

COMMUNITY HEALTH PLAN OF WASHINGTON

actemra sq

Drugs

ACTEMRA ACTPEN, ACTEMRA SUBCUTANEOUS

Exclusion Criteria

Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

Required Medical Information

Diagnosis, concurrent medications, previous drugs tried.

Age Restriction

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 Restriction

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 Xeljanz/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, Xeljanz, 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 one systemic CS or CS is contraindicated. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS (A and B): A) elevated acute phase reactants and B) diagnosis confirmed by high-resolution computed tomography. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. Example 1: preferred adalimumab products include Hadlima, Simlandi.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

ACTIMMUNE

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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

ACYCLOVIR (Topical)

Drugs

acyclovir topical ointment

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration

12 months

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

ADALIMUMAB

Drugs

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

Exclusion Criteria

Concurrent use with another biologic DMARD or targeted synthetic DMARD.

Required Medical Information

Diagnosis

Age Restriction

Initial therapy only: Crohn's disease (CD), 6 or older, Ulcerative colitis (UC), 5 or older, PP/ Pyoderma gangrenosum/ sarcoidosis/ scleritis/ sterile corneal ulceration/ non-radiographic axial spondyloarthritis-18 years and older, Behcet's disease-2 years and older

Prescriber Restriction

Initial therapy only for all dx-RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist. UV-ophthalmologist

Coverage Duration

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, 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 B) has ophthalmic manifestations. SARCOIDOSIS (A and B): A) tried one CS, and B) tried one immunosuppressant (e.g. MTX, mycophenolate mofetil, chlorambucil, thalidomide, 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

Part B Prerequisite

Behcet's disease, pyoderma gangrenosum, sarcoidosis, scleritis/sterile corneal ulceration, non-radiographic axial spondyloarthritis.

No

Prerequisite Therapy Required

Prerequisite Therapy Required

No

Drugs

ADEMPAS

Exclusion Criteria

Concurrent Use with Phosphodiesterase Inhibitors Used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators.

Required Medical Information

Age Restriction

Prescriber Restriction

PAH and CTEPH- must be prescribed by or in consultation with a cardiologist or a pulmonologist.

Coverage Duration

1 year

Other Criteria

For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1).

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

AIMOVIG

Drugs

AIMOVIG AUTOINJECTOR

Exclusion Criteria

Combination therapy with another cGRP inhibitor for migraine headache prevention

Required Medical Information

Diagnosis, number of migraine headaches per month

Age Restriction

18 years and older

Prescriber Restriction

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

Drugs

AKEEGA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Prostate cancer- Approve if the patient meets the following (A, B, C, and D): A)Patient has metastatic castration-resistant prostate cancer, AND B)Patient has a BReast CAncer (BRCA) mutation, AND C)The medication is used in combination with prednisone, AND D)Patient meets one of the following (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog, Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), and Orgovyx (relugolix tablets).OR ii. Patient has had a bilateral orchiectomy.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

ALECENSA

Exclusion Criteria

Required Medical Information

Age Restriction

Pediatric diffuse high grade glioma- less than or equal to 21 years old, All others- 18 years and older

Prescriber Restriction

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 as detected by an approved test. Anaplastic large cell lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease and (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory Myofibroblastic Tumor- pt has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) pt has advanced, recurrent or metastatic disease, or (ii) tumor is inoperable. Large B-Cell Lymphoma- pt has ALK-positive disease AND pt has relapsed or refractory disease. Pediatric diffuse high grade glioma- approve if (A and B): A) ALK-positive disease, and B) either (i or ii): i) medication is used as adjuvant treatment AND tumor is not diffuse midline glioma, H3 K27-altered or pontine location, or ii) medication is used for recurrent or progressive disease.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Anaplastic large cell lymphoma, Erdheim Chester disease, Inflammatory Myofibroblastic Tumor, Large B-Cell Lymphoma, Pediatric Diffuse High Grade Glioma

No

Prerequisite Therapy Required

No

ALOSETRON

Drugs

alosetron

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

12 months

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

ALPHA 1 PROTEINASE INHIBITORS

Drugs

PROLASTIN-C INTRAVENOUS SOLUTION

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Alpha1-Antitrypsin Deficiency with Emphysema (or Chronic Obstructive Pulmonary Disease)-approve if the patient has a baseline (pretreatment) AAT serum concentration of less than 80 mg/dL or 11 micromol/L

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

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

Exclusion Criteria

Required Medical Information

ALK status

Age Restriction

18 years and older

Prescriber Restriction

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 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

Part B Prerequisite

Erdheim-Chester disease, Inflammatory myofibroblastic tumor (IMT), Peripheral T-Cell Lymphoma

No

Prerequisite Therapy Required

Yes

ANTIBIOTICS (IV)

Drugs

amikacin injection solution 500 mg/2 ml, ampicillin sodium injection recon soln 1 gram, 10 gram, ampicillin-sulbactam injection, azithromycin intravenous, aztreonam, BICILLIN L-A, cefoxitin, ceftazidime, cefuroxime sodium injection recon soln 750 mg, cefuroxime sodium intravenous recon soln 1.5 gram, ciprofloxacin in 5 % dextrose intravenous piggyback 200 mg/100 ml, clindamycin in 5 % dextrose, clindamycin phosphate injection solution 150 mg/ml, colistin (colistimethate na), DOXY-100, doxycycline hyclate intravenous, ertapenem, gentamicin in nacl (iso-osm) intravenous piggyback 100 mg/100 ml, 60 mg/50 ml, 80 mg/100 ml, 80 mg/50 ml, gentamicin injection, imipenem-cilastatin, levofloxacin in d5w intravenous piggyback 500 mg/100 ml, 750 mg/150 ml, linezolid in dextrose 5%, meropenem intravenous recon soln 1 gram, 500 mg, metronidazole in nacl (iso-os), moxifloxacin-sod.chloride(iso), nafcillin injection, oxacillin, oxacillin in dextrose(iso-osm) intravenous piggyback 2 gram/50 ml, penicillin g potassium injection recon soln 20 million unit, penicillin g sodium, streptomycin, TAZICEF INJECTION, TEFLARO, tigecycline, tobramycin sulfate injection solution

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration

3 months

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

ANTIFUNGALS (IV)

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration

3 months

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

ARCALYST

Exclusion Criteria

Concurrent biologic therapy

Required Medical Information

Age Restriction

Initial tx CAPS/Pericarditis-Greater than or equal to 12 years of age.

Prescriber Restriction

Initial tx CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA initial-rheum, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis-cardiologist or rheumatologist

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

Yes

Drugs

ARIKAYCE

Exclusion Criteria

Required Medical Information

Diagnosis, previous medication history (as described in Other Criteria field)

Age Restriction

MAC-18 years and older (initial therapy)

Prescriber Restriction

MAC initial-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections.

Coverage Duration

1 year

Other Criteria

INITIAL THERAPY: MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE (all of A, B, and C): A) positive sputum culture for MAC [Note: any positive sputum culture taken after completion of a background multidrug regimen (throughout, see Example 1 below) fulfills this criterion], B) MAC isolate is susceptible to amikacin, and C) Arikayce will be used in combination with a background multidrug regimen. CONTINUATION THERAPY: MAC LUNG DISEASE (A and B): A) Arikayce prescribed in combination with a background multidrug regimen and B) patient meets one of the following (a or b): a) patient has not achieved negative sputum cultures for MAC or b) patient has achieved negative sputum cultures for MAC for less than 12 months. Example 1: background multidrug regimen example - a macrolide (azithromycin or clarithromycin), ethambutol, and a rifamycin (rifampin or rifabutin).

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

teriflunomide

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 Restriction

Prescriber Restriction

Prescribed by or in consultation with a neurologist or MS specialist.

Coverage Duration

Authorization will be for 1 year.

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

AUGTYRO

Drugs

AUGTYRO ORAL CAPSULE 160 MG, 40 MG

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

NSCLC - 18 and older, Solid tumors - 12 and older, Pediatric Diffuse High-Grade Glioma-less than 18

Prescriber Restriction

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

Part B Prerequisite

Pediatric Diffuse High-Grade Gliomas

No

Prerequisite Therapy Required

No

AUSTEDO

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

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

Drugs

AVMAPKI-FAKZYNJA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

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

Part B Prerequisite

Fallopian Tube or Primary Peritoneal Cancer

No

Prerequisite Therapy Required

Yes

Drugs

AVONEX INTRAMUSCULAR PEN INJECTOR KIT, AVONEX INTRAMUSCULAR SYRINGE KIT

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 Restriction

Prescriber Restriction

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

Drugs

AYVAKIT

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction**Coverage Duration**

1 year

Other Criteria

GIST-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation or if the patient has tried two of the following: Gleevec (imatinib), Sutent (sunitinib), Sprycel (dasatinib), Stivarga (regorafenib) or Qinlock (ripretinib). Myeloid/Lymphoid Neoplasms with eosinophilia-approve if the tumor is positive for PDGFRA D842V mutation. Systemic mastocytosis-Approve if the patient has a platelet count greater than or equal to 50,000/mcL and patient has either indolent systemic mastocytosis or one of the following subtypes of advanced systemic mastocytosis-aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm or mast cell leukemia.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses**Part B Prerequisite**

Myeloid/Lymphoid neoplasms with Eosinophilia

No

Prerequisite Therapy Required

Yes

Drugs

BALVERSA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy, other chemotherapy or checkpoint inhibitor therapy. Pancreatic adenocarcinoma-approve if (A, B, C and D): 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 and D) medication is used as a single agent. NSCLC- approve if patient has metastatic disease and FGFR alterations.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Pancreatic adenocarcinoma, non-small cell lung cancer

No

Prerequisite Therapy Required

Yes

Drugs

BENLYSTA SUBCUTANEOUS

Exclusion Criteria

Concurrent Use with Other Biologics or Lupkynis

Required Medical Information

Diagnosis

Age Restriction

Lupus Nephritis: 18 years and older (initial). SLE: 5 years and older (initial).

Prescriber Restriction

SLE-Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus Nephritis-nephrologist or rheum. (Initial/cont)

Coverage Duration

SLE-Initial-4 months, cont-1 year. Lupus Nephritis-6 mo initial, 1 year cont

Other Criteria

Lupus Nephritis Initial-approve if the patient has a diagnosis of lupus nephritis confirmed on biopsy (For example, World Health Organization class III, IV, or V lupus nephritis), AND the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid). Cont-approve if the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid) AND the patient has responded to Benlysta subcutaneous or intravenous. SLE-Initial-The patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA [anti-dsDNA] antibody AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity. Continuation-Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, 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

BESREMI

Drugs

BESREMI

Exclusion Criteria

Concomitant use with other interferon products

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Prescribed by or in consultation with an oncologist

Coverage Duration

1 year

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

BETASERON/EXTAVIA

Drugs

BETASERON SUBCUTANEOUS KIT

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 Restriction

Prescriber Restriction

Prescribed by or after consultation with a neurologist or an MS specialist.

Coverage Duration

Authorization will be for 1 year

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

BEXAROTENE (ORAL)

Drugs

bexarotene

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)

Coverage Duration

1 year

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

BEXAROTENE (TOPICAL)

Drugs

bexarotene

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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. Adult T-Cell Leukemia/Lymphoma- approve if the patient has smoldering symptomatic subtype and this medication is used as first-line therapy. Primary cutaneous B-Cell lymphoma-approve if used as skin-directed therapy for either (a or b): a) primary cutaneous marginal zone lymphoma or b) follicle center lymphoma.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Adult T-Cell Leukemia/Lymphoma, Primary Cutaneous B-Cell Lymphoma

No

Prerequisite Therapy Required

No

Drugs

ambrisentan, bosentan oral tablet

Exclusion Criteria

Required Medical Information

Pulmonary arterial hypertension (PAH) WHO Group 1, results of right heart cath

Age Restriction

Prescriber Restriction

For treatment of pulmonary arterial hypertension, ambrisentan or bosentan must be prescribed by or in consultation with a cardiologist or a pulmonologist. CTEPH - prescribed by or in consultation with a cardiologist or pulmonologist

Coverage Duration

Authorization will be for 1 year.

Other Criteria

CTEPH - pt must have tried Adempas, has a contraindication to Adempas, or is currently receiving bosentan for CTEPH. Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Chronic thromboembolic pulmonary hypertension (CTEPH) (bosentan)

No

Prerequisite Therapy Required

Yes

Drugs

BOSULIF ORAL CAPSULE 100 MG, 50 MG, BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

ALL - 15 years and older. Myeloid/lymphoid neoplasms w eosinophilia- 18 years and older

Prescriber Restriction

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

Part B Prerequisite

Patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia, myeloid/lymphoid neoplasms with eosinophilia

No

Prerequisite Therapy Required

Yes

Drugs

BRAFTOVI

Exclusion Criteria**Required Medical Information**

Diagnosis, BRAF V600 status

Age Restriction

18 years and older

Prescriber Restriction**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.

Off Label Uses**Part B Prerequisite**

Appendiceal adenocarcinoma

No

Prerequisite Therapy Required

Yes

BRUKINSA

Drugs

BRUKINSA ORAL CAPSULE, BRUKINSA ORAL TABLET

Exclusion Criteria

Required Medical Information

Diagnosis, prior therapies

Age Restriction

18 years and older

Prescriber Restriction

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

Part B Prerequisite

Hairy Cell Leukemia, Primary Central Nervous System Lymphoma

No

Prerequisite Therapy Required

Yes

C1 ESTERASE INHIBITORS

Drugs

CINRYZE

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

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 Cinryze 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 Cinryze as prophylactic therapy compared with baseline.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

CABLIVI INJECTION KIT

Exclusion Criteria

Required Medical Information

Diagnosis, concurrent medications

Age Restriction

18 years and older

Prescriber Restriction

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

Drugs

CABOMETYX

Exclusion Criteria

Required Medical Information

Diagnosis, histology, RET gene rearrangement status for NSCLC

Age Restriction

Neuroendocrine tumor/Thyroid carcinoma-12 years and older, other dx (except bone cancer)-18 years and older

Prescriber Restriction

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- approve if pt has locoregional unresectable or metastatic adrenocortical carcinoma. Pheochromocytoma/paraganglioma- approve if pt has locally unresectable disease.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Patients with Non-Small Cell Lung Cancer, Gastrointestinal stromal tumors (GIST), Bone cancer, Endometrial carcinoma, Adrenal gland tumor, Pheochromocytoma/paraganglioma

No

Prerequisite Therapy Required

Yes

Drugs

CALQUENCE (ACALABRUTINIB MAL)

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

CLL and SLL-approve. Mantle Cell Lymphoma- approve if the patient meets (A or B): A) has tried at least one systemic regimen or is not a candidate for a systemic regimen (e.g., rituximab, dexamethasone, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, bortezomib, or lenalidomide) or B) this medication is used in combination with rituximab. Marginal Zone Lymphoma-approve if patient has tried at least one systemic regimen (e.g., bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, lenalidomide, or chlorambucil). Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen (e.g., Brukinsa [zanubrutinib capsules], Imbruvica [ibrutinib tablets and capsules], rituximab, bendamustine, cyclophosphamide, dexamethasone, bortezomib, fludarabine, or cladribine)

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Marginal zone lymphoma.
No

Prerequisite Therapy Required

Yes

Drugs

CAMZYOS

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older (initial and continuation)

Prescriber Restriction

Prescribed by a cardiologist (initial and continuation)

Coverage Duration

Initial-8 months, continuation- 1 year

Other Criteria

Obstructive hypertrophic cardiomyopathy, initial-Approve if the pt meets the following criteria (i, ii and iii):
i.Pt meets both of the following (a and b): a)Pt has at least 1 symptom associated w/obstructive hypertrophic cardiomyopathy (Note: examples include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise), AND b)Pt has New York Heart Association Class II or III symptoms of heart failure (Note:Class II signifies mild symptoms with moderate physical activity and some exercise limitations whereas Class III denotes noticeable symptoms with minimal physical activity and patients are only comfortable at rest), AND ii.Pt has left ventricular hypertrophy and meets 1 of the following (a or b): a)Pt has maximal left ventricular wall thickness greater than or equal to 15 mm, OR b)Pt has familial hypertrophic cardiomyopathy with a maximal left ventricular wall thickness greater than or equal to 13 mm, AND iii.Pt has a peak left ventricular outflow tract gradient greater than or equal to 50 mmHg (at rest or after provocation [Valsalva maneuver or post exercise]). Cont-Approve if pt meets ALL of the following criteria (i, ii, iii and iv): i.Pt has been established on therapy for at least 8 months (Note: pt who has received less than 8 months of therapy or who is restarting therapy is reviewed under initial therapy), AND ii.Pt meets both of the following (a and b): a)Currently or prior to starting therapy, pt has or has experienced at least 1 symptom associated with obstructive hypertrophic cardiomyopathy, AND b)Currently or prior to starting therapy, pt is in or was in New York Heart Association Class II or III heart failure, AND iii.Pt has a current left ventricular ejection fraction of greater than or equal to 50 percent, AND iv.Pt meets at least 1 of the following (a or b): a)Pt experienced a beneficial clinical response when assessed by at least 1 objective measure (Note:Examples include improved peak oxygen consumption/mixed venous oxygen tension, decreases in left ventricular outflow tract gradient, reductions in N-terminal pro-B-type natriuretic peptide levels, decreased high-sensitivity cardiac troponin I levels, reduced ventricular mass index, and/or a reduction in maximum left atrial volume index), OR b)Pt experienced stabilization or improvement in at least 1 symptom related to obstructive hypertrophic cardiomyopathy (Note:Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, ability to perform physical exercise, and/or favorable changes in the Kansas City Cardiomyopathy Questionnaire-23 (KCCQ-23) Clinical Summary Score (CSS) or Hypertrophic Cardiomyopathy Symptom Questionnaire (HCMSQ) Shortness of Breath domain scores.)

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No H5826_RX344_Clinical_Criteria_Prior_Auth_Feb_2026_C

CAPRELSA

Drugs

CAPRELSA ORAL TABLET 100 MG, 300 MG

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

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

Part B Prerequisite

Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma.

No

Prerequisite Therapy Required

No

CARGLUMIC ACID

Drugs

carglumic acid

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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 - 3mo. Pt had genetic test - 12mo, other-approve 7 days

Other Criteria

N-Acetylglutamate synthase deficiency with hyperammonemia-Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency or if the patient has hyperammonemia. Propionic Acidemia or Methylmalonic Acidemia with Hyperammonemia, Acute Treatment-approve if the patient's plasma ammonia level is greater than or equal to 50 micromol/L and the requested medication will be used in conjunction with other ammonia-lowering therapies.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (generic carglumic acid)

No

Prerequisite Therapy Required

No

Drugs

CAYSTON

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with a pulmonologist, infectious diseases specialist or a physician who specializes in the treatment of cystic fibrosis.

Coverage Duration

1 year

Other Criteria

Approve if the patient has *Pseudomonas aeruginosa* in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture).

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

CHEMET

Drugs

CHEMET

Exclusion Criteria

Required Medical Information

Blood lead level

Age Restriction

Approve in patients between the age of 12 months and 18 years

Prescriber Restriction

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

Drugs

cinacalcet

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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

Part B Prerequisite

hyperparathyroidism in post-renal transplant patients

No

Prerequisite Therapy Required

No

CLOBAZAM

Drugs

clobazam oral suspension, clobazam oral tablet, SYMPAZAN

Exclusion Criteria

Required Medical Information

Diagnosis, other medications tried

Age Restriction

2 years and older (initial therapy)

Prescriber Restriction

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

Part B Prerequisite

Dravet Syndrome and treatment-refractory seizures/epilepsy

No

Prerequisite Therapy Required

Yes

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis.

Age Restriction

18 years and older

Prescriber Restriction

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 Lenvima (lenvatinib capsules) or sorafenib tablets.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma

No

Prerequisite Therapy Required

Yes

Drugs

COPIKTRA, DROXIA ORAL CAPSULE 200 MG

Exclusion Criteria

Required Medical Information

Diagnosis, previous therapies

Age Restriction

18 years and older

Prescriber Restriction

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 Venclexta (venetoclax)- based regimen. 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

Part B Prerequisite

T-cell Lymphoma

No

Prerequisite Therapy Required

Yes

Drugs

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

Exclusion Criteria

Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)

Required Medical Information

Diagnosis and previous medications use

Age Restriction

PP-6 yr and older. AS/Spondy/HS initial - 18 years of age and older. PsA-2 years and older. Enthesitis-4 years and older

Prescriber Restriction

PP initial-presc/consult dermat. 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

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

COTELLIC

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction**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**Part B Prerequisite**

Central Nervous System Cancer

No

Prerequisite Therapy Required

No

CRESEMBA (ORAL)

Drugs

CRESEMBA ORAL

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration

3 months

Other Criteria

Indications

All Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Candidiasis of the esophagus - HIV infection, sepsis

No

Prerequisite Therapy Required

No

CYSTEAMINE (OPHTHALMIC)

Drugs

CYSTARAN

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases

Coverage Duration

1 year

Other Criteria

Approve if the patient has corneal cysteine crystal deposits confirmed by slit-lamp examination

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

CYSTEAMINE (ORAL)

Drugs

CYSTAGON

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 Restriction

Prescriber Restriction

Prescribed by or in consultation with a nephrologist or a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)

Coverage Duration

1 year

Other Criteria

Cystinosis, nephropathic-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming biallelic pathogenic or likely pathogenic variants in the CTNS gene OR white blood cell cystine concentration above the upper limit of the normal reference range for the reporting laboratory.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

DALFAMPRIDINE

Drugs

dalfampridine

Exclusion Criteria

Required Medical Information

Age Restriction

18 years and older (initial and continuation therapy)

Prescriber Restriction

MS. If prescribed by, or in consultation with, a neurologist or MS specialist (initial and continuation).

Coverage Duration

Initial-4months, Continuation-1 year.

Other Criteria

Initial-approve if the patient is ambulatory, the requested medication is being used to improve or maintain mobility in a patient with MS and the patient has impaired ambulation as evaluated by an objective measure (e.g., timed 25 foot walk and multiple sclerosis walking scale-12). Continuation-approve if the patient is ambulatory, the requested medication is being used to improve or maintain mobility in a patient with MS and the patient has responded to or is benefiting from therapy.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

DAURISMO

Drugs

DAURISMO ORAL TABLET 100 MG, 25 MG

Exclusion Criteria

Required Medical Information

Diagnosis, medications that will be used in combination, comorbidities

Age Restriction

18 years and older

Prescriber Restriction

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

DEFERASIROX

Drugs

deferasirox oral tablet

Exclusion Criteria

Required Medical Information

Serum ferritin level

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with a hematologist

Coverage Duration

1 year

Other Criteria

Transfusion-related chronic iron overload, initial therapy - approve if the patient is receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) AND prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload, initial therapy - approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation therapy - approve if the patient is benefiting from therapy as confirmed by the prescribing physician.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

DEFERIPRONE

Drugs

deferiprone

Exclusion Criteria

Required Medical Information

Serum ferritin level

Age Restriction

Prescriber Restriction

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

DIABETIC SUPPLY - ALCOHOL PADS

Drugs

ALCOHOL PADS

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

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

DIABETIC SUPPLY - GAUZE PADS

Drugs

GAUZE PAD TOPICAL BANDAGE 2 X 2 "

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

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

DIABETIC SUPPLY - NEEDLES

Drugs

pen needle, diabetic needle 29 gauge x 1/2"

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

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

DIABETIC SUPPLY - SYRINGES

Drugs

insulin syringe-needle u-100 syringe 0.3 ml 29 gauge, 1 ml 29 gauge x 1/2", 1/2 ml 28 gauge

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

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

DIACOMIT

Drugs

DIACOMIT

Exclusion Criteria

Required Medical Information

Documentation of diagnosis.

Age Restriction

6 months and older (initial therapy)

Prescriber Restriction

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

DIMETHYL FUMARATE

Drugs

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

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 Restriction

Prescriber Restriction

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

DOPTELET

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older (for chronic ITP-initial therapy only)

Prescriber Restriction

Chronic ITP-prescribed by or after consultation with a hematologist (initial therapy)

Coverage Duration

Thrombo w/chronic liver disease-5 days, chronic ITP- initial-3 months, cont-1 year

Other Criteria

THROMBOCYTOPENIA WITH CHRONIC LIVER DISEASE (A and B): A) current platelet count less than 50 x 10⁹/L and B) scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy.
CHRONIC ITP, INITIAL THERAPY (A and B): A): (i or ii): i) platelet count less than 30,000 microliters or ii) platelet count less than 50,000 microliters and patient is at an increased risk of bleeding, and B) tried one other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, eltrombopag tablets and oral suspension, romiplostim subcutaneous injection, fostamatinib tablets, rituximab) or had a splenectomy. CHRONIC ITP, CONTINUATION THERAPY: patient had beneficial clinical response and remains at risk for bleeding complications.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

DRONABINOL

Drugs

dronabinol

Exclusion Criteria

Coverage is not provided for anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS). Coverage is not provided for weight gain for cosmetic reasons.

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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

DROXIDOPA

Drugs

droxidopa

Exclusion Criteria

Required Medical Information

Medication history (as described in Other Criteria field)

Age Restriction

18 years of age and older

Prescriber Restriction

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

Yes

DUAL OREXIN RECEPTOR ANTAGONIST

Drugs

BELSOMRA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

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

DUPIXENT

Drugs

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

Exclusion Criteria

Concurrent use with another Monoclonal Antibody (examples: Adbry, Cinqair, Ebglyss, Fasentra, 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) 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, defined by decreased itch severity, decreased number of hives or decreased size of hives.

Age Restriction

Initial therapy only: AD-6 months and older, asthma-6 years of age and older, Esophagitis-1 yr and older, Chronic Rhinosinusitis/CSU- 12 and older, Prurigo nodularis/COPD-18 and older

Prescriber Restriction

Initial therapy only: Atopic Dermatitis/prurigo nodularis/CSU-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist. Esophagitis-presc/consult-allergist or gastro. COPD-prescribed by or in consultation with an allergist, immunologist, or pulmonologist

Coverage Duration

AD-Init-4mo, Cont-1 yr, asthma/Rhinosinusitis/esophagitis/prurigo nod/COPD/CSU-init-6 mo, cont 1 yr

Other Criteria

INITIAL CRITERIA: AD: tried at least 1 medium to super-high-potency topical corticosteroid (CS), unless topical CS therapy not advisable or pt is less than 2 years old. ASTHMA (all of A, B, and C): A) blood eosinophil greater than or equal to 150 cells per microliter within previous 6 weeks or 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 or antibiotics or ii) COPD exacerbation requiring hospitalization in previous 12 months. CRSwNP (all of A, B, C and D): A) concurrent use with nasal CS, B) presence of at least two of the following symptoms for 6 months: nasal congestion, nasal obstruction, nasal discharge, reduction/loss of smell, C) received oral CS at least 5 days in last 2 years (unless contraindicated) or patient had prior surgery for nasal polyps, and D) diagnosis confirmed by direct exam, endoscopy, or sinus CT. EoE (all of

A, B, C, and D): A) weighs 15 kg or more, B) endoscopic biopsy demonstrating greater than or equal to 15 intraepithelial eosinophils per high-power field, C) does not have a secondary cause of EoE, and D) received an Rx-strength PPI for at least 8 weeks. PRURIGO NODULARIS: pruritus lasting at least 6 weeks. CSU: urticaria for greater than 6 weeks (prior to Dupixent), with symptoms at least 3 days/week despite daily non-sedating H1 antihistamine tx. Bullous Pemphigoid Initial: Approve.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

EMGALITY

Drugs

EMGALITY PEN, EMGALITY SYRINGE SUBCUTANEOUS SYRINGE 120 MG/ML

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 Restriction

18 years and older

Prescriber Restriction

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

Prerequisite Therapy Required

No

Drugs

ENBREL MINI, ENBREL SUBCUTANEOUS SOLUTION, ENBREL SUBCUTANEOUS SYRINGE, ENBREL SURECLICK

Exclusion Criteria

Concurrent use with biologic therapy or targeted synthetic DMARD

Required Medical Information

Diagnosis, concurrent medications, previous therapies tried.

Age Restriction

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 Restriction

Initial-RA/AS/JIA/JRA,prescribed by or in consult w/ rheumatologist. PsA, prescribed by or in consultation w/ rheumatologist or dermatologist. PP, prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist, hematologist, or physician affiliated w/ transplant center. 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): approve. BEHCET'S: tried at least one conventional therapy (e.g., systemic corticosteroid, immunosuppressant, interferon alfa, 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

Part B Prerequisite

Graft versus host disease (GVHD), Behcet's disease
No

Prerequisite Therapy Required

Yes

Drugs

glutamine (sickle cell)

Exclusion Criteria

Required Medical Information

Diagnosis, prescriber specialty

Age Restriction

Greater than or equal to 5 years of age

Prescriber Restriction

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

EPIDIOLEX

Drugs

EPIDIOLEX

Exclusion Criteria

Required Medical Information

Diagnosis, previous therapies

Age Restriction

Patients 1 year and older (initial therapy)

Prescriber Restriction

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 or clobazam or Fintepla. 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 if the patient is responding to therapy.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Refractory epilepsy

No

Prerequisite Therapy Required

Yes

Drugs

PROCRIT INJECTION SOLUTION 10,000 UNIT/ML, 2,000 UNIT/ML, 20,000 UNIT/ML, 3,000 UNIT/ML, 4,000 UNIT/ML, 40,000 UNIT/ML, RETACRIT

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

MDS anemia = 18 years of age and older

Prescriber Restriction

MDS anemia/myelofibrosis, prescribed by or in consultation with, a hematologist or oncologist.

Coverage Duration

Chemo-6m, Transfus-1m, CKD-1 yr, 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 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

Part B Prerequisite

Anemia due to myelodysplastic syndrome (MDS), Myelofibrosis

No

Prerequisite Therapy Required

No

Drugs

ERIVEDGE

Exclusion Criteria

BCC (La or Met) - must not have had disease progression while on Odomzo.

Required Medical Information

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Basal cell carcinoma, locally advanced-patients new to therapy-approve if (A or B): A) pt has recurrent BCC following surgery or radiation therapy OR B) pt is not a candidate for surgery and is not a candidate for radiation therapy. Basal cell carcinoma, locally advanced-patients currently on therapy-approve. Central nervous system cancer (this includes brain and spinal cord tumors)-approve if the patient has medulloblastoma, the patient has tried at least one chemotherapy agent and according to the prescriber, the patient has a mutation of the sonic hedgehog pathway. Basal cell carcinoma, metastatic (this includes primary or recurrent nodal metastases and distant metastases)-approve. 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

Part B Prerequisite

Central nervous System Cancer, diffuse basal cell carcinoma formation

No

Prerequisite Therapy Required

Yes

Drugs

ERLEADA ORAL TABLET 240 MG, 60 MG

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Prostate cancer-non-metastatic, castration resistant and prostate cancer-metastatic, castration sensitive-approve if the requested medication will be used in combination with a gonadotropin-releasing hormone (GnRH) analog [for example: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

erlotinib oral tablet 100 mg, 150 mg, 25 mg

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

Authorization will be for 1 year.

Other Criteria

Advanced or Metastatic NSCLC, approve if the patient has EGFR mutation positive non-small cell lung cancer as detected by an approved test. Note-Examples of EGFR mutation-positive non-small cell lung cancer include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. RCC, approve if the patient 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

Part B Prerequisite

Renal Cell Carcinoma, vulvar cancer and Bone Cancer-Chordoma.

No

Prerequisite Therapy Required

Yes

EVEROLIMUS

Drugs

everolimus (antineoplastic) oral tablet, everolimus (antineoplastic) oral tablet for suspension 2 mg, 3 mg, 5 mg, TORPENZ

Exclusion Criteria

Required Medical Information

Breast Cancer-HER2 status, hormone receptor (HR) status.

Age Restriction

All dx except TSC associated SEGA, renal angiomyolipoma or partial onset seizures-18 years and older.

Prescriber Restriction

Coverage Duration

Authorization will be for 1 year.

Other Criteria

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

Part B Prerequisite

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

No

Prerequisite Therapy Required

Yes

FINGOLIMOD

Drugs

fingolimod

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 Restriction

10 years and older

Prescriber Restriction

Prescribed by, or in consultation with, a neurologist or an MS specialist.

Coverage Duration

Authorization will be for 1 year.

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

FINTEPLA

Drugs

FINTEPLA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

2 years and older (initial therapy)

Prescriber Restriction

Prescribed by or in consultation with an neurologist (initial therapy)

Coverage Duration

1 year

Other Criteria

Dravet Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex, Clobazam or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. Lennox-Gastaut Syndrome, initial-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Lennox-Gastaut Syndrome, continuation-approve if the patient is responding to therapy.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

FIRMAGON

Drugs

FIRMAGON KIT W DILUENT SYRINGE

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with a oncologist

Coverage Duration

1 year

Other Criteria

Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Patients new to therapy, are required to try Eligard prior to approval of Firmagon.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

FOTIVDA

Exclusion Criteria

Required Medical Information

Diagnosis, other therapies

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

Authorization will be for 1 year.

Other Criteria

Renal Cell Carcinoma (RCC)-approve if the patient has relapsed or Stage IV disease and has tried at least two other systemic regimens. Note: Examples of systemic regimens for renal cell carcinoma include axitinib tablets, axitinib + pembrolizumab injection, cabozantinib tablets, cabozantinib + nivolumab injection, sunitinib malate capsules, pazopanib tablets, sorafenib tablets, and lenvatinib capsules + everolimus.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years of age and older

Prescriber Restriction**Coverage Duration**

1 year

Other Criteria

Colon cancer, rectal cancer, or appendiceal cancer-Approve if the patient meets the following (A, B and C): A.Patient has advanced or metastatic disease, AND B. Patient meets (i or ii): i. has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease, or ii. patient is ineligible for or progressed on checkpoint inhibitor therapy (examples: Keytruda [pembrolizumab intravenous infusion] and Opdivo [nivolumab intravenous infusion]) and meets ONE of the following (a or b): a. has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or b. is polymerase epsilon/delta (POLE/POLD1) mutation positive, AND C. Patient has previously been treated with the following (i, ii, and iii): i.Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, Note: Examples of fluoropyrimidine agents include 5-fluorouracil (5-FU) and capecitabine. AND ii.An anti-vascular endothelial growth factor (VEGF) agent, Note: Examples of anti-VEGF agents include bevacizumab. AND iii. If the tumor is RAS wild-type (KRAS wild-type and NRAS wild-type) [that is, the tumor or metastases are KRAS and NRAS mutation negative], the patient meets ONE of the following (a or b): a.According to the prescriber, anti-epidermal growth factor receptor (EGFR) therapy is NOT medically appropriate, OR b. The patient has received an anti-EGFR therapy. Note: Examples of anti-EGFR therapy includes Erbitux (cetuximab intravenous infusion) and Vectibix (panitumumab intravenous infusion).

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses**Part B Prerequisite**

Appendiceal cancer

No

Prerequisite Therapy Required

Yes

Drugs

GATTEX 30-VIAL

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

1 year and older

Prescriber Restriction

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

Yes

GAVRETO

Drugs

GAVRETO

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

NSCLC-18 years and older, thyroid cancer-12 years and older

Prescriber Restriction

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

Part B Prerequisite

Medullary Thyroid Cancer, Anaplastic Thyroid Cancer

No

Prerequisite Therapy Required

No

Drugs

gefitinib

Exclusion Criteria

Required Medical Information

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

NSCLC-approve if the patient has advanced or metastatic disease and the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

NSCLC with EGFR L861Q, G719X, or S768I mutations.

No

Prerequisite Therapy Required

No

Drugs

GILOTRIF

Exclusion Criteria

Required Medical Information

For NSCLC - EGFR exon deletions or mutations or if NSCLC is squamous cell type

Age Restriction

18 years and older

Prescriber Restriction

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

Part B Prerequisite

Head and neck cancer

Yes

Prerequisite Therapy Required

Yes

GLATIRAMER

Drugs

glatiramer subcutaneous syringe 20 mg/ml, 40 mg/ml, GLATOPA SUBCUTANEOUS SYRINGE 20 MG/ML, 40 MG/ML

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 Restriction

Prescriber Restriction

Prescribed by or after consultation with a neurologist or an MS specialist.

Coverage Duration

Authorization will be for 1 year.

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

glucagon-like peptide-1 agonists

Drugs

exenatide subcutaneous pen injector 10 mcg/dose(250 mcg/ml) 2.4 ml, 5 mcg/dose (250 mcg/ml) 1.2 ml, liraglutide, TRULICITY

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration

Authorization will be for 1 year

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

GOMEKLI

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

2 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

NEUROFIBROMATOSIS TYPE 1- patient has or had symptomatic plexiform neurofibromas prior to starting Gomekli and the tumor is not amenable to complete resection.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

GONADOTROPIN-RELEASING HORMONE AGONISTS - ONCOLOGY

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Prostate cancer- prescribed by or in consultation with an oncologist or urologist. Head and neck-salivary gland tumors- prescribed by or in consultation with an oncologist.

Coverage Duration

1 year

Other Criteria

Head and neck cancer-salivary gland tumor- approve if pt has recurrent, unresectable, or metastatic disease AND androgen receptor-positive disease.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Head and neck cancer- salivary gland tumors (Eligard only)

No

Prerequisite Therapy Required

No

Drugs

OMNITROPE

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 Restriction

ISS 5 y/o or older, SGA 2 y/o or older

Prescriber Restriction

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 1. endocrine must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. has known perinatal insults, congenital or genetic defects or structural hypothalamic 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 0.4 mcg/L, or Macrilen peak less than 2.8 ng/ml AND BMI is less than or equal to 40 AND if a transitional adolescent must be off tx for at least one month before retesting. Cont tx - endocrine must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than 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.

Off Label Uses

Part B Prerequisite

Short bowel syndrome

No

Prerequisite Therapy Required

No

Drugs

HERNEXEOS

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

NON-SMALL CELL LUNG CANCER-all the following (A, B, C, and D): A) Unresectable or metastatic disease, AND B) Human epidermal growth factor receptor 2 (HER2) [ERBB2] activating mutation, AND C) Mutation was detected by an approved test, AND D) Received at least one prior systemic therapy. Note: Examples include checkpoint inhibitors such as Keytruda (pembrolizumab intravenous infusion), Libtayo (cemiplimab-rwlc intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), or Imjudo (tremelimumab-actl intravenous infusion) in combination with chemotherapy (e.g., carboplatin, cisplatin, pemetrexed, paclitaxel, albumin-bound paclitaxel, bevacizumab), chemotherapy alone (e.g., docetaxel, gemcitabine, etoposide, vinorelbine, other chemotherapy noted above).

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

HIGH RISK MEDICATIONS - ANTIPARKINSON AGENTS

Drugs

benztropine oral

Exclusion Criteria

Required Medical Information

Age Restriction

Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply

Prescriber Restriction

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.

Indications

All Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

high risk medications - benzodiazepines

Drugs

clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg, DIAZEPAM INTENSOL, diazepam oral solution 5 mg/5 ml (1 mg/ml), diazepam oral tablet, LORAZEPAM INTENSOL, lorazepam oral tablet 0.5 mg, 1 mg, 2 mg

Exclusion Criteria

Required Medical Information

Age Restriction

Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

Prescriber Restriction

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. Insomnia, may approve lorazepam if the patient has had a trial with two of the following: ramelteon, doxepin 3mg or 6 mg, eszopiclone, zolpidem, or zaleplon 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

Prerequisite Therapy Required

Yes

high risk medications - first generation antihistamines

Drugs

hydroxyzine hcl oral tablet, promethazine oral

Exclusion Criteria

Required Medical Information

Age Restriction

Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

Prescriber Restriction

Coverage Duration

Authorization will be for 3 months.

Other Criteria

For promethazine, for the treatment of emesis, approve if the patient has tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant). For hydroxyzine hydrochloride or hydroxyzine pamoate, 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. Require clinical justification.

Indications

All Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

HIGH RISK MEDICATIONS - PHENOBARBITAL

Drugs

phenobarbital

Exclusion Criteria

Coverage is not provided for use in sedation/insomnia.

Required Medical Information

Age Restriction

Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

Prescriber Restriction

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

HIGH RISK MEDICATIONS - SKELETAL MUSCLE RELAXANTS

Drugs

cyclobenzaprine oral tablet 10 mg, 5 mg

Exclusion Criteria

Required Medical Information

Age Restriction

Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

Prescriber Restriction

Coverage Duration

Authorization will be for 3 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. Require clinical justification.

Indications

All Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

IBRANCE

Exclusion Criteria**Required Medical Information****Age Restriction**

18 years and older

Prescriber Restriction**Coverage Duration**

1 year

Other Criteria

Breast cancer - approve recurrent or metastatic, hormone receptor positive (HR+) [i.e., estrogen receptor positive- (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and this medication will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant 2, pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonists, or has had surgical bilateral oophorectomy, or ovarian irradiation AND this medication will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) and meets (a or b): a) is receiving GnRH analog AND this medication will be used in combination with anastrozole, exemestane or letrozole or b) this medication will be used in combination with fulvestrant. Liposarcoma-approve if the patient has well-differentiated/dedifferentiated liposarcoma (WD-DDLS).

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses**Part B Prerequisite**

Liposarcoma

No

Prerequisite Therapy Required

No

IBTROZI

Drugs

IBTROZI

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

NON-SMALL CELL LUNG CANCER-locally advanced or metastatic disease and ROS1-positive non-small cell lung cancer as detected by an approved test.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

icatibant, SAJAZIR

Exclusion Criteria**Required Medical Information****Age Restriction****Prescriber Restriction**

Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.

Coverage Duration

Authorization will be for 1 year.

Other Criteria

Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant-the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment.

Indications

All FDA-approved Indications.

Off Label Uses**Part B Prerequisite**

No

Prerequisite Therapy Required

No

Drugs

ICLUSIG

Exclusion Criteria

Required Medical Information

Diagnosis, the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status

Age Restriction

All indications except ALL - 18 years and older

Prescriber Restriction

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 or Ayvakit (avapritinib tablets), AND Sunitinib or Sprycel (dasatinib tablets), AND Stivarga (regorafenib tablets), AND Qinlock (ripretinib tablets). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has ABL1 rearrangement or FGFR1 rearrangement.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia

No

Prerequisite Therapy Required

Yes

IDHIFA

Drugs

IDHIFA

Exclusion Criteria

Required Medical Information

IDH2-mutation status

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

Authorization will be for 1 year.

Other Criteria

AML - approve if the patient is IDH2-mutation status positive as detected by an approved test

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

IMATINIB

Drugs

imatinib oral tablet 100 mg, 400 mg, IMKELDI

Exclusion Criteria

Required Medical Information

Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.

Age Restriction

ASM, DFSP, HES, MDS/MPD/Myeloid/Lymphoid Neoplasms/Kaposi Sarcoma/Cutaneous Melanoma-18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

For ALL-approve for Ph-positive or ABL-class translocation ALL. CML-approve for Ph-positive or BCR::ABL1-mutation positive CML. Kaposi's Sarcoma-approve if the patient has tried at least one regimen AND has relapsed or refractory disease. Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT)-patient has tried Turalio or 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-PDGFR or PDGFRB rearrangement. Approve Imkeldi if the patient has had a trial of imatinib tablets (brand or generic) dispersed in a glass of water or apple juice (per product labeling).

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

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.

No

Prerequisite Therapy Required

Yes

Drugs

IMBRUVICA ORAL CAPSULE 140 MG, 70 MG, IMBRUVICA ORAL SUSPENSION, IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

GVHD-1 year and older, other-18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

CLL- Approve. GVHD-Approve if the patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], imatinib, low-dose methotrexate, sirolimus, mycophenolate mofetil, Jakafi [ruxolitinib tablets]). B-cell lymphoma-approve if the patient has tried at least one systemic regimen (e.g., cisplatin, cytarabine, rituximab, oxaliplatin, gemcitabine, ifosfamide, carboplatin, etoposide, or rituximab). Central nervous system Lymphoma (primary)- approve if the patient is not a candidate for or is intolerant to high-dose methotrexate OR has tried at least one therapy (e.g., methotrexate, rituximab, vincristine, procarbazine, cytarabine, thiotepa, carmustine, intrathecal methotrexate, cytarabine, or rituximab). Hairy Cell Leukemia - approve if the patient has tried at least two systemic regimens (cladribine, Nipent [pentostatin injection], rituximab, or Pegasys [peginterferon alfa-2a subcutaneous injection]).

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma

No

Prerequisite Therapy Required

Yes

IMPAVIDO

Drugs

IMPAVIDO

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with an infectious diseases specialist

Coverage Duration

1 month

Other Criteria

Ameba related infections: approve if the patient is being treated for an infection due to one of the following: Acanthameoba, Balamuthia mandrillaris, or Naegleria fowleri. Note: Examples of ameba related infections are Acanthamoeba keratitis, granulomatous amebic encephalitis (GAE), and primary amebic meningoencephalitis (PAM).

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Ameba related infections

No

Prerequisite Therapy Required

No

INBRIJA

Drugs

INBRIJA INHALATION CAPSULE, W/INHALATION DEVICE

Exclusion Criteria

Asthma, COPD, other chronic underlying lung disease

Required Medical Information

Diagnosis, medications that will be used in combination

Age Restriction

Prescriber Restriction

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

Yes

INJECTABLE TESTOSTERONE PRODUCTS

Drugs

testosterone cypionate intramuscular oil 100 mg/ml, 200 mg/ml, testosterone enanthate

Exclusion Criteria

Required Medical Information

Diagnosis, lab results

Age Restriction

Delayed puberty or induction of puberty in males-14 years and older, 12 years and older (testosterone cypionate)

Prescriber Restriction

Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.

Coverage Duration

Delayed puberty or induction of puberty in males-6 months, all others-12 months

Other Criteria

Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. Delayed puberty or induction of puberty in males - Approve testosterone enanthate or testosterone cypionate. Breast cancer in females-approve testosterone enanthate. Male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Female is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression. Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-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

Part B Prerequisite

Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).

No

Prerequisite Therapy Required

No

Drugs

INLURIYO

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction**Coverage Duration**

1 year

Other Criteria

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

Indications

All FDA-approved Indications.

Off Label Uses**Part B Prerequisite**

No

Prerequisite Therapy Required

No

Drugs

INLYTA ORAL TABLET 1 MG, 5 MG

Exclusion Criteria

Required Medical Information

Age Restriction

18 years and older

Prescriber Restriction

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

Part B Prerequisite

Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma, Soft tissue sarcoma, thymic carcinoma

No

Prerequisite Therapy Required

No

Drugs
INQOVI

Exclusion Criteria

Required Medical Information
Diagnosis

Age Restriction
18 years and older

Prescriber Restriction

Coverage Duration
1 year

Other Criteria

Indications
All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite
Myelodysplastic Syndrome With Myeloproliferative Neoplasm Overlap Syndrome
No

Prerequisite Therapy Required
No

INREBIC

Drugs

INREBIC

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

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. 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

Part B Prerequisite

Myeloid/Lymphoid Neoplasms with Eosinophilia, accelerated or blast phase myeloproliferative neoplasm
No

Prerequisite Therapy Required

No

Drugs

ITOVEBI ORAL TABLET 3 MG, 9 MG

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction**Coverage Duration**

1 year

Other Criteria

BREAST CANCER (all of A, B, C, D, E and F): A. Patient meets ONE of the following (i or ii): i. Patient is a postmenopausal female, OR ii. Patient meets BOTH of the following (a and b): a. Patient is a pre/perimenopausal female or a male, AND b. Patient is receiving a gonadotropin-releasing hormone (GnRH) agonist OR had surgical bilateral oophorectomy or ovarian irradiation (female) or orchiectomy (male), Note: Examples of a GnRH agonist include leuprolide acetate, leuprolide acetate intramuscular injection, triptorelin pamoate intramuscular injection, goserelin acetate subcutaneous injection. AND B. Patient has locally advanced or metastatic hormone receptor (HR)-positive disease, AND C. Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D. Patient has PIK3CA-mutated breast cancer as detected by an approved test, AND E. Patient meets (i or ii): i) has disease progression while on adjuvant endocrine therapy or ii) had disease recurrence within 12 months after completing adjuvant endocrine therapy, Note: Examples of endocrine therapy include tamoxifen, anastrozole, letrozole, exemestane, toremifene. AND F. The medication will be used in combination with palbociclib capsules/tablets and fulvestrant injection.

Indications

All FDA-approved Indications.

Off Label Uses**Part B Prerequisite**

No

Prerequisite Therapy Required

Yes

IVERMECTIN (ORAL)

Drugs

ivermectin oral tablet 3 mg, 6 mg

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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

Part B Prerequisite

Ascariasis, Enterobiasis (pinworm infection), Hookworm-related cutaneous larva migrans, *Mansonella ozzardi* infection, *Mansonella streptocerca* infection, Pediculosis, Scabies. Trichuriasis, *Wucheria bancrofti* infection
No

Prerequisite Therapy Required

Yes

Drugs

GAMUNEX-C INJECTION SOLUTION 1 GRAM/10 ML (10 %)

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

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

IWILFIN

Drugs

IWILFIN

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Neuroblastoma-Approve if the patient meets the following (A, B and C): A) Patient has high-risk disease, AND B) The medication is being used to reduce the risk of relapse, AND C) Patient has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy. Note: Examples of anti-GD2 immunotherapy includes Unituxin (dinutuximab intravenous infusion).

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

JAKAFI

Exclusion Criteria**Required Medical Information****Age Restriction**

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 Restriction**Coverage Duration**

1 year

Other Criteria

For polycythemia vera patients must have tried hydroxyurea or peginterferon alfa-2a or Besremi (ropeginterferon alfa-2b-njft subcutaneous injection). ALL-approve if the mutation/pathway is Janus associated kinase (JAK)-related. GVHD, chronic-approve if the patient has tried one conventional systemic treatment for graft versus host disease (for example: prednisone, ibrutinib capsules/tablets). GVHD, acute-approve if the patient has tried one systemic corticosteroid. Atypical chronic myeloid leukemia-approve if the patient has a CSF3R mutation or a janus associated kinase 2 (JAK2) mutation. Chronic monomyelocytic leukemia-2 (CMML-2)-approve if the patient is also receiving a hypomethylating agent. Essential thrombocythemia-approve if the patient has tried hydroxyurea, peginterferon alfa-2a or anagrelide. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the tumor has a janus associated kinase 2 (JAK2) rearrangement. T-Cell Lymphoma - approve if pt has (A or B): A) peripheral T-cell lymphoma or B) meets (i and ii): i) pt has T-cell prolymphocytic leukemia, T-cell large granular lymphocytic leukemia, hepatosplenic T-cell lymphoma, or breast implant-associated anaplastic large cell lymphoma and ii) pt has tried at least one systemic regimen. Accelerated or blast phase myeloproliferative neoplasm-approve if pt has at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses**Part B Prerequisite**

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

No

Prerequisite Therapy Required

Yes

Drugs

JAYPIRCA ORAL TABLET 100 MG, 50 MG

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction**Coverage Duration**

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 systemic 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, cisplatin, 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 to DLBCL- pt has tried at least one chemotherapy regimen or is not a candidate for a chemotherapy regimen. Marginal Zone Lymphoma - approve if pt has tried at least one Bruton tyrosine kinase inhibitor. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma - approve if pt has tried at least one systemic regimen. Note: Examples of a systemic regimen contain one or more of the following products: Brukinsa (zanubrutinib capsules), Imbruvica (ibrutinib tablets, capsules, and oral solution), rituximab, bendamustine, cyclophosphamide, dexamethasone, bortezomib, Kyprolis (carfilzomib intravenous infusion), or Ninlaro (ixazomib capsule).

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses**Part B Prerequisite**

Richter's Transformation to Diffuse Large B-Cell Lymphoma, Marginal Zone Lymphoma, Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma

No

Prerequisite Therapy Required

Yes

Drugs

tolvaptan (polycystic kidney dis)

Exclusion Criteria

Patient is currently receiving another tolvaptan product

Required Medical Information

Diagnosis, renal function

Age Restriction

18 years and older

Prescriber Restriction

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.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

KALYDECO

Exclusion Criteria

Combination use with other CF Transmembrane Regulator Modulators

Required Medical Information

Age Restriction

1 month of age and older

Prescriber Restriction

prescribed by or in consultation with a pulmonologist or a physician who specializes in CF

Coverage Duration

1 year

Other Criteria

CF - must meet A, B, and C: A) pt must have one mutation in the cystic fibrosis transmembrane conductance regulator gene that is considered to be pathogenic or likely pathogenic B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal 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

KERENDIA

Drugs

KERENDIA

Exclusion Criteria

Concomitant use with spironolactone or eplerenone

Required Medical Information

Diagnosis

Age Restriction

18 years and older (initial and continuation therapy)

Prescriber Restriction

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 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 to ACE inhibitor and ARB therapy.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

KESIMPTA PEN

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 Restriction

18 years and older

Prescriber Restriction

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

Drugs

KINERET

Exclusion Criteria

Concurrent use with another biologic DMARD or targeted synthetic DMARD

Required Medical Information

Diagnosis

Age Restriction

RA/AOSD/Pericarditis-18 years and older, SJIA-2 years and older

Prescriber Restriction

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, Xeljanz/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, C and D): A) recurrent pericarditis, B) hx of at least 3 episodes of pericarditis prior to starting Kineret, C) C-reactive protein level greater than 1 mg/dL, and D) 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 products include Actemra, Tyenne.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Adult onset Still's disease (SD). Systemic Juvenile Idiopathic Arthritis (SJIA). Immunotherapy-related toxicities associated with Chimeric Antigen Receptor (CAR) T-cell therapy. Pericarditis

No

Prerequisite Therapy Required

Yes

Drugs

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

Exclusion Criteria

Required Medical Information

Age Restriction

18 years and older

Prescriber Restriction

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 will 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 all of (A, B and C): A) pt has recurrent or metastatic disease, and B) has estrogen receptor (ER)-positive tumors, and C) if request is for Kisqali, Kisqali will be used in combination with letrozole.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Endometrial cancer

No

Prerequisite Therapy Required

No

Drugs

mifepristone oral tablet 300 mg

Exclusion Criteria

Required Medical Information

Diagnosis, prior surgeries

Age Restriction

18 years and older

Prescriber Restriction

Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome.

Coverage Duration

1 year

Other Criteria

Endogenous Cushing's Syndrome-Approve if mifepristone is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance AND pt meets (i, ii or iii):
i) patient is not a candidate for surgery or surgery has not been curative, or (ii) patient is awaiting surgery for endogenous Cushing's Syndrome or (iii) patient is awaiting therapeutic response after radiotherapy for endogenous Cushing's Syndrome.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

KOSELUGO

Drugs

KOSELUGO ORAL CAPSULE

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Neurofibromatosis Type 1-approve if prior to starting Koselugo, the patient has symptomatic, inoperable plexiform neurofibromas. Circumscribed Glioma-approve if (A and B): A) the patient has recurrent, refractory 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

Part B Prerequisite

Circumscribed Glioma, Langerhans Cell Histiocytosis

No

Prerequisite Therapy Required

Yes

Drugs

KRAZATI

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction**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, as determined by an approved test 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 or Rectal Cancer- approve if pt has unresectable, advanced, or metastatic disease AND pt has KRAS G12C mutation-positive disease AND medication is prescribed as part of a combination regimen or the patient is unable to tolerate combination therapy AND pt has previously received a chemotherapy regimen for colon or rectal cancer. Ampullary adenocarcinoma-approve if (A, B and C): A) metastatic disease, B) KRAS G12C mutation-positive disease, and C) will be used as subsequent therapy. Biliary tract cancer- approve if (A, B and C): A) unresectable or metastatic disease, B) KRAS G12C mutation-positive disease, and C) previously treated with at least one systemic regimen. Pancreatic adenocarcinoma- approve if (A and B): A) KRAS G12C mutation-positive disease, and B) either (i or ii): (i) locally advanced or metastatic disease and previously treated with at least one 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**Part B Prerequisite**Ampullary adenocarcinoma, biliary tract cancer, pancreatic adenocarcinoma, small bowel adenocarcinoma
No**Prerequisite Therapy Required**

Yes

Drugs

lapatinib

Exclusion Criteria

Required Medical Information

Diagnosis for which lapatinib is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status.

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

HER2-positive recurrent or metastatic breast cancer, approve if lapatinib will be used in combination with capecitabine OR trastuzumab and the patient has tried at least two prior anti-HER2 based regimens OR the medication will be used in combination with an aromatase inhibitor and the patient has HR+ disease and the patient is a postmenopausal woman or the patient is premenopausal or perimenopausal woman and is receiving ovarian suppression/ablation with a GnRH agonist, surgical bilateral oophorectomy or ovarian irradiation OR the patient is a man and is receiving a GnRH analog. Colon or rectal cancer-approve if the patient has unresectable advanced or metastatic disease that is human epidermal receptor 2 (HER2) amplified and with wild-type RAS and BRAF disease and the patient has tried at least one chemotherapy regimen or is not a candidate for intensive therapy and the medication is used in combination with trastuzumab (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan) and the patient has not been previously treated with a HER2-inhibitor. Bone Cancer-approve if the patient has recurrent chordoma and if the patient has epidermal growth-factor receptor (EGFR)-positive disease.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Bone cancer-chordoma, colon or rectal cancer, breast cancer in pre/peri-menopausal women and men
Yes

Prerequisite Therapy Required

Yes

Drugs

LAZCLUZE ORAL TABLET 240 MG, 80 MG

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

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

Drugs

lenalidomide

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older (except Kaposi Sarcoma, Castleman Disease, Primary CNS Lymphoma)

Prescriber Restriction

Coverage Duration

Authorization will be for 1 year.

Other Criteria

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. MCL-approve -if the patient is using lenalidomide in combination with rituximab or has tried at least one other regimen. MZL-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one other regimen. Multiple myeloma-approve. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]), OR 4) meets (i, ii and iii): i) pt has myelodysplastic syndrome/myeloproliferative neoplasm overlap neoplasm, and ii) has SF3B1 mutation, and iii) pt has thrombocytosis. B-cell-lymphoma (other) [examples: diffuse large B-cell lymphoma, high grade B-cell lymphoma, post-transplant lymphoproliferative disorders, HIV-related B-cell lymphoma]-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia with presence of del(5q) and will use this in combination with prednisone. Primary CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease, or is not a candidate for high-dose MTX, or had intolerance to high-dose MTX. Hodgkin lymphoma, classic-approve if (A and B): A) pt has relapsed or refractory disease, and B) pt is not a candidate for high-dose therapy and autologous stem cell rescue. Castleman disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease. Systemic light chain amyloidosis-approve if lenalidomide is used in combination with dexamethasone. Histiocytic 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.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

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.

No H5826_RX344_Clinical_Criteria_Prior_Auth_Feb_2026_C

Prerequisite Therapy Required

Yes

Drugs

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

Exclusion Criteria

Required Medical Information

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

DTC - Approve if pt meets (i OR ii): i) pt meets (a AND b): a) pt has papillary or follicular thyroid carcinoma and b) the disease is refractory to radioactive iodine therapy OR ii) pt has oncocytic 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 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 (A AND B): A) Pt meets (i OR ii): i) Pt meets (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 (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. 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

Part B Prerequisite

Patients with Medullary Thyroid Carcinoma (MTC), thymic carcinoma, Melanoma, Anaplastic thyroid carcinoma

No

Prerequisite Therapy Required

Yes

LIDOCAINE PATCH

Drugs

lidocaine topical adhesive patch,medicated 5 %, LIDOCAN III, TRIDACAINE II

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration

Authorization will be for 12 months

Other Criteria

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Diabetic neuropathic pain, chronic back pain

No

Prerequisite Therapy Required

No

Drugs

LIVDELZI

Exclusion Criteria

Concomitant use with Iqirvo

Required Medical Information

Diagnosis

Age Restriction

18 years and older (initial)

Prescriber Restriction

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 for greater than or equal to 1 year 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

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

LIVTENCITY

Exclusion Criteria

Concomitant use with ganciclovir or valganciclovir

Required Medical Information

Diagnosis

Age Restriction

12 years and older (initial therapy)

Prescriber Restriction

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

Prerequisite Therapy Required

Yes

LONG ACTING OPIOIDS

Drugs

hydromorphone oral tablet extended release 24 hr, methadone oral solution 10 mg/5 ml, 5 mg/5 ml, methadone oral tablet 10 mg, 5 mg, morphine oral tablet extended release

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 Restriction

Prescriber Restriction

Coverage Duration

Authorization will be for 12 months.

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) 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. Patients with cancer, in hospice, sickle cell disease 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 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

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

LONSURF

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction**Coverage Duration**

Authorization will be for 1 year.

Other Criteria

Colon, rectal or appendiceal cancer- approve if patients meets (A, B, and C): A) advanced or metastatic disease, B) meets (i or ii): i) has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease or ii) is ineligible for or progressed on checkpoint inhibitor therapy and meets ONE of the following (a or b): a) has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease, or b) is polymerase epsilon/delta (POLE/POLD1) mutation positive, and C) has previously been treated with ALL of the following per labeling (i, ii and iii): i) fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, ii) an anti-vascular endothelial growth factor (VEGF) agent (ex: bevacizumab), and iii) if the tumor is wild-type RAS (KRAS wild-type and NRAS wild-type), patient has received anti-EGFR therapy (ex: Erbitux or Vectibix) or EGFR therapy is not medically appropriate. 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**Part B Prerequisite**

Appendiceal cancer

No

Prerequisite Therapy Required

Yes

Drugs

LORBRENA ORAL TABLET 100 MG, 25 MG

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Pediatric Diffuse High-Grade Glioma- less than 18 years old, All others- 18 years and older

Prescriber Restriction

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, as detected by an approved test. NSCLC-ROS1 Rearrangement-Positive, advanced or metastatic NSCLC-approve if the patient has tried at least one of crizotinib, entrectinib or ceritinib. Large B-Cell Lymphoma- approve if ALK-positive disease and disease is relapsed or refractory. Pediatric Diffuse High-Grade Glioma- approve if ALK-positive disease and (i or ii): i) used as adjuvant therapy, or ii) used for recurrent or progressive disease.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Non-small cell lung cancer (NSCLC)-ROS1 Rearrangement-Positive, Erdheim Chester Disease, Inflammatory Myofibroblastic Tumor (IMT), Large B-Cell Lymphoma, Pediatric Diffuse High-Grade Glioma
No

Prerequisite Therapy Required

Yes

Drugs

LUMAKRAS ORAL TABLET 120 MG, 240 MG, 320 MG

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction**Coverage Duration**

Authorization will be for 1 year.

Other Criteria

Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test AND has been previously treated with at least one systemic regimen. Ampullary adenocarcinoma - approve if pt has KRAS G12C-mutated disease as determined by an approved test AND this is used as subsequent therapy. Colon or rectal cancer - approve if pt meets all (A, B, C and D): A) 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 for colon or rectal cancer. Pancreatic Adenocarcinoma- approve if patient has KRAS G12C-mutated disease, as determined by an approved test AND either (i or ii): (i) patient has locally advanced or metastatic disease and has been previously treated with at least one systemic regimen OR (ii) patient has recurrent disease after resection. Small bowel adenocarcinoma- approve if pt meets all of (A, B and C): A) has advanced or metastatic disease, and B) has KRAS G12C mutation-positive disease, and C) medication will be used as subsequent therapy.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses**Part B Prerequisite**

Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma, Small Bowel Adenocarcinoma

No

Prerequisite Therapy Required

Yes

LUPRON DEPOT

Drugs

LUPRON DEPOT

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Premenstrual disorders - 18 years and older

Prescriber Restriction

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

Part B Prerequisite

abnormal uterine bleeding, breast cancer, gender dysphoria/gender reassignment, head and neck cancer-salivary gland tumors, ovarian cancer including fallopian tube and primary peritoneal cancers, premenstrual disorders including premenstrual syndrome and premenstrual dysphoric disorder, prophylaxis or treatment of uterine bleeding or menstrual suppression in pts with hematologic malignancy or undergoing cancer treatment or prior to bone marrow or stem cell transplant, uterine cancer

No

Prerequisite Therapy Required

Yes

Drugs

LYNPARZA

Exclusion Criteria

Required Medical Information

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if the patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND The patient is in complete or partial response to at least one platinum-based chemotherapy regimen (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Ovarian, fallopian tube, or primary peritoneal cancer-maintenance, combination therapy-approve if the medication is used in combination with bevacizumab, the patient has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and the patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast cancer, adjuvant-approve if the patient has germline BRCA mutation-positive, HER2-negative breast cancer and the patient has tried neoadjuvant or adjuvant therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has recurrent or metastatic disease and has (i or ii): i) germline BRCA mutation-positive breast cancer or ii) germline PALB2 mutation-positive breast cancer. Pancreatic Cancer-maintenance therapy-approve if the patient has a germline BRCA mutation-positive metastatic disease and the disease has not progressed on at least 16 weeks of treatment with a first-line platinum-based chemotherapy regimen. Prostate cancer-castration resistant-approve if the patient has metastatic disease, the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or the patient has had a bilateral orchiectomy, and the patient meets either (i or ii): i) the patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test and the patient has been previously treated with at least one androgen receptor directed therapy or ii) the patient has a BRCA mutation and the medication is used in combination with abiraterone plus one of prednisone or prednisolone. Uterine Leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried at least one systemic regimen.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Uterine Leiomyosarcoma

No

Prerequisite Therapy Required

Yes

LYTGOBI

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease, tumor has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements as detected by an approved test and if the patient has been previously treated with at least one systemic regimen. Note: Examples of systemic regimens include gemcitabine + cisplatin, 5-fluorouracil + oxaliplatin or cisplatin, capecitabine + cisplatin or oxaliplatin, gemcitabine + Abraxane (albumin-bound paclitaxel) or capecitabine or oxaliplatin, and gemcitabine + cisplatin + Abraxane.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

MAVYRET ORAL PELLETS IN PACKET, MAVYRET ORAL TABLET

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

3 years or older

Prescriber Restriction

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

Part B Prerequisite

Indications consistent with current AASLD/IDSA guidance

No

Prerequisite Therapy Required

No

MEGESTROL

Drugs

megestrol oral suspension 400 mg/10 ml (40 mg/ml), 625 mg/5 ml (125 mg/ml), megestrol oral tablet

Exclusion Criteria

Coverage is not provided for weight gain for cosmetic reasons.

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration

12 months

Other Criteria

Indications

All Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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 Tafenlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafenlar 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 Tafenlar. Glioma-patient meets (A or 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 Tafenlar or ii) pt has circumscribed glioma. Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis or Erdheim Chester disease or Rosai-Dorfman disease. Solid Tumors [Note: Examples of solid tumors are: biliary tract cancer, brain metastases due to melanoma, differentiated thyroid carcinoma, gastrointestinal stromal tumors, gastric cancer, esophageal and esophagogastric junction cancers, salivary gland tumors, pancreatic adenocarcinoma, neuroendocrine tumors, occult primary, ampullary adenocarcinoma, small bowel adenocarcinoma]-Approve if the patient meets the following (A and B): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafenlar (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 Tafenlar.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Histiocytic Neoplasm, Hairy Cell Leukemia, Epithelioid Hemangioendothelioma
No

Prerequisite Therapy Required

Yes

MEKTOVI

Drugs

MEKTOVI

Exclusion Criteria

Required Medical Information

Diagnosis, BRAF V600 status, concomitant medications

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

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

Part B Prerequisite

Histiocytic Neoplasms

No

Prerequisite Therapy Required

No

memantine

Drugs

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

Exclusion Criteria

Required Medical Information

Indication for which memantine is being prescribed.

Age Restriction

Prescriber Restriction

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Patients with mild to moderate vascular dementia.

No

Prerequisite Therapy Required

No

Drugs

armodafinil, modafinil oral tablet 100 mg, 200 mg

Exclusion Criteria

Required Medical Information

Age Restriction

18 years and older

Prescriber Restriction

Excessive daytime sleepiness associated with narcolepsy-prescribed by or in consultation with a sleep specialist physician or neurologist

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD)-approve if the patient is working at least 5 overnight shifts per month. Adjunctive/augmentation treatment for depression in adults-if the patient is concurrently receiving other medication therapy for depression. Excessive daytime sleepiness associated with obstructive sleep apnea/hypoapnea syndrome-approve. Excessive daytime sleepiness associated with Narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Idiopathic hypersomnia - approve if diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i.e., sleep center).

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Excessive daytime sleepiness (EDS) associated with myotonic dystrophy - modafinil only.

Adjunctive/augmentation for treatment of depression in adults - modafinil only. Idiopathic hypersomnia - modafinil only.

No

Prerequisite Therapy Required

Yes

Drugs

MODEYSO

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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

MYFEMBREE

Drugs

MYFEMBREE

Exclusion Criteria

Required Medical Information

Diagnosis, test results

Age Restriction

18 years and older

Prescriber Restriction

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, levonorgestrel-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 suspension]) or Orilissa (elagolix tablets).

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

NAYZILAM

Drugs

NAYZILAM

Exclusion Criteria

Required Medical Information

Diagnosis, other medications used at the same time

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with a neurologist

Coverage Duration

1 year

Other Criteria

Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiepileptic medication(s).

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

NEMLUVIO

Exclusion Criteria

Concurrent use with another monoclonal antibody therapy

Required Medical Information

Diagnosis

Age Restriction

AD: 12 years and older (initial therapy), PN: 18 years and older (initial therapy)

Prescriber Restriction

Prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)

Coverage Duration

Initial-4 months, Continuation-1 year

Other Criteria

INITIAL CRITERIA: ATOPIC DERMATITIS-All of (A, B and C): A) AD involvement estimated greater than or equal to 10 percent BSA, B) tried at least one medium to super-high potency topical corticosteroid (CS), unless topical CS therapy is not advisable, and C) will be used with a topical CS and/or topical calcineurin inhibitor or AD has improved sufficiently with Nemluvio and topical therapy has been discontinued.

PRURIGO NODULARIS-All of (A, B and C): 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 AND C) Tried at least one high- or super-high potency prescription topical corticosteroid and experienced inadequate efficacy. 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.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

NERLYNX

Exclusion Criteria**Required Medical Information**

Stage of cancer, HER2 status, previous or current medications tried

Age Restriction

18 years and older

Prescriber Restriction**Coverage Duration**

Adjuvant tx breast cancer-Approve for 1 year (total), all others-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-trastuzumab emtansine intravenous infusion) and the patient has brain metastases. Breast Cancer, Recurrent or Metastatic HER2 Negative Disease: Approve if pt meets (A, B, C and D): A) has HER2-negative breast cancer AND B) cancer has a HER2-activating mutation AND C) meets (i or ii): i) Pt is a postmenopausal female or a male OR ii) pre/perimenopausal female and meets (a or b): a) receiving ovarian suppression/ovarian ablation with a gonadotropin-releasing hormone (GnRH) agonist OR b) has had surgical bilateral oophorectomy or ovarian irradiation AND D) meets (i or ii): i) meets (a and b): a) has hormone receptor (HR)-positive disease AND b) has tried at least one CDK4/6 inhibitor therapy OR ii) has (HR)-negative disease. Cervical Cancer: Approve if patient meets (A, B and C): A) HER2-mutant disease AND B) recurrent or metastatic disease AND C) tried at least one systemic regimen.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses**Part B Prerequisite**

Breast Cancer - Recurrent or Metastatic HER2 Negative Disease, Cervical Cancer

No

Prerequisite Therapy Required

Yes

Drugs

NEXLETOL

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 Restriction

18 years and older

Prescriber Restriction**Coverage Duration**

Authorization will be for 1 year

Other Criteria

HYPERLIPIDEMIA WITH 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) phenotypic confirmation (Note 1) of 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). **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. **PRIMARY HYPERLIPIDEMIA (not associated with established CVD or HeFH) [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 (apo B), 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

Yes

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older, ALL - 15 years and older

Prescriber Restriction

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 chronic myeloid leukemia- approve. For GIST, approve if the patient has tried two of the following: imatinib, avapritinib, sunitinib, dasatinib, regorafenib or ripretinib.

Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement. Pigmented villonodular synovitis/tenosynovial giant cell tumor-approve if the patient has tried Turalio or 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

Part B Prerequisite

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.

No

Prerequisite Therapy Required

Yes

NILUTAMIDE

Drugs

nilutamide

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Prostate cancer-approve if nilutamide is used concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

NINLARO

Exclusion Criteria

Required Medical Information

Age Restriction

18 years and older

Prescriber Restriction

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

Part B Prerequisite

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

Yes

Prerequisite Therapy Required

Yes

NITISINONE

Drugs

nitisinone

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 Restriction

Prescriber Restriction

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

Hereditary Tyrosinemia, 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

Drugs

NIVESTYM

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction**Prescriber Restriction**

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 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**Part B Prerequisite**

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)
No

Prerequisite Therapy Required

No

NON-INJECTABLE TESTOSTERONE PRODUCTS

Drugs

testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1 %), 20.25 mg/1.25 gram (1.62 %), testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram), 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram), testosterone transdermal solution in metered pump w/app

Exclusion Criteria

Required Medical Information

Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]

Age Restriction

Prescriber Restriction

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

Authorization will be for 12 months.

Other Criteria

Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] 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

Part B Prerequisite

Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).

No

Prerequisite Therapy Required

No

Drugs

NUBEQA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (See Note 1) or if the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration sensitive-approve if the medication will be used in combination with a GnRH analog (See Note 1) or if the patient had a bilateral orchiectomy. Note 1: examples of GnRH analogs are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

NUEDEXTA

Drugs

NUEDEXTA

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with a neurologist

Coverage Duration

1 year

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

NUPLAZID

Drugs

NUPLAZID

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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

Drugs

NURTEC ODT

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 Restriction

18 years and older

Prescriber Restriction

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

Prerequisite Therapy Required

Yes

Drugs

NYVEPRIA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Patients undergoing PBPC collection and therapy

No

Prerequisite Therapy Required

No

OCTREOTIDE INJECTABLE

Drugs

octreotide acetate injection solution

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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-prescr/consult with oncologist. Diarrhea assoc w chemo-prescr/consult with oncologist/gastro. Small bowel bleed/angiodyspasia-prescr/consult gastroenterologist.

Coverage Duration

Enterocutaneous fistula/diarrhea w/chemo-3 mos, small bowel bleed/angiodyspasia-6 mos, others-1 yr

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 megacolon), or other colitis-related life-threatening conditions] and B) patient has tried at least one antimotility medication. SMALL BOWEL BLEEDS/ANGIODYSPASIA RELATED BLEEDING: pt has chronic, recurrent gastrointestinal bleeds lasting greater than or equal to 3 months.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Meningioma, thymoma and thymic carcinoma, pheochromocytoma and paraganglioma, enterocutaneous fistulas, diarrhea associated with chemotherapy, small bowel bleeds/angiodyspasia related bleeding

No

Prerequisite Therapy Required

No

Drugs

ODOMZO

Exclusion Criteria

Required Medical Information

BCC - Must not have had disease progression while on Erivedge (vismodegib).

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Locally advanced BCC approve if the BCC has recurred following surgery/radiation therapy or if the patient is not a candidate for surgery AND the patient is not a candidate for radiation therapy, according to the prescribing physician. Metastatic BCC - approve, if the disease is limited to nodal metastases. (Note-This includes primary or recurrent nodal metastases. A patient with distant metastasis does not meet this requirement.) 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

Part B Prerequisite

Metastatic BCC, diffuse basal cell carcinoma formation

No

Prerequisite Therapy Required

No

Drugs

OFEV

Exclusion Criteria

Required Medical Information

Age Restriction

18 years of age and older

Prescriber Restriction

IPF-Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis-prescribed by or in consultation with a pulmonologist or rheumatologist.

Coverage Duration

1 year

Other Criteria

IDIOPATHIC PULMONARY FIBROSIS (IPF), 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.

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, INITIAL (all of A, B and C): A) FVC greater than or equal to 45 percent of the predicted value, B) fibrosing lung disease impacting more than 10 percent of lung volume on HRCT, and C) clinical signs of progression. ALL INDICATIONS, CONTINUATION: approve.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

OGSIVEO ORAL TABLET 100 MG, 150 MG, 50 MG

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Desmoid tumors (aggressive fibromatosis)-approve if the patient has progressing desmoid tumors, the desmoid tumors are not amenable to surgery or radiotherapy and if the patient requires systemic treatment. Note: Progressing desmoid tumors are defined as greater than or equal to 20 percent progression within 12 months

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

6 months of age and older

Prescriber Restriction

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

Drugs

OJJAARA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years of age and older

Prescriber Restriction

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).

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Accelerated or blast phase myeloproliferative neoplasm

No

Prerequisite Therapy Required

No

Drugs

ONUREG

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

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

Part B Prerequisite

Peripheral T-cell lymphoma

No

Prerequisite Therapy Required

No

Drugs

OPSUMIT

Exclusion Criteria

Required Medical Information

PAH WHO group, right heart catheterization results

Age Restriction

Prescriber Restriction

PAH - must be prescribed by or in consultation with a cardiologist or a pulmonologist.

Coverage Duration

Authorization will be for 1 year.

Other Criteria

Pulmonary arterial hypertension (PAH) WHO Group 1 patients are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

OPSYNVI

Exclusion Criteria

Concurrent use with guanylate cyclase stimulators

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation)

Coverage Duration

1 year

Other Criteria

Pulmonary arterial hypertension (PAH) WHO Group 1-approve if patient has had a right-heart catheterization to confirm the diagnosis.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

ORGOVYX

Drugs

ORGOVYX

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

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

Drugs

ORKAMBI ORAL GRANULES IN PACKET, ORKAMBI ORAL TABLET

Exclusion Criteria

Combination use with other CF Transmembrane Conductance Regulator Modulators

Required Medical Information

Age Restriction

1 year of age and older

Prescriber Restriction

prescribed by or in consultation with a pulmonologist or a physician who specializes in CF

Coverage Duration

1 year

Other Criteria

CF - Approve if the pt meets A, B and C: A) pt has 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

Drugs

ORSERDU ORAL TABLET 345 MG, 86 MG

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction**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**Part B Prerequisite**

No

Prerequisite Therapy Required

Yes

Drugs

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

Exclusion Criteria

Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARD).

Required Medical Information

Diagnosis, previous drugs tried

Age Restriction

PP- 6 years and older (initial), All other dx - 18 years and older (initial)

Prescriber Restriction

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) [A, B or C]: 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 with a biologic also counts) or B) contraindication to MTX or C) patient has mild to moderate disease and the patient requires systemic therapy. 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

Yes

OXERVATE

Drugs

OXERVATE

Exclusion Criteria

Treatment duration greater than 16 weeks per affected eye(s)

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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

PANRETIN

Drugs

PANRETIN

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with a dermatologist, oncologist, or infectious disease specialist

Coverage Duration

1 year

Other Criteria

Kaposi Sarcoma-approve if the patient is not receiving systemic therapy for Kaposi Sarcoma.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

PEMAZYRE

Drugs

PEMAZYRE

Exclusion Criteria

Required Medical Information

Diagnosis, prior therapies

Age Restriction

18 years and older

Prescriber Restriction

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, as detected by an approved test AND the patient has been previously treated with at least one systemic therapy regimen. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the cancer has fibroblast growth factor receptor 1 (FGFR1) rearrangement, as detected by an approved test.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

PENICILLAMINE

Drugs

penicillamine oral tablet

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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

PHENYL BUTYRATE

Drugs

sodium phenylbutyrate

Exclusion Criteria

Concomitant therapy with more than one phenylbutyrate product

Required Medical Information

Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)

Coverage Duration

Pt meets criteria with no genetic test - 3 mo approval. Pt had genetic test - 12 mo approval

Other Criteria

Urea cycle disorders-approve if genetic or enzymatic testing confirmed a urea cycle disorder or if the patient has hyperammonemia diagnosed with an ammonia level above the upper limit of the normal reference range for the reporting laboratory.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

PHEOCHROMOCYTOMA

Drugs

metyrosine

Exclusion Criteria

Required Medical Information

Diagnosis, prior medication trials

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial and continuation therapy for metyrosine)

Coverage Duration

Authorization will be for 1 year

Other Criteria

If the requested drug is metyrosine for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin). If the requested drug is metyrosine for continuation therapy, approve if the patient is currently receiving metyrosine or has received metyrosine in the past.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

PHOSPHODIESTERASE-5 INHIBITORS

Drugs

ALYQ, *sildenafil (pulm.hypertension) oral tablet*, *tadalafil (pulm. hypertension)*

Exclusion Criteria

Concurrent Use With Guanylate Cyclase Stimulators.

Required Medical Information

Diagnosis, right heart cath results

Age Restriction

Prescriber Restriction

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 for sildenafil 20 mg tablets require 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

Part B Prerequisite

Raynaud's Phenomenon

No

Prerequisite Therapy Required

Yes

Drugs

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

Exclusion Criteria**Required Medical Information**

Diagnosis, prior therapies

Age Restriction**Prescriber Restriction****Coverage Duration**

1 year

Other Criteria

Breast Cancer. Approve if the patient meets the following criteria (A, B, C, D, E and F): A) The patient is a postmenopausal female, male or pre/perimenopausal and is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene or fulvestrant) AND F) Piqray will be used in combination with fulvestrant injection.

Indications

All FDA-approved Indications.

Off Label Uses**Part B Prerequisite**

No

Prerequisite Therapy Required

Yes

PIRFENIDONE

Drugs

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

Exclusion Criteria

Required Medical Information

Age Restriction

18 years of age and older

Prescriber Restriction

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 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

POMALYST

Drugs

POMALYST

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Kaposi Sarcoma/MM/Systemic light chain amyloidosis-18 years and older

Prescriber Restriction

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. patient is Human Immunodeficiency Virus (HIV)-negative OR ii. patient meets both of the following (a and b): a) The patient is Human Immunodeficiency Virus (HIV)-positive AND b) The patient continues to receive highly active antiretroviral therapy (HAART). MM-approve if the patient has 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.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Systemic Light Chain Amyloidosis, Primary Central Nervous System (CNS) Lymphoma

No

Prerequisite Therapy Required

Yes

POSACONAZOLE (ORAL)

Drugs

posaconazole oral tablet, delayed release (dr/ec)

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration

6 months

Other Criteria

Indications

All Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

mucormycosis - maintenance, fusariosis, invasive - treatment fungal infections (systemic) in patients with human immunodeficiency virus (HIV) infections (e.g., histoplasmosis, coccidioidomycosis) - treatment.

No

Prerequisite Therapy Required

No

PREVYMIS

Drugs

PREVYMIS INTRAVENOUS SOLUTION 480 MG/24 ML, PREVYMIS ORAL TABLET

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration

6 months

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

eltrombopag olamine

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 Restriction

Prescriber Restriction

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 microliters or less than 50, 000 microliters and the patient is at an increased risk for bleeding AND the patient has tried ONE other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Nplate, Tavalisse, Doptelet, rituximab) or has undergone a splenectomy. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Treatment of thrombocytopenia in patients with Chronic Hepatitis C initial - approve if the patient will be receiving interferon-based therapy for chronic hepatitis C AND if the patient has low platelet counts at baseline (eg, less than 75,000 microliters). Aplastic anemia initial - approve if the patient has low platelet counts at baseline/pretreatment (e.g., less than 30,000 microliter) AND tried one immunosuppressant therapy (e.g., cyclosporine) OR patient will be using Promacta in combination with standard immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response. MDS initial-approve if patient has low-to intermediate-risk MDS AND the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and is at an increased risk for bleeding. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Thrombocytopenia post-allogeneic transplantation, initial - approve if, according to the prescriber, the patient has poor graft function AND has a platelet count less than 50,000/mcL. Cont- patient demonstrated a beneficial clinical response.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Thrombocytopenia in Myelodysplastic Syndrome (MDS), Thrombocytopenia in a patient post-allogeneic transplantation

No

Prerequisite Therapy Required

Yes

PYRIMETHAMINE

Drugs

pyrimethamine

Exclusion Criteria

Required Medical Information

Patient's immune status (Toxoplasma gondii Encephalitis, chronic maintenance and prophylaxis, primary)

Age Restriction

Prescriber Restriction

Toxoplasma gondii Encephalitis, Chronic Maintenance and Prophylaxis (Primary)-prescribed by or in consultation with an infectious diseases specialist. Toxoplasmosis Treatment-prescribed by or in consultation with an infectious diseases specialist, a maternal-fetal medicine specialist, or an ophthalmologist.

Coverage Duration

12 months

Other Criteria

Toxoplasma gondii Encephalitis, Chronic Maintenance, approve if the patient is immunosuppressed.

Toxoplasma gondii Encephalitis Prophylaxis (Primary), approve if the patient is immunosuppressed.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis

No

Prerequisite Therapy Required

No

Drugs

QINLOCK

Exclusion Criteria

Required Medical Information

Diagnosis, other therapies tried

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

Authorization will be for 1 year.

Other Criteria

Gastrointestinal stromal tumor (GIST)-approve if the patient has tried imatinib or avapritinib tablets, AND the patient meets one of the following criteria (i, ii, or iii): i. Patient has tried sunitinib and regorafenib tablets, OR ii. Patient has tried dasatinib tablets, OR iii. Patient is intolerant of sunitinib. Melanoma, cutaneous-approve if the patient has metastatic or unresectable disease, AND the patient has an activating KIT mutation, AND the patient has tried at least one systemic regimen.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Melanoma, cutaneous

No

Prerequisite Therapy Required

Yes

Drugs

RADICAVA ORS STARTER KIT SUSP

Exclusion Criteria

Required Medical Information

ALSFRS-R score

Age Restriction

Prescriber Restriction

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 Tigtutik 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

Prerequisite Therapy Required

Yes

Drugs

REPATHA SURECLICK, REPATHA SYRINGE

Exclusion Criteria

Concurrent use of Leqvio or Praluent.

Required Medical Information

LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)

Age Restriction

ASCVD/Primary Hyperlipidemia - 18 yo and older, HoFH/HeFH - 10 yo and older.

Prescriber Restriction

Coverage Duration

Approve for 1 year

Other Criteria

HYPERLIPIDEMIA WITH 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 16 years old), b) phenotypic confirmation (Note 1) of 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) and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below).

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. PRIMARY HYPERLIPIDEMIA (not associated with established CVD, HeFH, or HoFH) or 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 and LDL-C remains 70 mg/dL or higher or B) statin intolerant. HYPERLIPIDEMIA WITH HoFH (both A and B): A) meets (a or b): a) phenotypic confirmation of 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 20 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 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 (apo B), 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

Yes

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Medullary Thyroid Cancer/Thyroid Cancer/Solid tumors-2 years and older, all others 18 years and older

Prescriber Restriction

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

Part B Prerequisite

Anaplastic thyroid carcinoma, histiocytic neoplasm

No

Prerequisite Therapy Required

No

REVCOVI

Drugs

REVCOVI

Exclusion Criteria

Required Medical Information

Diagnosis, lab values, genetic tests (as specified in the Other Criteria field)

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with, an immunologist, hematologist/oncologist, or physician that specializes in ADA-SCID or related disorders.

Coverage Duration

12 months

Other Criteria

ADA-SCID - approve if the patient had absent or very low (less than 1% of normal) ADA catalytic activity at baseline (i.e., prior to initiating enzyme replacement therapy) OR if the patient had molecular genetic testing confirming bi-allelic pathogenic variants in the ADA gene.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

REVUFORJ

Drugs

REVUFORJ ORAL TABLET 110 MG, 160 MG, 25 MG

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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

Drugs

REZDIFFRA

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older (initial)

Prescriber Restriction

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) WITH MODERATE-ADVANCED LIVER FIBROSIS: All of (i, ii and iii): i) Diagnosed by (a or b): a) Liver biopsy performed within 3 years preceding treatment with Rezdifra showing non-alcoholic fatty liver disease activity score of greater than or equal to 4 with a score of greater than or equal to 1 in ALL of the following: steatosis, ballooning and lobular inflammation, or b) One of the following within 6 months preceding treatment with Rezdifra (1, 2 or 3): 1) Elastography (e.g. vibration-controlled transient elastography (e.g., FibroScan), transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, shear wave elastography) or 2) Computed tomography or 3) Magnetic resonance imaging, and ii) stage F2 or F3 fibrosis prior to Rezdifra and iii) 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, ii and iii): i) completed greater than or equal to 1 year of therapy and has not had worsening of fibrosis or MASH/NASH, and ii) has not progressed to stage F4 (cirrhosis) and iii) This will be used in combination with appropriate diet and exercise therapy (prescriber 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

REZLIDHIA

Drugs

REZLIDHIA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Acute myeloid leukemia-approve if the patient has relapsed or refractory disease and the patient has isocitrate dehydrogenase-1 (IDH1) mutation positive disease as detected by an approved test.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

REZUROCK

Drugs

REZUROCK

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

12 years and older (initial therapy)

Prescriber Restriction

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], Nektimvo [axatilimab-csfr], ibrutinib) for chronic graft-versus-host disease. Graft-versus-host disease, continuation-approve if patient has demonstrated a beneficial clinical response.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

RILUZOLE

Drugs

riluzole

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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

Drugs

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

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 Restriction

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 Restriction

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): 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial or use of TNFi is clinically inadvisable per the prescriber. ATOPIC DERMATITIS (AD): 90 day trial of at least one systemic therapy (e.g., Dupixent [dupilumab subcutaneous injection], Ebglyss (lebrikizumab-lbkz subcutaneous injection), Nemludio (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

Yes

RINVOQ LQ

Drugs

RINVOQ LQ

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 Restriction

PsA-2 years and older (initial therapy)

Prescriber Restriction

JIA-prescribed by or in consultation with a rheumatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or a dermatologist (initial therapy)

Coverage Duration

Approve through end of plan year

Other Criteria

INITIAL THERAPY: JUVENILE IDIOPATHIC ARTHRITIS (JIA)/ PSORIATIC ARTHRITIS (PsA) - 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial.
CONTINUATION THERAPY: ALL INDICATIONS - patient responded to therapy.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

ROFLUMILAST (ORAL)

Drugs

roflumilast

Exclusion Criteria

Required Medical Information

Chronic Obstructive Pulmonary Disease (COPD), medications tried.

Age Restriction

Prescriber Restriction

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.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

ROMVIMZA

Drugs

ROMVIMZA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

TENOSYNOVIAL GIANT CELL TUMOR (PIGMENTED VILLONODULAR SYNOVITIS)-tumor is not amenable to improvement with surgery.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

ROZLYTREK

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

NSCLC-18 years and older, Solid Tumors-1 month and older, Pediatric Diffuse High-Grade Glioma-less than 18 years old

Prescriber Restriction

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

Part B Prerequisite

Pediatric Diffuse High-Grade Glioma

No

Prerequisite Therapy Required

No

Drugs

RUBRACA

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 Restriction

18 years and older

Prescriber Restriction

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 (germline and/or somatic) AND B) The patient meets one of the following criteria (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy AND C) The patient has been previously treated with at least one androgen receptor-directed therapy, and D) for new starts, the patient has tried one of the preferred products, Lynparza or Talzenna, unless the prescriber indicates that both Lynparza and Talzenna are inappropriate for the patient's specific clinical situation. Pancreatic adenocarcinoma-approve if pt has a BRCA mutation or PALB2 mutation AND pt has tried platinum-based chemotherapy AND has not had disease progression following the most recent platinum-based chemotherapy. Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Uterine Leiomyosarcoma, Pancreatic Adenocarcinoma

No

Prerequisite Therapy Required

Yes

RUFINAMIDE

Drugs

rufinamide

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Patients 1 years of age or older

Prescriber Restriction

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

Part B Prerequisite

Treatment-Refractory Seizures/Epilepsy

No

Prerequisite Therapy Required

No

Drugs

RYDAPT

Exclusion Criteria

Required Medical Information

For AML, FLT3 status

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

AML-approve if the patient is FLT3-mutation positive as detected by an approved test. Myeloid or lymphoid Neoplasms with eosinophilia-approve if the patient has an FGFR1 rearrangement or has an FLT3 rearrangement. Indolent systemic mastocytosis-pt has symptomatic disease and has tried at least one systemic regimen. Smoldering systemic mastocytosis-pt has tried at least one systemic regimen.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Myeloid or lymphoid Neoplasms with eosinophilia, indolent systemic mastocytosis, smoldering systemic mastocytosis

No

Prerequisite Therapy Required

Yes

SAPROPTERIN

Drugs

sapropterin

Exclusion Criteria

Concurrent use with Palynziq

Required Medical Information

Diagnosis, Phe concentration

Age Restriction

Prescriber Restriction

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

Drugs

SCSEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction**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**Part B Prerequisite**

Myeloid/Lymphoid Neoplasms with Eosinophilia, Acute Lymphoblastic Leukemia (ALL)

No

Prerequisite Therapy Required

Yes

SIGNIFOR

Drugs

SIGNIFOR

Exclusion Criteria

Required Medical Information

Age Restriction

18 years and older (initial therapy)

Prescriber Restriction

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

SIRTURO

Drugs

SIRTURO

Exclusion Criteria

Patients weighing less than 15 kg

Required Medical Information

Diagnosis, concomitant therapy

Age Restriction

Patients 5 years of age or older

Prescriber Restriction

Prescribed by, or in consultation with an infectious diseases specialist or pulmonologist

Coverage Duration

9 months

Other Criteria

Tuberculosis (Pulmonary) -Approve if the patient has Mycobacterium tuberculosis resistant to at least rifampin and isoniazid and the requested medication is prescribed as part of a combination regimen with other anti-tuberculosis agents

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

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

Exclusion Criteria

Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)

Required Medical Information

Diagnosis, Previous medication use

Age Restriction

PP/UC-18 years of age and older (initial therapy)

Prescriber Restriction

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. UICERATIVE 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

Prerequisite Therapy Required

No

SOMAVERT

Drugs

SOMAVERT

Exclusion Criteria

Required Medical Information

Diagnosis, previous therapy, concomitant therapy

Age Restriction

Prescriber Restriction

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

Drugs

sorafenib

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

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, avapritinib, sunitinib, dasatinib, ripretinib or regorafenib. Differentiated thyroid carcinoma (DTC), approve if the patient meets (A or B): A) has papillary or follicular thyroid carcinoma and the disease is refractory to radioactive iodine treatment or B) has oncocytic (formerly Hurthle cell) carcinoma. Medullary thyroid carcinoma, approve if the patient has tried at least one systemic therapy. AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test and the medication is used in combination with azacitidine or decitabine or patient has had an allogeneic stem cell transplant and is in remission. Renal cell carcinoma (RCC)-approve if the patient has relapsed or advanced clear cell histology and the patient has tried at least one systemic therapy (e.g., Inlyta, Votrient, Sutent Cabometyx). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and sorafenib is used in combination with topotecan. HCC-approve if the patient has unresectable or metastatic disease. Soft tissue sarcoma-approve if the patient has angiosarcoma or desmoid tumors (aggressive fibromatosis) or solitary fibrous tumor/hemangiopericytoma. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement. Please note for all diagnoses: Part B before Part D Step Therapy applies only to beneficiaries enrolled in an MA-PD plan

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

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

Yes

Prerequisite Therapy Required

Yes

Drugs

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

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 Restriction

GIST/bone cancer/ melanoma, cutaneous-18 years and older

Prescriber Restriction

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 imatinib or avapritinib. For melanoma, cutaneous - approve if patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

GIST, bone cancer, melanoma cutaneous

No

Prerequisite Therapy Required

Yes

Drugs

STIVARGA

Exclusion Criteria

Required Medical Information

Diagnosis for which Stivarga is being used. Prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status.

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

For GIST, (A or B): A) patient has previously been treated with (i and ii): i) imatinib or Ayvakit and ii) sunitinib or Sprycel, or B) medication is used as first-line therapy 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 non-adipocytic sarcoma, angiosarcoma, or pleomorphic rhabdomyosarcoma. Bone Cancer-approve if the patient has relapsed/refractory or metastatic disease AND the patient has tried one systemic chemotherapy regimen AND pt has Ewing sarcoma or osteosarcoma. Colon and Rectal cancer/Appendiceal cancer-approve if the patient has advanced or metastatic disease, has been previously treated with a fluoropyrimidine, oxaliplatin, irinotecan and if the patient meets one of the following (i or ii): i. patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type), the patient has tried Erbitux or Vectibix or the patient's tumor did not originate on the left side of the colon (from the splenic fixture to rectum) or ii. the patient's tumor or metastases has a RAS mutation (either KRAS mutation or NRAS mutation). CNS tumors (Glioblastoma or H3-mutated high-grade glioma)-approve if the patient has recurrent or progressive disease. Uterine sarcoma- (A and B): A) pt has recurrent, advanced, inoperable, or metastatic disease, and B) tried at least one systemic regimen.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Soft tissue Sarcoma, Bone Cancer, CNS tumors (Glioblastoma/H3-mutated high-grade glioma), Appendiceal cancer, Uterine sarcoma

No

Prerequisite Therapy Required

Yes

Drugs

SUCRAID

Exclusion Criteria

Required Medical Information

Diagnosis, genetic and lab test results (as specified in the Other Criteria field)

Age Restriction

Prescriber Restriction

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

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

sunitinib malate

Exclusion Criteria**Required Medical Information****Age Restriction**

18 years and older

Prescriber Restriction**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**Part B Prerequisite**

Chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), extraskeletal myxoid chondrosarcoma, differentiated (ie, papillary, follicular, and oncocytic carcinoma) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma, pheochromocytoma/paraganglioma, myeloid/lymphoid neoplasms with eosinophilia, GIST-unresectable succinate dehydrogenase (SDH)-deficient GIST.

No

Prerequisite Therapy Required

Yes

Drugs

SYMDEKO

Exclusion Criteria

Combination therapy with other CF transmembrane conductance regulator modulators

Required Medical Information

Diagnosis, specific CFTR gene mutations

Age Restriction

Six years of age and older

Prescriber Restriction

Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF

Coverage Duration

1 year

Other Criteria

CF - Approve if the pt meets A, B and C: A) pt has at least one mutation in the cystic fibrosis transmembrane conductance regulator gene that is considered to be pathogenic or likely pathogenic or patient has TWO copies of the F508 del mutation, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal 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

Drugs

TABRECTA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

Authorization will be for 1 year.

Other Criteria

Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has advanced or metastatic disease AND the tumor is positive for a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping or high-level MET amplification, as detected by an approved test.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Non-small cell lung cancer with high-level MET amplification.

No

Prerequisite Therapy Required

No

TADALAFIL

Drugs

tadalafil oral tablet 2.5 mg, 5 mg

Exclusion Criteria

Treatment of erectile dysfunction (ED)

Required Medical Information

Indication for which tadalafil is being prescribed.

Age Restriction

Prescriber Restriction

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

Drugs

VYNDAMAX

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]). Concurrent use of Vyndaqel and Vyndamax.

Required Medical Information

Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)

Age Restriction

18 years and older

Prescriber Restriction

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

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

TAFINLAR ORAL CAPSULE, TAFINLAR ORAL TABLET FOR SUSPENSION

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

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 the patient has BRAF-positive disease. Histiocytic neoplasm-approve if (A and B): A) patient has Langerhans cell histiocytosis or Erdheim Chester disease AND B) patient has BRAF V600-mutation positive disease. Solid tumors [examples: biliary tract cancer, brain metastases due to melanoma, ovarian/fallopian tube/primary peritoneal cancer, gastrointestinal stromal tumors, gastric cancer, esophageal and esophagogastric junction cancers, salivary gland tumors, occult primary, pancreatic adenocarcinoma, neuroendocrine tumors, ampullary adenocarcinoma, small bowel adenocarcinoma]-approve if BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib). Hairy Cell Leukemia, approve if pt has not previously been treated with a BRAF inhibitor therapy and this will be used for relapsed/refractory disease and will be taken in combination with Mekinist.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Histiocytic neoplasm, hairy cell leukemia

No

Prerequisite Therapy Required

Yes

Drugs

TAGRIS

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction**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 as detected by an approved test. Note- examples of EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. NSCLC-EGFR T790M mutation positive-approve if the patient has advanced or metastatic EGFR T790M mutation-positive NSCLC as detected by an approved test and has progressed on treatment with at least one of the EGFR tyrosine kinase inhibitors. NSCLC-Post resection-approve if the patient has completely resected disease and has received previous adjuvant chemotherapy or if the patient is ineligible to receive platinum based chemotherapy and the patient has EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test. NSCLC- Unresectable Stage III - approve if the patient has locally advanced, unresectable (stage III) disease AND EGFR exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an approved test AND not had disease progression during or following platinum-based chemoradiation therapy. (Note: Patients could have received concurrent or sequential chemoradiation therapy.)

Indications

All FDA-approved Indications.

Off Label Uses**Part B Prerequisite**

No

Prerequisite Therapy Required

Yes

Drugs

TALZENNA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

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

Prerequisite Therapy Required

No

TAZAROTENE

Drugs

tazarotene topical cream, tazarotene topical gel

Exclusion Criteria

Cosmetic uses

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Indications

All Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

TAZVERIK

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Epithelioid Sarcoma-16 years and older, Follicular Lymphoma-18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Epithelioid Sarcoma-approve if the patient has metastatic or locally advanced disease and the patient is not eligible for complete resection. Follicular Lymphoma-approve if the patient has relapsed or refractory disease and there are no appropriate alternative therapies or the patient has tried at least two prior systemic therapies.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

TEPMETKO

Drugs

TEPMETKO

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

NSCLC-approve if the patient has advanced or metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutations or patient has high-level MET amplification, as detected by an approved test.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Non-small cell lung cancer with high-level MET amplification.

No

Prerequisite Therapy Required

No

TERIPARATIDE

Drugs

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

Exclusion Criteria

Concomitant use with other medications for osteoporosis

Required Medical Information

Age Restriction

Prescriber Restriction

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: Postmenopausal Osteoporosis (PMO) Treatment, Increase Bone Mass in Men (see Note 1 below) with Primary or Hypogonadal Osteoporosis, and Treatment of Glucocorticosteroid-Induced Osteoporosis (GIO): (one of A, B, C, D or E): A) tried one oral bisphosphonate or cannot take due to swallowing difficulties or inability to remain upright after administration, B) pre-existing gastrointestinal condition (e.g., esophageal lesions/ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), C) tried an IV bisphosphonate (PMO-ibandronate or zoledronic acid, all other diagnoses-zoledronic acid), D) severe renal impairment (creatinine clearance [CrCL] less than 35 mL/min) or chronic kidney disease (CKD), or E) patient had an osteoporotic fracture or fragility fracture at any time in the past. 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

Yes

TETRABENAZINE

Drugs

tetrabenazine oral tablet 12.5 mg, 25 mg

Exclusion Criteria

Required Medical Information

Age Restriction

18 years and older

Prescriber Restriction

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

Part B Prerequisite

Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.
No

Prerequisite Therapy Required

No

Drugs

THALOMID ORAL CAPSULE 100 MG, 50 MG

Exclusion Criteria

Required Medical Information

Age Restriction

MM, histiocytic neoplasms-18 years and older, medulloblastoma- less than 18 years old

Prescriber Restriction

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 tried at least one medication AND has relapsed or refractory disease. Castleman disease-approve if the patient has multicentric disease and is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). 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 Rosai-Dorfman cutaneous disease. Medulloblastoma- 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

Part B Prerequisite

Discoid lupus erythematosus or cutaneous lupus erythematosus, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi Sarcoma, Castleman Disease, histiocytic neoplasms, medulloblastoma.

No

Prerequisite Therapy Required

Yes

TIBSOVO

Drugs

TIBSOVO

Exclusion Criteria

Required Medical Information

Diagnosis, IDH1 Status

Age Restriction

All diagnoses (except chondrosarcoma)-18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

AML- approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive, as detected by an approved test. Cholangiocarcinoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive and has been previously treated with at least one chemotherapy regimen (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan). Chondrosarcoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. Central nervous system cancer-approve if the patient has oligodendroglioma or astrocytoma. Myelodysplastic Syndrome-approve if patient has isocitrate dehydrogenase-1 (IDH1) mutation-positive disease AND relapsed or refractory disease.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Chondrosarcoma, Central nervous system cancer

Yes

Prerequisite Therapy Required

Yes

TOBRAMYCIN (NEBULIZATION)

Drugs

tobramycin in 0.225 % nacl, tobramycin inhalation

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Bronchiectasis, Non-cystic fibrosis-18 years and older

Prescriber Restriction

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

Part B Prerequisite

Bronchiectasis, non-cystic fibrosis

No

Prerequisite Therapy Required

No

Drugs

tolvaptan

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 Restriction

18 years and older

Prescriber Restriction

Coverage Duration

Authorization will be for 30 days for initial therapy, 3 months for continuation of therapy

Other Criteria

Hyponatremia, initial therapy (including new starts, patients on therapy for less than 30 days, and patients restarting therapy) - Pt must meet ONE of the following: 1. serum sodium less than 125 mEq/L at baseline, OR 2. marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on tolvaptan and has received less than 30 days of therapy. Hyponatremia, continuation of therapy for patients established on therapy for at least 30 days - approve if the serum sodium level has increased from baseline (prior to initiating the requested drug) OR if the patient experienced improvement in at least one symptom, such as nausea, vomiting, headache, lethargy, or confusion.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

TOPICAL AGENTS FOR ATOPIC DERMATITIS

Drugs

EUCRISA, *pimecrolimus*, *tacrolimus topical*

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid.

Indications

All Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

topical retinoid products

Drugs

tretinoin

Exclusion Criteria

Coverage is not provided for cosmetic use.

Required Medical Information

Age Restriction

Prescriber Restriction

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

Drugs

topiramate oral capsule, sprinkle 15 mg, 25 mg, topiramate oral solution, topiramate oral tablet, ZONISADE, zonisamide

Exclusion Criteria

Coverage is not provided for weight loss or smoking cessation.

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration

Authorization will be for 1 year.

Other Criteria

Indications

All Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

TRANSDERMAL FENTANYL

Drugs

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

Exclusion Criteria

Acute (i.e., non-chronic) pain.

Required Medical Information

Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies

Age Restriction

Prescriber Restriction

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) 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. Patients with cancer, sickle cell disease, in hospice 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

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

TRELSTAR INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Prostate cancer: Prescribed by or in consultation with a oncologist or urologist. Head and neck cancer - salivary gland tumors: Prescribed by or in consultation with a oncologist.

Coverage Duration

1 year

Other Criteria

Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. 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

Part B Prerequisite

Head and neck cancer - salivary gland tumors

No

Prerequisite Therapy Required

Yes

Drugs

TREMFYA PEN INDUCTION PK(2PEN), TREMFYA PEN SUBCUTANEOUS PEN INJECTOR 200 MG/2 ML, TREMFYA SUBCUTANEOUS SYRINGE

Exclusion Criteria

Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)

Required Medical Information

Diagnosis

Age Restriction

PP/UC/CD/PsA-18 years of age and older (initial therapy)

Prescriber Restriction

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, initial therapy - approve if the pt meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: a biologic that is not a biosimilar of the requested product will also count) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. ULCERATIVE COLITIS- pt will receive 3 induction doses with Tremfya IV within 3 months of initiating Tremfya SC AND (A or B): A) tried a systemic therapy (e.g., 6-MP, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a CS) or B) has pouchitis and tried therapy with an antibiotic, probiotic, CS enema, or mesalamine (Rowasa) enema. CROHN'S DISEASE (CD) [one of A, B, C, or D]: A) tried or currently taking corticosteroid (CS) or CS is contraindicated, B) tried one other conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX], certolizumab, infliximab, ustekinumab, vedolizumab), C) had ileocolonic resection, or D) enterocutaneous (perianal or abdominal) or rectovaginal fistulas. PP/PsA/UC/CD continuation of therapy - approve if the pt is responding to therapy.

Indications

All FDA-approved Indications.

Off Label Uses**Part B Prerequisite**

No

Prerequisite Therapy Required

Yes

TRIENTINE

Drugs

trientine oral capsule 250 mg

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.

Coverage Duration

Authorization will be for 1 year

Other Criteria

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

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

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

Exclusion Criteria

Combination therapy with other CF transmembrane conductance regulator modulators.

Required Medical Information

Diagnosis

Age Restriction

2 years of age and older

Prescriber Restriction

Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF

Coverage Duration

1 year

Other Criteria

CF -Approve if the pt meets A, B and C: A) pt has at least one mutation in the cystic fibrosis transmembrane conductance regulator gene that is considered to be pathogenic or likely pathogenic 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 mutations or (iii) abnormal nasal potential difference.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

TRUQAP

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction**Coverage Duration**

1 year

Other Criteria

Breast Cancer-Approve if the patient meets the following (A, B, C, D and E): A) Patient has locally advanced or metastatic disease, AND B) Patient has hormone receptor positive (HR+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has at least one phosphatidylinositol 3-kinase (PIK3CA), serine/threonine protein kinase (AKT1), or phosphatase and tensin homolog (PTEN)-alteration, AND E) Patient meets one of the following (i or ii): i. Patient has had progression with at least one endocrine-based regimen in the metastatic setting (Note: Examples of endocrine therapy include anastrozole, exemestane, and letrozole.) and has had progression with at least one cyclin-dependent kinase (CDK) 4/6 inhibitor in the metastatic setting (Note: Examples of CDK4/6 inhibitor include: Ibrance (palbociclib tablets or capsules), Verzenio (abemaciclib tablets), Kisqali (ribociclib tablets), Kisqali Femara Co-Pack (ribociclib and letrozole tablets) OR ii. Patient has recurrence on or within 12 months of completing adjuvant endocrine therapy.

Indications

All FDA-approved Indications.

Off Label Uses**Part B Prerequisite**

No

Prerequisite Therapy Required

Yes

Drugs

TUKYSA ORAL TABLET 150 MG, 50 MG

Exclusion Criteria**Required Medical Information**

Diagnosis, prior therapies

Age Restriction

18 years and older

Prescriber Restriction**Coverage Duration**

1 year

Other Criteria

Breast Cancer-approve if the patient has recurrent or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti-HER2-based regimen in the metastatic setting and Tukysa is used in combination with trastuzumab and capecitabine. Colon/Rectal Cancer-approve if the requested medication is used in combination with trastuzumab, patient has unresectable or metastatic disease, human epidermal growth factor receptor 2 (HER2)-amplified disease, AND Patient's tumor or metastases are wild-type RAS (KRAS wild-type and NRAS wild-type). Biliary tract cancer- approve if the patient meets all of (a, b, c, and d): a) unresectable or metastatic disease, b) HER2 positive disease, c) tried at least one systemic regimen, d) will use in combination with trastuzumab.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses**Part B Prerequisite**

Biliary tract cancer

No

Prerequisite Therapy Required

Yes

TURALIO

Drugs

TURALIO ORAL CAPSULE 125 MG

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

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

Part B Prerequisite

Histiocytic Neoplasms

No

Prerequisite Therapy Required

No

Drugs

TYENNE AUTOINJECTOR, TYENNE SUBCUTANEOUS

Exclusion Criteria

Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

Required Medical Information

Diagnosis, concurrent medications, previous drugs tried.

Age Restriction

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 Restriction

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 Xeljanz/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, Xeljanz, 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 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

Yes

UPTRAVI

Drugs

UPTRAVI ORAL TABLET, UPTRAVI ORAL TABLETS,DOSE PACK

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 Restriction

Prescriber Restriction

PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist.

Coverage Duration

1 year

Other Criteria

Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Patient new to therapy must meet a) OR b): a) tried one or is currently taking one oral therapy for PAH for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas, OR b) receiving or has received in the past one prostacyclin therapy for PAH (eg, Orenitram, Ventavis, or epoprostenol injection).

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

OTULFI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML, PYZCHIVA SUBCUTANEOUS SOLUTION, PYZCHIVA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML, SELARSDI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML, STELARA SUBCUTANEOUS SOLUTION, *ustekinumab subcutaneous solution, ustekinumab-aekn subcutaneous syringe 45 mg/0.5 ml, 90 mg/ml*, YESINTEK SUBCUTANEOUS SOLUTION, YESINTEK SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML

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 Restriction

PP/PsA-6 years and older (initial therapy). UC/CD-18 years and older (initial therapy)

Prescriber Restriction

Plaque psoriasis. 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-prescribed by or in consultation with a gastroenterologist (initial therapy).

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. ALL INDICATIONS, INITIAL AND CONTINUATION in addition to the above criteria: patients requesting Stelara must have a trial of two of the following preferred ustekinumab products first: Otulfi, Pyzchiva, Selarsdi, Yesintek.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

VALCHLOR

Drugs

VALCHLOR

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Cutaneous lymphoma-18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Cutaneous Lymphomas (Note-includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders)-approve. Adult T-Cell Leukemia/Lymphoma-approve if the patient has smoldering subtype of adult T-cell leukemia/lymphoma. Langerhans cell histiocytosis-approve if the patient has unifocal Langerhans cell histiocytosis with isolated skin disease.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Adults with T-cell leukemia/lymphoma, Langerhans Cell Histiocytosis

No

Prerequisite Therapy Required

No

VALTOCO

Drugs

VALTOCO

Exclusion Criteria

Required Medical Information

Diagnosis, other medications used at the same time

Age Restriction

Prescriber Restriction

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

Yes

VANCOMYCIN

Drugs

vancomycin oral capsule 125 mg, 250 mg

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration

2 weeks

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

VANFLYTA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Acute Myeloid Leukemia: approve if the patient has FLT3-ITD mutation-positive disease as detected by an approved test. 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

Part B Prerequisite

Myeloid or lymphoid neoplasms

No

Prerequisite Therapy Required

No

Drugs

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

Exclusion Criteria**Required Medical Information**

Diagnosis, prior therapy

Age Restriction

18 years and older (all diagnoses except ALL)

Prescriber Restriction**Coverage Duration**

1 year

Other Criteria

AML-approve if used in combination with azacitidine, decitabine, or cytarabine. CLL/SLL- approve. ALL-approve if relapsed/refractory disease and will be used in combination with chemotherapy. Hairy cell leukemia-approve if disease resistance to BRAF inhibitor therapy. Mantle Cell Lymphoma- approve if (A or B): A) the patient has tried at least one systemic regimen or B) patient has TP53 mutation and will use this as induction therapy in combination with Brukinsa (zanubrutinib) and Gazyva (obinutuzumab intravenous infusion). MDS-approve if pt meets (A and B): A) pt meets (i or ii): (i) has chronic myelomonocytic leukemia-2 or (ii) has higher risk disease (note: includes international prognostic scoring system (IPSS-R) intermediate-, high-, or very-high risk disease) and B) will use in combination with azacitidine or decitabine. Myeloproliferative neoplasm- approve if pt has accelerated or blast phase disease and will use in combination with azacitidine or decitabine. Multiple Myeloma- approve if the patient has t (11,14) translocation AND has tried at least one systemic regimen for multiple myeloma AND Venclexta will be used in combination with dexamethasone. Systemic light chain amyloidosis-approve if the patient has t (11, 14) translocation and has tried at least one systemic regimen. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses**Part B Prerequisite**

Mantle Cell Lymphoma, waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, multiple myeloma, systemic light chain amyloidosis, acute lymphoblastic leukemia, hairy cell leukemia, myelodysplastic syndrome, myeloproliferative neoplasm

No

Prerequisite Therapy Required

Yes

Drugs

VERZENIO

Exclusion Criteria**Required Medical Information**

Breast cancer: HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status

Age Restriction

18 years and older

Prescriber Restriction**Coverage Duration**

1 year

Other Criteria

Breast Cancer, Early-pt meets (A,B,C and D): A)Pt HR+disease, AND B) HER2-negative breast cancer, AND C)node-positive disease at high risk of recurrence AND D)meets 1 of the following (i or ii): i.Verzenio will be used in combo w/anastrozole, exemestane, or letrozole AND pt meets one of the following (a,b, or c): a)Pt is postmenopausal woman, OR b)Pt is pre/perimenopausal woman and meets one of the following 1 or 2:1-Pt receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Pt had surgical bilateral oophorectomy or ovarian irradiation, OR c)Pt is man and pt is receiving a GnRH analog, OR ii.Verzenio will be used in combo with tamoxifen AND pt meets 1 of the following (a or b): a)Pt is postmenopausal woman or man OR b)Pt is pre/perimenopausal woman and meets 1 of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Pt had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer-Recurrent or Metastatic in Women-pt meets (A, B and C): A)has HR+ disease, AND B)Pt meets 1 of following criteria (i or ii): i.Pt is postmenopausal woman, OR ii.Pt is pre/perimenopausal woman and meets 1 of the following (a or b): a)receiving ovarian suppression/ablation with a GnRH agonist, OR b)Pt had surgical bilateral oophorectomy or ovarian irradiation, AND C) either (1 or 2): 1) HER2-negative breast cancer and Pt meets 1 of following criteria (i, ii, or iii): i.Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.pt meets following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least 1 prior endocrine therapy, AND c)has tried chemo for metastatic breast cancer or 2)has HER2-positive breast cancer and has received at least 3 prior anti-HER2-based regimens in metastatic setting and will use this in combo with fulvestrant and trastuzumab.Breast Cancer-Recurrent or Metastatic in Men-pt meets following criteria (A and B): A)HR+ disease, AND B)either (1 or 2): 1) HER2-negative disease and Pt meets 1 of following criteria (i, ii, or iii): i.Pt meets BOTH of the following conditions (a and b): a)receiving a GnRH analog, AND b)Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.Pt meets the following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least 1 prior endocrine therapy, AND c)Pt has tried chemo for metastatic breast cancer, or 2) has HER2-positive disease and has received at least 3 prior anti-HER2-based regimen in metastatic setting and will use this medication in combo with fulvestrant and trastuzumab. Endometrial cancer-pt meets all of (A, B, And C): A)has recurrent or metastatic disease, and B)has estrogen receptor (ER)-positive tumors, and C)will be using in combination with letrozole.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses**Part B Prerequisite**

Endometrial cancer

No H5826_RX344_Clinical_Criteria_Prior_Auth_Feb_2026_C

Prerequisite Therapy Required

Yes

VIGABATRIN

Drugs

vigabatrin, VIGADRONE

Exclusion Criteria

Required Medical Information

Diagnosis, medication history (complex partial seizures)

Age Restriction

Refractory complex partial seizures - patients 2 years of age or older. Infantile spasms - patients less than or equal to 2 years of age

Prescriber Restriction

Prescribed by, or in consultation with, a neurologist

Coverage Duration

Infantile spasms- 6 mos. Treatment-Refractory Partial Seizures- initial- 3 mos, cont- 1 year

Other Criteria

Infantile spasms-requested medication is being used as monotherapy. Treatment refractory complex partial seizures initial-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

Yes

VITRAKVI

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis, NTRK gene fusion status

Age Restriction

Pediatric Diffuse High-Grade Glioma- less than or equal to 21 years old

Prescriber Restriction

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

Part B Prerequisite

Pediatric Diffuse High-Grade Glioma

No

Prerequisite Therapy Required

No

VIZIMPRO

Drugs

VIZIMPRO

Exclusion Criteria

Required Medical Information

Diagnosis, EGFR status, exon deletions or substitutions

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

NSCLC-approve if the patient has advanced or metastatic disease, has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768L.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

VONJO

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

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 $50 \times 10^9 /L$ (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 $50 \times 10^9 /L$ (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).

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Accelerated or blast phase myeloproliferative neoplasm

No

Prerequisite Therapy Required

No

VORANIGO

Drugs

VORANIGO ORAL TABLET 10 MG, 40 MG

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

12 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

GLIOMAS-All of (A, B and C): A. Susceptible isocitrate dehydrogenase-1 (IDH1) or IDH2 mutation-positive disease, AND B. Grade 2 or greater oligodendroglioma OR Grade 2 or greater astrocytoma, AND C. Prior surgery, including biopsy, sub-total resection, or gross total resection

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

VORICONAZOLE (ORAL)

Drugs

voriconazole

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration

6 months

Other Criteria

Indications

All Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Aspergillus Infections - prophylaxis, oropharyngeal candidiasis (fluconazole-refractory) - treatment, candidia endophthalmitis - treatment, blastomycosis - treatment, fungal infections (systemic) in patients at risk of neutropenia - prophylaxis, fungal infections (systemic) in patients with human immunodeficiency virus (HIV) - prophylaxis or treatment.

No

Prerequisite Therapy Required

No

VOSEVI

Drugs

VOSEVI

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years or older

Prescriber Restriction

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

Part B Prerequisite

Indications consistent with current AASLD/IDSA guidance

No

Prerequisite Therapy Required

No

Drugs

pazopanib oral tablet 200 mg

Exclusion Criteria

Required Medical Information

Age Restriction

18 years and older

Prescriber Restriction

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. Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or advanced disease or VonHippel-Lindau disease. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease. GIST - approve if the patient has succinate dehydrogenase (SDH)-deficient GIST OR the patient has tried TWO of the following: Gleevec, Ayvakit, Sutent, Sprycel, Qinlock or Stivarga. Medullary Thyroid Carcinoma, approve if the patient has tried at least one systemic therapy. Bone cancer-approve if the patient has chondrosarcoma and has metastatic widespread disease.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

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.

No

Prerequisite Therapy Required

Yes

VOWST

Drugs

VOWST

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

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

VYVGART

Drugs

VYVGART HYTRULO SUBCUTANEOUS SYRINGE

Exclusion Criteria

Concomitant Use with Another Neonatal Fc Receptor Blocker, a Complement Inhibitor, or a Rituximab Product

Required Medical Information

Diagnosis

Age Restriction

18 years and older (initial and continuation)

Prescriber Restriction

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. For gMG: All treatment cycles should be no more frequent than every 50 days from the start of the previous treatment cycle.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

WELIREG

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction**Coverage Duration**

1 year

Other Criteria

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 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

Yes

Drugs

WINREVAIR

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older (initial)

Prescriber Restriction

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-All of (A, B, C): A) right-heart catheterization to confirm the diagnosis, and B) Functional Class II or III or IV, and C) One of (a or b): a)currently receiving at least two other PAH therapies from the following different pharmacologic categories, each for greater than or equal to 60 days: phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), and prostacyclins or b) currently receiving at least one other PAH therapy for greater than or equal to 60 days and is intolerant to combination therapy with a phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), or prostacyclin. 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

Prerequisite Therapy Required

Yes

Drugs

XALKORI ORAL CAPSULE, XALKORI ORAL PELLETT 150 MG, 20 MG, 50 MG

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Anaplastic large cell lymphoma/IMT-patients greater than or equal to 1 year of age. All other diagnoses-18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Metastatic non-small cell lung cancer-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease, as detected by an approved test and patients new to therapy must have a trial of Alecensa or Lorbrina prior to approval of Xalkori. Metastatic non-small cell lung cancer, approve if the patient has ROS1 rearrangement positive disease, as detected by an approved test. Anaplastic Large Cell Lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Histiocytic neoplasm-approve if the patient has ALK rearrangement/fusion-positive disease and meets one of the following criteria (i, ii, or iii): (i. Patient has Langerhans cell histiocytosis, OR ii. Patient has Erdheim-Chester disease OR iii. Patient has Rosai-Dorfman disease. NSCLC with MET mutation-approve if the patient has high level MET amplification or MET exon 14 skipping mutation. Inflammatory Myofibroblastic Tumor-approve if the patient has ALK positive disease and the patient has advanced, recurrent or metastatic disease or the tumor is inoperable. Melanoma, cutaneous-approve if the patient has ALK fusion disease or ROS1 fusion disease.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

NSCLC with high level MET amplification or MET Exon 14 skipping mutation, Histiocytic neoplasms, melanoma, cutaneous.

No

Prerequisite Therapy Required

Yes

Drugs

XDEMVY

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration

6 months

Other Criteria

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

XELJANZ ORAL SOLUTION, XELJANZ ORAL TABLET, XELJANZ XR

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, concurrent medications, previous drugs tried.

Age Restriction

AS/RA/UC-18 years and older (initial therapy), JIA/JRA/PsA-2 years and older (initial therapy)

Prescriber Restriction

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 Xeljanz/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 Xeljanz immediate release tablets or oral solution (patients 2 years and older) or Xeljanz 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 Xeljanz/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 spondyloarthritis/active sacroiliac arthritis]-initial-approve Xeljanz 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 Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. Continuation Therapy - Patient must have responded, as determined by the prescriber.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

XERMELO

Drugs

XERMELO

Exclusion Criteria

Required Medical Information

Diagnosis, previous therapy, concomitant therapy

Age Restriction

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

Initial therapy - approve if the patient meets ALL of the following criteria: 1) patient has been on long-acting somatostatin analog (SSA) therapy (eg, Somatuline Depot [lanreotide for injection]), AND 2) while on long-acting SSA therapy (prior to starting Xermelo), the patient continues to have at least four bowel movements per day, AND 3) Xermelo will be used concomitantly with a long-acting SSA therapy. Continuation therapy - approve if the patient is continuing to take Xermelo concomitantly with a long-acting SSA therapy for carcinoid syndrome diarrhea.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

XIFAXAN ORAL TABLET 200 MG, 550 MG

Exclusion Criteria**Required Medical Information**

Diagnosis

Age Restriction

Traveler's diarrhea - 12 years of age or older. Hepatic encephalopathy, irritable bowel syndrome with diarrhea - 18 years of age or older.

Prescriber Restriction

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. Travelers Diarrhea-approve Xifaxan 200 mg tablets if the patient is afebrile and does not have blood in the stool. Small intestine bacterial overgrowth-approve Xifaxan 200mg or 550 mg tablets if the diagnosis has been confirmed by a glucose hydrogen breath test, lactulose hydrogen breath test, or small bowel aspiration and culture. Chronic antibiotic-dependent pouchitis- approve Xifaxan 200mg or 550mg tablets if patient meets all of (a, b, c and d): a) recurrent pouchitis (Note: recurrent pouchitis is typically considered history of at least 3 pouchitis episodes within a 12 month period), and b) episodes of pouchitis respond to antibiotic therapy but relapse shortly after antibiotic discontinuation, and c) alternative causes of recurrent pouchitis have been ruled out, and d) has tried long-term antibiotic therapy trials (at least 4 weeks) of BOTH ciprofloxacin and metronidazole for remission maintenance.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses**Part B Prerequisite**

Small intestine bacterial overgrowth, chronic antibiotic-dependent pouchitis

No

Prerequisite Therapy Required

Yes

Drugs

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

Exclusion Criteria

Concurrent use with another monoclonal antibody therapy.

Required Medical Information

Diagnosis

Age Restriction

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 Restriction

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-Initial tx 4 months, 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 Xolair or another monoclonal antibody and meets one of the following (a, b, c, d, or e): a) experienced two or more asthma exacerbations requiring systemic CSs in the past year, b) experienced one or more asthma exacerbation requiring hospitalization/urgent care visit/emergency department visit in the past year, c) forced expiratory volume in 1 second (FEV1) less than 80% predicted, d) FEV1/forced vital capacity (FVC) less than 0.80, or e) asthma worsens upon tapering of oral CS. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRwNP) [all of A, B, C, D, and E]: A) diagnosis by direct exam, endoscopy, or sinus CT scan, B) baseline (prior to Xolair or another monoclonal antibody that may lower IgE) IgE at least 30 IU/ml, C) at least two of the following symptoms for 6 months: nasal congestion, obstruction, discharge, reduction/loss of smell, D) tried intranasal CS and will continue in combination with Xolair, and E) one of the following (a, b, or c): a) had systemic CS at least 5 days in past 2 years, b) contraindication to systemic CS, or c) had nasal polyp surgery. CHRONIC IDIOPATHIC URTICARIA (CIU): urticaria more than 6 weeks prior to treatment with Xolair with symptoms present more than 3 days per week despite daily non-sedating H1-antihistamine therapy. IgE-MEDIATED FOOD ALLERGY (all of A, B, C and D): A) baseline IgE greater than or equal to 30 IU/mL, B) positive skin prick test 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 an epinephrine auto-injector, and D) patient has been prescribed an epinephrine auto-injector. 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 Dupixent 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

Yes

XOSPATA

Drugs

XOSPATA

Exclusion Criteria

Required Medical Information

Diagnosis, FLT3-mutation status

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

1 year

Other Criteria

AML - approve if the disease is FLT3-mutation positive as detected by an approved test. Lymphoid, Myeloid Neoplasms-approve if the patient has eosinophilia and the disease is FLT3-mutation positive as detected by an approved test.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Lymphoid, Myeloid Neoplasms

No

Prerequisite Therapy Required

No

Drugs

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

Exclusion Criteria**Required Medical Information**

Diagnosis, prior therapies

Age Restriction

18 years and older

Prescriber Restriction**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 (daratumumab infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Kyprolis (carfilzomib intravenous infusion). Note: Examples of prior regimens include Darzalex (daratumumab intravenous infusion)/bortezomib/lenalidomide/dexamethasone, bortezomib/lenalidomide/dexamethasone, Kyprolis (carfilzomib infusion)/lenalidomide/dexamethasone, Darzalex (daratumumab injection)/bortezomib or Kyprolis/dexamethasone, or other regimens containing a proteasome inhibitor, immunomodulatory drug, and/or anti-CD38 monoclonal antibody. Diffuse large B-cell lymphoma Note:this includes patients with histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma)-approve if the patient has tried at least two prior therapies. B-Cell lymphoma-approve if (A and B): A) pt has high-grade B-cell lymphoma or HIV-related B-cell lymphoma or post-transplant lymphoproliferative disorders and B) has tried at least two prior therapies.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses**Part B Prerequisite**

Treatment of multiple myeloma in combination with daratumumab or pomalidomide, B-cell lymphoma

No

Prerequisite Therapy Required

Yes

Drugs

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

Exclusion Criteria

Required Medical Information

Diagnosis for which Xtandi is being used.

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

Authorization will be for 1 year.

Other Criteria

Prostate cancer-castration-resistant [Metastatic or Non-metastatic] and Prostate cancer-metastatic, castration sensitive-approve if Xtandi will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog [for example: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy. Prostate cancer- Non-Metastatic, Castration-Sensitive - approve if pt has biochemical recurrence and is at high risk for metastasis. [Note: High-risk biochemical recurrence is defined as prostate-specific antigen (PSA) doubling time less than or equal to 9 months.]

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

sodium oxybate

Exclusion Criteria

Concomitant use with Xywav, Wakix or Sunosi

Required Medical Information

Medication history (as described in Other Criteria field)

Age Restriction

7 years and older

Prescriber Restriction

Prescribed by a sleep specialist physician or a Neurologist

Coverage Duration

12 months.

Other Criteria

For Excessive daytime sleepiness (EDS) in patients with narcolepsy - narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Patients requesting sodium oxybate who are 18 years or older-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil. Patients less than 18 years old requesting sodium oxybate-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextramphetamine) or modafinil. Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

Drugs

ZEJULA ORAL TABLET

Exclusion Criteria

Required Medical Information

Age Restriction

18 years and older

Prescriber Restriction

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 one systemic regimen. In addition, patients new to therapy must have a trial of Lynparza prior to approval of Zejula.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Uterine Leiomyosarcoma

No

Prerequisite Therapy Required

Yes

Drugs

ZELBORAF

Exclusion Criteria

Required Medical Information

BRAFV600 mutation status required.

Age Restriction

All diagnoses (except CNS cancer)-18 years and older

Prescriber Restriction

Coverage Duration

Authorization will be for 1 year.

Other Criteria

Melanoma, patient new to therapy 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 the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, c or d): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) 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 the medication will be taken in combination with Cotellic (cobimetinib tablets). Histiocytic Neoplasm-approve if the patient has Langerhans cell histiocytosis AND the patient has BRAF V600-mutation positive disease.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

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

No

Prerequisite Therapy Required

Yes

ZOLINZA

Drugs

ZOLINZA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

Classic Hodgkin Lymphoma-18 years and older

Prescriber Restriction

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

Part B Prerequisite

Classic Hodgkin Lymphoma

No

Prerequisite Therapy Required

No

Drugs

ZTALMY

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

2 years and older

Prescriber Restriction

Prescribed by or in consultation with a neurologist

Coverage Duration

1 year

Other Criteria

Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder-approve if the patient has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene and patient has tried or is concomitantly receiving two other antiepileptic drugs.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

Yes

ZURZUVAE

Drugs

ZURZUVAE ORAL CAPSULE 20 MG, 25 MG, 30 MG

Exclusion Criteria

Previous treatment with Zurzuvae during the current episode of postpartum depression

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

Prescribed by or in consultation with a psychiatrist or an obstetrician-gynecologist

Coverage Duration

14 days

Other Criteria

Postpartum depression-approve if the patient meets the following (A, B and C): A.Patient meets BOTH of the following (i and ii): i. Patient has been diagnosed with severe depression, AND ii. Symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery, AND B. Patient is less than or equal to 12 months postpartum, AND C. Patient is not currently pregnant.

Indications

All FDA-approved Indications.

Off Label Uses

Part B Prerequisite

No

Prerequisite Therapy Required

No

Drugs

ZYDELIG

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration

Authorization will be for 1 year

Other Criteria

CLL/SLL-approve if the patient has tried at least one Bruton tyrosine kinase inhibitor (examples: ibrutinib, zanubrutinib, acalabrutinib, pirtobrutinib) and at least one Venclexta (venetoclax)-based regimen.

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

small lymphocytic lymphoma

No

Prerequisite Therapy Required

Yes

Drugs

ZYKADIA

Exclusion Criteria

Required Medical Information

Diagnosis

Age Restriction

18 years and older

Prescriber Restriction

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 or Lorbrena prior to approval of Zykadia. NSCLC, ROS1 Rearrangement-approve if the patient has advanced or metastatic disease. Peripheral T-Cell Lymphoma- approve if patient has ALK-positive anaplastic large cell lymphoma (ALCL).

Indications

All FDA-approved Indications, Some Medically-accepted Indications.

Off Label Uses

Part B Prerequisite

Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Patients with NSCLC with ROS1 Rearrangement. Erdheim-Chester disease. Peripheral T-Cell Lymphoma.

No

Prerequisite Therapy Required

Yes

ZYMFENTRA

Drugs

ZYMFENTRA

Exclusion Criteria

Concurrent use with a biologic or with a targeted synthetic disease-modifying antirheumatic drug (DMARD).

Required Medical Information

Diagnosis

Age Restriction

18 years and older (initial therapy)

Prescriber Restriction

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

Prerequisite Therapy Required

No

Drugs

abiraterone oral tablet 250 mg, 500 mg, ABIRTEGA

Exclusion Criteria

Required Medical Information

Age Restriction

18 years and older

Prescriber Restriction

Coverage Duration

Authorization will be for 1 year.

Other Criteria

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

Part B Prerequisite

Prostate Cancer-Regional Risk Group, Prostate cancer-very-high-risk group, Prostate cancer- radical prostatectomy or post radiation, Salivary Gland Tumors

No

Prerequisite Therapy Required

No

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