOSIS (A and B): A) tried one CS, and B) tried one immunosuppressant (e.g. MTX, mycophenolate mofetil, infliximab, chloroquine). SCLERITIS/STERILE CORNEAL ULCERATION: tried one other therapy (e.g. CS, CSA). NON RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: objective signs of inflammation defined as either (A or B): A) C-reactive protein elevated beyond upper limit of normal, or B) sacroiliitis on MRI. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Behcet's disease, pyoderma gangrenosum, sarcoidosis, scleritis/sterile corneal ulceration, non-radiographic axial spondyloarthritis.
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

ADBRY

Products Affected

- Adbry

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy (examples: Dupixent, Exdensur, Cinqair, Ebglyss, Fasenra, Nemluvio, Nucala, Tezspire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical] (examples: Cibinqo, Leqselvi, Rinvoq/LQ, Opzelura)
Required Medical Information	Diagnosis
Age Restrictions	AD-12 years of age and older (initial therapy)
Prescriber Restrictions	Atopic Dermatitis-prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Atopic Dermatitis, initial-approve. Continuation- Approve if the patient has been receiving Adbry for at least 4 months and patient has responded to therapy. Note: A patient who has received less than 4 months of therapy or who is restarting therapy with Adbry should be considered under initial therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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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

PENDING CMS REVIEW & APPROVAL

AIMOVIG

Products Affected

- Aimovig

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with another cGRP inhibitor for migraine headache prevention
Required Medical Information	Diagnosis, number of migraine headaches per month
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) If pt is currently taking Aimovig, the pt has had significant clinical benefit from the medication. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Aimovig was initiated.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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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

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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.

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

PENDING CMS REVIEW & APPROVAL

ALOSETRON

Products Affected

- Alosetron HCl

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

PENDING CMS REVIEW & APPROVAL

ALPHA 1 PROTEINASE INHIBITORS

Products Affected

- Prolastin-C

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 pulmonologist (initial)
Coverage Duration	1 year
Other Criteria	Alpha1-Antitrypsin Deficiency with Emphysema (or Chronic Obstructive Pulmonary Disease), initial-approve if the patient has a baseline (pretreatment) AAT serum concentration of less than 80 mg/dL or 11 micromol/L, had genotyping or phenotyping demonstrating ONE of the following types: PI-ZZ, PI-(null)(null), PI-Z(null), PI-SZ or other rare disease-causing alleles associated with serum alpha1-antitrypsin (AAT) level less than or equal to 11 micromol/L, and has clinical evidence of emphysema or chronic obstructive pulmonary disease. Continuation-approve if the patient has a baseline (pretreatment) AAT serum concentration of less than 80 mg/dL or 11 micromol/L.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No



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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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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

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ANTIFUNGALS (IV) - FLUCONAZOLE

Products Affected

- Fluconazole in Sodium Chloride

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

PENDING CMS REVIEW & APPROVAL

ANTIFUNGALS (IV) - VORICONAZOLE

Products Affected

- Voriconazole

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

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arcalyst

Products Affected

- Arcalyst

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

PENDING CMS REVIEW & APPROVAL

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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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AUSTEDO

Products Affected

- Austedo
- Austedo XR
- Austedo XR Patient Titration

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

PENDING CMS REVIEW & APPROVAL

AVMAPKI-FAKZYNJA

Products Affected

- Avmapki Fakzynja Co-Pack

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- ALL of the following (A, B and C): A) Patient has recurrent low-grade serous cancer, AND B) The cancer has a KRAS mutation, AND C) Patient has tried at least one systemic therapy. Note: Examples of systemic therapy include one or more of the following medications: paclitaxel, carboplatin, bevacizumab, letrozole, anastrozole, or exemestane.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Fallopian Tube or Primary Peritoneal Cancer
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

avonex

Products Affected

- Avonex Pen
- Avonex Prefilled

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of other disease-modifying agent used for multiple sclerosis
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	
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

PENDING CMS REVIEW & APPROVAL

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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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.



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

PENDING CMS REVIEW & APPROVAL

BENLYSTA

Products Affected

- Benlysta

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Biologics or Lupkynis
Required Medical Information	Diagnosis
Age Restrictions	5 years and older (initial).
Prescriber Restrictions	SLE-Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus Nephritis-nephrologist or rheum. (Initial/cont)
Coverage Duration	1 year
Other Criteria	Lupus Nephritis Initial-approve if the patient has a diagnosis of lupus nephritis confirmed on biopsy (For example, World Health Organization class III, IV, or V lupus nephritis), AND the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid). Cont-approve if the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid) AND the patient has responded to Benlysta subcutaneous or intravenous. SLE-Initial-The patient has autoantibody-positive SLE, defined as positive for at least one of the following: antinuclear antibodies (ANA), anti-double-stranded DNA (anti-dsDNA) antibodies, anti-Smith (anti-Sm) antibodies AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity. Continuation-Benlysta is being

PA Criteria	Criteria Details
	used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity AND The patient has responded to Benlysta subcutaneous or intravenous.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

BETASERON/EXTAVIA

Products Affected

- Betaseron

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

BOSENTAN

Products Affected

- Bosentan

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	No

PENDING CMS REVIEW & APPROVAL

bosulif

Products Affected

- Bosulif
- Bosutinib

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	No

PENDING CMS REVIEW & APPROVAL

BRAFTOVI

Products Affected
- Braftovi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, BRAF V600 status
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation. Colon or Rectal cancer-approve if the patient meets the following (A and B): A) The patient has BRAF V600E mutation-positive disease AND B) meets (i or ii): i) will be used as first-line systemic therapy for metastatic disease in combination with (a and b) a) Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion) and b) FOLFOX (5-FU, leucovorin, and oxaliplatin) or ii) patient has previously received a chemotherapy regimen for colon or rectal cancer and this is prescribed in combination with Erbitux or Vectibix (panitumumab intravenous infusion). NSCLC- approve if pt has BRAF V600E mutation-positive recurrent, advanced or metastatic disease AND this medication will be taken in combination with Mektovi (binimetinib tablets). Appendiceal adenocarcinoma-approve if (A, B and C): A) BRAF V600E mutation-positive, and B) pt has advanced or metastatic disease, and C) used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.



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PA Criteria	Criteria Details
Off Label Uses	Appendiceal adenocarcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

BRIVARACETAM

Products Affected
- Brivaracetam

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

PENDING CMS REVIEW & APPROVAL

BRUKINSA

Products Affected

- Brukinsa

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. Mantle Cell Lymphoma-approve if patient meets one of (A, B, C or D): A) tried at least one systemic regimen, or B) is not a candidate for a chemotherapy regimen, or C) will use this medication in combination with rituximab, or D) patient has TP53 mutation and this medication is used as induction therapy in combination with Venclexta (venetoclax tablets) and Gazyva (obinutuzumab intravenous infusion). Marginal zone lymphoma-approve if the patient has tried at least one systemic regimen. Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma-approve. Hairy Cell Leukemia - approve if pt has received therapy for relapsed or refractory disease AND pt has progressive disease. Primary Central Nervous System Lymphoma - approve if pt has tried at least one systemic regimen and the medication is used in combination with autologous stem cell reinfusion.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Hairy Cell Leukemia, Primary Central Nervous System Lymphoma

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

C1 ESTERASE INHIBITORS

Products Affected

- Cinryze

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

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

CABLIVI

Products Affected

- Cablivi

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

PENDING CMS REVIEW & APPROVAL

CABOMETYX

Products Affected

- Cabometyx

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Neuroendocrine tumor/Thyroid carcinoma-12 years and older, other dx (except bone cancer)-18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Renal Cell Carcinoma-Approve if the patient has relapsed or stage IV disease. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). Bone cancer-approve if the patient has Ewing sarcoma or osteosarcoma and has tried at least one previous systemic regimen. Thyroid carcinoma-approve if the patient has differentiated thyroid carcinoma, patient is refractory to radioactive iodine therapy and the patient has tried Lenvima or sorafenib. Endometrial carcinoma-approve if the patient has tried one systemic regimen. GIST-approve if the patient has tried two of the following-imatinib, Ayvakit, sunitinib, dasatinib, Stivarga or Qinlock. NSCLC-approve if the patient has RET rearrangement positive tumor and has progressed on one of the first-line therapies, Gavreto (pralsetinib capsules) or Retevmo (selpercatinib capsules or tablets). Neuroendocrine tumors- approve if (A, B, C and D): A) pt has locally advanced, unresectable, or metastatic disease, and B) patient has well-differentiated neuroendocrine tumors, and C) patient has pancreatic or extra-pancreatic neuroendocrine tumors and D) the medication will be used as subsequent therapy. Adrenal gland tumor-

PA Criteria	Criteria Details
	approve if pt has locoregional unresectable or metastatic adrenocortical carcinoma. Pheochromocytoma/paraganglioma- approve if pt has locally unresectable disease or distant metastases. Soft tissue sarcoma-Approve if pt has advanced, metastatic, or unresectable disease, has been previously treated with at least one systemic therapy, and has ONE of the following (A, B, C, D, E, F, or G): A) Extremity/body wall, head/neck soft tissue sarcoma or B) Retroperitoneal/intra-abdominal soft tissue sarcoma or C) Rhabdomyosarcoma or D) Borderline/malignant phyllodes tumor of the breast or E) Alveolar soft part sarcoma or F) Extraskeletal myxoid chondrosarcoma or G) Epithelioid hemangioendothelioma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients with Non-Small Cell Lung Cancer, Gastrointestinal stromal tumors (GIST), Bone cancer, Endometrial carcinoma, Adrenal gland tumor, Pheochromocytoma/paraganglioma, Soft tissue sarcoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

CALQUENCE

Products Affected

- Calquence

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.

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

CAMZYOS

Products Affected
- Camzyos

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by a cardiologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	Obstructive hypertrophic cardiomyopathy, initial-Approve if the pt meets the following criteria (i, ii, iii and iv): i.Pt meets both of the following (a and b): a)Pt has at least 1 symptom associated w/obstructive hypertrophic cardiomyopathy (Note: examples include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise), AND b)Pt has New York Heart Association Class II or III symptoms of heart failure, AND ii.Pt has left ventricular hypertrophy and meets 1 of the following (a or b): a)Pt has maximal left ventricular wall thickness greater than or equal to 15 mm, OR b)Pt has familial hypertrophic cardiomyopathy with a maximal left ventricular wall thickness greater than or equal to 13 mm, AND iii.Pt has a peak left ventricular outflow tract gradient at least 30 mmHg at rest or at least 50 mmHg (after provocation (Valsalva maneuver or post exercise) AND iv. tried or is currently receiving at least one beta-blocker or nondihydropyridine calcium channel blocker for at least 3 months unless the patient has a contraindication or intolerance to a beta-blocker or nondihydropyridine calciumn channel blocker. Cont-Approve if pt meets ALL of the following criteria (i, ii, and iii): i.Pt has been established on therapy for at least 1 year (Note: pt who has received less than 1 year of

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

CARGLUMIC ACID

Products Affected

- Carglumic Acid

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 a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	NAGS-Pt meets criteria no genetic test-3 mo. Pt had genetic test-12 mo, other-approve 7 days
Other Criteria	N-Acetylglutamate synthase deficiency with hyperammonemia-Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency or if the patient has hyperammonemia. Propionic Acidemia or Methylmalonic Acidemia with Hyperammonemia, Acute Treatment-approve if the patient's plasma ammonia level is greater then or equal to 50 micromol/L and the requested medication will be used in conjunction with other ammonia-lowering therapies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (generic carglumic acid)
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

cimzia

Products Affected

- Cimzia
- Cimzia (1 Syringe)
- Cimzia (2 Syringe)
- Cimzia-Starter

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried
Age Restrictions	18 years and older for AS, nr-axSpA, PsA, RA CD and PP (initial therapy). 2 years and older for JIA (initial therapy).
Prescriber Restrictions	All dx initial therapy only. RA, AS, JIA, prescribed by or in consultation with a rheumatologist. Crohn's disease, prescribed by or in consultation with a gastroenterologist. PsA prescribed by or in consultation with a rheumatologist or dermatologist. PP, prescribed by or in consultation with a dermatologist. nr-axSpA-prescribed by or in consultation with a rheumatologist
Coverage Duration	Approve through end of plan year
Other Criteria	AS initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, tofacitinib/XR, Cosentyx. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product will also count. PsA initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Cosentyx, Tremfya, a preferred ustekinumab product, Otezla, Rinvoq, Skyrizi or tofacitinib/XR. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab/ustekinumab product will also count. RA initial tx, approve if the patient has tried two of the following drugs in the past: Enbrel, a preferred adalimumab product, Rinvoq or tofacitinib/XR. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product will also

PA Criteria	Criteria Details
	count. CD initial tx, approve if patient has previously tried ONE of the following drugs in the past: a preferred adalimumab product, a preferred infliximab product, a preferred ustekinumab product, Skyrizi, Rinvoq, or Tremfya. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab/infliximab/ustekinumab product will also count. Plaque Psoriasis (PP), initial tx-approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Skyrizi, a preferred ustekinumab product, Otezla, Cosentyx, Tremfya. A trial of a non-preferred adalimumab/ustekinumab also counts. JIA initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, Rinvoq/LQ, tofacitinib, a preferred adalimumab product. Note pt does not meet this requirement, a trial with a non-preferred adalimumab, Simponi Aria, tocilizumab, Kevzara, or inflixmab will also count. Cont tx, AS/PsA/RA/CD/PP/JIA - approve if the pt had a response as determined by the prescriber. Non-radiographic axial spondylitis (nr-axSpA), initial tx-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroilitis reported on MRI. nr-axSpA continuation tx-approve if the patient has had a response as determined by the prescriber. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab products include Remicade, infliximab IV (brand name product), Zymfentra. Preferred ustekinumab products include Otulfi, Pyzchiva (NDCs beginning with 61314-), Yesintek.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

CINACALCET

Products Affected
- Cinacalcet HCl

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

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

CLOBAZAM

Products Affected

- cloBAZam
- Sympazan

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, other medications tried
Age Restrictions	2 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Lennox-Gastaut Syndrome, initial therapy-patient has tried and/or is concomitantly receiving one of the following: lamotrigine, topiramate, rufinamide, felbamate, Fintepla, Epidiolex or valproic acid. Treatment refractory seizures/epilepsy, initial therapy-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs (e.g., valproic acid, lamotrigine, topiramate, clonazepam, levetiracetam, zonisamide, felbamate). Continuation-prescriber confirms patient is responding to therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Dravet Syndrome and treatment-refractory seizures/epilepsy
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

cometriq

Products Affected

- Cometriq (100 MG Daily Dose)
- Cometriq (140 MG Daily Dose)
- Cometriq (60 MG Daily Dose)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis.
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	MTC - approve. Non-Small Cell Lung Cancer-approve if patient meets (A, B and C): A) recurrent, advanced, or metastatic disease, B) has RET gene rearrangement-positive tumor, and C) has progressed on one of the first-line therapies, Gavreto (pralsetinib capsules) or Retevmo (selpercatinib capsules or tablets). Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy and patient has tried tried Lenvima (lenvatinib capsules) or sorafenib tablets.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma
Part B Prerequisite	No

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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	No

PENDING CMS REVIEW & APPROVAL

COSENTYX

Products Affected

- Cosentyx
- Cosentyx (300 MG Dose)
- Cosentyx Sensoready (300 MG)
- Cosentyx UnoReady

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis and previous medications use
Age Restrictions	PP-6 yr and older. Spondy initial - 18 years of age and older. PsA-2 years and older. Enthesitis-4 years and older, HS/AS initial-12 yr and older
Prescriber Restrictions	PP initial-presc/consult derm. PsA initial - prescribed by or in consultation with a dermatologist or rheumatologist. AS/spondylo/enthesitis initial- by or in consultation with rheumatologist. HS initial - by or in consult w/ dermatologist
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: HIDRADENITIS SUPPURATIVA (HS): tried at least one other therapy (e.g. systemic antibiotics, isotretinoin). NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: objective signs of inflammation and meets a or b: a) C-reactive protein elevated beyond the upper limit of normal or b) sacroiliitis reported on MRI. PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of at least one biologic that is not Cosentyx or a Cosentyx biosimilar also counts) or B) contraindication to MTX. CONTINUATION THERAPY: ALL INDICATIONS: patient has experienced benefit from the medication.
Indications	All FDA-approved Indications.
Off Label Uses	

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

CRESEMBA (ORAL)

Products Affected

- Cresemba

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

DALFAMPRIDINE

Products Affected

- Dalfampridine ER

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

PENDING CMS REVIEW & APPROVAL

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	No

PENDING CMS REVIEW & APPROVAL

DEFERASIROX

Products Affected

- Deferasirox
- Deferasirox Granules

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

PENDING CMS REVIEW & APPROVAL

DEFERIPRONE

Products Affected

- Deferiprone

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	Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias-Initial therapy - approve. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

DENOSUMAB (NON-OSTEOPOROSIS)

Products Affected

- Bomyntra
- Wyost

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	MM, Bone mets w/solid tumors-18 years and older
Prescriber Restrictions	MM, Bone mets w/solid tumors-Prescribed by or in consultation with a hematologist or an oncologist
Coverage Duration	Hypercalcemia of malignancy-2 months, all others-1 year
Other Criteria	BONE METASTASES FROM SOLID TUMORS-PREVENTION OF SKELETAL-RELATED EVENTS (examples of cancer in this clinical scenario include breast cancer, prostate cancer, and non-small cell lung cancer) - Patient has bone metastases AND patient with prostate cancer must have castration-resistant prostate cancer. Note: This includes patients who have progressed after treatment with hormonal therapy or after surgical castration (e.g., bilateral orchiectomy). Examples of hormonal therapies for prostate cancer include Lupron Depot (leuprolide for depot suspension), Eligard (leuprolide acetate for injectable suspension), Trelstar (triptorelin pamoate for injectable suspension), or Zoladex (goserelin implant). GIANT CELL TUMOR OF BONE-approve. HYPERCALCEMIA OF MALIGNANCY-patient has a current malignancy and has an albumin-corrected calcium (cCa) greater than or equal to 11.5 mg/dL. MULTIPLE MYELOMA - PREVENTION OF SKELETAL-RELATED EVENTS-approve.
Indications	All FDA-approved Indications.
Off Label Uses	

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

DIABETIC SUPPLY - ALCOHOL PADS

Products Affected

- Alcohol Swabs
- Alcohol Wipes

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

PENDING CMS REVIEW & APPROVAL

DIABETIC SUPPLY - GAUZE PADS

Products Affected

- Gauze Pads

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

PENDING CMS REVIEW & APPROVAL

DIABETIC SUPPLY - NEEDLES

Products Affected

- Insulin Needles
- Insulin Pen Needles

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

PENDING CMS REVIEW & APPROVAL

DIABETIC SUPPLY - SYRINGES

Products Affected

- Insulin Syringes

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

PENDING CMS REVIEW & APPROVAL

DIACOMIT

Products Affected

- Diacomit

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of diagnosis.
Age Restrictions	6 months and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Dravet Syndrome-Initial therapy-approve if the patient is concomitantly receiving clobazam or is unable to take clobazam due to adverse events. Dravet Syndrome-Continuation-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

DICLOFENAC (TOPICAL)

Products Affected

- Diclofenac Sodium External

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 mos.
Other Criteria	Patients requesting Diclofenac 2% solution pump must have a trial of generic diclofenac 1.5% topical solution.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

DIMETHYL FUMARATE

Products Affected

- Dimethyl Fumarate
- Dimethyl Fumarate Starter Pack

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

PENDING CMS REVIEW & APPROVAL

DOPTELET

Products Affected

- Doptelet
- Doptelet Sprinkle

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	For Doptelet Sprinkle: patient must be less than 6 years of age. For Doptelet tablets: Chronic/persistent ITP - no restriction, Thrombocytopenia in chronic liver disease - 18 years and older
Prescriber Restrictions	Chronic/persistent ITP-prescribed by or after consultation with a hematologist (initial therapy)
Coverage Duration	Thrombo w/chronic liver disease-5 days, chronic/persistent ITP initial-14 weeks, cont-1 year
Other Criteria	THROMBOCYTOPENIA WITH CHRONIC LIVER DISEASE [Doptelet tablets only] (A and B): A) current platelet count less than 50 x 109/L and B) scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. CHRONIC/PERSISTENT ITP, INITIAL THERAPY [Doptelet tablets and sprinkle] (A and B): A): (i or ii): i) platelet count less than 30,000/mcL or ii) platelet count less than 50,000/mcL and patient is at an increased risk of bleeding, and B) tried one other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, eltrombopag tablets and oral suspension, romiplostim subcutaneous injection, fostamatinib tablets, rituximab, rilzabrutinib tablets) or had a splenectomy. CHRONIC/PERSISTENT ITP, CONTINUATION THERAPY: patient had beneficial clinical response and remains at risk for bleeding complications.
Indications	All FDA-approved Indications.
Off Label Uses	



PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

DRONABINOL

Products Affected

- Dronabinol

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

PENDING CMS REVIEW & APPROVAL

DROXIDOPA

Products Affected

- Droxidopa

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

PENDING CMS REVIEW & APPROVAL

DUAL OREXIN RECEPTOR ANTAGONIST - SUVOREXANT

Products Affected

- Belsomra

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Treatment of insomnia, characterized by difficulties with sleep onset and /or sleep maintenance-approve.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

DUPIXENT

Products Affected

- Dupixent

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another Monoclonal Antibody (examples: Adbry, Cinqair, Ebglyss, Fasenra, Nemluvio, Nucala, Tezspire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical].
Required Medical Information	Diagnosis. CONTINUATION CRITERIA: AD: responding positively to therapy. ASTHMA: responding positively to therapy and concurrent use with ICS. COPD (all of A, B and C): A) received Dupixent for at least 6 months and B) continues LABA and LAMA, and C) beneficial response (e.g. reduced symptoms, exacerbations, hospitalizations, ED/urgent care visits, improved lung function). CRSwNP (all of A, B, and C): A) received Dupixent for at least 6 months, B) responding positively to therapy, and C) concurrent use with intranasal CS. EoE (A and B): A) received Dupixent for at least 6 months and B) beneficial response (e.g. reduction in intraepithelial eosinophil count, decreased dysphagia/pain upon swallowing, or reduced frequency/severity of food impaction). PRURIGO NODULARIS (A and B): A) received Dupixent for at least 6 months and B) reduction in nodular lesion count, pruritis, or nodular lesion size. CSU (A and B): A) received at least 6 months of Dupixent and B) experienced a beneficial clinical response (e.g. decreased itch severity, decreased number of hives or decreased size of hives). Bullous Pemphigoid: meets both (i and ii): i. already received at least 6 months of therapy with Dupixent AND ii. experienced a beneficial clinical response (e,g, decreased area of skin involvement, lesions, including blisters or erosions (bullae), urticaria, erythema, or reduced or no need for systemic or topical corticosteroid therapy). AFRS (A and B): A) received at least 6 months of Dupixent and B) experienced a beneficial clinical response, defined by reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sinonasal symptoms, improved sense of smell, or reduced use of systemic corticosteroids.
Age Restrictions	Initial therapy only: AD-6 months and older, asthma/AFRS-6 years of age and older, Esophagitis-1 yr and older, CSU-2 and older, Chronic Rhinosinusitis- 12 and older, Prurigo nodularis/COPD/BP-18 and older

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prescriber Restrictions	Init therapy only: AD/PN/CSU-Prescr/consult with an allergist, immunologist or derm, asthma-prescr/consult with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescr/consult with an allergist, immunologist or otolaryngologist. Esophagitis-presc/consult-allergist or gastro. COPD-prescr/consult with an allergist, immunologist, or pulmonologist. BP-prescr/consult with derm, AFRS-prescr/consult with allergist, immunologist, otolaryngologist, rhinologist, pulmonologist, or ID specialist
Coverage Duration	AD-1 yr, asthma/Rhinosinusitis/esophagitis/PN/COPD/CSU/BP/AFRS-init-6 mo, cont 1 yr
Other Criteria	INITIAL CRITERIA: AD: approve. ASTHMA (all of A, B, and C): A) blood eosinophil greater than or equal to 150 cells per microliter within previous 6 weeks or prior to Dupixent or another monoclonal antibody or has oral CS-dependent asthma, B) used an ICS in combination with at least one additional asthma controller/maintenance medication, and C) uncontrolled asthma prior to any asthma monoclonal antibody as defined by one of the following (one of a, b, c, d, or e): a) two or more asthma exacerbations requiring oral CS in the past year, b) one or more asthma exacerbations requiring hospital/urgent care/ED visit in the past year, c) FEV1 less than 80 percent predicted or less than 90% predicted for pts less than 18, d) FEV1/FVC less than 0.8 or less than 0.9 for pts less than 18, or e) worsened asthma with oral CS taper. COPD: meets (all of A, B, and C): A) blood eosinophil at least 300 cells per microliter within previous 6 weeks or prior to Dupixent or another monoclonal antibody, and B) received at least 3 months of combination therapy with at least two of LAMA, LABA or ICS, and C) meets (i or ii): i) two or more COPD exacerbations in previous 12 months requiring systemic CS with or without antibiotics or ii) COPD exacerbation requiring hospitalization in previous 12 months. CRSwNP (all of A, B, C, D and E): A) concurrent use with nasal CS, B) presence of at least two of the following symptoms for 8 weeks: nasal congestion, nasal obstruction, nasal discharge, reduction/loss of smell, C) received course of systemic CS within previous year (unless contraindicated) or patient had prior surgery for nasal polyps, D) diagnosis confirmed by direct exam, endoscopy, or sinus CT, and E) dx of CRSwNP for at least 6 months. EoE (all of A, B, C, and D): A) weighs 15 kg or more, B) endoscopic biopsy demonstrating greater than or equal to 15 intraepithelial eosinophils per high-power field, C) does not have a secondary cause of EoE, and D) received an Rx-strength PPI for at

PA Criteria	Criteria Details
	least 8 weeks. PRURIGO NODULARIS: pruritus lasting at least 6 weeks. CSU: urticaria for at least 6 weeks (prior to Dupixent), and tried oral second generation H1 antihistamine tx. Bullous Pemphigoid Initial: Approve. ALLERGIC FUNGAL RHINOSINUSITIS (AFRS): Approve if pt has AFRS confirmed by IgE-mediated inflammatory response to fungal hyphae confirmed by specific IgE serology or skin test AND nasal polyps confirmed by direct exam, endoscopy, or sinus CT AND signs characteristic of AFRS on CT scan AND pt has had at least one prior sino-nasal surgery.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

EMGALITY

Products Affected

- Emgality

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with another cGRP inhibitor for migraine headache prevention
Required Medical Information	Diagnosis, number of migraine or cluster headaches per month
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Migraine headache prevention-Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) If pt is currently taking Emgality, pt has had significant clinical benefit from the medication. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Emgality was initiated. Episodic cluster headache treatment-approve if the patient has between one headache every other day and eight headaches per day.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

enbrel

Products Affected

- Enbrel
- Enbrel Mini
- Enbrel SureClick

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologic therapy or targeted synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried.
Age Restrictions	Initial therapy: AS/RA- 18 years and older, JIA/PsA/Behcet's-2 years and older, GVHD-6 years and older, PP-4 years and older
Prescriber Restrictions	Initial only-RA/Ankylosing spondylitis/JIA/JRA,prescribed by or in consult w/ rheumatologist. Psoriatic arthritis, prescribed by or in consultation w/ rheumatologist or dermatologist.Plaque psoriasis (PP), prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center.Behcet's disease,prescribed by or in consult w/rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist.
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA)/JUVENILE IDIOPATHIC ARTHRITIS (JIA)/JRA/ANKYLOSING SPONDYLITIS: approve if the patient has tried one preferred adalimumab product (a trial of a non-preferred adalimumab also counts). PLAQUE PSORIASIS (PP)/PSORIATIC ARTHRITIS: approve if the patient has tried one preferred adalimumab product (a non-preferred adalimumab also counts), unless the patient is less than 18 years of age. GRAFT VERSUS HOST DISEASE (GVHD): tried at least one systemic treatment (e.g., corticosteroids, imatinib, methotrexate, Rezurock [belumosudil tablets], Niktimvo [axatilimab-csfr intravenous infusion], Jakafi [ruxolitinib tablets], Imbruvica [ibrutinib]). BEHCET'S: tried at least one conventional therapy (e.g., systemic corticosteroid, immunosuppressant, interferon alfa,

PA Criteria	Criteria Details
	mycophenolate), adalimumab, or infliximab. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. Please Note: preferred adalimumab products include Hadlima, Simlandi.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Graft versus host disease (GVHD), Behcet's disease
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

ENDARI

Products Affected

- L-Glutamine

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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

PA Criteria	Criteria Details
	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. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab products include Remicade, infliximab IV (brand name product), Zymfentra. Preferred ustekinumab products include Otulfi, Pyzchiva (NDCs beginning with 61314-), Yesintek.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	Yes
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

EPIDIOLEX

Products Affected

- Epidiolex

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	Patients 1 year and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Dravet Syndrome (initial therapy)-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs or if the patient has tried or is concomitantly receiving one of Diacomit (stiripentol capsules, powder for oral suspension) or clobazam or Fintepla (fenfluramine oral solution). Lennox Gastaut Syndrome (initial therapy)-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs. Tuberous Sclerosis Complex (initial therapy)-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs. Refractory epilepsy (initial therapy)-approve if patient tried or is concomitantly receiving at least two other antiseizure drugs. Continuation of therapy for all indications-approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Refractory epilepsy
Part B Prerequisite	No

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

EPOETIN ALFA

Products Affected

- Procrit
- Retacrit

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	MDS anemia = 18 years of age and older
Prescriber Restrictions	MDS anemia, myelofibrosis- prescribed by or in consultation with, a hematologist or oncologist.
Coverage Duration	Chemo-6m,Transfus-1m, CKD-1yr, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr
Other Criteria	Anemia in a pt with Chronic Kidney Disease (CKD) not on dialysis- for initial therapy, approve if hemoglobin (Hb) is less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children, or for continuation of therapy in a pt currently on an erythropoiesis-stimulating agent (ESA) approve if Hb is less than or equal to 12 g/dL. Anemia in a pt with cancer due to chemotherapy- approve if pt is currently receiving myelosuppressive chemo as a non-curative treatment and (for initial therapy) Hb is less than 10.0 g/dL or (if currently on ESA) Hb is less than or equal to 12.0 g/dL. Anemia in HIV with zidovudine- for initial therapy, approve if Hb is less than 10.0 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA, approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - Approve if Hb is less than or equal to 13, AND surgery is elective, nonvascular and non-cardiac AND pt is unwilling or unable to donate autologous blood prior to surgery. MDS- for initial therapy, approve if Hb is less than 10 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA approve if Hb is 12.0 g/dL or less. Myelofibrosis- for Initial therapy approve if patient has a Hb less than 10 or serum erythropoietin less than



PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
	or equal to 500 mU/mL, or for continuation of therapy in pt currently on ESA hemoglobin is less than or equal to 12g/dL. Anemia in patients with chronic renal failure on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundled payment benefit).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Anemia due to myelodysplastic syndrome (MDS), Myelofibrosis
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

ERLEADA

Products Affected

- Erleada

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 in combination with a gonadotropin-releasing hormone (GnRH) analog [for example: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy. Prostate Cancer-castration-sensitive- approve if the requested medication will be used in combination with a GnRH analog or if the patient has had a bilateral orchiectomy, AND meets one (A or B): A) Pt has high risk second biochemical recurrence (Note: High risk is defined as prostate-specific antigen doubling time (PSADT) less than or equal to 9 months, prostate-specific antigen (PSA) at least 0.5 ng/mL, prior adjuvant or secondary radiation therapy or patient is not a candidate for radiation therapy) or B) Pt has metastatic castration-sensitive disease.
Indications	All FDA-approved Indications.
Off Label Uses	

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

ERLOTINIB

Products Affected
- Erlotinib HCl

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.

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

EVEROLIMUS

Products Affected

- Everolimus Oral Tablet 10 MG, 2.5 MG, 5 MG, 7.5 MG
- Everolimus Oral Tablet Soluble
- Torpenz
- 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.
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

PA Criteria	Criteria Details
	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.
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



PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

FASENRA

Products Affected

- Fasenra
- Fasenra Pen

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

PA Criteria	Criteria Details
	department/urgent care visits, physician visits, requirement for oral corticosteroid therapy) and B) continues to receive therapy with an ICS. EGPA: patient has responded to therapy (e.g. reduced rate of relapse, CS dose reduction, reduced eosinophil levels).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

FILSPARI

Products Affected
- Filspari

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with any renin-angiotensin-aldosterone antagonists (e.g., angiotensin converting enzyme inhibitors or angiotensin receptor blockers), endothelin receptor antagonists, or aliskiren, or with other medications indicated for the treatment of Immunoglobulin A Nephropathy (e.g., Fabhalta and Vanrafia)
Required Medical Information	Diagnosis
Age Restrictions	IgAN- 18 years and older (initial/continuation), FSGS- 8 years and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with an nephrologist (initial/continuation)
Coverage Duration	1 year
Other Criteria	Primary Immunoglobulin A Nephropathy, initial-approve if the diagnosis has been confirmed by biopsy AND patient is at high risk of disease progression, defined by meeting the following criteria (a and b): a) Proteinuria greater than or equal to 0.5 g/day or urine protein-to-creatinine ratio greater than or equal to 0.5 g/g, AND b) patient has received a maximally tolerated dose of an angiotensin converting enzyme inhibitor or angiotensin receptor blocker for greater than or equal to 12 weeks prior to starting Filspari. Primary Immunoglobulin A Nephropathy, continuation-approve if the diagnosis has been confirmed by biopsy and the patient has had a response to therapy. Focal Segmental Glomerulosclerosis, initial-approve if patient does not have nephrotic syndrome (Presence of nephrotic syndrome is a current proteinuria of greater than 3.5 g/day for adults or at least 2 g/g for patients less than 18 yo), and has urine protein-to-creatinine ratio of at least 1.5 g/g, and estimated glomerular filtration rate of at least 30ml/min/1.73 m2, AND one of (a or b): a) biopsy

PA Criteria	Criteria Details
	confirming the disease or b) genetic variant associated with disease. Focal Segmental Glomerulosclerosis, continuation-approve if patient has had response to the medication, and estimated glomerular filtration rate of at least 30ml/min/1.73 m2.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	Yes
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

FINGOLIMOD

Products Affected

- Fingolimod HCl

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

PENDING CMS REVIEW & APPROVAL

FINTEPLA

Products Affected
- Fintepla

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

PENDING CMS REVIEW & APPROVAL

FIRMAGON

Products Affected

- Firmagon
- Firmagon (240 MG Dose)

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	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	No

PENDING CMS REVIEW & APPROVAL

FOTIVDA

Products Affected

- Fotivda

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Renal Cell Carcinoma (RCC)-approve if the patient has relapsed or Stage IV disease and the medication is being used as subsequent therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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	No

PENDING CMS REVIEW & APPROVAL

FULPHILA

Products Affected

- Fulphila

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Cancer patients receiving chemotherapy-prescribed by or in consultation with an oncologist or hematologist. PBPC - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC-30 days.
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following: 1) is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), 2) patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status or HIV infection patients with low CD4 counts), or 3) patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

GABAPENTINOID - GABAPENTIN

Products Affected

- Gabapentin (Once-Daily)

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

PENDING CMS REVIEW & APPROVAL

GATTEX

Products Affected

- Gattex

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	1 year and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	Initial-approve if the patient is currently receiving parenteral nutrition on 3 or more days per week or according to the prescriber, the patient is unable to receive adequate total parenteral nutrition required for caloric needs. Continuation-approve if the patient has experienced improvement.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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



PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

GLATIRAMER

Products Affected

- Glatiramer Acetate
- 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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

glucagon-like peptide-1 agonists - SEMAGLUTIDE

Products Affected

- Ozempic
- Ozempic (0.25 or 0.5 MG/DOSE)
- Ozempic (1 MG/DOSE)
- Ozempic (2 MG/DOSE)

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

GONADOTROPIN-RELEASING HORMONE AGONISTS - ONCOLOGY

Products Affected

- Eligard
- Leuprolide Acetate

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

PENDING CMS REVIEW & APPROVAL

growth hormones

Products Affected

- Omnitrope

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

PA Criteria	Criteria Details
	athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalmic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. has known perinatal insults, congenital or genetic defects or structural hypothalmic pituitary defects, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin), AND age and gender adjusted IGF1 below the lower limits of the normal reference range AND other causes of low serum IGF-1 have been excluded, C. Neg response to ONE preferred GH stim test (insulin peak response less than or equal to 5 mcg/L, Glucagon peak less than or equal to 3 mcg/L (BMI is less than or equal to 25), less than or equal to 3 and BMI is greater than or equal to 25 and less than or equal to 30 with a high pretest probability of GH deficiency, less than or equal to 1 and BMI is greater than or equal to 25 and less than or equal to 30 with a low pretest probability of GH deficiency or less than or equal to 1 mcg/L (BMI is greater than 30), if insulin and glucagon contraindicated then Arginine test with peak of less than or equal to 6.5 mcg/L, or Macrilen peak equal to or less than 2.8 ng/ml AND BMI is less than or equal to 40. Cont tx - endocrine must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR) is a. less than 4 cm/yr for pts greater than or equal to 5 or b. growth velocity is less than 10th percentile. CKD initial - CKD defined by abnormal CrCl, baseline ht less than 5th percentile and baseline ht velocity below 25th percentile. Noonan initial - baseline height less than 5th percentile. PW cont tx in adults or adolescents who don't meet child requir - physician certifies not being used for anti-aging or to enhance athletic performance. SHOX initial - SHOX def by chromo analysis, open epiphyses, height less than 3rd percentile. SGA initial - baseline ht less than 5th percentile and born SGA (birth weight/length more than 2 SD below mean for gestational age/gender and insufficient catch up growth by 2-4 y/o). TS- dx by karyotype analysis and baseline ht less than 5th percentile. TS cont- dx by karyotype analysis and response to tx. Cont Tx for ISS, CKD, Noonan, PW in child/adoles, SHOX, SGA - prescriber confirms response to therapy. SBS - approve if pt already started on somatropin tx for this dx or responded to it in past.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Off Label Uses	Short bowel syndrome
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

HIGH RISK MEDICATIONS - ANTIPARKINSON AGENTS

Products Affected

- Benztropine Mesylate

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

PENDING CMS REVIEW & APPROVAL

high risk medications - benzodiazepines - CLORAZEPATE

Products Affected

- Clorazepate Dipotassium

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
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	All medically accepted indications, approve if the physician has assessed risk versus benefit in using the High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

high risk medications - benzodiazepines - DIAZEPAM

Products Affected

- diazePAM Intensol
- diazePAM Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	Procedure-related sedation = 1mo. All other conditions = 6 months.
Other Criteria	All medically accepted indications, approve if the physician has assessed risk versus benefit in using the High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

high risk medications - benzodiazepines - LORAZEPAM

Products Affected

- LORazepam
- LORazepam Intensol

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	Procedure-related sedation = 1mo. All other conditions = 6 months.
Other Criteria	All medically accepted indications other than insomnia, approve if the physician has assessed risk versus benefit in using the High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy. For requests for lorazepam (NOT including Loreev) for the treatment of insomnia, approve if the patient has had a trial with ramelteon or doxepin 3mg or 6 mg and the physician has assessed risk versus benefit in using the HRM in this patient and has confirmed that he/she would still like initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

high risk medications - first generation antihistamines - HYDROXYZINE

Products Affected

- hydrOXYzine HCl

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For the treatment of anxiety, approve if the patient has tried at least two other FDA-approved products. Additionally for all covered indications, the prescriber must confirm that he/she has assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy. Please note that this risk assessment should include the concomitant use of other anticholinergic drugs at the same time as the requested medication.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

high risk medications - first generation antihistamines - PROMETHAZINE

Products Affected

- Promethazine HCl

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For the treatment of emesis, approve if the patient has tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant).Additionally for all covered indications, the prescriber must confirm that he/she has assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy. Please note that this risk assessment should include the concomitant use of other anticholinergic drugs at the same time as the requested medication.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

HIGH RISK MEDICATIONS - PHENOBARBITAL

Products Affected

- PHENobarbital

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for use in sedation/insomnia.
Required Medical Information	
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 the treatment of seizures, approve only if the patient is currently taking phenobarbital. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

HIGH RISK MEDICATIONS - SKELETAL MUSCLE RELAXANTS - CYCLOBENZAPRINE

Products Affected

- Cyclobenzaprine HCl

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

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PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

IBRANCE

Products Affected
- Ibrance

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Breast cancer (including endocrine-resistant PIK3CA-mutated, HR-positive, HER2-negative locally advanced or metastatic breast cancer) - approve if patient meets all (A, B, and C): A) locally advanced, recurrent or metastatic, hormone receptor positive (HR+) [i.e., estrogen receptor positive- (ER+) and/or progesterone receptor positive (PR+)] disease, and B) meets one (i or ii): i) HER2-negative breast cancer or ii) HER2-positive breast cancer and the medication will be used in combination with an aromatase inhibitor, trastuzumab, and Perjeta (pertuzumab intravenous infusion) and C) meets ONE (a, b, or c): a) Pt is postmenopausal and this medication will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant OR b) pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonists, or has had surgical bilateral oophorectomy, or ovarian irradiation AND this medication will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant OR c) pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) and meets (1 or 2): 1) is receiving GnRH analog AND this medication will be used in combination with anastrozole, exemestane or letrozole or 2) this medication will be used in

PA Criteria	Criteria Details
	combination with fulvestrant. Liposarcoma-approve if the patient has well-differentiated/dedifferentiated liposarcoma (WD-DDLS). Endometrial Cancer- approve if pt has estrogen receptor (ER)-positive tumors and the medication will be used in combination with letrozole and meets (A or B): A) not a candidate for surgery or B) recurrent or metastatic disease. Uterine sarcoma - Approve if pt has advanced, recurrent, metastatic, or inoperable disease and CDK4 amplified disease and has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Liposarcoma, Endometrial cancer, Uterine sarcoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

ICATIBANT

Products Affected

- Icatibant Acetate
- Sajazir

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant -the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment. HAE with Normal C1-INH [Type III], Treatment of Acute Attacks: Approve.
Indications	All FDA-approved Indications.
Off Label Uses	

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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

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

PENDING CMS REVIEW & APPROVAL

ICOTYDE

Products Affected

- Icotyde

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic oral small molecule drug
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist (initial therapy)
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: PLAQUE PSORIASIS (PP) [A and B]: A) patient is at least 40 kg, AND B) patient meets (i or ii): i) tried at least one traditional systemic agent (e.g., MTX, cyclosporine (CSA), acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of a biologic will also count) or ii) contraindication to MTX. CONTINUATION THERAPY: patient has responded to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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	No

PENDING CMS REVIEW & APPROVAL

IMATINIB

Products Affected

- Imatinib Mesylate
- 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

PA Criteria	Criteria Details
	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.
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	No

PENDING CMS REVIEW & APPROVAL

imbruvica

Products Affected

- Imbruvica

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	GVHD-1 year and older, other-18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	CLL- Approve. GVHD-Approve if the patient has tried one systemic medication for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], imatinib, low-dose methotrexate, sirolimus, mycophenolate mofetil, Jakafi [ruxolitinib tablets], Rezurock (belumosudil tablets), Niktimvo (axatilimab-csfr intravenous infusion), rituximab, pentostatin, cyclosporine, tacrolimus, sirolimus, an etanercept product). B-cell lymphoma-approve if the patient has tried at least one systemic regimen (e.g., cisplatin, cytarabine, rituximab, oxaliplatin, gemcitabine, ifosfamide, carboplatin, etoposide, or rituximab). Primary central nervous system Lymphoma - approve if the patient is not a candidate for or is intolerant to high-dose methotrexate OR has tried at least one therapy (e.g., methotrexate, rituximab, vincristine, procarbazine, cytarabine, thiotepa, carmustine, intrathecal methotrexate, cytarabine, or rituximab). Hairy Cell Leukemia - approve if the patient has tried at least two systemic regimens (cladribine, pentostatin, rituximab, Pegasys [peginterferon alfa-2a subcutaneous injection], Mekinist (trametinib tablets or oral solution), Tafinlar (dabrafenib capsules or tablets for oral suspension), or Zelboraf (vemurafenib tablets).

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PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

INBRIJA

Products Affected

- Inbrija

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

PENDING CMS REVIEW & APPROVAL

INGREZZA

Products Affected

- Ingrezza

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

PENDING CMS REVIEW & APPROVAL

INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- Testosterone Cypionate
- Testosterone Enanthate

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

PA Criteria	Criteria Details
	expression. Female is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression. Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-approve.Note: For a patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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

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

PENDING CMS REVIEW & APPROVAL

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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

INPEFA

Products Affected

- Inpefa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Heart Failure, to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit-approve. Type 2 Diabetes, to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit-approve if the patient has chronic kidney disease AND has one or more cardiovascular risk factor(s).Note: Patients with heart failure should be reviewed under criteria for Heart Failure.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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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

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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	No

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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.



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

PENDING CMS REVIEW & APPROVAL

IVERMECTIN (ORAL)

Products Affected

- Ivermectin

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	30 days
Other Criteria	Pediculosis-approve if the patient has infection caused by pediculus humanus capitis (head lice), pediculus humanus corporis (body lice), or has pediculosis pubis caused by phthirus pubis (pubic lice). Scabies-approve if the patient has classic scabies, treatment resistant scabies, is unable to tolerate topical treatment, has crusted scabies or is using ivermectin tablets for prevention and/or control of scabies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Ascariasis, Enterobiasis (pinworm infection), Hookworm-related cutaneous larva migrans, Mansonella ozzardi infection, Mansonella streptocerca infection, Pediculosis, Scabies. Trichuriasis, Wucheria bancrofti infection
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

ivig

Products Affected

- Gamunex-C

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

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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	No

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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
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

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PA Criteria	Criteria Details
	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	No

PENDING CMS REVIEW & APPROVAL

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

PA Criteria	Criteria Details
	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) .
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	No

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JIDEYTRO

Products Affected

- Jideytro

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. ROS1-positive non-small cell lung cancer, AND C. Previously treated with a ROS1 kinase inhibitor. Note: Examples of a ROS1 kinase inhibitor include Augtyro (repotrectinib capsules), Ibtrozi (taletrectinib capsules), Rozlytrek (entrectinib capsules), Xalkori (crizotinib capsules and oral pellets).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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JYNARQUE

Products Affected

- Tolvaptan

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

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KALYDECO

Products Affected

- Kalydeco

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other CF Transmembrane Regulator Modulators
Required Medical Information	
Age Restrictions	1 month of age and older
Prescriber Restrictions	prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF - must meet A, B, and C: A) pt must have one variant in the cystic fibrosis transmembrane conductance regulator gene that is considered pathogenic or likely pathogenic B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator variants or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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KERENDIA

Products Affected

- Kerendia

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with spironolactone or eplerenone
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Diabetic kidney disease-initial-approve if the patient meets the following criteria (i, ii and iii)i. Patient has a diagnosis of type 2 diabetes AND ii. Patient meets one of the following (a or b): a) Patient is currently receiving a maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b) According to the prescriber, patient has a contraindication or has experienced significant intolerance to ACE inhibitor and ARB therapy AND iii. At baseline (prior to the initiation of Kerendia), patient meets all of the following (a, b, and c): a) Estimated glomerular filtration rate greater than or equal to 25 mL/min/1.73 m2 AND b) Urine albumin-to-creatinine ratio greater than or equal to 30 mg/g AND c) Serum potassium level less than or equal to 5.0 mEq/L. Diabetic kidney disease-continuation-approve if the patient meets the following criteria (i and ii): i. Patient has a diagnosis of type 2 diabetes AND ii. Patient meets one of the following (a or b): a) Patient is currently receiving a maximally tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b) According to the prescriber, patient has a contraindication or has experienced significant intolerance to ACE inhibitor and ARB therapy. Heart failure-initial-Pt meets all (i, ii, and ii):

PA Criteria	Criteria Details
	i) has left ventricular ejection fraction of at least 40 percent AND ii) tried or is currently receiving one of the following SGLT-2 inhibitors: Farxiga (dapagliflozin tabs, authorized generic) Inpefa (sotagliflozin tabs), or Jardiance (empagliflozin tabs) OR has contraindication or has experienced significant intolerance to SGLT-2 inhibitors AND iii) at baseline (prior to initiation of Kerendia), meets all (a and b): a) estimated glomerular filtration rate of at least 25 mL/min/1.73m2 AND b) serum potassium level of less than or equal to 5.0 mEq/L. Heart failure-continuation-Pt meets all (i and ii): i) has left ventricular ejection fraction of at least 40 percent AND ii) tried or is currently receiving one of the following SGLT-2 inhibitors: Farxiga (dapagliflozin tabs, authorized generic) Inpefa or (sotagliflozin tabs), or Jardiance (empagliflozin tabs) or has contraindication or has experienced significant intolerance to SGTL-2 inhibitors.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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KESIMPTA

Products Affected

- Kesimpta

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

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KEVZARA

Products Affected

- Kevzara

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	RA/polymyalgia rheumatica-18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist (initial therapy).
Coverage Duration	Approve through end of plan year
Other Criteria	RA initial - approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, a preferred tocilizumab product, Rinvoq or tofacitinib/XR (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: Cimzia, an infliximab product, golimumab SC/IV, Orencia or another non-preferred adalimumab or non-preferred tocilizumab product. OR , B) patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx - pt must have had a response as determined by the prescriber. PJIA initial - approve if the patient meets one of the following (A or B): A) has tried TWO of the following drugs in the past: Enbrel, Rinvoq, tofacitinib, a preferred tocilizumab product, or a preferred adalimumab product. (Note: if the patient does not meet this requirement, a previous trial with Orencia, infliximab, a non-preferred adalimumab, or a non-preferred tocilizumab product also counts toward meeting the try two requirement.) OR B) patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx - pt must have had a response to therapy. Polymyalgia rheumatica, initial-approve if the patient has tried one systemic

PA Criteria	Criteria Details
	corticosteroid. Cont tx-pt must have had a response to therapy. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred tocilizumab product is Tyenne.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	Yes
Prerequisite Therapy Required	No

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kineret

Products Affected
- Kineret

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD
Required Medical Information	Diagnosis
Age Restrictions	RA/AOSD/Pericarditis-18 years and older, SJIA-2 years and older
Prescriber Restrictions	Initial therapy only-RA, SJIA and Still's disease, prescribed by or consult with a rheumatologist. CAPS (Neonatal-Onset Multisystem Inflammatory Disease or Chronic Infantile Neurological Cutaneous and Articular syndrome), prescribed by or consult with a rheumatologist, geneticist, allergist/immunologist, or dermatologist.DIRA-rheum, geneticist, dermatologist, or physician specializing in autoinflammatory disorder. Pericarditis, prescribed by or consult with cardiologist or rheumatologist.
Coverage Duration	Approve through end of plan year
Other Criteria	RA initial. Approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Rinvoq, tofacitinib/XR, or a preferred tocilizumab product. [Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: a non-preferred tocilizumab product, Orencia, Cimzia, infliximab, Kevzara, golimumab IV/SC or another non-preferred adalimumab product.] DIRA initial-approve if genetic testing has confirmed bi-allelic pathogenic variants in the IL1RN gene. Adult Onset Still's Disease, approve. SJIA-initial-approve. cont tx - approve if the patient had responded to therapy as determined by the prescriber. Immunotherapy-related toxicities associated with CAR-T cell therapy: approve if patient has or will be treated with CAR-T cell therapy. Pericarditis, initial: approve if (A, B, and C): A) recurrent pericarditis, B) C-reactive protein level greater than 1 mg/dL,

PA Criteria	Criteria Details
	and C) for current episode pt is receiving standard treatment or standard treatment is contraindicated [examples of standard treatment: NSAIDs such as ibuprofen, colchicine, systemic corticosteroids]. Pericarditis, cont: experienced beneficial response. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred tocilizumab product is Tyenne.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Adult onset Still's disease (SD). Systemic Juvenile Idiopathic Arthritis (SJIA). Immunotherapy-related toxicities associated with Chimeric Antigen Receptor (CAR) T-cell therapy. Pericarditis
Part B Prerequisite	No
Prerequisite Therapy Required	No

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KISQALI

Products Affected

- Kisqali (200 MG Dose)
- Kisqali (400 MG Dose)
- Kisqali (600 MG Dose)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Breast cancer - approve for hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative early (stage II or III), recurrent, or metastatic breast cancer [for early breast cancer must be adjuvant treatment and high risk of recurrence] when the pt meets ONE of the following (1, 2, 3 or 4): 1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole 2. meets (a, b and c): a) pt is premenopausal or perimenopausal and b) is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND c) Kisqali will be used in combination with anastrozole, exemestane, or letrozole 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Kisqali with be used in combination with anastrozole, exemestane or letrozole. 4. Patient meets (a and b): a) is postmenopausal, pre/perimenopausal (patient receiving ovarian suppression/ablation with a GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man, and b) Kisqali will be used in combination with fulvestrant. Endometrial cancer - approve if pt meets

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

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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

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KORLYM

Products Affected

- miFEPRIStone

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

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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

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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
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

PA Criteria	Criteria Details
	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	No

PENDING CMS REVIEW & APPROVAL

LAPATINIB

Products Affected

- Lapatinib Ditosylate

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



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PA Criteria	Criteria Details
	patient has recurrent chordoma and if the patient has epidermal growth-factor receptor (EGFR)-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Bone cancer-chordoma, colon or rectal cancer, breast cancer in pre/peri-menopausal women and men
Part B Prerequisite	Yes
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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	No

PENDING CMS REVIEW & APPROVAL

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.
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

PA Criteria	Criteria Details
	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.
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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

LENVIMA

Products Affected

- Lenvima (10 MG Daily Dose)
- Lenvima (12 MG Daily Dose)
- Lenvima (14 MG Daily Dose)
- Lenvima (18 MG Daily Dose)
- Lenvima (20 MG Daily Dose)
- Lenvima (24 MG Daily Dose)
- Lenvima (4 MG Daily Dose)
- Lenvima (8 MG Daily Dose)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	DTC - Approve if patient meets one of the following (i or ii): i) Patient meets both of the following (a and b): a) Patient has papillary or follicular thyroid carcinoma and b) the disease is refractory to radioactive iodine therapy OR ii) Patient has oncocytic (formulary Hurthle cell) carcinoma. RCC - approve if the pt meets ALL of the following criteria: 1) pt has advanced disease AND if the patient meets i or ii-i. Lenvima is is being used in combination with Keytruda OR ii. Lenvima is used in combination with Afinitor/Afinitor Disperz and the patient meets a or b-a. Patient has clear cell histology and patient has tried one antiangiogenic therapy or b. patient has non-clear cell histology. MTC-approve if the patient has tried at least one systemic therapy. Endometrial Carcinoma-Approve if the patient meets all of the following criteria (A and B): A) Patient meets one of the following (i or ii): i) Patient meets all of the following (a, b and c): a) The patient has advanced endometrial carcinoma that is mismatch repair proficient (pMMR) or not microsatellite instability-high (MSI-H) AND b) The medication is used in combination with Keytruda

PA Criteria	Criteria Details
	(pembrolizumab for intravenous injection) AND c) the patient has tried at least one systemic therapy OR ii) Lenvima is used as a single agent for second-line or subsequent therapy AND B) The patient is not a candidate for curative surgery or radiation. HCC-approve if the patient has unresectable or metastatic disease AND the medication is used as first-line therapy. Thymic carcinoma-approve if the patient has tried at least one chemotherapy regimen. Melanoma - approve if the patient has unresectable or metastatic melanoma AND the medication will be used in combination with Keytruda (pembrolizumab intravenous injection) AND the patient has disease progression on anti-programmed death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1)-based therapy. Anaplastic thyroid carcinoma-approve if the medication is used in combination with Keytruda (pembrolizumab intravenous infusion).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients with Medullary Thyroid Carcinoma (MTC), thymic carcinoma, Melanoma, Anaplastic thyroid carcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

LEQEMBI IQLIK

Products Affected

- Leqembi Iqlik
- Leqembi Iqlik (500 MG Dose)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or under the supervision of a neurologist
Coverage Duration	1 year
Other Criteria	Approve if patient meets all (A and B): A) Per dosing and administration section of product labeling, patient must have completed 18 months of Leqembi IV, and B) Per clinical studies section of product labeling, patient has not progressed beyond a Clinical Dementia Rating-Global Score of 1.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

LEUKINE

Products Affected

- Leukine

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	Yes
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

LIDOCAINE PATCH

Products Affected

- Lidocaine
- Lidocan

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

PENDING CMS REVIEW & APPROVAL

LIDOCAINE/COMBINATION TOPICAL (NON-PATCH) - LIDOCAINE

Products Affected

- Lidocaine

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

PENDING CMS REVIEW & APPROVAL

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

Products Affected

- Lidocaine-Prilocaine

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

PENDING CMS REVIEW & APPROVAL

LIFYORLI

Products Affected

- Lifyorli (125 MG DOSE)
- Lifyorli (150 MG DOSE)

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	Yes
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

LIVDELZI

Products Affected
- Livdelzi

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Iqirvo
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial)
Coverage Duration	6 months initial, 1 year cont.
Other Criteria	INITIAL THERAPY: PRIMARY BILIARY CHOLANGITIS/CIRRHOSIS-All of (A and B): A): Diagnosis confirmed by TWO of the following i, ii, or iii: i) Alkaline phosphatase is elevated above the upper limit of normal, ii) positive anti-mitochondrial antibodies or other primary biliary cholangitis-specific auto-antibodies, including sp100 or gp210, if anti-mitochondrial antibodies are negative or iii) histologic evidence of primary biliary cholangitis from a liver biopsy, B): Receiving ursodiol therapy and had inadequate response or was unable to tolerate ursodiol therapy. Note: examples of ursodiol therapy include ursodiol generic tablets and capsules, Urso 250, Urso Forte, and Actigall. CONTINUATION THERAPY: PRIMARY BILIARY CHOLANGITIS/CIRRHOSIS- patient has demonstrated a response to therapy. Note: Examples of a response to therapy are improved biochemical markers of primary biliary cholangitis (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT]).
Indications	All FDA-approved Indications.
Off Label Uses	

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

PENDING CMS REVIEW & APPROVAL

LIVTENCITY

Products Affected

- Livtencity

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with ganciclovir or valganciclovir
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, infectious diseases specialist, oncologist, or a physician affiliated with a transplant center. (initial therapy)
Coverage Duration	2 months
Other Criteria	Cytomegalovirus Infection, Treatment, initial therapy-approve if the patient meets the following criteria (A, B, and C): A) Patient weighs greater than or equal to 35 kg, AND B) Patient is post-transplant, AND Note: This includes patients who are post hematopoietic stem cell transplant or solid organ transplant. C) Patient has cytomegalovirus infection/disease that is refractory to treatment with at least one of the following: cidofovir, foscarnet, ganciclovir, or valganciclovir or patient has a significant intolerance to ganciclovir or valganciclovir. Cytomegalovirus Infection, Treatment, continuation of therapy - approve if patient has responded as demonstrated by cytomegalovirus polymerase chain DNA laboratory results within 4 weeks demonstrating improvement in cytomegalovirus levels.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

LONG ACTING OPIOIDS - BUPRENORPHINE

Products Affected

- Buprenorphine

PA Criteria	Criteria Details
Exclusion Criteria	Acute (ie, non-chronic) pain
Required Medical Information	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For pain severe enough to require daily, around-the-clock, long-term opioid treatment (with no cancer or sickle cell diagnosis, not in long term care facility and not in hospice), approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off Label Uses	

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

LONG ACTING OPIOIDS - HYDROMORPHONE

Products Affected

- HYDROmorphone HCl ER

PA Criteria	Criteria Details
Exclusion Criteria	Acute (ie, non-chronic) pain
Required Medical Information	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For pain severe enough to require daily, around-the-clock, long-term opioid treatment (with no cancer or sickle cell diagnosis, not in long term care facility and not in hospice), approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off Label Uses	

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

LONG ACTING OPIOIDS - METHADONE

Products Affected

- Methadone HCl

PA Criteria	Criteria Details
Exclusion Criteria	Acute (ie, non-chronic) pain
Required Medical Information	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For pain severe enough to require daily, around-the-clock, long-term opioid treatment (with no cancer or sickle cell diagnosis, not in long term care facility and not in hospice), approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off Label Uses	

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

LONG ACTING OPIOIDS - MORPHINE

Products Affected

- Morphine Sulfate ER

PA Criteria	Criteria Details
Exclusion Criteria	Acute (ie, non-chronic) pain
Required Medical Information	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For pain severe enough to require daily, around-the-clock, long-term opioid treatment (with no cancer or sickle cell diagnosis, not in long term care facility and not in hospice), approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off Label Uses	

PENDING CMS REVIEW & APPROVAL

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

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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	No

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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.

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

PENDING CMS REVIEW & APPROVAL

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.

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PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma, Small Bowel Adenocarcinoma, Appendiceal cancer
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

LUPRON DEPOT

Products Affected

- Lupron Depot (1-Month)

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.
Off Label Uses	abnormal uterine bleeding, breast cancer, gender dysphoria/gender reassignment, head and neck cancer-salivary gland tumors, ovarian cancer including fallopian tube and primary peritoneal cancers, premenstrual

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

PENDING CMS REVIEW & APPROVAL

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
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-

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PA Criteria	Criteria Details
	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	No

PENDING CMS REVIEW & APPROVAL

LYTGOBI

Products Affected

- Lytgobi (12 MG Daily Dose)
- Lytgobi (16 MG Daily Dose)
- Lytgobi (20 MG Daily Dose)

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	No

PENDING CMS REVIEW & APPROVAL

MAVYRET

Products Affected

- Mavyret

PA Criteria	Criteria Details
Exclusion Criteria	
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	Chronic HCV- Criteria will be applied consistent with AASLD/IDSA guidance, Acute HCV-8 weeks
Other Criteria	For Chronic Hepatitis C Virus, criteria will be applied consistent with current AASLD/IDSA guidance. For Acute Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6: Approve if the patient meets (A, B and C): A) Does not have cirrhosis OR has compensated cirrhosis AND B) has quantifiable HCV RNA AND C) ONE of the following (i, ii, or iii): i. conversion of negative to positive results in anti-HCV antibody, HCV RNA, and/or HCV core antigen OR ii. signs and symptoms of acute hepatitis C virus OR iii. has engaged in a risk behavior for HCV infection within the prior 6 months.
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

PENDING CMS REVIEW & APPROVAL

MEGESTROL

Products Affected

- Megestrol Acetate Oral Suspension
- Megestrol Acetate Oral Tablet

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

PENDING CMS REVIEW & APPROVAL

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.
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

PA Criteria	Criteria Details
	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	No

PENDING CMS REVIEW & APPROVAL

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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

memantine - DONEPEZIL/MEMANTINE

Products Affected

- Memantine HCl-Donepezil HCl ER

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	
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

PENDING CMS REVIEW & APPROVAL

memantine - MEMANTINE

Products Affected

- Memantine HCl
- Memantine HCl ER

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	
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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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	No

PENDING CMS REVIEW & APPROVAL

MYFEMBREE

Products Affected

- Myfembree

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, test results (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	Fibroids-Prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health
Coverage Duration	24 months of total therapy between Myfembree or Oriahnn
Other Criteria	Uterine Fibroids (Leiomyomas)-approve if the patient is premenopausal (before menopause) and is experiencing heavy menstrual bleeding associated with the uterine fibroids, the uterine fibroids have been confirmed by a pelvic ultrasound, including transvaginal ultrasonography or sonohysterography, hysteroscopy, or magnetic resonance imaging. Endometriosis-approve if the patient is premenopausal and patient has previously tried one of the following (i or ii): i. A contraceptive (e.g., combination oral contraceptives, levnorgestrel-releasing intrauterine systems, a depo-medroxyprogesterone injection), unless contraindicated OR ii. An oral progesterone (e.g., norethindrone tablets), unless contraindicated.Note: An exception to this requirement can be made if the patient has previously used a gonadotropin-releasing hormone agonist (e.g., Lupron Depot [leuprolide depot suspenion]) or Orilissa (elagolix tablets).
Indications	All FDA-approved Indications.
Off Label Uses	

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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	No

PENDING CMS REVIEW & APPROVAL

NEMLUVIO

Products Affected

- Nemluvio

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy. Concurrent use with Janus kinase (JAK) inhibitors (oral or topical)
Required Medical Information	Diagnosis
Age Restrictions	AD: 12 years and older (initial therapy), PN: 18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
Coverage Duration	1 year
Other Criteria	INITIAL CRITERIA: ATOPIC DERMATITIS-approve if this medication will be used with a topical corticosteroid (CS) and/or topical calcineurin inhibitor or AD has improved sufficiently with Nemluvio and topical therapy has been discontinued. PRURIGO NODULARIS-All of (A and B): A) Pruritis for greater than or equal to 6 weeks, AND B) Meets i or ii: i) prurigo nodularis is NOT medication induced or secondary to a non-dermatologic condition such as neuropathy or a psychiatric disease, OR ii) secondary cause of prurigo nodularis has been identified and adequately managed. CONTINUATION CRITERIA: ATOPIC DERMATITIS-patient has received at least 4 months of therapy with Nemluvio and has responded to therapy. PRURIGO NODULARIS-patient has received at least 4 months of therapy with Nemluvio, and experienced beneficial clinical response defined by ONE of the following (A, B, or C): A) reduced nodular lesion count, OR B) Decreased pruritus, OR C) Reduced nodular lesion size. Note: A patient who has received less than 4 months of therapy or who is restarting therapy with Nemluvio should be considered under initial therapy.

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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

PA Criteria	Criteria Details
	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.
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	No

PENDING CMS REVIEW & APPROVAL

NEXLETOL

Products Affected

- Nexletol

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL, b) Genetic testing confirming (Note 1) HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, AND B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and ezetimibe and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below). TO REDUCE MAJOR ADVERSE CV EVENTS IN PATIENTS AT INCREASED RISK WITH ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and ezetimibe and LDL-C remains 55 mg/dL or higher or b) statin intolerant. HYPERCHOLESTEROLEMIA (not associated with established CVD or HeFH) or TO REDUCE MAJOR ADVERSE CV EVENTS IN PATIENTS AT INCREASED RISK WITHOUT ESTABLISHED CVD [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB),

PA Criteria	Criteria Details
	proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

NEXLIZET

Products Affected
- Nexlizet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL, b) Genetic testing confirming (Note 1) HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, AND B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below). TO REDUCE MAJOR ADVERSE CV EVENTS IN PATIENTS AT INCREASED RISK WITH ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 55 mg/dL or higher or b) statin intolerant. HYPERCHOLESTEROLEMIA (not associated with established CVD or HeFH) or TO REDUCE MAJOR ADVERSE CV EVENTS IN PATIENTS AT INCREASED RISK WITHOUT ESTABLISHED CVD [A or B]: A) tried one high-intensity statin for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein

PA Criteria	Criteria Details
	convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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.

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

PENDING CMS REVIEW & APPROVAL

NILUTAMIDE

Products Affected

- Nilutamide

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

NINTEDANIB

Products Affected

- Nintedanib Esylate
- Ofev

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age and older
Prescriber Restrictions	IPF-Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis/Progressive Pulmonary Fibrosis-prescribed by or in consultation with a pulmonologist or rheumatologist.
Coverage Duration	1 year
Other Criteria	IDIOPATHIC PULMONARY FIBROSIS (IPF), INITIAL [A and B]: A) diagnosis confirmed by presence of usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) or surgical lung biopsy and B) forced vital capacity (FVC) greater than or equal to 40 percent of the predicted value at baseline (before any antifibrotic therapy such as Ofev, Jascayd, pirfenidone). INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS, INITIAL (A and B): A) diagnosis confirmed by HRCT and B) FVC greater than or equal to 40 percent of the predicted value. CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE (Progressive Pulmonary Fibrosis), INITIAL (all of A, B and C): A) FVC greater than or equal to 40 percent of the predicted value, B) fibrosing lung disease impacting more than 10 percent of lung volume on HRCT, and C) clinical signs of progression. ALL INDICATIONS, CONTINUATION: approve. PLUS, for all indications for both initial and continuation of therapy, if the request is for a brand Ofev product, the patient is required to try generic nintedanib first.

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

NIVESTYM

Products Affected

- Nivestym

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Cancer/AML, MDS, ALL-oncologist or a hematologist. Cancer patients receiving BMT and PBPC-prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. Radiation-expertise in acute radiation. SCN-hematologist. HIV/AIDS neutropenia-infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
Coverage Duration	chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,ALL,BMT,Radiation-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), 2)patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status, or HIV infection patients with low CD4 counts), 3)patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or

PA Criteria	Criteria Details
	frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil count less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, pneumonia or other clinically documented infections, invasive fungal infection, hospitalization at the time of fever, prior episode of febrile neutropenia).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia.Acute lymphocytic leukemia (ALL), Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome)
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

NON-INJECTABLE TESTOSTERONE PRODUCTS - TESTOSTERONE

Products Affected

- Testosterone

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

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PA Criteria	Criteria Details
	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.
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

PENDING CMS REVIEW & APPROVAL

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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

NUCALA

Products Affected

- Nucala

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy.
Required Medical Information	COPD initial - Approve if pt meets all (A, B AND C): A) pt has a blood eosinophil level at least 300 cells per microliter within the previous 6 weeks or prior to treatment with Nucala or another monoclonal antibody therapy that may alter blood eosinophil levels AND B) received at least 3 months of combination therapy with at least two of LAMA, LABA or ICS, AND C) pt meets (i or ii): i) experienced two or more COPD exacerbations requiring treatment with a systemic corticosteroid with or without an antibiotic in the previous 12 months OR ii) experienced one or more COPD exacerbations requiring a hospitalization in the previous 12 months. Cont - Approve if pt meets all (A, B and C): A) has already received at least 6 months of therapy with Nucala AND B) continues to receive combination therapy with an inhaled LABA and LAMA AND C) patient has experienced a beneficial clinical response, defined by one of the following: reduced symptoms, exacerbations, hospitalizations, ED/urgent care visits, improved lung function).
Age Restrictions	(Initial therapy only): Asthma-6 years of age and older. EGPA/Polyps/COPD-18 years of age and older. HES-12 years and older.
Prescriber Restrictions	(Initial therapy only): Asthma/COPD-Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. EGPA-prescribed by or in consultation with an allergist, immunologist, pulmonologist or rheumatologist. HES-prescribed by or in consultation with an allergist, immunologist, hematologist, pulmonologist or rheumatologist. Polyps-prescribed by or in consult with allergist, immunologist or Otolaryngologist
Coverage Duration	Initial-Asthma/polyps/COPD-6 months, EGPA/HES-8 months. 12 months continuation.

PA Criteria	Criteria Details
Other Criteria	Asthma initial - must have blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks (or prior to tx with Nucala or another monoclonal antibody therapy that may lower blood eosinophil levels) AND has received combo tx w/inhaled corticosteroid AND at least 1 additional asthma controller/maintenance med (Examples: LAMA, LABA, leukotriene receptor antagonist, monoclonal antibody) AND pt's asthma cont to be uncontrolled, or was uncontrolled prior to starting Nucala or another monoclonal antibody therapy for asthma as defined by 1 of following-pt experi 2 or more asthma exacer req tx w/systemic corticosteroids in prev yr, pt experienced 1 or more asthma exacer requiring hospitalization, urgent care visit or ED visit in the prev yr, pt has a FEV1 less than 80% predicted (90% for pt under 18), Pt has FEV1/FVC less than 0.80 (0.9 for pt under 18), or Pt's asthma worsens upon taper of oral (systemic) corticosteroid therapy. Cont-pt responded to Nucala tx as determined by the prescribing physician AND Pt cont to receive tx with an inhaled corticosteroid. EGPA initial-approve if pt has active, non-severe disease, has/had a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks or prior to any monoclonal antibody that may lower blood eosinophil levels. Cont-pt responded to Nucala tx as determined by the prescribing physician.HES initial-pt has had hypereosinophilic synd for greater than or equal to 6 months AND has FIP1L1-PDGFRalpha-negative dis AND pt does NOT have identifiable non-hematologic secondary cause of hypereosinophilic synd AND prior to initiating tx with monoclonal antibody that may lower blood eosinophil levels, pt has/had a blood eosinophil level of greater than or equal to 1,000 cells per microliter. Cont-approve if the patient has responded to Nucala tx. CRSwNP, initial-approve if pt meets ALL of the following criteria(A, B, C, D and E):A) pt has chronic rhinosinusitis w/nasal polyps as evidenced by direct examination, endoscopy, or sinus CT scan AND B) dx of CRSwNP for at least 6 months, and C) pt experienced 2 or more of the following sympt for at least 8 weeks:nasal congest/obstruct/discharge, and/or reduction/loss of smell AND D)pt meets BOTH of the following (a and b): a)Pt has received tx with intranasal corticosteroid AND b)Pt will continue to receive tx with intranasal corticosteroid concomitantly with Nucala AND E) pt meets 1 of the following (a, b or c): a)Pt has received at least 1 course of tx with a systemic corticosteroid in previous year, OR b)Pt has a contraindication to systemic corticosteroid tx, OR c)Pt had prior surgery for nasal polyps.Cont-approve if the pt has received at least 6 months of therapy,

PA Criteria	Criteria Details
	continues to receive tx with an intranasal corticosteroid and has responded to tx.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

NUEDEXTA

Products Affected

- Dextromethorphan-quiNIDine

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

PENDING CMS REVIEW & APPROVAL

NUPLAZID

Products Affected

- Nuplazid

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
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

PENDING CMS REVIEW & APPROVAL

NURTEC

Products Affected

- Nurtec

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention if Nurtec ODT is being taking for the preventive treatment of episodic migraine.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Migraine, Acute treatment-approve if the patient has tried at least one triptan or has a contraindication to triptans. Preventive treatment of episodic migraine-approve if the patient has greater than or equal to 4 but less than 15 migraine headache days per month (prior to initiating a migraine preventive medication) and if the patient is currently taking Nurtec ODT, the patient has had a significant clinical benefit from the medication. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Nurtec ODT was initiated.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

NYVEPRIA

Products Affected

- Nyvepria

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Cancer patients receiving chemotherapy-prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following: 1) is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), 2) patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status or HIV infection patients with low CD4 counts), or 3) patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

OCTREOTIDE INJECTABLE

Products Affected

- Octreotide Acetate

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Acromegaly-prescr/consult w/endocrinologist. NETs-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist, neurosurg/thymoma/thymic carcinoma-presc/consult with oncologist. Diarrhea assoc w chemo-presc/consult with oncologist/gastro. Small bowel bleed/angiodysplasia-presc/consult gastroenterologist.
Coverage Duration	Enterocutaneous fistula/diarrhea asssoc w chemo - 3 months, all others - 1 year
Other Criteria	ACROMEGALY (A or B): A) inadequate response to surgery and/or radiotherapy or patient not an appropriate candidate or B) patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) and has pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender. DIARRHEA ASSOC W CHEMO (A and B): A) grade 3 or 4 diarrhea [Examples: more than 6 bowel movements above baseline per day, colitis symptoms, interference with activities of daily living, hemodynamic instability, hospitalization, serious complications (eg, ischemic bowel, perforation, toxic mega-colon), or other colitis-related life-threatening conditions] and B) patient has tried at least one antimotility medication. SMALL BOWEL BLEEDS/ANGIODYSPLASIA RELATED BLEEDING: pt has chronic, recurrent gastrointestinal bleeds lasting greater than or equal to 3 months.

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Meningioma, thymoma and thymic carcinoma, pheochromocytoma and paraganglioma, enterocutaneous fistulas, diarrhea associated with chemotherapy, small bowel bleeds/angiodysplasia related bleeding
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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	No

PENDING CMS REVIEW & APPROVAL

OGSIVEO

Products Affected

- Ogsiveo

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

ONUREG

Products Affected

- Onureg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	AML - Approve if the medication is used for post-remission maintenance therapy AND allogeneic hematopoietic stem cell transplant is not planned. Peripheral T-cell lymphoma - approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Peripheral T-cell lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

opsumit

Products Affected

- Macitentan

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

ORKAMBI

Products Affected
- Orkambi

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other CF Transmembrane Conductance Regulator Modulators
Required Medical Information	
Age Restrictions	1 years of age and older
Prescriber Restrictions	prescribed by or inconsultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF - Approve if the pt meets A, B and C: A) pt has two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator gene, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

ORSERDU

Products Affected

- Orserdu

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 criteria (A, B, C, D, E and F): A) Patient has recurrent or metastatic disease, AND B) Patient has hormone receptor positive (HR+) [i.e. estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has estrogen receptor 1 gene (ESR1)-mutated disease, AND E) Patient has tried at least one endocrine therapy, Note: Examples of endocrine therapy include fulvestrant, anastrozole, exemestane, letrozole, and tamoxifen. AND F) meets one of the following (i or ii): i) pt is a postmenopausal woman or a man, or ii) pt is a pre/perimenopausal woman and meets (a or b): a) receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist [examples: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection)] or b) pt has had surgical bilateral oophorectomy or ovarian irradiation.
Indications	All FDA-approved Indications.
Off Label Uses	

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

otezla

Products Affected

- Otezla
- Otezla XR
- Otezla/Otezla XR Initiation Pk

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARD).
Required Medical Information	Diagnosis
Age Restrictions	PP/PsA- 6 years and older (initial), All other dx - 18 years and older (initial)
Prescriber Restrictions	All dx, initial only-PsA - Prescribed by or in consultation with a dermatologist or rheumatologist. PP - prescribed by or in consultation with a dermatologist. Behcet's-prescribed by or in consultation with a dermatologist or rheumatologist
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: PLAQUE PSORIASIS (PP): Approve. PSORIATIC ARTHRITIS (PsA): approve. BEHCET'S-oral ulcers or other mucocutaneous involvement. CONTINUATION THERAPY (PP/PsA/Behcet's): received 4 months of therapy and had a response.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

OXERVATE

Products Affected

- Oxervate

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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	No

PENDING CMS REVIEW & APPROVAL

PENICILLAMINE

Products Affected
- penicillAMINE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Wilson's Disease-Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant physician
Coverage Duration	1 year
Other Criteria	Cystinuria-approve. Wilson's disease-approve if diagnosis is confirmed by ONE of the following (i or ii): i. Genetic testing results confirming biallelic pathogenic ATP7B mutations (in either symptomatic or asymptomatic individuals), OR ii. Confirmation of at least two of the following (a, b, c, d): a) Presence of Kayser-Fleischer rings, b) Serum ceruloplasmin level less than 20 mg/dL, c) Liver biopsy findings consistent with Wilson's disease, d) 24-hour urinary copper greater than 40 mcg/24 hours.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

PHEOCHROMOCYTOMA - METYROSINE

Products Affected

- metyroSINE

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

PENDING CMS REVIEW & APPROVAL

PHOSPHATE BINDERS AND SIMILAR AGENTS - CALCIUM ACETATE

Products Affected

- Calcium Acetate (Phos Binder)

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

PENDING CMS REVIEW & APPROVAL

PHOSPHATE BINDERS AND SIMILAR AGENTS - SEVELAMER

Products Affected

- Sevelamer Carbonate

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

PENDING CMS REVIEW & APPROVAL

phosphodiesterase-5 inhibitors - SILDENAFIL

Products Affected

- Sildenafil Citrate Oral Tablet 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use With Guanylate Cyclase Stimulators.
Required Medical Information	Diagnosis, right heart cath results
Age Restrictions	
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	No

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phosphodiesterase-5 inhibitors - TADALAFIL

Products Affected

- Alyq
- Tadalafil (PAH)

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	No

PENDING CMS REVIEW & APPROVAL

PIQRAY

Products Affected

- Piqray (200 MG Daily Dose)
- Piqray (250 MG Daily Dose)
- Piqray (300 MG Daily Dose)

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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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PIRFENIDONE

Products Affected

- Pirfenidone

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	1 year
Other Criteria	IPF (initial therapy)- must have FVC greater than or equal to 40 percent of the predicted value at baseline (before any antifibrotic therapy such as pirfenidone, Ofev, Jascayd) AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP. IPF (continuation of therapy)-approve.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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PLEGRIDY

Products Affected

- Plegridy

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	
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

PENDING CMS REVIEW & APPROVAL

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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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POSACONAZOLE (ORAL)

Products Affected

- Posaconazole

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

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PREVYMIS

Products Affected

- Prevymis

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

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promacta

Products Affected

- Eltrombopag Olamine

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy. MDS-platelet counts.
Age Restrictions	
Prescriber Restrictions	Immune Thrombocytopenia or Aplastic Anemia, prescribed by, or after consultation with, a hematologist (initial therapy). Hep C, prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease (initial therapy). MDS-presc or after consult with heme/onc (initial therapy). Post-transplant, prescribed by or in consult with a hematologist, oncologist or stem cell transplant specialist physician (initial)
Coverage Duration	ImmuneThrombo/MDS init3mo,cont1yr,AAinit4mo,cont1yr,Thrombo/HepC1yr,Transplant-init3mo,cont6mo
Other Criteria	Thrombocytopenia in patients with immune thrombocytopenia, initial-approve if the patient has a platelet count less than 30, 000/mcL or less than 50, 000/mcL and the patient is at an increased risk for bleeding AND the patient has tried ONE other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Nplate, Tavalisse, Doptelet, rituximab, Wayrilz) or has undergone a splenectomy. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Treatment of thrombocytopenia in patients with Chronic Hepatitis C initial - approve if the patient will be receiving interferon-based therapy for chronic hepatitis C AND if the patient has low platelet counts at baseline (eg, less than 75,000/mcL). Aplastic anemia initial - approve if the patient has low platelet counts at baseline/pretreatment (e.g., less than 30,000/mcL) AND

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PA Criteria	Criteria Details
	tried one immunosuppressant therapy (e.g., cyclosporine) OR patient will be using eltrombopag in combination with standard immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response. MDS initial-approve if patient has low- to intermediate-risk MDS AND the patient has a platelet count less than 30, 000/mcL or less than 50, 000/mcL and is at an increased risk for bleeding. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Thrombocytopenia post-allogeneic transplantation, initial - approve if, according to the prescriber, the patient has poor graft function AND has a platelet count less than 50,000/mcL. Cont- patient demonstrated a beneficial clinical response.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Thrombocytopenia in Myelodysplastic Syndrome (MDS), Thrombocytopenia in a patient post-allogeneic transplantation
Part B Prerequisite	No
Prerequisite Therapy Required	No

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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

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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	No

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QULIPTA

Products Affected

- Qulipta

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Migraine headache prevention-approve if the patient meets (A and B): A) has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication, and B) if the pt is currently taking Qulipta, the pt has had significant clinical benefit. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Qulipta was initiated.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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RADICAVA ORS

Products Affected

- Radicava ORS Starter Kit

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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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RELEUKO

Products Affected

- Releuko

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Cancer/AML, MDS, ALL-oncologist or a hematologist. Cancer patients receiving BMT and PBPC-prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. SCN-hematologist. HIV/AIDS neutropenia-infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS. Radiation syndrome-prescribed by or in consultation with expert in acute radiation.
Coverage Duration	chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N, ALL,BMT,Radi-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), 2)patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status, or HIV infection patients with low CD4 counts), 3)patient has had a neutropenic complication from prior chemotherapy

PA Criteria	Criteria Details
	cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy, has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil count less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, pneumonia or other clinically documented infection, invasive fungal infection, hospitalization at the time of fever, prior episode of febrile neutropenia)
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Neutropenia associated with HIV or AIDS, Treatment of myelodysplastic syndromes (MDS), Drug induced agranulocytosis or neutropenia, Acute lymphocytic leukemia (ALL), peripheral blood progenitor cell transplantation in patients with cancer
Part B Prerequisite	No
Prerequisite Therapy Required	No

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REPATHA

Products Affected

- Repatha SureClick

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Leqvio or Praluent or Lerochol.
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	ASCVD/Primary Hyperlipidemia - 18 yo and older, HoFH/HeFH - 10 yo and older.
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL (or 155 mg/dL if less than 18 years old), b) Genetic testing confirming (Note 1) HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) or b) statin intolerant (throughout, see Definition 2 below). TO REDUCE MAJOR ADVERSE CV EVENTS IN PATIENTS AT INCREASED RISK WITH ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 55 mg/dL or higher or b) statin intolerant. HYPERCHOLESTEROLEMIA (not associated with established CVD, HeFH, or HoFH) [A or B]: A) tried one high-intensity statin and LDL-C remains 70 mg/dL or higher or B) statin intolerant. TO REDUCE MAJOR ADVERSE CV EVENTS IN PTS AT INCREASED RISK THAT DO NOT HAVE ESTABLISHED CVD [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer

PA Criteria	Criteria Details
	or B) statin intolerant. HoFH (both A and B): A) meets (a or b): a) Genetic testing confirming HoFH, or b) meets (i and ii): i) untreated LDL-C greater than 400 mg/dL or treated LDL-C greater than or equal to 300 mg/dL, and ii) clinical manifestations of HoFH before 10 years of age or at least one parent with untreated LDL-C or total cholesterol consistent with FH, AND B) meets (a or b): a) tried one high-intensity statin or b) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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RETEVMO

Products Affected
- Retevmo

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



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

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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

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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

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REZDIFFRA

Products Affected

- Rezdiffra

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist (initial/continuation)
Coverage Duration	1 year
Other Criteria	INITIAL THERAPY: METABOLIC-DYSFUNCTION ASSOCIATED STEATOHEPATITIS (MASH)/NON-ALCOHOLIC STEATOHEPATITIS (NASH): Both (i and ii): i) Stage F2 or F3 fibrosis prior to initiating treatment with Rezdiffra or Wegvovy identified by one of the following (a or b): a) Liver biopsy performed within 3 years preceding treatment with Rezdiffra or Wegovy, or b) One of the following within 6 months preceding treatment with Rezdiffra or Wegovy (1, 2 or 3): 1) Vibration-controlled transient elastography (VCTE) or 2) Magnetic resonance elastography (MRE) or 3) Enhanced Liver Fibrosis (ELF) test with score greater than or equal to 9.2 and less than or equal to 10.5, and ii) This will be used in combination with appropriate diet and exercise therapy (prescriber confirms the patient has received counseling on diet and exercise). CONTINUATION THERAPY (on therapy less than 1 year or restarting, review as initial therapy): MASH/NASH: All of (i and ii): i) completed greater than or equal to 1 year of therapy and has not had worsening of fibrosis or MASH/NASH, and ii) This will be used in combination with appropriate diet and exercise therapy (prescriber confirms the patient has received counseling on diet and exercise).



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

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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

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REZUROCK

Products Affected

- Rezurock

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

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RILUZOLE

Products Affected

- Riluzole

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

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RINVOQ

Products Affected
- Rinvoq

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic oral small molecule drug, Concurrent use with other potent immunosuppressants, or concurrent use with a biologic immunomodulator.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	PsA/JIA - 2 years and older (initial therapy), RA/UC/AS/CD/nr-axSpA/GCA-18 years and older (initial therapy), AD-12 years and older (initial therapy)
Prescriber Restrictions	RA/AS/Non-Radiographic Spondy/JIA/GCA, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. AD-prescr/consult with allergist, immunologist or derm. UC/CD-prescribed by or in consultation with a gastroenterologist. (all apply to initial therapy only)
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA)/PSORIATIC ARTHRITIS (PsA)/ANKYLOSING SPONDYLITIS (AS)/JUVENILE IDIOPATHIC ARTHRITIS (JIA): 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial. ULCERATIVE COLITIS (UC)/CROHN'S DISEASE (CD): meets (A, B or C): A) 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or B) unable to tolerate a 3-month trial or C) use of TNFi is clinically inadvisable per the prescriber and the patient has had a 3-month trial of at least one other advanced therapy unless intolerant (advanced therapies include biologics and targeted synthetic oral small molecule drugs). ATOPIC DERMATITIS (AD): 90 day trial of at least one systemic therapy (e.g., Dupixent [dupilumab subcutaneous injection], Ebglyss (lebrikizumab-lbkz subcutaneous injection), Nemluvio

PA Criteria	Criteria Details
	(nemolizumab-ilto subcutaneous injection), and Adbry [tralokinumab-ldrm subcutaneous injection]. Azathioprine, cyclosporine, or mycophenolate mofetil also count.) or unable to tolerate a 90 day trial. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (A and B): A) objective signs of inflammation defined as having at least one of the following (a or b): a) C-reactive protein elevated beyond the upper limit of normal or b) sacroiliitis reported on MRI and B) 3-month trial of at least one TNFi or was unable to tolerate a 3-month trial. GIANT CELL ARTERITIS: tried one or is currently taking a systemic corticosteroid or corticosteroids are contraindicated. CONTINUATION THERAPY: ALL INDICATIONS: patient responded to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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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	No

PENDING CMS REVIEW & APPROVAL

ROFLUMILAST (ORAL)

Products Affected

- Roflumilast

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD), medications tried.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial therapy - 6 months, Continuation of therapy - 1 year
Other Criteria	INITIAL THERAPY, COPD: all of (A, B, C and D): A) patient has forced expiratory volume in 1 second (FEV1) less than 50 percent predicted, and B) history of two or more moderate COPD exacerbations or one or more severe COPD exacerbations [Note: A moderate exacerbation is an exacerbation that required treatment with a short-acting bronchodilator and a systemic corticosteroid. A severe COPD exacerbation is an exacerbation that required hospitalization or an Emergency Department visit.], and C) patient has chronic bronchitis, and D) patient tried a medication from two of the three following drug categories: long-acting beta2-agonist (LABA) [eg, salmeterol, olodaterol], long-acting muscarinic antagonist (LAMA) [eg, tiotropium], inhaled corticosteroid (eg, fluticasone). CONTINUATION THERAPY, COPD: both (A and B): A) patient continues to receive combination therapy with a LABA and a LAMA, and B) patient has beneficial response defined by one of the following: reduced COPD symptoms, reduced COPD exacerbations, reduced COPD-related hospitalizations, reduced emergency department or urgent care visits, or improved lung function parameters.
Indications	All FDA-approved Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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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

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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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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-

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

PENDING CMS REVIEW & APPROVAL

RUFINAMIDE

Products Affected

- Rufinamide

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Patients 1 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Initial therapy-approve if rufinamide is being used for adjunctive treatment. Continuation-approve if the patient is responding to therapy
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Treatment-Refractory Seizures/Epilepsy
Part B Prerequisite	No
Prerequisite Therapy Required	No

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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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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SAPROPTERIN

Products Affected

- Sapropterin Dihydrochloride

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

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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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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SIGNIFOR

Products Affected

- Signifor

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

PENDING CMS REVIEW & APPROVAL

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	No

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SKYRIZI

Products Affected

- Skyrizi
- Skyrizi Pen

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis, Previous medication use
Age Restrictions	PP/UC/CD/PsA-18 years of age and older (initial therapy)
Prescriber Restrictions	PP-Prescribed by or in consultation with a dermatologist (initial therapy), PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy), CD/UC-presc/consult-gastro (initial therapy)
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or PUVA) for at least 3 months, unless intolerant. (Note: a 3-month trial or previous intolerance to at least one biologic also counts) or B) contraindication to MTX. PSORIATIC ARTHRITIS (PsA): approve. CROHN'S DISEASE (CD): approve. UlCERATIVE COLITIS (UC)-approve. CD/UC: Patient must be receiving induction dosing with Skyrizi IV within 3 months of initiating therapy with Skyrizi subcutaneous. CONTINUATION THERAPY: ALL INDICATIONS: patient has responded to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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solaraze

Products Affected

- Diclofenac Sodium External

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

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SOMAVERT

Products Affected

- Somavert

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

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SORAFENIB

Products Affected
- SORAfenib Tosylate

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



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PA Criteria	Criteria Details
	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
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	No

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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	No

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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.

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PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Soft tissue Sarcoma, Bone Cancer, Appendiceal cancer, Uterine sarcoma, Biliary tract cancers
Part B Prerequisite	No
Prerequisite Therapy Required	No

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SUCRAID

Products Affected
- Sucraid

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, genetic and lab test results (as specified in the Other Criteria field)
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, gastroenterologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of congenital diarrheal disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient meets the following criteria (A and B): A) The diagnosis is established by one of the following (i or ii): i. Patient has endoscopic biopsy of the small bowel with disaccharidase levels consistent with congenital sucrose-isomaltase deficiency as evidenced by ALL of the following (a, b, c, and d): a) Decreased (usually absent) sucrase (normal reference: greater than 25 U/g protein), b) Decreased or normal isomaltase (palatinase) [normal reference: greater than 5 U/g protein], c) Decreased maltase (normal reference: greater than 100 U/g protein), d) Decreased or normal lactase (normal reference: greater than 15 U/g protein) OR ii. Patient has a molecular genetic test demonstrating homozygous or compound heterozygous pathogenic or likely pathogenic sucrase-isomaltase gene variant AND B) Patient has symptomatic congenital sucrose-isomaltase deficiency (e.g., diarrhea, bloating, abdominal cramping).
Indications	All FDA-approved Indications.
Off Label Uses	

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

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SUNITINIB

Products Affected
- SUNItinib Malate

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Gastrointestinal stromal tumors (GIST), approve if the patient has tried imatinib or if the patient has succinate dehydrogenase (SDH)-deficient GIST. Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient meets (A or B): A) has papillary or follicular thyroid carcinoma and the disease is refractory to radioactive iodine therapy or B) has oncocytic (formerly Hurthle cell) carcinoma. Medullary thyroid carcinoma, approve if the patient has tried at least one systemic therapy. Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried at least one systemic chemotherapy. Renal Cell Carcinoma (RCC)-approve if the patient has relapsed or advanced disease. Neuroendocrine tumors of the pancreas-approve for advanced or metastatic disease. Pheochromocytoma/paraganglioma-approve if the patient has unresectable or metastatic disease. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Chordoma, angiosarcoma, solitary fibrous tumor, alveolar soft part sarcoma (ASPS), extraskeletal myxoid chondrosarcoma, differentiated (ie,

PA Criteria	Criteria Details
	papillary, follicular, and oncocytic carcinoma) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma, pheochromocytoma/paraganglioma, myeloid/lymphoid neoplasms with eosinophilia, GIST-unresectable succinate dehydrogenase (SDH)-deficient GIST.
Part B Prerequisite	No
Prerequisite Therapy Required	No

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SYMDEKO

Products Affected

- Symdeko

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with other CF transmembrane conductance regulator modulators
Required Medical Information	Diagnosis, specific CFTR gene mutations
Age Restrictions	6 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF - Approve if the pt mees A, B and C: A) pt has at least one variant in the cystic fibrosis transmembrane conductance regulator gene that is considered pathogenic or likely pathogenic or patient has TWO copies of the F508 del variant, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator variants or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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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

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TADALAFIL

Products Affected

- Tadalafil

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

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TAFAMIDIS

Products Affected

- Vyndamax

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other medications indicated for polyneuropathy of hereditary transthyretin-mediated amyloidosis or transthyretin-mediated amyloidosis-cardiomyopathy (e.g., Amvuttra (vutrisiran subcutaneous injection), Attruby (acoramidis tablets), Onpattro (patisiran lipid complex intravenous infusion), Tegsedi (inotersen subcutaneous injection), or Wainua [eplontersen subcutaneous injection]).
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis
Coverage Duration	1 year
Other Criteria	Cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis-approve if patient meets (A, B and C): A) the diagnosis was confirmed by one of the following (i, ii or iii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy), ii. tissue biopsy with confirmatory TTR amyloid typing by mass spectrometry, immunoelectron microscopy or immunohistochemistry OR iii. patient had genetic testing which, according to the prescriber, identified a TTR pathogenic variant AND B) Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum), and C) patient has heart failure but does not have NYHA class IV disease.
Indications	All FDA-approved Indications.
Off Label Uses	

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

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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.
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,

PA Criteria	Criteria Details
	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	No

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TAGRISSO

Products Affected

- Tagrisso

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-EGFR Mutation Positive (other than EGFR T790M-Positive Mutation)- approve if the patient has advanced or metastatic disease, has EGFR mutation-positive NSCLC. Note-examples of EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. NSCLC-EGFR T790M mutation positive-approve if the patient has advanced or metastatic EGFR T790M mutation-positive NSCLC and has progressed on treatment with at least one of the EGFR tyrosine kinase inhibitors. NSCLC- neoadjuvant or adjuvant therapy-approve if the patient has resectable disease and has EGFR exon 19 deletions or exon 21 L858R substitution mutation and has Stage IB, Stage II or Stage III disease and meets one (A or B): A) medication will be used as neoadjuvant therapy or B) medication will be used as adjuvant therapy. NSCLC- Unresectable Stage III - approve if the patient has locally advanced, unresectable (stage III) disease AND EGFR exon 19 deletions or exon 21 (L858R) substitution mutation AND not had disease progression during or following platinum-based chemoradiation therapy. (Note: Patients could have received concurrent or sequential chemoradiation therapy.)

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

PENDING CMS REVIEW & APPROVAL

TALZENNA

Products Affected

- Talzenna

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Recurrent or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive disease. Prostate cancer - approve if the patient has metastatic castration resistant prostate cancer, AND is using this medication concurrently with a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy AND the patient has homologous recombination repair (HRR) gene-mutated disease [Note: HRR gene mutations include ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C] AND the medication is used in combination with Xtandi (enzalutamide capsules and tablets).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

TARPEYO

Products Affected

- Tarpeyo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	10 months total therapy
Other Criteria	Primary Immunoglobulin A Nephropathy-A) Initial therapy-Approve if the patient meets the following criteria criteria (i, ii and iii): i. The diagnosis has been confirmed by biopsy, AND ii. Patient is at high risk of disease progression, defined by meeting a and b: a) Patient meets ONE of the following: Proteinuria greater than or equal to 0.5 g/day, OR Urine protein-to-creatinine ratio greater than or equal to 0.8 g/g, AND b) Patient has been receiving the maximum or maximally tolerated dose of ONE of the following for greater than or equal to 90 days: Angiotensin converting enzyme inhibitor OR Angiotensin receptor blocker, AND iii.Patient has not previously been treated with Tarpeyo Note: For a patient currently receiving Tarpeyo, review using Criterion B. B) Continuation of therapy-approve if the patient meets the following criteria (i and ii): i. The diagnosis has been confirmed by biopsy, AND ii. Patient has been receiving the maximum or maximally tolerated dose of ONE of the following for greater than or equal to 90 days: Angiotensin converting enzyme inhibitor OR Angiotensin receptor blocker.
Indications	All FDA-approved Indications.
Off Label Uses	



PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

TAZAROTENE

Products Affected

- Tazarotene
- 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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

TERIPARATIDE

Products Affected

- Bonsity
- Teriparatide

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications for osteoporosis
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	High risk for fracture-2 yrs, Not high risk-approve a max of 2 yrs of therapy (total)/lifetime.
Other Criteria	INITIAL THERAPY: Increase Bone Mass in Men (see Note 1 below) with Primary or Hypogonadal Osteoporosis, and Treatment of Glucocorticosteroid-Induced Osteoporosis (GIO): (one of A, B, C, D or E): A) tried one oral bisphosphonate or cannot take due to swallowing difficulties or inability to remain upright after administration, B) pre-existing gastrointestinal condition (e.g., esophageal lesions/ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), C) tried an IV bisphosphonate (zoledronic acid), D) severe renal impairment (creatinine clearance [CrCL] less than 35 mL/min) or chronic kidney disease (CKD), or E) patient had an osteoporotic fracture or fragility fracture at any time in the past. INITIAL THERAPY: Postmenopausal Osteoporosis (PMO) Treatment, Increase Bone Mass in Men (see Note 1 below) with Primary or Hypogonadal Osteoporosis, and Treatment of Glucocorticosteroid-Induced Osteoporosis (GIO): (one of A, B, C, D, E, or F): A) tried one oral bisphosphonate or cannot take due to swallowing difficulties or inability to remain upright after administration, B) pre-existing gastrointestinal condition (e.g., esophageal lesions/ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), C) tried an IV bisphosphonate

PA Criteria	Criteria Details
	(ibandronate or zoledronic acid), D) severe renal impairment (creatinine clearance [CrCL] less than 35 mL/min) or chronic kidney disease (CKD), or E) patient had an osteoporotic fracture or fragility fracture at any time in the past, or F) pt has a very low T-score less than -3.0. CONTINUATION THERAPY: ALL INDICATIONS: if the patient has taken teriparatide for two years, approve if the patient is at high risk for fracture. Examples of high risk for fracture include a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, and very low bone mineral density. Note 1: a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

TETRABENAZINE

Products Affected

- Tetrabenazine

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

TEZSPIRE

Products Affected
- Tezspire

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Tezspire with another monoclonal antibody therapy
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	CRSwNP: Prescribed by or in consultation with allergist, immunologist, or an otolaryngologist. Asthma: Prescribed by or in consultation with an allergist, immunologist, pulmonologist
Coverage Duration	Initial- 6 months, Continuation-1 year
Other Criteria	Asthma, initial-approve if the patient meets (i and ii): i. received combination therapy with BOTH of the following: an inhaled corticosteroid (CS) and at least one additional asthma controller or asthma maintenance medication, ii.Patient has asthma that is uncontrolled or was uncontrolled at baseline (baseline is defined as prior to receiving Tezspire or another monoclonal antibody therapy for asthma) as defined by ONE of the following (a, b, c, d, or e): a) Patient experienced two or more asthma exacerbations requiring systemic CS in the previous year, OR b) one or more asthma exacerbation(s) requiring hospitalization, an Emergency Department visit, or an urgent care visit in the previous year, OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80 percent predicted or less than 90 percent predicted for patients less than 18, OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 or less than 0.9 for pts less than 18, OR e) asthma that worsens upon tapering of oral (systemic) CS therapy AND Note: Baseline is defined as prior to receiving any Tezspire, anti-interleukin-5 therapies (i.e., Cinqair, Fasenra, or Nucala), Dupixent, or omalizumab. Asthma, continuation-approve if patient continues to receive therapy with one inhaled CS or one

PA Criteria	Criteria Details
	inhaled CS-containing combination inhaler and the patient has responded to therapy. CRSwNP, initial - approve if (A, B, C and D): A) dx as evidenced by direct examination, endoscopy, or sinus CT scan AND B) at least 2 symptoms for at least 8 weeks: nasal congestion/obstruction/discharge and/or reduction/loss of smell, AND C) BOTH of (a and b): a) received tx with intranasal CS AND b)will continue to receive tx with intranasal CS, AND D) at least 1 course of systemic CS in previous year (unless contraindicated) or prior surgery for nasal polyps. CRSwNP, Cont-approve if received at least 6 months of therapy, continues intranasal CS and has responded to tx.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	Yes
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

thalomid

Products Affected
- Thalomid

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	MM, histiocytic neoplasms-18 years and older, medulloblastoma- less than 18 years old
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Erythem Nodosum Leprosum-approve. Multiple Myeloma-approve. Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried at least two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). Prurigo nodularis, approve. Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried at least two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). Kaposi Sarcoma-approve if the patient has immune reconstitution inflammatory syndrome (IRIS), AND meets one (i or ii): i) tried at least one medication or ii) has Kaposi sarcoma-associated herpesvirus (KSHV)-associated inflammatory cytokine syndrome. Castleman disease-approve if the patient has multicentric disease or has relapsed/refractory or progressive disease. Histiocytic neoplasms-approve if (A or B): A) pt 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 or Rosai-Dorfman cutaneous disease. Medulloblastoma-

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PA Criteria	Criteria Details
	approve if pt has recurrent or progressive disease AND medication is being used as a part of the MEMMAT regimen (i.e. Thalomid, celecoxib, fenofibrate, oral etoposide, cyclophosphamide, bevacizumab, and intraventricular etoposide).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Discoid lupus erythematosus or cutaneous lupus erythematosus, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi Sarcoma, Castleman Disease, histiocytic neoplasms, medulloblastoma.
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

TOBRAMYCIN (NEBULIZATION)

Products Affected

- Tobramycin Inhalation

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

PENDING CMS REVIEW & APPROVAL

TOLVAPTAN

Products Affected

- Tolvaptan (Hyponatremia)

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



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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

TOPICAL AGENTS FOR ATOPIC DERMATITIS - CRISABOROLE

Products Affected

- Eucrisa

PA Criteria	Criteria Details
Exclusion Criteria	
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

PENDING CMS REVIEW & APPROVAL

TOPICAL AGENTS FOR ATOPIC DERMATITIS - PIMECROLIMUS

Products Affected

- Pimecrolimus

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

TOPICAL AGENTS FOR ATOPIC DERMATITIS - TACROLIMUS

Products Affected

- Tacrolimus External

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

topical retinoid products - TRETINOIN

Products Affected

- Tretinoin External

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

PENDING CMS REVIEW & APPROVAL

TOPIRAMATE

Products Affected

- Topiramate

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

PENDING CMS REVIEW & APPROVAL

TRANSDERMAL FENTANYL

Products Affected

- fentaNYL

PA Criteria	Criteria Details
Exclusion Criteria	Acute (i.e., non-chronic) pain.
Required Medical Information	Pain type (chronic vs acute)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) AND 3) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 4) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, in hospice, sickle cell diagnosis or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids (including transdermal fentanyl products) require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off Label Uses	



PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

TRELSTAR

Products Affected

- Trelstar Mixject

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prostate cancer: Prescribed by or in consultation with a oncologist or urologist. Head and neck cancer - salivary gland tumors, breast cancer: Prescribed by or in consultation with a oncologist.
Coverage Duration	1 year
Other Criteria	Prostate cancer: Patients new to therapy, are required to try Eligard prior to approval of Trelstar. Head and neck cancer - salivary gland tumors: approve if patient has recurrent, unresectable, or metastatic disease and androgen receptor-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Head and neck cancer - salivary gland tumors, breast cancer
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

TREMFYA SC

Products Affected

- Tremfya
- Tremfya One-Press
- Tremfya Pen
- Tremfya-CD/UC Induction

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis
Age Restrictions	PP/PsA - 6 years of age or older (initial therapy), UC/CD-18 years of age and older (initial therapy)
Prescriber Restrictions	PP-Prescribed by or in consultation with a dermatologist (initial therapy only). PsA-prescribed by or in consultation with a dermatologist or rheumatologist (initial therapy). UC/CD-prescribed by or in consultation with a gastroenterologist (initial therapy).
Coverage Duration	Approve through end of plan year
Other Criteria	PP, intial therapy - approve if the pt meets (A and B): A) meets (1 or 2): 1) 18 years of age or older, or 2) 6 to 17 years old and weighs at least 40 kg, and B) meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: a biologic that is not a biosimilar of the requested product will also count) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. PsA, initial theray - approve if pt meets (1 or 2): 1) 18 years of age or older, or 2) 6 to 17 years old and weighs at least 40 kg. ULCERATIVE COLITIS-approve. CROHN'S DISEASE (CD): approve. PP/PsA/UC/CD continuation of therapy - approve it the pt is responding to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	



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

PENDING CMS REVIEW & APPROVAL

TREPROSTINIL INHALATION POWDER

Products Affected

- Yutrepia

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with oral or parenteral prostacyclin agents used for pulmonary hypertension.
Required Medical Information	Diagnosis
Age Restrictions	Pulmonary Hypertension w/Interstitial lung disease - 18 years and older (intial/cont)
Prescriber Restrictions	Prescribed by, or in consultation with, a cardiologist or a pulmonologist (initial and continuation).
Coverage Duration	1 year
Other Criteria	PAH, WHO Group 1, initial therapy-approve if the patient has had a right heart catheterization to confirm the diagnosis and if the patient meets i or ii: i. Patient is intermediate-high risk or high-risk or, ii. Patient is low-risk or intermediate-low risk and the patient has tried or is currently receiving at least one agent for PAH from the following different categories (either alone or in combination) for at least 60 days: PDE5 inhibitors or endothelin receptor antagonists or Adempas (riociguat tablets) or Winrevair (sotatercept-csrk subcutaneous injection) or prostacyclin analogs/mimetics. Continuation-approve if the patient has had a right heart catheterization to confirm the diagnosis. Pulmonary Hypertension associated with interstitial lung disease, WHO Group 3 (this involves diagnosis such as idiopathic interstitial pneumonia, combined pulmonary fibrosis and emphysema, WHO Group 3 connective disease and chronic hypersensitivity pneumonitis), initial therapy - approve if the patient has evidence of diffuse parenchymal lung disease on computed tomography of the chest. Continuation- approve if the patient has had a response to therapy.



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

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TRIENTINE

Products Affected

- Trientine HCl

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

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

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TRIKAFTA

Products Affected
- Trikafta

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with other CF transmembrane conductance regulator modulators.
Required Medical Information	Diagnosis
Age Restrictions	2 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF -Approve if the pt meets A, B, C, and D: A) pt has at least one variant in the cystic fibrosis transmembrane conductance regulator gene that is considered to be pathogenic or likely pathogenic, and B) Patient meets one of (i or ii): i) The variant in the cystic fibrosis transmembrane conductance regulator gene is responsive to the medication based on clinical and/or in vitro data or ii) the variant in the cystic fibrosis transmembrane conductance regulator gene results in production of cystic fibrosis transmembrane regulator protein, AND C) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and D) evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off Label Uses	

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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	

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

PENDING CMS REVIEW & APPROVAL

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
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

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

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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

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TYENNE SC

Products Affected

- Avtozma
- Tyenne

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	Interstitial lung disease-18 years and older (initial and continuation). GCA/RA-18 years and older (initial only). SJIA/PJIA-2 years and older (initial only).
Prescriber Restrictions	RA/GCA/PJIA/SJIA - Prescribed by or in consultation with a rheumatologist (initial therapy only). Lung disease-presc/consult-pulmonologist or rheum (initial and cont)
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA) [A or B): A) tried one of the following: Enbrel, preferred adalimumab product (see Example 1), Rinvoq or tofacitinib/XR (Note: trials with the following will also count: Cimzia, infliximab, Kevzara, golimumab SC/IV, non-preferred adalimumab product, Orencia), or B) heart failure or a previously treated lymphoproliferative disorder. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) [A or B]: A) tried one of the following: Enbrel, Rinvoq, tofacitinib, preferred adalimumab product. (Note: trials with Kevzara, infliximab, Orencia or a non-preferred adalimumab product will also count), or B) heart failure or a previously treated lymphoproliferative disorder. SYSTEMIC-ONSET JIA (SJIA): Approve. GIANT CELL ARTERITIS: tried or is currently taking a systemic CS or CS are contraindicated. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS (A and B): A) elevated acute phase reactants and B) diagnosis confirmed by high-resolution computed tomography. CONTINUATION THERAPY: ALL

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PA Criteria	Criteria Details
	INDICATIONS: patient had a response to therapy. Example 1: preferred adalimumab products include Hadlima, Simlandi.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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TYMLOS

Products Affected
- Tymlos

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



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PA Criteria	Criteria Details
	impairment (creatinine clearance [CrCL] less than 35 mL/min) or chronic kidney disease (CKD), or E) patient had an osteoporotic fracture or fragility fracture at any time in the past, or F) pt has a very low T-score less than -3.0.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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UBRELVY

Products Affected

- Ubrelvy

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Migraine, Acute treatment-approve if the patient has tried at least one triptan or has a contraindication to triptans.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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UPTRAVI

Products Affected

- Uptravi
- Uptravi Titration

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Inhaled or Parenteral Prostacyclin Agents Used for Pulmonary Hypertension.
Required Medical Information	Confirmation of right heart catheterization, medication history (as described in Other Criteria)
Age Restrictions	
Prescriber Restrictions	PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	1 year
Other Criteria	Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Initial therapy must meet (A or B): A) Pt is intermediate-high risk or high risk OR B) Pt is low-risk or intermediate-low risk and has tried or is currently taking at least one agent for PAH from the following different categories (either alone or in combination) for 60 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Revatio), or endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas (riociguat tablets), or Winrevair (sotatercept-csrk subcutaneous injection) or prostacyclin analogs/mimetics.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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USTEKINUMAB SC

Products Affected

- Otulfi
- Pyzchiva
- Yesintek

PA Criteria	Criteria Details
Exclusion Criteria	Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	PP/PsA-6 years and older (initial therapy). UC-18 years and older (initial therapy). CD-2 years and older (initial therapy).
Prescriber Restrictions	Plaque psoriasis.Prescribed by or in consultation with a dermatologist (initial therapy only). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy only). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy only).
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: PLAQUE PSORIASIS (PP) [A or B]: A) tried one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, psoralen plus PUVA) for at least 3 months, unless intolerant or B) contraindication to MTX. (Note: a 3-month trial or intolerance of at least one biologic that is not ustekinumab also counts.) CROHN'S DISEASE (CD): approve if pt receiving/received single IV loading dose within 2 months of initiating therapy with ustekinumab SC. ULCERATIVE COLITIS (UC): receiving/received single IV loading dose within 2 months of initiating therapy with ustekinumab SC. CONTINUATION THERAPY: PP/PsA/CD/UC: patient has responded to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	

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

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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

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VALTOCO

Products Affected

- Valtoco 10 MG Dose
- Valtoco 15 MG Dose
- Valtoco 20 MG Dose
- Valtoco 5 MG Dose

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 antiseizure medication(s).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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VANCOMYCIN

Products Affected

- Vancomycin HCl Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	2 weeks
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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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

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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

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PA Criteria	Criteria Details
	Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
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	No

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VERZENIO

Products Affected

- Verzenio

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, Early-Approve if pt meets (A, B, C and D): A) has HR+ disease AND B) has HER2-negative breast cancer, AND C) has node-positive disease at high risk of recurrence AND D) meets ONE (i or ii): i. Verzenio will be used in combo w/anastrozole, exemestane, or letrozole AND pt meets one (a, b, or c): a) is a postmenopausal woman OR b) is a pre/perimenopausal woman and meets one (1 or 2): 1) receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, OR 2) has had surgical bilateral oophorectomy or ovarian irradiation, OR c) is a man and pt is receiving a GnRH analog, OR ii. Verzenio will be used in combo with tamoxifen AND pt meets one (a or b): a) is a postmenopausal woman or man OR b) is a pre/perimenopausal woman and meets one (1 or 2): 1) is receiving ovarian suppression/ablation with a GnRH agonist, OR 2) has had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer-Recurrent or Metastatic in Women-Approve if pt meets (A, B and C): A) has HR+ disease, AND B) meets ONE (i or ii): i. is a postmenopausal woman, OR ii. is a pre/perimenopausal woman and meets one (a or b): a) receiving ovarian suppression/ablation with a GnRH agonist, OR b) has had surgical bilateral oophorectomy or ovarian irradiation, AND C) either (1 or 2): 1)

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PA Criteria	Criteria Details
	HER2-negative breast cancer and meets ONE (i, or ii): i. Verzenio will be used in combo with anastrozole, exemestane, letrozole, fulvestrant, or Inluriyo (imlunestrant tablets), OR ii.pt meets all (a, b, and c): a) Verzenio will be used as monotherapy, AND b) breast cancer has progressed on at least one prior endocrine therapy, AND c) has tried chemotherapy for metastatic breast cancer or 2) has HER2-positive breast cancer and has received at least two prior anti-HER2-based regimens in the metastatic setting and will use this in combination with fulvestrant and trastuzumab. Breast Cancer-Recurrent or Metastatic in Men-Approve if pt meets both (A and B): A) has HR+ disease, AND B) either (1 or 2): 1) has HER2-negative disease and meets ONE (i, ii, or iii): i. meets BOTH (a and b): a) Pt is receiving a GnRH analog, AND b) Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant or Inluriyo (imlunestrant tablets), OR iii. meets all (a, b, and c): a) Verzenio will be used as monotherapy, AND b) breast cancer has progressed on at least one prior endocrine therapy, AND c) has tried chemotherapy for metastatic breast cancer, or 2) has HER2-positive disease and has received at least two prior anti-HER2-based regimen in the metastatic setting and will use this medication with fulvestrant and trastuzumab. Endometrial cancer- approve if pt meets all (A, B, and C): A) recurrent or metastatic disease or not a candidate for surgery, and B) estrogen receptor (ER)-positive tumors, and C) Verzenio will be used in combo with letrozole. Liposarcoma-Approve if patient has dedifferentiated lipsarcoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Endometrial cancer, liposarcoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

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VIGABATRIN

Products Affected

- Vigabatrin
- Vigadrone

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, medication history (complex partial seizures)
Age Restrictions	Refractory complex partial seizures - patients 2 years of age or older. Infantile spasms - patients less than or equal to 2 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist
Coverage Duration	Infantile spasms- 6 mo. Treatment-Refractory Partial Seizures-initial therapy 3 mo, cont-1 year
Other Criteria	Infantile spasms-requested medication is being used as monotherapy. Treatment refractory complex partial seizures intial-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs. Treatment refractory complex partial seizures continuation- the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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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

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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.

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PA Criteria	Criteria Details
Off Label Uses	Accelerated or blast phase myeloproliferative neoplasm, myeloid or lymphoid neoplasms
Part B Prerequisite	No
Prerequisite Therapy Required	No

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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

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VORICONAZOLE (ORAL)

Products Affected

- Voriconazole

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

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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	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

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votrient

Products Affected
- PAZOPanib HCl

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Soft tissue sarcoma other than GIST-approve if the patient has advanced or metastatic disease and has ONE of the following: alveolar soft part sarcoma, angiosarcoma, dedifferentiated chordoma, dedifferentiated liposarcoma, desmoid tumors (aggressive fibromatosis), dermatofibrosarcoma protuberans with fibrosarcomatous transformation, epithelioid hemangioendothelioma, extraskeletal myxoid chondrosarcoma, non-adipocytic sarcoma, pleomorphic rhabdomyosarcoma, or solitary fibrous tumor/hemangiopericytoma. Differentiated thyroid carcinoma, approve if the patient meets (A or B): A) has papillary or follicular thyroid carcinoma and the disease is refractory to radioactive iodine therapy or B) has oncocytic (formerly Hurthle cell) carcinoma. Uterine sarcoma, approve if the patient has recurrent or metastatic disease. Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or advanced disease or VonHippel-Lindau disease. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease. GIST - approve if the patient has succinate dehydrogenase (SDH)-deficient GIST OR the patient has tried TWO of the following: imatinib, sunitinib, Qinlock or Stivarga. Medullary Thyroid Carcinoma, approve if the patient



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PA Criteria	Criteria Details
	has tried at least one systemic therapy. Bone cancer-approve if the patient has chondrosarcoma and has metastatic widespread disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Differentiated (ie, papillary, follicular, oncocytic carcinoma) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma, bone cancer.
Part B Prerequisite	No
Prerequisite Therapy Required	No

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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

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VUMERITY

Products Affected

- Vumerity

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

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VYVGART

Products Affected

- Vyvgart Hytrulo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial and continuation)
Coverage Duration	Initial-6 months, Continuation-1 year
Other Criteria	CIDP (Vyvgart Hytrulo only), Initial Therapy - approve if diagnosis was supported by electrodiagnostic studies AND pt previously received treatment with an intravenous or subcutaneous immune globulin and had inadequate efficacy or significant intolerance or patient has a contraindication to IV or SC immune globulin. Generalized myasthenia gravis, Initial Therapy-Approve if the patient meets the following criteria (A, B, and C): A. Patient has confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis, AND B. Patient has evidence of unresolved symptoms of generalized myasthenia gravis, such as difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility) AND C. patient has myasthenia gravis foundation of america classification of II to IV. CIDP (Vyvgart Hytrulo only), Cont therapy - pt has clinically significant improvement in neurologic symptoms (Examples include improvement in disability: nerve conduction study results improved or stabilized, physical examination shows improvement in neurological symptoms, strength, and sensation). Generalized myasthenia gravis, Continuation Therapy-Approve if patient is continuing to derive benefit from Vyvgart.

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

PENDING CMS REVIEW & APPROVAL

WEGOVY

Products Affected

- Wegovy

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other glucagon-like peptide-1 (GLP-1) agonists or GLP-1/ glucose-dependent insulinotropic polypeptide (GIP) receptor agonists
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	MASH, initial and cont: prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist
Coverage Duration	1 year
Other Criteria	To reduce the risk of major adverse cardiovascular events in a patient with established cardiovascular disease who is either obese or overweight: approve if the patient meets (A, B, C and D): A) at baseline, the patient has body mass index greater than or equal to 27 kg/m2 (refers to baseline prior to Wegovy) AND B) the patient meets one of the following (a, b, or c): a) prior myocardial infarction, b) prior stroke or c) history of symptomatic peripheral arterial disease as evidenced by one of the following: (1) intermittent claudication, (2) peripheral arterial revascularization procedure, or (3) amputation due to atherosclerotic disease AND C) the medication will be used in combination with pharmacotherapy for established cardiovascular disease as deemed appropriate by the prescribing physician AND D) the medication will be used in combination with a reduced calorie diet (e.g. Prescriber confirms that patient has received counseling on diet). Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH), initial: approve if patient meets (A, B and C): A) does not have cirrhosis, B) Stage F2 or F3 fibrosis prior to initiating treatment with Wegvovy identified by one of the following (i or ii): i) Liver biopsy

PA Criteria	Criteria Details
	performed within 3 years preceding treatment with Wegovy, or ii) One of the following preceding treatment with Wegovy (1, 2 or 3): 1) Vibration-controlled transient elastography (VCTE) or 2) Magnetic resonance elastography (MRE) or 3) Enhanced Liver Fibrosis (ELF) test with score greater than or equal to 9.2 and less than or equal to 10.5, and C) This will be used in combination with appropriate diet and exercise therapy (prescriber confirms the patient has received counseling on diet and exercise). MASH/NASH, continuation: All of (A, B and C): A) completed greater than or equal to 1 year of therapy, and B) pt does not have stage F4 (cirrhosis) and C) This will be used in combination with appropriate diet and exercise therapy (prescriber confirms the patient has received counseling on diet and exercise).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

WELIREG

Products Affected

- Welireg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Pheochromocytoma/paraganglioma-12 years and older, Other indications-18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Pheochromocytoma/paraganglioma- approve if pt has locally advanced, unresectable, or metastatic disease. Renal Cell Carcinoma- approve if patient meets the following (A, B, C and D): A) pt has advanced disease AND B) has clear cell histology AND C) has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor AND D) has tried at least one a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). [Note: Examples of PD-1 inhibitor or PD-L1 inhibitor include: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), and Bavencio (avelumab intravenous infusion). Examples of VEGF-TKI include Cabometyx (cabozantinib tablets), Lenvima (lenvatinib capsules), Inlyta (axitinib tablets), Fotivda (tivozanib capsules), pazopanib, sunitinib, and sorafenib.] Van Hippel-Lindau Disease-approve if the patient meets the following (A, B, and C): A) Patient has a von Hippel-Lindau (VHL) germline alteration as detected by genetic testing, B) Does not require immediate surgery and C) Patient requires therapy for ONE of the following conditions (i, ii, iii, or iv): i. Central nervous system

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PA Criteria	Criteria Details
	hemangioblastomas, OR ii. Pancreatic neuroendocrine tumors, OR iii. Renal cell carcinoma, OR iv. Retinal hemangioblastoma.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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WINREVAIR

Products Affected

- Winrevair

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation)
Coverage Duration	Initial-6 months, Continuation-1 year
Other Criteria	INITIAL THERAPY-PULMONARY ARTERIAL HYPERTENSION (PAH) WHO GROUP 1-Both (A and B): A) right-heart catheterization to confirm the diagnosis, and B) One of (a or b): a) Pt is intermediate-high risk or high risk OR b) Pt is low-risk or intermediate-low risk and has tried or is currently receiving at least one agent for PAH from one of the following different categories (either alone or in combination) for greater than or equal to 60 days: phosphodiesterase type 5 inhibitors (PDE5i), or endothelin receptor antagonists (ERAs), or Adempas (riociguat tablets) or prostacyclin inhibitors. CONTINUATION THERAPY-PAH WHO GROUP 1-patient has had a right heart catheterization to confirm the diagnosis.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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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.

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

PENDING CMS REVIEW & APPROVAL

XDEMVY

Products Affected

- Xdemvy

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

PENDING CMS REVIEW & APPROVAL

xeljanz

Products Affected

- Tofacitinib Citrate
- Tofacitinib Citrate ER

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



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PA Criteria	Criteria Details
	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	Yes
Prerequisite Therapy Required	No

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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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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
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

PA Criteria	Criteria Details
	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	No

PENDING CMS REVIEW & APPROVAL

xolair

Products Affected
- Xolair

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy.
Required Medical Information	Diagnosis
Age Restrictions	Moderate to severe persistent asthma-6 years and older. CIU-12 years and older. Polyps-18 years and older. Food Allergy-1 yr and older
Prescriber Restrictions	Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist. Polyps-prescribed by or in consult with an allergist, immunologist, or otolaryngologist. Food allergy- allergist or immunologist
Coverage Duration	asthma-1 year, Polyps/CIU-initial-6 months, continued tx 12 months, Food allergy-1 yr
Other Criteria	MODERATE TO SEVERE PERSISTENT ASTHMA (A, B, C and D): A)baseline IgE greater than or equal to 30 IU/mL, and B)baseline positive skin test or in vitro test for 1 or more perennial or seasonal aeroallergens C)received at least 3 months of combination therapy with an inhaled corticosteroid (ICS) and additional asthma controller/maintenance medication (e.g., LABA, LAMA, leukotriene receptor antagonist, monoclonal antibody) [see Exception 1 below] and D)asthma is uncontrolled or was uncontrolled prior to receiving omalizumab or another monoclonal antibody and meets one of (a, b, c, d, or e): a) experienced two or more asthma exacerbations requiring systemic CSs in the past year, b) experienced one or more asthma exacerbation requiring hospitalization/urgent care visit/emergency department visit in the past year, c) FEV1 less than 80% predicted or less than 90% for pts less than 18, d) FEV1/forced vital capacity (FVC) less than 0.80 or 0.90 for pts less than 18, or e) asthma worsens upon tapering of oral CS. CHRONIC

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PA Criteria	Criteria Details
	RHINOSINUSITIS WITH NASAL POLYPS (CRwNP) [all of A, B, C, D, E, and F]: A) diagnosis by direct exam, endoscopy, or sinus CT scan, B) baseline (prior to omalizumab or another monoclonal antibody that may lower IgE) IgE at least 30 IU/ml, C) at least two of the following symptoms for 8 weeks: nasal congestion, obstruction, discharge, reduction/loss of smell, D) tried intranasal CS and will continue in combination with omalizumab, E) one of the following (a, b, or c): a) had systemic CS in previous year, b) contraindication to systemic CS, or c) had nasal polyp surgery, and F) dx for at least 6 months. CHRONIC SPONTANEOUS URTICARIA (CSU): urticaria at least 6 weeks prior to treatment with omalizumab and tried oral second generation H1 antihistamine tx. IgE-MEDIATED FOOD ALLERGY (all of A, B, C and D): A) baseline IgE greater than or equal to 30 IU/mL, B) positive skin prick test or positive in vitro test for IgE to one or more foods, C) history of allergic reaction that met all of the following (a, b, and c): a) signs and symptoms of a significant systemic allergic reaction, b) reaction occurred within a short period of time following a known ingestion of the food, and c) prescriber deemed this reaction significant enough to require a prescription for injectable/nasal epinephrine, and D) patient has been prescribed injectable/nasal epinephrine. CONTINUATION THERAPY: ASTHMA: patient responded to therapy and continues to receive an ICS. CRwNP: patient responded after 6 months of therapy and continues intranasal CS. CIU: received at least 6 months of omalizumab and experienced a beneficial clinical response, defined by decreased itch severity, decreased number of hives or decreased size of hives. Exception 1: an exception to the requirement of a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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

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XPOVIO

Products Affected

- Xpovio (100 MG Once Weekly)
- Xpovio (40 MG Once Weekly)
- Xpovio (40 MG Twice Weekly)
- Xpovio (60 MG Once Weekly)
- Xpovio (60 MG Twice Weekly)
- Xpovio (80 MG Once Weekly)
- Xpovio (80 MG Twice Weekly)

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	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

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PA Criteria	Criteria Details
	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	No

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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.
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

PA Criteria	Criteria Details
	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	No

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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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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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

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PA Criteria	Criteria Details
	gonadotropin-releasing hormone (GnRH) analog or pt has had a bilateral orchiectomy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Uterine Leiomyosarcoma, Prostate Cancer Metastatic Castration-Resistant and Castration-Sensitive
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

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

PA Criteria	Criteria Details
	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.
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	No

PENDING CMS REVIEW & APPROVAL

ZENBEXUS

Products Affected

- Zenbexus

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	MULTIPLE MYELOMA - A and B: A) Medication will be taken in combination with Darzalex (daratumumab intravenous infusion) or Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection) AND dexamethasone, AND B) Tried at least one proteasome inhibitor and at least one immunomodulatory agent. Note: Examples of a proteasome inhibitor include bortezomib, Kyprolis (carfilzomib intravenous infusion), or Ninlaro (ixazomib capsules). Note: Examples of an immunomodulatory agent include lenalidomide, pomalidomide, or Thalomid (thalidomide capsules).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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PENDING CMS REVIEW & APPROVAL

ZEPOSIA

Products Affected

- Zeposia
- Zeposia 7-Day Starter Pack
- Zeposia Starter Kit

PA Criteria	Criteria Details
Exclusion Criteria	MS-Concurrent use with other disease-modifying agents used for multiple sclerosis. UC- Concurrent Use with a Biologic or with a Targeted Synthetic Disease-modifying Antirheumatic Drug (DMARD) for Ulcerative Colitis
Required Medical Information	Diagnosis
Age Restrictions	UC-18 years and older
Prescriber Restrictions	MS-Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. UC-Prescribed by or in consultation with a gastroenterologist
Coverage Duration	MS-1 year, UC initial, 6 months, cont-1 year
Other Criteria	MS-approve. Ulcerative Colitis, initial-approve if the patient has tried TWO of the following: a preferred adalimumab product, a preferred ustekinumab product, a preferred infliximab product, Rinvoq, Skyrizi, Tremfya. Note-a trial of Simponi SC, Entyvio IV/SC, Omvoh IV/SC, a non-preferred adalimumab product, a non-preferred ustekinumab product or a non-preferred infliximab would also count). Cont tx-approve if the patient has been established on Zeposia. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab products include Remicade, infliximab IV (brand name product), Zymfentra. Preferred ustekinumab products include Otulfi, Pyzchiva (NDCs beginning with 61314-), Yesintek.
Indications	All FDA-approved Indications.
Off Label Uses	

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

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	No

PENDING CMS REVIEW & APPROVAL

ZONISAMIDE

Products Affected

- Zonisade
- Zonisamide

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

PENDING CMS REVIEW & APPROVAL

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

PENDING CMS REVIEW & APPROVAL

ZURZUVAE

Products Affected

- Zurzuvae

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

PENDING CMS REVIEW & APPROVAL

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	No

PENDING CMS REVIEW & APPROVAL

ZYMFENTRA

Products Affected

- Zymfentra (2 Pen)
- Zymfentra (2 Syringe)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic disease-modifying antirheumatic drug (DMARD).
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist (initial therapy)
Coverage Duration	Approve through end of plan year
Other Criteria	Crohn's Disease, initial therapy-Approve if the patient is currently receiving infliximab intravenous maintenance therapy or will receive induction dosing with an infliximab intravenous product within 3 months of initiating therapy with Zymfentra. Crohn's Disease, continuation-approve if the patient has had a response to therapy. Ulcerative Colitis, initial therapy-Approve if the patient is currently receiving infliximab intravenous maintenance therapy or will receive induction dosing with an infliximab intravenous product within 3 months of initiating therapy with Zymfentra. Ulcerative Colitis, continuation-approve if the patient has had a response to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PENDING CMS REVIEW & APPROVAL

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PENDING CMS REVIEW & APPROVAL

zytiga

Products Affected

- Abiraterone Acetate
- 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.
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

PA Criteria	Criteria Details
	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
Prerequisite Therapy Required	No