

ABIRATERONE

Products Affected

- *abiraterone acetate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Castration-resistant metastatic prostate cancer (CRPC), or B.) High risk, castration-sensitive metastatic prostate cancer (CSPC). For treatment of CRPC and CSPC, abiraterone will be used in combination with prednisone AND one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog (e.g. leuprolide, triptorelin), OR 2) Patient has received bilateral orchiectomy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ACITRETIN

Products Affected

- *acitretin*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Severely impaired liver or kidney function, B.) Chronic abnormally elevated blood lipid values, C.) Concomitant use of methotrexate or tetracyclines, D.) Pregnancy
Required Medical Information	Diagnosis of severe, recalcitrant psoriasis (including plaque, guttate, erythrodermic palmar- plantar and pustular) AND patient must have tried and failed, contraindication or intolerance to one formulary first line agent (e.g., Topical Corticosteroids (betamethasone, fluocinonide, desoximetasone), Topical Calcipotriene/Calcitriol, Topical Calcipotriene, OR Topical Tazarotene)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ACTIMMUNE

Products Affected

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic granulomatous disease for use in reducing the frequency and severity of serious infections, or B.) Severe, malignant osteopetrosis (SMO)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ADEMPAS

Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant administration with nitrates or nitric oxide donors (such as amyl nitrate) in any form, B.) Concomitant administration with phosphodiesterase inhibitors, including specific PDE-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or non-specific PDE inhibitors (such as dipyridamole or theophylline), C.) Pregnancy, or D.) Patients with pulmonary hypertension associated with idiopathic interstitial pneumonia
Required Medical Information	Diagnosis of one of the following A.) Pulmonary arterial hypertension (WHO group I) and diagnosis was confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.), or B.) Chronic thromboembolic pulmonary hypertension (CTEPH, WHO group 4) and patient has persistent or recurrent disease after surgical treatment (e.g., pulmonary endarterectomy) or has CTEPH that is inoperable (Female patients must be enrolled in the ADEMPAS REMS program)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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AKEEGA

Products Affected

- AKEEGA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) AND used in combination with prednisone
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ALECENSA

Products Affected

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ALPHA-1 PROTEINASE INHIBITOR

Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Immunoglobulin A (IgA) deficiency with antibodies against IgA
Required Medical Information	Diagnosis of alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency in adult patients with emphysema
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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ALUNBRIG

Products Affected

- ALUNBRIG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of anaplastic lymphoma kinase-positive (ALK) metastatic non-small cell lung cancer (NSCLC)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ALVAIZ

Products Affected

- ALVAIZ

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic idiopathic thrombocytopenic purpura (ITP), B.) Chronic hepatitis C infection associated thrombocytopenia, or C.) Severe aplastic anemia with insufficient response to immunosuppressive therapy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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AMBRISENTAN

Products Affected

- *ambrisentan*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Pregnancy, or B.) Idiopathic pulmonary fibrosis (IPF), including those with pulmonary hypertension
Required Medical Information	Diagnosis of pulmonary arterial hypertension classified as WHO Group I, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ARCALYST

Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells Syndrome (MWS), B.) Deficiency of interleukin-1 receptor antagonist (DIRA) and patient requires maintenance therapy for remission, or C.) Recurrent pericarditis (RP) and reduction in risk of recurrence
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ARIKAYCE

Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	Known sensitivity to any aminoglycoside
Required Medical Information	Diagnosis of pulmonary Mycobacterium avium complex (MAC) infection and used as part of a combination antibacterial regimen in treatment refractory patients (greater than 6 months of a multidrug background regimen)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist or pulmonologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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AUGTYRO

Products Affected

- AUGTYRO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Locally advanced or metastatic ROS1-positive non-small cell lung cancer, or B.) solid tumors that have an NTRK gene fusion are locally advanced, metastatic, or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy
Age Restrictions	12 years or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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AURYXIA

Products Affected

- AURYXIA

PA Criteria	Criteria Details
Exclusion Criteria	Iron overload syndrome (e.g. hemochromatosis)
Required Medical Information	Diagnosis of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or nephrologist
Coverage Duration	12 months
Other Criteria	Ferric Citrate is NOT approvable for iron deficiency anemia per Part D law
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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AUSTEDO

Products Affected

- AUSTEDO
- AUSTEDO XR ORAL TABLET
EXTENDED RELEASE 24 HOUR 12
MG, 24 MG, 6 MG
- AUSTEDO XR PATIENT TITRATION

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Suicidal ideation and/or untreated or inadequately treated depression in a patient with Huntington's Disease, B.) Hepatic impairment, C.) Concomitant use of MAOIs, reserpine, tetrabenazine, or valbenazine
Required Medical Information	Diagnosis of one of the following A.) Chorea associated with Huntington's disease (Huntington's chorea), or B.) Tardive dyskinesia
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or psychiatrist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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AYVAKIT

Products Affected

- AYVAKIT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Unresectable or metastatic gastrointestinal stromal tumor, with a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations, B.) Advanced Systemic Mastocytosis (AdvSM), including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), or mast cell leukemia (MCL), and platelet count of at least 50,000/mcL, or C.) Indolent systemic mastocytosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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BALVERSA

Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of locally advanced or metastatic urothelial carcinoma and both of the following 1.) Susceptible fibroblast growth factor receptor (FGFR)3 or FGFR2 genetic alterations confirmed by an FDA-approved diagnostic test, and 2.) Patient has progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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BENLYSTA

Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Active, autoantibody-positive, system lupus erythematosus (SLE), or B.) Active lupus nephritis and patient is receiving standard therapy
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or rheumatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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BESREMI

Products Affected

- BESREMI

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Existence of, or history of severe psychiatric disorders (severe depression, suicidal ideation, or suicide attempt), B.) Hypersensitivity to interferons including interferon alfa-2b or excipients, C.) Hepatic impairment (Child-Pugh B or C), D.) History or presence of active serious or untreated autoimmune disease, or E.) Immunosuppressed transplant recipients
Required Medical Information	Diagnosis of polycythemia vera
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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BEXAROTENE GEL

Products Affected

- *bexarotene external*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of primary cutaneous T-cell lymphoma (CTCL Stage 1A/1B) and patient had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) indicated for cutaneous manifestations of CTCL
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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BEXAROTENE ORAL

Products Affected

- *bexarotene oral*

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of cutaneous T-cell lymphoma (CTCL) and patient is not a candidate for or had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) for cutaneous manifestations of CTCL
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an dermatologist, hematologist, or oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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BOSENTAN

Products Affected

- *bosentan*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant cyclosporine A or glyburide therapy, or B.) Pregnancy
Required Medical Information	Diagnosis of pulmonary arterial hypertension (WHO Group I) and patient has New York Heart Association (NYHA) Functional Class II-IV, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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BOSULIF

Products Affected

- BOSULIF

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or inadequate response to prior therapy, or B.) Newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) CML
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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BRAFTOVI

Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) unresectable or metastatic melanoma with documented BRAF V600E or V600K mutation as detected by a FDA-approved test and used in combination with binimetinib, B.) metastatic colorectal cancer with documented BRAF V600E mutation as detected by a FDA-approved test, patient has received prior therapy, and braftovi used in combination with cetuximab, or C.) Metastatic non-small cell lung cancer with a BRAF V600E mutation as detected by an FDA-approved test and used in combination with binimetinib
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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BRONCHITOL

Products Affected

- BRONCHITOL

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Cystic fibrosis of the lung
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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BRUKINSA

Products Affected

- BRUKINSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following: A.) mantle cell lymphoma (MCL) and patient has received at least one prior therapy, B.) Treatment of adult patients with Waldenstrom macroglobulinemia, C.) Treatment of adult patients with relapsed or refractory marginal zone lymphoma who have received at least one anti-CD20-based regimen, D.) Chronic lymphocytic leukemia, E.) Small lymphocytic lymphoma, or F.) Relapsed or refractory follicular lymphoma, in combination with obinutuzumab, after 2 or more lines of systemic therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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BYLVAY

Products Affected

- BYLVAY
- BYLVAY (PELLETS)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Progressive familial intrahepatic cholestasis-associated pruritus, or B.) Cholestatic pruritus in patients with Alagille syndrome
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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CABLIVI

Products Affected

- CABLIVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) and used in combination with plasma exchange and immunosuppression therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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CABOMETYX

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Advanced hepatocellular carcinoma (HCC) and patient has been previously treated with sorafenib, C.) Advanced renal cell carcinoma and used as first line treatment in combination with nivolumab or D.) treatment of adults and pediatric patients 12 years and older with locally advanced or metastatic differentiated thyroid cancer that has progressed following VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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CALQUENCE

Products Affected

- CALQUENCE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Mantle cell lymphoma (MCL) and patient has received at least 1 prior therapy, B.) Chronic lymphocytic leukemia (CLL), or C.) Small lymphocytic lymphoma (SLL)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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CAMZYOS

Products Affected

- CAMZYOS

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) in adult patients
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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CAPRELSA

Products Affected

- CAPRELSA

PA Criteria	Criteria Details
Exclusion Criteria	Congenital long QT syndrome
Required Medical Information	Diagnosis of metastatic or unresectable locally advanced medullary thyroid cancer (MTC) AND disease is symptomatic or progressive
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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CARGLUMIC ACID

Products Affected

- *carglumic acid oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) N-acetyl glutamate synthase (NAGS) deficiency (confirmed by appropriate genetic testing) with acute or chronic hyperammonemia, or B.) Propionic or methylmalonic acidemia with acute hyperammonemia
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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CAYSTON

Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis (confirmed by appropriate diagnostic or genetic testing) and patient has Pseudomonas aeruginosa lung infection confirmed by positive culture
Age Restrictions	7 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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CNS STIMULANTS

Products Affected

- *armodafinil*
- *modafinil oral*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Obstructive sleep apnea (OSA) confirmed by sleep lab evaluation, B.) Narcolepsy confirmed by sleep lab evaluation, or C.) Shift work disorder (SWD)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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COMETRIQ

Products Affected

- COMETRIQ (100 MG DAILY DOSE)
ORAL KIT 80 & 20 MG
- COMETRIQ (140 MG DAILY DOSE)
ORAL KIT 3 X 20 MG & 80 MG
- COMETRIQ (60 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of progressive, metastatic medullary thyroid cancer
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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COPIKTRA

Products Affected

- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsed or refractory chronic lymphocytic leukemia (CLL), or B.) Relapsed or refractory small lymphocytic lymphoma (SLL). For CLL or SLL, the patient must have history of at least 2 prior therapies
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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CORLANOR

Products Affected

- CORLANOR ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Decompensated acute heart failure, B.) hypotension (i.e. blood pressure less than 90/50 mmHg), C.) sick sinus syndrome or sinoatrial block or 3rd degree AV block (unless a functioning demand pacemaker is present), D.) bradycardia (i.e., resting heart rate less than 60 bpm prior to treatment), E.) Severe hepatic impairment (Child-Pugh C), F.) Pacemaker dependent (heart rate maintained exclusively by the pacemaker), G.) Concomitant use of strong CYP3A4 inhibitors
Required Medical Information	Diagnosis of one of the following A.) Adult patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction 35% or less, who are in sinus rhythm with resting heart rate 70 beats per minute or more and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use, or B.) Pediatric patients with stable, symptomatic heart failure due to dilated cardiomyopathy and are in sinus rhythm with an elevated heart rate
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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COSENTYX

Products Affected

- COSENTYX (300 MG DOSE)
- COSENTYX SENSOREADY (300 MG)
- COSENTYX SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 75 MG/0.5ML
- COSENTYX UNOREADY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Ankylosing spondylitis and patient has trial and failure, contraindication, or intolerance to two preferred products, (i.e. Enbrel, Humira, Rinvoq), B.) Moderate to severe plaque psoriasis in adults and patient has trail and failure, contraindication, or intolerance to two preferred products, (i.e. Enbrel, Humira, Skyrizi, Stelara), C.) Moderate to severe plaque psoriasis in patients 6 years to less than 18 years of age and patient has trial and failure, contraindication, or intolerance to two preferred products, (i.e. Enbrel, Stelara), D.) Active psoriatic arthritis in adult patient and has trial and failure, contraindication, or intolerance to two preferred products, (i.e. Enbrel, Humira, Rinvoq, Skyrizi, Stelara), E.) Active psoriatic arthritis in patients 2 years to less than 18 years of age, F.) Non-radiographic axial spondyloarthritis and patient has trail and failure, contraindication, or intolerance to one preferred product, (i.e. Rinvoq), G.) Active enthesitis-related arthritis, or H.) Moderate to severe hidradenitis suppurativa in adults and patient has trial and failure, contraindication, or intolerance to one preferred product, (i.e. Humira)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment

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

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COTELLIC

Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.)unresectable or metastatic malignant melanoma with BRAF V600E OR V600K mutation, and documentation of combination therapy with vemurafenib (Zelboraf), or B.) Histiocytic neoplasms
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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CYSTAGON

Products Affected

- CYSTAGON

PA Criteria	Criteria Details
Exclusion Criteria	Known serious hypersensitivity to penicillamine or cysteamine
Required Medical Information	Diagnosis of nephropathic cystinosis confirmed by the presence of increased cystine concentration in leukocytes or by genetic testing
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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CYSTEAMINE OPHTH

Products Affected

- CYSTADROPS
- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystinosis and patient has corneal cystine crystal accumulation
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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DALFAMPRIDINE

Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) History of seizure. B.) Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute)
Required Medical Information	Diagnosis of multiple sclerosis and patient must demonstrate sustained walking impairment, but with the ability to walk 25 feet (with or without assistance) prior to starting dalfampridine
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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DAURISMO

Products Affected

- DAURISMO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of newly diagnosed acute myeloid leukemia (AML) and used in combination with cytarabine in patients 75 years of age or older OR in patients that have comorbidities that preclude use of intensive induction chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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DAYBUE

Products Affected

- DAYBUE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Rett syndrome
Age Restrictions	2 years of age and older
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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DEFERASIROX

Products Affected

- *deferasirox granules*
- *deferasirox oral tablet*
- *deferasirox oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Creatinine clearance less than 40 mL/min, B.) Poor performance status, C.) Platelet count less than 50 x 10 ⁹ /L, D.) Advanced malignancy, E.) High-risk myelodysplastic syndrome (MDS)
Required Medical Information	Diagnosis of one of the following A.) Chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes who have liver iron concentrations of at least 5 mg Fe/g dry weight AND serum ferritin level greater than 300 mcg/L, or B.) Chronic iron overload due to blood transfusions (transfusion hemosiderosis) as evidenced by transfusion of at least 100 mL/kg packed red blood cells AND serum ferritin level greater than 1000 mcg/L
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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DEFERIPRONE

Products Affected

- *deferiprone*
- FERRIPROX TWICE-A-DAY
- FERRIPROX ORAL SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) Diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease, or other anemias, 2.) Patient has failed prior chelation therapy, and 3.) Patient has an absolute neutrophil count greater than $1.5 \times 10^9/L$
Age Restrictions	3 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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DIACOMIT

Products Affected

- DIACOMIT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of severe myoclonic epilepsy in infancy (Dravet syndrome) in patients taking clobazam
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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DICLOFENAC TOPICAL

Products Affected

- *diclofenac sodium external gel 3 %*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Actinic keratosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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DIFICID

Products Affected

- DIFICID

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of diarrhea associated with clostridioides difficile infection and patient has had an inadequate treatment response, intolerance, or contraindication to generic oral vancomycin
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	4 weeks
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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DIMETHYL FUMARATE

Products Affected

- *dimethyl fumarate oral*
- *dimethyl fumarate starter pack oral capsule delayed release therapy pack*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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DOJOLVI

Products Affected

- DOJOLVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Long-chain fatty acid oxidation disorder (LC-FAOD)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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DRONABINOL

Products Affected

- *dronabinol*

PA Criteria	Criteria Details
Exclusion Criteria	Sesame oil hypersensitivity
Required Medical Information	Diagnosis of one of the following A.) Anorexia associated to AIDS, or B.) Chemotherapy-induced nausea and vomiting
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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DROXIDOPA

Products Affected

- *droxidopa*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure (e.g., Parkinson disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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DUPIXENT

Products Affected

- DUPIXENT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe atopic dermatitis and if patient is 2 years or older has trial/failure, contraindication, or intolerance to two of the following 1.) Topical corticosteroid and/or 2.) Topical calcineurin inhibitor, B.) Eosinophilic phenotype or oral corticosteroid-dependent moderate to severe asthma and used as an adjunct treatment, or C.) Chronic rhinosinusitis with nasal polyposis and used as an adjunct treatment, D.) Eosinophilic esophagitis, or E.) Prurigo nodularis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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EMGALITY

Products Affected

- EMGALITY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic or episodic migraine disorder and patient has documented trial, inadequate response, or contraindication to at least 2 generic formulary drugs used for migraine prevention (i.e., propranolol, topiramate, divalproex, timolol), or B.) Episodic cluster headache
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ENBREL

Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5ML
- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- ENBREL SURECLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, or E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ENDARI

Products Affected

- ENDARI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of sickle cell disease AND one of the following 1.) Patient has acute complications and is being treated with Hydroxyurea, or 2.) Patient has acute complications and is unable to tolerate Hydroxyurea
Age Restrictions	5 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ENSPRYNG

Products Affected

- ENSPRYNG

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Active Hepatitis B infection, or B.) Active or untreated latent tuberculosis
Required Medical Information	Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, immunologist, or ophthalmologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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EPIDIOLEX

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Lennox-Gastaut syndrome, B.) Severe myoclonic epilepsy in infancy (Dravet syndrome), or C.) Seizures associated with tuberous sclerosis complex (TSC)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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EPOETIN THERAPY

Products Affected

- RETACRIT INJECTION SOLUTION UNIT/ML, 4000 UNIT/ML, 40000
10000 UNIT/ML, 10000 UNIT/ML(1ML), UNIT/ML
2000 UNIT/ML, 20000 UNIT/ML, 3000

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Non-myeloid neoplastic disease and utilized for the treatment of chemotherapy induced anemia, B.) HIV infection and utilized for the treatment of zidovudine induced anemia, C.) Chronic kidney disease resulting in anemia, or D.) High risk surgical candidate status at risk for perioperative blood loss and undergoing elective, noncardiac, or nonvascular surgery
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ERIVEDGE

Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Metastatic basal cell carcinoma, or B.) Locally advanced basal cell carcinoma that has recurred following surgery or the patient is not a candidate for surgery or radiation
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ERLEADA

Products Affected

- ERLEADA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Nonmetastatic, castration-resistant prostate cancer (nmCRPC), or B.) Metastatic, castration-sensitive prostate cancer (mCSPC). For treatment of nmCRPC and mCSPC, one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog, OR 2) Patient has received bilateral orchiectomy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ERLOTINIB

Products Affected

- *erlotinib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Locally advanced, unresectable, or metastatic pancreatic cancer and erlotinib will be used in combination with gemcitabine, B.) Locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility AND one of the following 1.) Erlotinib will be used as first-line treatment, 2.) Failure with at least one prior chemotherapy regimen, or 3.) No evidence of disease progression after four cycles of first-line platinum-based chemotherapy and erlotinib will be used as maintenance treatment
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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EVEROLIMUS

Products Affected

- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Hypersensitivity to everolimus or excipients, or B.) Hypersensitivity to rapamycin derivatives (e.g. sirolimus)
Required Medical Information	Diagnosis of one of the following A.) Renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery, B.) Advanced hormone receptor-positive, HER2 negative breast cancer in postmenopausal women and taken in combination with exemestane, after failure with letrozole or anastrozole, C.) Progressive, well-differentiated, nonfunctional neuroendocrine tumors of gastrointestinal or lung origin and disease is unresectable, locally advanced, or metastatic, D.) Pancreatic progressive neuroendocrine tumors and disease is unresectable, locally advanced, or metastatic, E.) Advanced renal cell carcinoma (RCC) after failure with sunitinib or sorafenib, F.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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EVEROLIMUS SUSPENSION

Products Affected

- *everolimus oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Hypersensitivity to everolimus , or B.) Hypersensitivity to rapamycin derivatives (e.g. sirolimus)
Required Medical Information	Diagnosis of one of the following A.) Tuberous sclerosis complex (TSC)-associated partial-onset seizures, or B.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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EVRYSDI

Products Affected

- EVRYSDI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of spinal muscular atrophy (SMA)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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FEBUXOSTAT

Products Affected

- *febuxostat*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of azathioprine or mercaptopurine
Required Medical Information	Diagnosis of Gout and all of the following 1.) documented inadequate treatment response, adverse event, or contraindication to maximally titrated dose of Allopurinol, and 2.) patients with established cardiovascular disease, prescriber attests that benefit of treatment outweighs the risk of treatment
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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FENTANYL ORAL

Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Management of acute or postoperative pain (including headache/migraine, dental pain, and use in the emergency room), B.) Use in opioid non-tolerant patients, C.) Known or suspected gastrointestinal obstruction, including paralytic ileus, D.) Acute or severe bronchial asthma and used in an unmonitored setting (absence of resuscitative equipment)
Required Medical Information	Must meet all of the following 1.) Diagnosis of cancer-related breakthrough pain, 2.) Patient is currently receiving/tolerant to around-the-clock opioid therapy for persistent cancer pain, and 3.) Patient and prescriber are enrolled in the TIRF REMS Access Program
Age Restrictions	16 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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FENTANYL PATCH

Products Affected

- *fentanyl*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Management of acute or postoperative pain (including headache/migraine, dental pain, and use in the emergency room), B.) Mild or intermittent pain management, C.) Use in opioid non-tolerant patients, D.) Known or suspected gastrointestinal obstruction, including paralytic ileus, E.) Acute or severe bronchial asthma and used in an unmonitored setting (absence of resuscitative equipment)
Required Medical Information	Must meet all of the following 1.) Patient is opioid tolerant (taking for one week or longer at least 60mg of morphine or equivalent daily) and 2.) Patient has tried at least one extended release oral opioids or is unable to take extended release oral opioids secondary to allergy, adverse events, swallowing difficulty, or uncontrollable nausea/vomiting
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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FILSPARI

Products Affected

- FILSPARI

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Pregnancy or B.) Concomitant use with angiotensin receptor blockers (ARBs), endothelin receptor antagonists (ERAs), or aliskiren
Required Medical Information	Diagnosis of treatment of primary immunoglobulin A (IgA) nephropathy at risk of rapid disease progression, generally a urine protein to creatinine ratio (UPCR) of 1.5 g/g or more, to reduce proteinuria
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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FINGOLIMOD

Products Affected

- *fingolimod hcl*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure, B.) History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker, C.) Baseline QTC interval greater than or equal to 500 milliseconds, D.) Receiving concurrent treatment with Class Ia or Class III anti-arrhythmic drugs (quinidine, procainamide, amiodarone, sotalol)
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	10 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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FINTEPLA

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI
Required Medical Information	Diagnosis of Severe myoclonic epilepsy in infancy (Dravet syndrome) or seizures associated with Lennox-Gastaut syndrome
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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FIRMAGON

Products Affected

- FIRMAGON (240 MG DOSE)
- FIRMAGON SUBCUTANEOUS SOLUTION RECONSTITUTED 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	none
Required Medical Information	Diagnosis of advanced prostate cancer
Age Restrictions	none
Prescriber Restrictions	none
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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FOTIVDA

Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of relapsed or refractory advanced renal cell cancer (RCC) following 2 or more prior systemic therapies
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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FRUZAQLA

Products Affected

- FRUZAQLA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic colorectal cancer (mCRC) and all of the following: A.) patient has been previously treated with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapy, B.) an anti-VEGF therapy, and C.) if RAS wild-type and medically appropriate, patient has also been previously treated with anti-EGFR therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	3 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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GALAFOLD

Products Affected

- GALAFOLD

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Fabry disease with an amenable galactosidase alpha gene (GLA) mutation
Age Restrictions	16 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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GATTEX

Products Affected

- GATTEX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of short bowel syndrome and patient is dependent on parenteral support
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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GAVRETO

Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test, B.) Advanced or metastatic RET-mutant medullary thyroid cancer and patient requires systemic therapy, or C.) Advanced or metastatic RET fusion-positive thyroid and patient requires systemic therapy and is radioactive iodine-refractory, when radioactive iodine is appropriate
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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GEFITINIB

Products Affected

- *gefitinib*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic non-small cell lung cancer (NSCLC) and must meet all of the following 1.) Tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility and 2.) Used as first-line treatment
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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GILOTRIF

Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test, or B.) Metastatic squamous NSCLC with progression after platinum-based chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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GLATIRAMER

Products Affected

- COPAXONE SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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GLEOSTINE

Products Affected

- GLEOSTINE ORAL CAPSULE 10 MG, 100 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet one of the following: A.) Hodgkin's disease in patient who has relapsed during or failed to respond to primary therapy and is being used in combination with other agents OR B.) Intracranial tumor
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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GLP1

Products Affected

- MOUNJARO
- OZEMPIC (0.25 OR 0.5 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 2 MG/3ML
- OZEMPIC (1 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 4 MG/3ML
- OZEMPIC (2 MG/DOSE)
- RYBELSUS
- TRULICITY
- VICTOZA SUBCUTANEOUS SOLUTION PEN-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) The drug is prescribed for an FDA-approved indication, 2.) For a diagnosis of Type 2 Diabetes Mellitus the patient has a trial and failure, contraindication or intolerance to metformin or any metformin combination product
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 monthd
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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GROWTH HORMONE

Products Affected

- OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE
- OMNITROPE SUBCUTANEOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Use for growth promotion in pediatric patients with closed epiphyses, B.) Acute critical illness caused by complications following open-heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure, C.) Active malignancy, D.) Active proliferative or severe nonproliferative diabetic retinopathy, E.) Prader-Willi Syndrome in patients who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment
Required Medical Information	Diagnosis of pediatric indication: A.) GHD and bone age at least 1 year or 2 standard deviations (SD) delayed compared with chronological age and 2 stim tests with peak GH secretion below 10 ng/mL or IGF-1/IGFBP3 level more than 2 SDS below mean if CNS pathology, h/o irradiation, or proven genetic cause, B.) SGA and birth weight or length 2 or more SDS below mean for gestational age and fails to manifest catch up growth by age 2 (height 2 or more SDS below mean for age and gender), C.) CRI and metabolic abnormalities have been corrected, and patient has not had renal transplant D.) SHOX deficiency or Noonan syndrome E.) PWS confirmed by genetic testing, F.) Turner Syndrome confirmed by chromosome analysis. For GHD, CRI, SHOX deficiency, Noonan syndrome, and PWS one of the following height more than 3 SDS below mean for age and gender, or height more than 2 SDS below mean with GV more than 1 SDS below mean, or GV over 1 year 2 SDS below mean. OR Diagnosis of an adult indication: A.) childhood- or adult-onset GHD confirmed by 2 standard GH stim tests (provide assay): 1 test must be insulin tolerance test (ITT) with blood glucose nadir less than 40 mg/dL (2.2 mmol/L). If contraindicated, use a standardized stim test (i.e. arginine plus GH releasing hormone [preferred], glucagon, arginine), B.) GHD with at least 1 other pituitary hormone deficiency and failed at least 1 GH stim test (ITT preferred), C.) GHD with panhypopituitarism (3 or more pituitary hormone deficiencies), D.) GHD with irreversible hypothalamic-pituitary structural lesions due to tumors, surgery or radiation of pituitary or hypothalamus region AND a subnormal IGF-1 (after at least 1 month off GH therapy) AND Objective evidence of GHD complications, such as: low bone

Formulary ID: 24447 version 15
 Last Updated: 07/24/2024
 Effective: 08/01/2024

PA Criteria	Criteria Details
	density, increased visceral fat mass, or cardiovascular complications AND Completed linear growth (GV less than 2 cm/year) AND GH has been discontinued for at least 1 month (if previously receiving GH)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or nephrologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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HEPATITIS C

Products Affected

- MAVYRET
- *sofosbuvir-velpatasvir*
- VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of HCV genotype, subtype and quantitative HCV RNA (viral load) testing any time prior to therapy. Must document cirrhosis status, prior treatment history (if any), and planned duration of treatment. All genotypes will require trial/failure, contraindication to, or intolerance to Mavyret or Sofosbuvir-Velpatasvir prior to the approval of Vosevi. Genotype and subtype are not required for: (1) initial treatment of patients without cirrhosis if using Sofosbuvir-Velpatasvir or Mavyret OR (2) treatment of patients with compensated cirrhosis if using Mavyret
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
Coverage Duration	Duration of approval per AASLD Guidelines
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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HUMIRA

Products Affected

- HUMIRA (2 PEN)
- HUMIRA (2 SYRINGE)
SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML
- HUMIRA-CD/UC/HS STARTER
SUBCUTANEOUS PEN-INJECTOR KIT 80 MG/0.8ML
- HUMIRA-PED \geq 40KG UC STARTER
- HUMIRA-PSORIASIS/UVEIT STARTER

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate, F.) Moderate to severe Crohn's disease in patients who have had an inadequate response to conventional therapy, G.) Moderate to severe ulcerative colitis in patients who have had an inadequate response to immunosuppressants (e.g. corticosteroids, azathioprine), H.) Non-infectious uveitis (including intermediate, posterior, and panuveitis), or I.) Moderate to severe hidradenitis suppurativa
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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PA Criteria	Criteria Details
Part B Prerequisite	No

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HYFTOR

Products Affected

- HYFTOR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Facial angiofibroma associated with tuberous sclerosis
Age Restrictions	6 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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IBRANCE

Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer used in combination with fulvestrant and disease has progressed following endocrine therapy, or B.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and used in combination with an aromatase inhibitor in a male or female patient as initial endocrine-based therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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ICATIBANT

Products Affected

- *icatibant acetate subcutaneous solution prefilled syringe*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following and used as treatment for acute attacks A.) Hereditary angioedema (HAE) with C1 inhibitor deficiency (Type 1) confirmed by laboratory testing, or B.) HAE with C1 inhibitor dysfunction (Type 2) confirmed by laboratory testing, or C.) HAE with normal C1 inhibitor (Type 3) confirmed by laboratory testing and one of the following 1.) Positive test for an F12, angiopoietin-1, or plasminogen gene mutation, or 2.) Family history of angioedema and the angioedema was refractory to a trial of an antihistamine for at least one month
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist, hematologist, or immunologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ICLUSIG

Products Affected

- ICLUSIG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) in adult patients who are T315I-positive or for whom no other tyrosine kinase inhibitor therapy is indicated, B.) Chronic phase, chronic myeloid leukemia (CML) in adult patients with resistance or intolerance to at least two prior kinase inhibitors, or C.) Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in adult patients who are T315I-positive or for whom no other tyrosine kinase inhibitor therapy is indicated
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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IDHIFA

Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase 2 (IDH2) mutation as detected by an FDA approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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IMATINIB

Products Affected

- *imatinib mesylate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), B.) Ph+ acute lymphoblastic leukemia (ALL), C.) Gastrointestinal stromal tumor (GIST) where patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST or patient had resection of c-KIT positive GIST and imatinib will be used as an adjuvant therapy, D.) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic, E.) Hypereosinophilic syndrome or chronic eosinophilic leukemia, F.) Myelodysplastic syndrome or myeloproliferative disease associated with platelet-derived growth factor receptor gene re-arrangements, or G.) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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IMBRUVICA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL), B.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion, C.) Waldenstrom's macroglobulinemia (WM), or D.) Chronic graft vs host disease (cGVHD) after failure of at least one first-line corticosteroid therapy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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INBRIJA

Products Affected

- INBRIJA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concurrent use with nonselective monoamine oxidase inhibitors (MAOIs) (e.g. phenelzine and tranylcypromine), B.) Recent use (within 2 weeks) with a nonselective MAOI
Required Medical Information	Must meet all of the following A.) Diagnosis of Parkinson's disease and used for intermittent treatment of off episodes, and B.) Concurrent therapy with carbidopa/levodopa
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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INCRELEX

Products Affected

- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Active or suspected malignancy, B.) Use for growth promotion in patients with closed epiphyses, or C.) Intravenous administration
Required Medical Information	Diagnosis of one of the following A.) Severe primary insulin-like growth factor-1 (IGF-1) deficiency and utilized for pediatric treatment of growth failure, or B.) Growth hormone (GH) gene deletion and patient has developed neutralizing antibodies to GH and utilized for pediatric treatment of growth failure
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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INLYTA

Products Affected

- INLYTA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Advanced renal cell carcinoma and patient failed one or more systemic therapies for renal cell carcinoma (e.g., sunitinib-, bevacizumab-, temsirolimus-, or cytokine-containing regimens), or B.) Advanced renal cell carcinoma and used as first-line therapy in combination with avelumab or pembrolizumab
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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INQOVI

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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INREBIC

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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INTRAROSA

Products Affected

- INTRAROSA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Vaginal bleeding or dysfunctional uterine bleeding of an undetermined origin, or B.) Known or suspected estrogen-dependent neoplasia
Required Medical Information	Diagnosis of one of the following A.) moderate to severe dyspareunia due to menopause, or B.) atrophic vaginitis due to menopause
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Initial: 3 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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ISTURISA

Products Affected

- ISTURISA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Cushing's disease in patients for whom pituitary surgery is not an option or has not been curative
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ITRACONAZOLE

Products Affected

- *itraconazole oral*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Ventricular dysfunction (e.g., congestive heart failure (CHF) or history of CHF), B.) Concurrent therapy with a CYP3A4 substrate (e.g., methadone, lovastatin, simvastatin, etc.), C.) Concurrent use of CYP2D6 inhibitors (e.g., bupropion, fluoxetine, paroxetine, quinidine, terbinafine), D.) Renal or hepatic impairment and concomitant use of colchicine, fesoterodine, solifenacin, or telithromycin, E.) Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), or B.) Onychomycosis confirmed by one of the following: positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ITRACONAZOLE SOLN

Products Affected

- *itraconazole oral*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Ventricular dysfunction (e.g., congestive heart failure (CHF) or history of CHF), B.) Concurrent therapy with a CYP3A4 substrate (e.g., methadone, lovastatin, simvastatin, etc.), C.) Concurrent use of CYP2D6 inhibitors (e.g., bupropion, fluoxetine, paroxetine, quinidine, terbinafine), D.) Renal or hepatic impairment and concomitant use of colchicine, fesoterodine, solifenacin, or telithromycin, E.) Pregnancy
Required Medical Information	Diagnosis of candidiasis (esophageal or oropharyngeal) that is refractory to treatment with fluconazole
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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IVERMECTIN

Products Affected

- *ivermectin oral*

PA Criteria	Criteria Details
Exclusion Criteria	Prevention or treatment of COVID-19
Required Medical Information	Diagnosis of one of the following: A.) Strongyloidiasis of the intestinal tract or B.) Onchocerciasis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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IWILFIN

Products Affected

- IWILFIN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of high-risk neuroblastoma to be used to reduce the risk of relapse in adult and pediatric patients who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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JAKAFI

Products Affected

- JAKAFI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis, B.) Polycythemia vera AND patient has had an inadequate response to or is intolerant of hydroxyurea, C.) Acute graft versus host disease AND disease is refractory to steroid therapy, or D.) Chronic graft-versus-host disease (cGVHD) after failure of corticosteroid therapy (alone or in combination with a calcineurin inhibitor) and up to one additional line of systemic therapy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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JAYPIRCA

Products Affected

- JAYPIRCA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) relapsed or refractory mantle cell lymphoma (MCL) and is being used after at least two lines of systemic therapy, including a BTK inhibitor or B.) chronic lymphocytic leukemia or small lymphocytic lymphoma who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase inhibitor and a B-cell lymphoma 2 inhibitor.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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JOENJA

Products Affected

- JOENJA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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JUXTAPID

Products Affected

- JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Moderate to severe liver impairment or active liver disease including unexplained persistent abnormal liver function tests, B.) Pregnancy, or C.) Concomitant use with strong or moderate CYP3A4 inhibitors
Required Medical Information	Diagnosis of HoFH as confirmed by one of the following A.) Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (LDLRAP1 or ARH), or B.) Both of the following 1.) Either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL, and 2.) Either xanthoma before 10 years of age or evidence of heterozygous FH in both parents
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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KALYDECO

Products Affected

- KALYDECO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis (CF) and the patient has 1 mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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KESIMPTA

Products Affected

- KESIMPTA

PA Criteria	Criteria Details
Exclusion Criteria	Active Hepatitis B infection
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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KINERET

Products Affected

- KINERET SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe active rheumatoid arthritis and patient has trial and failure, contraindication, or intolerance to two preferred products, (i.e. Humira, Enbrel), B.) Cryopyrin-associated periodic syndromes (i.e., neonatal-onset multisystem inflammatory disease), or C.) Deficiency of interleukin-1 receptor antagonist
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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KISQALI

Products Affected

- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and one of the following A.) The patient is a pre-or perimenopausal woman or man and the requested drug will be used in combination with an aromatase inhibitor as initial endocrine-based therapy, B.) The patient is a postmenopausal woman or man, the requested drug will be used in combination with an aromatase inhibitor as initial endocrine-based therapy, and the patient has experienced disease progression, an intolerable adverse event, or contraindication to Ibrance (palbociclib) or Verzenio (abemaciclib), C.) The patient is a pre-or perimenopausal woman or man and the requested drug is being used with fulvestrant as initial endocrine-based therapy, or D.) The patient is a postmenopausal woman or man, the requested drug is being used following disease progression on endocrine therapy, and the patient has experienced disease progression, an intolerable adverse event, or contraindication to Ibrance (palbociclib) or Verzenio (abemaciclib)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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KISQALI FEMARA

Products Affected

- KISQALI FEMARA (200 MG DOSE)
- KISQALI FEMARA (400 MG DOSE)
- KISQALI FEMARA (600 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and one of the following A.) The patient is pre-or perimenopausal woman or male and the requested drug will be used as initial endocrine-based therapy, B.) The patient is postmenopausal, the requested drug will be used as initial endocrine-based therapy, and the patient has experienced disease progression, an intolerable adverse event, or contraindication to Ibrance (palbociclib) or Verzenio (abemaciclib)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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KOSELUGO

Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of neurofibromatosis type 1 (NF1) in a patient who has symptomatic, inoperable plexiform neurofibromas (PN)
Age Restrictions	2 years of age to 17 years of age
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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KRAZATI

Products Affected

- KRAZATI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) as determined by an FDA-approved test and patient has received at least one prior systemic therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LAPATINIB

Products Affected

- *lapatinib ditosylate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced or metastatic breast cancer with tumors that overexpress human epidermal growth factor receptor 2 (HER2) AND meets one of the following A.) Used in combination with capecitabine in a patient who has received prior therapy including an anthracycline, a taxane, and trastuzumab, OR B.) Used in combination with letrozole in a postmenopausal female for whom hormonal therapy is indicated
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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LENALIDOMIDE

Products Affected

- *lenalidomide*

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Multiple myeloma and medication will be used in combination with dexamethasone, B.) Autologous hematopoietic stem-cell transplantation (HSCT) in multiple myeloma patients, C.) Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality or without additional cytogenetic abnormalities, D.) Mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib, E.) Follicular lymphoma and used in combination with rituximab, or F.) Marginal zone lymphoma and used in combination with rituximab
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LENVIMA

Products Affected

- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)
- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer, B.) Advanced renal cell carcinoma, in combination with everolimus, following one prior anti-angiogenic therapy, C.) Unresectable hepatocellular carcinoma, first-line therapy, D.) Advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient, in combination with pembrolizumab, when disease has progressed following prior systemic therapy and patient is not a candidate for curative surgery or radiation, or E.) Advanced renal cell carcinoma, in combination with pembrolizumab and used as first-line therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LEUKINE

Products Affected

- LEUKINE INJECTION SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Patient has undergone allogeneic or autologous bone marrow transplant (BMT) and engraftment is delayed or failed, B.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, C.) Medication will be used for myeloid reconstitution after an autologous or allogeneic BMT, D.) Patient has acute myeloid leukemia and administration will be after completion of induction chemotherapy, E.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS) or F.) Autologous peripheral blood stem cell transplant, Following myeloablative chemotherapy.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LEUPROLIDE

Products Affected

- ELIGARD
- *leuprolide acetate (3 month)*
- *leuprolide acetate injection*
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)
- LUPRON DEPOT-PED (1-MONTH) INTRAMUSCULAR KIT 7.5 MG
- LUPRON DEPOT-PED (3-MONTH) INTRAMUSCULAR KIT 11.25 MG
- LUPRON DEPOT-PED (6-MONTH)

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Pregnancy, B.) Undiagnosed abnormal uterine bleeding
Required Medical Information	Must meet one of the following: 1.) Eligard only: Advanced or metastatic prostate cancer, 2.) For Lupron depot and leuprolide products only: A.) Advanced or metastatic prostate cancer and patient has failed or is intolerant to Eligard (7.5 mg 1-month, 22.5 mg 3-month, 30 mg 4-month, & 45 mg 6-month depots only), B.) Endometriosis (3.75 mg 1-month & 11.25 mg 3-month depots only), C.) Anemia due to uterine leiomyomata (Fibroids) (3.75 mg 1-month & 11.25 mg 3-month depots only) and patient is preoperative, or D.) Central precocious puberty (idiopathic or neurogenic) in children
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LIDOCAINE PATCH

Products Affected

- *lidocaine external patch 5 %*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Pain associated with diabetic neuropathy, B.) Pain associated with cancer-related neuropathy, C.) Post-herpetic neuralgia, D.) Chronic back pain, or E.) Osteoarthritis of the knee or hip
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LINEZOLID

Products Affected

- *linezolid intravenous solution 600 mg/300ml*
- *linezolid oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI
Required Medical Information	Diagnosis of one of the following A.) Community acquired pneumonia, B.) Hospital-acquired pneumonia, C.) Vancomycin-resistant Enterococcus faecium infection, D.) Complicated skin and skin structure infections, or E.) Uncomplicated skin and skin structure infections
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	IV formulation: B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LIVMARLI

Products Affected

- LIVMARLI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Cholestatic pruritus in patients with Alagille syndrome (ALGS), or B.) Cholestatic pruritus in patients 5 years and older with progressive familial intrahepatic cholestasis (PFIC), but patient is not in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in nonfunctional or complete absence of bile salt export pump protein
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LIVTENCITY

Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LONSURF

Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic colorectal cancer, previously treated with fluoropyrimidine, oxaliplatin, and irinotecan-based regimens, an anti-VEGF therapy, and if RAS wild-type, an anti-EGFR therapy, or B.) Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan and if appropriate, HER2/neu-targeted therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LORBRENA

Products Affected

- LORBRENA

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with strong CYP3A4 inducers
Required Medical Information	Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LUMAKRAS

Products Affected

- LUMAKRAS

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) as determined by an FDA-approved test, and patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LUPKYNIS

Products Affected

- LUPKYNIS

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin)
Required Medical Information	Initial: Diagnosis of systemic lupus erythematosus (SLE) with active lupus nephritis (LN) Classes III, IV, V (alone or in combination), and all of the following: 1.) Baseline renal function of 45 mL/min/1.73 m ² or greater, 2.) Will be used in combination with a background immunosuppressive therapy regimen (e.g. mycophenolate, oral steroids, etc). Renewal: Documentation of positive clinical response to therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or nephrologist
Coverage Duration	Initial: 12 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LYNPARZA

Products Affected

- LYNPARZA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	<p>Diagnosis of one of the following A.) HER2-negative, deleterious or suspected deleterious germline BRCA mutated high-risk early or metastatic breast cancer AND patient has been previously treated with chemotherapy in neoadjuvant, adjuvant, or metastatic setting, B.) Recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer AND used for maintenance treatment in patients who are in complete or partial response to platinum-based chemotherapy (e.g. cisplatin, carboplatin), C.) Deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients with complete or partial response to first-line platinum-based chemotherapy, D.) Deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma and disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen, E.) Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA-mutation and/or genomic instability AND are using in combination with bevacizumab for maintenance treatment, F.) Deleterious or suspected deleterious germline or somatic homologous recombination repair gene mutated metastatic castration-resistant prostate cancer in patients who have progressed following prior treatment with enzalutamide or abiraterone, or G.) Deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer in combination with abiraterone and prednisone or prednisolone</p>
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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LYTGOBI

Products Affected

- LYTGOBI (12 MG DAILY DOSE)
- LYTGOBI (16 MG DAILY DOSE)
- LYTGOBI (20 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements and previously treated
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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MATULANE

Products Affected

- MATULANE

PA Criteria	Criteria Details
Exclusion Criteria	Inadequate marrow reserve
Required Medical Information	Diagnosis of Hodgkin's Disease, Stages III and IV and used in combination with other anticancer drugs
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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MAYZENT

Products Affected

- MAYZENT
- MAYZENT STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) CYP2C9*3/*3 genotype, B.) In the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, Class III-IV heart failure, or C.) Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker
Required Medical Information	Diagnosis of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease and the following A.) Patients with relapsing forms of multiple sclerosis have history of/or contraindication to Avonex, Betaseron, Copaxone/Glatiramer, Gilenya/Fingolimod, or Dimethyl Fumarate
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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MEKINIST

Products Affected

- MEKINIST

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and used in combination with dabrafenib and no locoregional treatment options, B.) Malignant melanoma with lymph node involvement and following complete resection with BRAF V600E or V600K mutations and used in combination with dabrafenib, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutations and used in combination with dabrafenib or as monotherapy, D.) Metastatic non-small cell lung cancer, with BRAF V600E mutation, in combination with dabrafenib, E.) Unresectable or metastatic solid tumors with BRAF V600E mutation, in combination with dabrafenib, and have progressed following prior treatment and have no satisfactory alternative treatment options, F.) Low-grade glioma with a BRAF V600E mutation and require systemic therapy, in combination with dabrafenib
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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MEKTOVI

Products Affected

- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Unresectable or metastatic malignant melanoma with documented BRAF V600E or V600K mutation as detected by an FDA approved test AND used in combination with encorafenib or B.) Metastatic non-small cell lung cancer with a BRAF V600E mutation as detected by an FDA-approved test AND used in combination with encorafenib
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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MIFEPRISTONE

Products Affected

- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) pregnancy, B.) coadministration with simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges, C.) concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses, D.) history of unexplained vaginal bleeding, E.) endometrial hyperplasia with atypia or endometrial carcinoma
Required Medical Information	Diagnosis of endogenous Cushing syndrome in patients with type 2 diabetes mellitus or glucose intolerance and must meet all of the following 1.) Used to control hyperglycemia secondary to hypercortisolism, and 2.) Patient has failed or is not a candidate for surgery
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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MIGLUSTAT

Products Affected

- *miglustat*
- YARGESA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of mild to moderate type 1 Gaucher disease and patient is not a candidate for enzyme replacement therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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MS INTERFERONS

Products Affected

- AVONEX PEN INTRAMUSCULAR AUTO-INJECTOR KIT
- AVONEX PREFILLED INTRAMUSCULAR PREFILLED SYRINGE KIT
- BETASERON SUBCUTANEOUS KIT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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NAMZARIC

Products Affected

- NAMZARIC

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Hypersensitivity to memantine, donepezil, or excipients, or B.) Hypersensitivity to piperidine derivatives
Required Medical Information	Diagnosis of moderate to severe dementia associated with Alzheimer's disease
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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NERLYNX

Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Early stage HER2-positive breast cancer and used following adjuvant trastuzumab therapy, or B.) Advanced or metastatic HER2-positive breast cancer, used in combination with capecitabine, AND patient has received 2 or more prior anti-HER2-based regimens in the metastatic setting
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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NINLARO

Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of multiple myeloma, used in combination with lenalidomide and dexamethasone, AND patient has history of at least 1 prior therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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NITISINONE

Products Affected

- *nitisinone*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hereditary tyrosinemia type 1 confirmed by one of the following A.) Biochemical testing (e.g., detection of succinylacetone in urine), or B.) DNA testing (mutation analysis)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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NUBEQA

Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Non-metastatic, castration-resistant prostate cancer (nmCRPC) or B.) Metastatic hormone-sensitive prostate cancer in combination with docetaxel. For treatment of nmCRPC, one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient has received bilateral orchiectomy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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NUCALA

Products Affected

- NUCALA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Severe asthma with eosinophilic phenotype and used as an adjunct treatment, B.) Eosinophilic granulomatosis with polyangiitis (EGPA), C.) Hypereosinophilic syndrome lasting at least 6 months without an identifiable non-hematologic secondary cause, or D.) Chronic rhinosinusitis with nasal polyps and used as an adjunct treatment
Age Restrictions	6 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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NUEDEXTA

Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) History of prolonged QT interval, congenital long QT syndrome or Torsades de pointes, B.) Heart failure, C.) Complete AV block without an implanted pacemaker or high risk of complete AV block, D.) Concomitant use with quinidine, quinine, mefloquine, or drugs that prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), E.) Concomitant use with MAOIs or within 14 days of MAOI therapy, F.) History of quinine-, mefloquine-, or quinidine-induced thrombocytopenia, bone marrow depression, or lupus-like syndrome
Required Medical Information	Diagnosis of pseudobulbar affect
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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NUPLAZID

Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Parkinson's disease and both of the following apply A.) Used for treatment of hallucinations and/or delusions associated with Parkinson's disease psychosis, and B.) Diagnosis of Parkinson's disease was made prior to the onset of psychotic symptoms
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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OCTREOTIDE

Products Affected

- *octreotide acetate injection solution 100 mcg/ml, 1000 mcg/ml, 200 mcg/ml, 50 mcg/ml, 500 mcg/ml*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Acromegaly confirmed by high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range and patient has had inadequate response to or is ineligible for surgery, radiation, or bromocriptine mesylate, or B.) Metastatic carcinoid syndrome with associated diarrhea or flushing, or C.) Vasoactive intestinal peptide-secreting tumors (VIPomas) with associated diarrhea
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ODOMZO

Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of locally advanced basal cell carcinoma of the skin and one of the following A.) Cancer has recurred following surgery or radiation therapy, B.) Patient is not a candidate for surgery or radiation therapy.
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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OFEV

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Idiopathic pulmonary fibrosis (IPF), B.) Systemic sclerosis-associated interstitial lung disease (ILD), or C.) Chronic fibrosing interstitial lung disease with a progressive phenotype
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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OGSIVEO

Products Affected

- OGSIVEO ORAL TABLET 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of progressing desmoid tumors who require systemic treatment
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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OJJAARA

Products Affected

- OJJAARA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [postpolycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ONUREG

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of acute myeloid leukemia (AML) used in maintenance treatment for adult patients who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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OPSUMIT

Products Affected

- OPSUMIT

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ORGOVYX

Products Affected

- ORGOVYX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced prostate cancer
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ORKAMBI

Products Affected

- ORKAMBI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis (CF) with documented homozygous F508del mutation confirmed by FDA-approved CF mutation test
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ORSERDU

Products Affected

- ORSERDU

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced or metastatic, ER-positive, HER2-negative, ESR1-mutated, breast cancer in postmenopausal women or adult men after at least 1 line of endocrine therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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OSPHENA

Products Affected

- OSPHENA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Undiagnosed abnormal genital bleeding, B.) Known or suspected estrogen-dependent neoplasia, C.) Active deep vein thrombosis (DVT), pulmonary embolism (PE), or a history of these conditions, D.) Active arterial thromboembolic disease (e.g. stroke, myocardial infarction) or a history of these conditions, or E.) Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause, or B.) Moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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OTEZLA

Products Affected

- OTEZLA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following: A.) Active psoriatic arthritis and patient has trial and failure or intolerance or contraindication to two preferred products, (i.e. Humira, Enbrel, Rinvoq, Skyrizi, Stelara), B.) Moderate to severe plaque psoriasis, patient is a candidate for phototherapy or systemic therapy, and patient has trial and failure or intolerance or contraindication to two preferred products, (i.e. Humira, Enbrel, Skyrizi, Stelara), C.) Mild plaque psoriasis, patient is a candidate for phototherapy or systemic therapy, and patient has trial and failure or intolerance or contraindication to at least one topical psoriasis product (e.g., medium to high potency corticosteroid and/or vitamin D analog), or D.) Behcet's Disease and patient has active oral ulcers
Age Restrictions	6 years of age and older
Prescriber Restrictions	PsA: Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis: Prescribed by or in consultation with a dermatologist.
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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PANRETIN

Products Affected

- PANRETIN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of AIDS-related Kaposi's sarcoma and both of the following 1.) Used to treat cutaneous lesions, and 2.) Systemic anti-Kaposi's Sarcoma therapy is not indicated (e.g., patient does not have more than 10 new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS, or symptomatic visceral involvement)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or HIV specialist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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PAZOPANIB

Products Affected

- *pazopanib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Advanced renal cell carcinoma, or B.) Advanced soft tissue sarcoma and patient received at least one prior chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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PEGYLATED INTERFERON

Products Affected

- PEGASYS SUBCUTANEOUS SOLUTION 180 MCG/ML
- PEGASYS SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Autoimmune hepatitis, B.) Hepatic decompensation (Child-Pugh score greater than 6 (Class B and C) in cirrhotic patients before treatment, OR hepatic decompensation (Child-Pugh score greater than or equal to 6) in cirrhotic patients co-infected with hepatitis C and HIV before treatment, C.) Hypersensitivity reactions, including urticaria, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome to alfa interferons or any component of the product, or D.) Pregnancy with concomitant ribavirin use
Required Medical Information	Diagnosis of one of the following A.) Chronic hepatitis B infection, or B.) Chronic hepatitis C and required criteria will be applied consistent with current AASLD-IDSA guidance with compensated liver disease
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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PEMAZYRE

Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with confirmed fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or B.) Relapsed or refractory myeloid/lymphoid neoplasms with fibroblast growth factor receptor 1 rearrangement
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, gastroenterologist, or hepatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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PIQRAY

Products Affected

- PIQRAY (200 MG DAILY DOSE)
- PIQRAY (250 MG DAILY DOSE)
- PIQRAY (300 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hormone receptor (HR) positive, HER2-negative, PIK3CA-mutated, advanced or metastatic breast cancer and must meet all of the following 1.) Used in combination with fulvestrant, 2.) Disease has progressed on or after an endocrine-based regimen, and 3.) Patient is a male or postmenopausal female
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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PIRFENIDONE

Products Affected

- *pirfenidone*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of idiopathic pulmonary fibrosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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POMALYST

Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) AIDS-related Kaposi sarcoma and patient has failure on highly active antiretroviral therapy (HAART), B.) Kaposi sarcoma in HIV-negative adults, or C.) Multiple myeloma and in combination with dexamethasone in adults who have received at least 2 prior therapies (including lenalidomide and a proteasome inhibitor) and have demonstrated disease progression on or within 60 days of completion of the last therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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POSACONAZOLE

Products Affected

- *posaconazole oral*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant treatment with sirolimus, B.) Concomitant use of CYP3A4 substrates that prolong QT interval (pimozide, quinidine), C.) Concomitant use of HMG-CoA Reductase inhibitors primarily metabolized through CYP3A4, or D.) Concomitant use of ergot alkaloids
Required Medical Information	Diagnosis of one of the following A.) Oropharyngeal candidiasis, B.) Patient is severely immunocompromised and requires prophylaxis of invasive aspergillosis or candidiasis due to high risk of infection, or C.) Invasive aspergillosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 weeks
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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POSACONAZOLE SUSPENSION

Products Affected

- NOXAFIL ORAL PACKET
- *posaconazole oral*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant treatment with sirolimus, B.) Concomitant use of CYP3A4 substrates that prolong QT interval (pimozide, quinidine), C.) Concomitant use of HMG-CoA Reductase inhibitors primarily metabolized through CYP3A4, or D.) Concomitant use of ergot alkaloids
Required Medical Information	Diagnosis of one of the following A.) Oropharyngeal candidiasis, B.) Patient is severely immunocompromised and requires prophylaxis of invasive aspergillosis or candidiasis due to high risk of infection, or C.) Invasive aspergillosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 weeks
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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PREVYMIS

Products Affected

- PREVYMIS ORAL

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use with pimozone or ergot alkaloids (ergotamine, dihydroergotamine), B.) Concomitant use with pitavastatin or simvastatin when coadministered with cyclosporine
Required Medical Information	Diagnosis of one of the following A.) Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant, or B.) Prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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PROMACTA

Products Affected

- PROMACTA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic idiopathic thrombocytopenic purpura (ITP), B.) Chronic hepatitis C infection associated thrombocytopenia, or C.) Severe aplastic anemia with insufficient response to immunosuppressive therapy or in combination with standard immunosuppressive therapy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
Last Updated: 07/24/2024
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QINLOCK

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced gastrointestinal stromal tumor (GIST) and patient has received prior treatment with 3 or more kinase inhibitors, including imatinib
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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QUININE SULFATE

Products Affected

- *quinine sulfate oral*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Prolongation of QT interval, B.) Glucose-6-phosphate dehydrogenase deficiency, C.) Myasthenia gravis, D.) Known hypersensitivity to mefloquine or quinidine, E.) Optic neuritis, F.) Diagnosis of Blackwater fever, G.) Use solely for treatment or prevention of nocturnal leg cramps
Required Medical Information	Diagnosis of one of the following A.) uncomplicated Plasmodium falciparum malaria, B.) uncomplicated Plasmodium vivax malaria, or C.) babesiosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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RAVICTI

Products Affected

- RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of urea cycle disorders
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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REGRANEX

Products Affected

- REGRANEX

PA Criteria	Criteria Details
Exclusion Criteria	Known neoplasm at the site of application
Required Medical Information	Diagnosis of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply
Age Restrictions	16 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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REPATHA

Products Affected

- REPATHA
- REPATHA SURECLICK
- REPATHA PUSHTRONEX SYSTEM

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH), B.) homozygous familial hypercholesterolemia, C.) established cardiovascular disease and myocardial infarction prophylaxis, stroke prophylaxis, or coronary revascularization prophylaxis is required, or D.) clinical atherosclerotic cardiovascular disease (CVD) as defined as one of the following 1.) acute coronary syndrome, 2.) history of myocardial infarction, 3.) stable/unstable angina, 4.) coronary or other arterial revascularization, 5.) stroke, 6.) transient ischemic stroke (TIA), or 7.) peripheral arterial disease presumed to be atherosclerotic region
Age Restrictions	10 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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RETEVMO

Products Affected

- RETEVMO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Advanced or metastatic RET-mutant medullary thyroid cancer (MTC) in patients who require systemic therapy, B.) Metastatic RET fusion-positive non-small cell lung cancer (NSCLC), C.) Advanced or metastatic RET fusion-positive thyroid cancer in patients who require systemic therapy and are refractory to radioactive iodine, if appropriate, or D.) Locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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REZLIDHIA

Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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REZUROCK

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of chronic graft-vs-host disease and patient has failed at least 2 prior lines of systemic therapy.
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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RILUZOLE

Products Affected

- *riluzole*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of amyotrophic lateral sclerosis (ALS)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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RINVOQ

Products Affected

- RINVOQ

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Active psoriatic arthritis, C.) Moderate to severe atopic dermatitis and patient has trial/failure, contraindication, or intolerance to two of the following 1.) Topical corticosteroid and/or 2.) Topical calcineurin inhibitor, D.) Moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers, E.) Active ankylosing spondylitis who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers, F.) Active nonradiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to tumor necrosis factor blocker therapy, or G.) Moderate to severe active Crohn's disease who have had an inadequate response or intolerance to tumor necrosis factor blocker therapy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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RIVFLOZA

Products Affected

- RIVFLOZA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Primary hyperoxaluria type 1 and the patient has relatively preserved kidney function (eGFR is greater than or equal to 30mL/min/1.73m ²)
Age Restrictions	9 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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ROZLYTREK

Products Affected

- ROZLYTREK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) ROS1-positive metastatic non-small cell lung cancer (NSCLC), or B.) Solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have either progressed following treatment or have no satisfactory alternative therapy
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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RUBRACA

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, used as maintenance treatment, and patient is in complete or partial response to platinum-based chemotherapy, or B.) Deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer and patient has been treated with androgen receptor-directed therapy and a taxane-based chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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RYDAPT

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) treatment naive FLT3 mutation-positive acute myelogenous leukemia (AML) and must be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation therapy, or B.) systemic mastocytosis or mast cell leukemia
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SAPROPTERIN

Products Affected

- *sapropterin dihydrochloride oral packet*
- *sapropterin dihydrochloride oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hyperphenylalaninemia (HPA) caused by tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Initial: 2 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SCSEMBLIX

Products Affected

- SCSEMBLIX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), or B.) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) with the T315I mutation
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SIGNIFOR

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Cushing disease and patient has had inadequate response to or is not a candidate for surgery. For renewal: Documentation of a clinically meaningful reduction in 24-hour urinary free cortisol (UFC) levels or improvement in signs or symptoms of the disease
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SILDENAFIL

Products Affected

- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Nitrate therapy, including intermittent use, B.) Concomitant use with riociguat or other guanylate cyclase stimulators, C.) Concomitant use with HIV protease inhibitors or elvitegravir/cobicistat/tenofovir/emtricitabine
Required Medical Information	Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SIRTURO

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) Diagnosis of pulmonary multidrug resistant tuberculosis (MDR-TB) and 2.) Used in combination with at least 3 other antibiotics for the treatment of pulmonary multi-drug resistant tuberculosis
Age Restrictions	5 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	24 weeks
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SKYRIZI

Products Affected

- SKYRIZI PEN
- SKYRIZI SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe plaque psoriasis and patient is a candidate for systemic therapy or phototherapy, B.) Active psoriatic arthritis, or C.) Moderately to severely active Crohn's disease
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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SODIUM OXYBATE

Products Affected

- *sodium oxybate*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant treatment with sedative hypnotic agents, B.) Succinic semialdehyde dehydrogenase deficiency
Required Medical Information	Diagnosis of one of the following A.) Narcolepsy with excessive daytime drowsiness and has trial of/or contraindication to a central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate) or a CNS wakefulness promoting drug (e.g., armodafinil, modafinil), or B.) Cataplexy and narcolepsy
Age Restrictions	7 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SOHONOS

Products Affected

- SOHONOS

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of fibrodysplasia ossificans progressiva (FOP)
Age Restrictions	8 years and older for females and 10 years and older for males
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SOLTAMOX

Products Affected

- SOLTAMOX

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant coumarin-type anticoagulant therapy, B.) history of thromboembolic disease such as DVT or PE
Required Medical Information	Diagnosis of breast cancer and documentation of inability to swallow tablet formulation
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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Last Updated: 07/24/2024

Effective: 08/01/2024

SOMAVERT

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of acromegaly confirmed by high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range and patient has had an inadequate response to or is ineligible for surgery or radiation therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SORAFENIB

Products Affected

- *sorafenib tosylate*

PA Criteria	Criteria Details
Exclusion Criteria	Squamous cell lung cancer being treated with carboplatin and paclitaxel
Required Medical Information	Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioactive iodine treatment, or C.) Unresectable hepatocellular carcinoma
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SPRYCEL

Products Affected

- SPRYCEL

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, B.) Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy, C.) Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy, or D.) Newly diagnosed Ph+ ALL in combination with chemotherapy
Age Restrictions	1 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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STELARA

Products Affected

- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML
- STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severely active Crohn disease, B.) Moderate to severe plaque psoriasis, C.) Active psoriatic arthritis, or D.) Moderate to severe active ulcerative colitis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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STIVARGA

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic colorectal cancer in patients previously treated with fluoropyrimidine, oxaliplatin, and irinotecan containing chemotherapy, anti-VEGF therapy, and if RAS wild type, anti-EGFR therapy, B.) Liver carcinoma in patients previously treated with sorafenib, or C.) Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) after treatment with imatinib and sunitinib
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SUNITINIB

Products Affected

- *sunitinib malate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Gastrointestinal stromal tumor after disease progression on or intolerance to imatinib, B.) Pancreatic neuroendocrine tumors in a patient with unresectable locally advanced or metastatic disease, C.) Advanced renal cell carcinoma, or D.) Renal cell carcinoma and used as adjuvant therapy following nephrectomy in patients who are at high risk for recurrence
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SYMDEKO

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis (CF) and must meet one of the following 1.) Patient is homozygous for the F508del mutation, or 2.) Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor verified by an FDA-cleared CF mutation test
Age Restrictions	6 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SYMLIN

Products Affected

- SYMLINPEN 120 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- SYMLINPEN 60 SUBCUTANEOUS SOLUTION PEN-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Confirmed diagnosis of gastroparesis, B.) Hypoglycemia unawareness
Required Medical Information	Diagnosis of type 1 or type 2 diabetes mellitus and patient uses mealtime insulin therapy and has failed to achieve desired glucose control
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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SYNAREL

Products Affected

- SYNAREL

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) pregnancy, B.) breastfeeding, C.) undiagnosed abnormal vaginal bleeding
Required Medical Information	Diagnosis of one of the following A.) Central precocious puberty, or B.) Endometriosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TABLOID

Products Affected

- TABLOID

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of acute myeloid leukemia (induction and consolidation therapy only)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TABRECTA

Products Affected

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TAFINLAR

Products Affected

- TAFINLAR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid carcinoma with BRAF V600E mutation, in combination with trametinib and no satisfactory locoregional treatment options, B.) Metastatic non-small cell lung cancer with BRAF V600E mutation, in combination with trametinib OR in patients previously treated as monotherapy, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutation, D.) Unresectable or metastatic solid tumors with BRAF V600E mutation, in combination with trametinib, and have progressed following prior treatment and have no satisfactory alternative treatment options, or E.) Low-grade glioma with a BRAF V600E mutation and require systemic therapy, in combination with trametinib
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TAGRISO

Products Affected

- TAGRISO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R mutation and used as first line therapy, B.) Metastatic non-small cell lung cancer with T790M EGFR mutation (as confirmed by an FDA-approved test) AND whose disease has progressed on or after EGFR tyrosine kinase inhibitor therapy, C.) Non-small cell lung cancer (NSCLC) with tumor epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations (as confirmed by an FDA-approved test) AND patient requires adjuvant therapy after tumor resection, or D.) First-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test, in combination with pemetrexed and platinum-based chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TAKHZYRO

Products Affected

- TAKHZYRO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following and used as routine prophylaxis A.) Hereditary angioedema (HAE) with C1 inhibitor deficiency (Type 1) confirmed by laboratory testing, or B.) HAE with C1 inhibitor dysfunction (Type 2) confirmed by laboratory testing, or C.) HAE with normal C1 inhibitor (Type 3) confirmed by laboratory testing and one of the following 1.) Positive test for an F12, angiopoietin-1, or plasminogen gene mutation, or 2.) Family history of angioedema and the angioedema was refractory to a trial of an antihistamine for at least one month
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, immunologist, or allergist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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Effective: 08/01/2024

TALZENNA

Products Affected

- TALZENNA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer, or B.) Homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer in combination with enzalutamide
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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TASIGNA

Products Affected

- TASIGNA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia
Required Medical Information	Diagnosis of one of the following A.) Newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML), B.) Chronic phase or accelerated phase Philadelphia chromosome-positive CML in a patient with resistance or intolerance to prior therapy that included imatinib, or C.) Chronic phase Philadelphia chromosome-positive CML in a patient with resistance or intolerance to prior tyrosine-kinase inhibitor therapy
Age Restrictions	1 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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Effective: 08/01/2024

TAVNEOS

Products Affected

- TAVNEOS

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) and both of the following apply 1.) Used as adjunctive treatment, and 2.) Used in combination with standard therapy including glucocorticoids
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TAZAROTENE

Products Affected

- *tazarotene external cream*
- *tazarotene external gel*
- TAZORAC EXTERNAL CREAM 0.05 %

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Acne vulgaris and patient has trial with at least one generic topical acne product, or B.) Stable moderate to severe plaque psoriasis with 20% or less body surface area involvement and patient has trial with at least one other topical psoriasis product (e.g., medium to high potency corticosteroid and/or vitamin D analogs)
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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TAZVERIK

Products Affected

- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic or locally advanced epithelioid sarcoma in patients not eligible for complete resection, B.) Relapsed or refractory follicular lymphoma in patients whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, or C.) Relapsed or refractory follicular lymphoma in patients who have no satisfactory alternative treatment options
Age Restrictions	16 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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TEGSEDI

Products Affected

- TEGSEDI

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Platelet count less than 100,000 per microliter, B.) Urinary protein to creatinine ratio (UPCR) of 1000 mg/g or higher
Required Medical Information	Diagnosis of Polyneuropathy of hereditary transthyretin-mediated amyloidosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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TEPMETKO

Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic non-small cell lung cancer (NSCLC) with mesenchymal-epithelial transition (MET) exon 14 skipping alterations
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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Effective: 08/01/2024

TERIPARATIDE

Products Affected

- *teriparatide (recombinant) subcutaneous solution pen-injector 620 mcg/2.48ml*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Osteoporosis in postmenopausal female patient with high risk for fracture and patient has contraindication or has tried/had inadequate response to a bisphosphonate or Tymlos, B.) Primary or hypogonadal osteoporosis in male patient with high risk for fracture and patient has contraindication or has tried/had inadequate response to a bisphosphonate, or C.) Osteoporosis due to associated sustained systemic glucocorticoid therapy in patient with high risk for fracture and patient has contraindication or has tried/had inadequate response to a bisphosphonate
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Initial: 12 months, Renewal: 12 months (Maximum 24 month treatment per patient lifetime)
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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TETRABENAZINE

Products Affected

- *tetrabenazine*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Actively suicidal, B.) Untreated or inadequately treated depression, C.) Impaired hepatic function, D.) Concomitant use of monoamine oxidase inhibitors, E.) Concomitant use of reserpine or within 20 days of discontinuing reserpine
Required Medical Information	Diagnosis of chorea associated with Huntington's disease
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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THALOMID

Products Affected

- THALOMID

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Multiple myeloma that is newly diagnosed, or B.) Erythema nodosum leprosum (ENL)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, infectious disease specialist, or dermatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TIBSOVO

Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test), B.) Previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test.), C.) Acute myeloid leukemia (newly-diagnosed) with susceptible isocitrate dehydrogenase-1 mutation and meets one of the following: 1.) Patient is 75 years of age or older, or 2.) Patient has comorbidities that preclude intensive induction chemotherapy, or D.) Relapsed or refractory myelodysplastic syndromes with a susceptible isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hematologist, hepatologist, or oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
Last Updated: 07/24/2024
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TOBI

Products Affected

- TOBI PODHALER

PA Criteria	Criteria Details
Exclusion Criteria	Known sensitivity to any aminoglycoside
Required Medical Information	Diagnosis of cystic fibrosis (confirmed by appropriate diagnostic or genetic testing) and patient has suspected or confirmed <i>Pseudomonas aeruginosa</i> infection in the lungs
Age Restrictions	6 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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TOLVAPTAN

Products Affected

- *tolvaptan*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD), B.) Urgent need to raise serum sodium acutely, C.) Inability to sense or appropriately respond to thirst, D.) Hypovolemic hyponatremia, E.) Concomitant use of strong CYP 3A Inhibitors (e.g. clarithromycin, ketoconazole, ritonavir), or F.) Anuria
Required Medical Information	Diagnosis of clinically significant hypervolemic or euvolemic hyponatremia (serum sodium less than 125 mEq/L or less marks hyponatremia that is symptomatic and has resisted correction with fluid restriction), including in patients with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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TOPICAL RETINOIDS

Products Affected

- *tretinoin external*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of mild to moderate acne vulgaris
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TOREMIFENE

Products Affected

- *toremifene citrate*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Acquired or congenital long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia
Required Medical Information	Diagnosis of metastatic breast cancer and patient must have previous inadequate response or intolerance to tamoxifen
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	6 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TRELSTAR

Products Affected

- TRELSTAR MIXJECT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced prostate cancer
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TRIENTINE

Products Affected

- *trientine hcl*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Wilson's disease in patients that are intolerant to penicillamine
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TRIKAFTA

Products Affected

- TRIKAFTA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis (CF) and patient has at least 1 F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to elxacaftor/tezacaftor/ivacaftor verified by an FDA-cleared CF mutation test
Age Restrictions	2 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TRUQAP

Products Affected

- TRUQAP

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with 1 or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test and, A.) patient has had disease progression following 1 or more endocrine-based regimen(s) in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy, and B.) will be used in combination with fulvestrant injection.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TUKYSA

Products Affected

- TUKYSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following: A.) advanced unresectable or metastatic HER2-positive breast cancer (including brain metastases) in patients who have received one or more prior anti-HER2-based regimens in the metastatic setting and drug is being used in combination with trastuzumab and capecitabine, or B.) unresectable or metastatic RAS wild-type, HER2-positive colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy and drug is being used in combination with trastuzumab
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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TURALIO

Products Affected

- TURALIO ORAL CAPSULE 125 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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TYMLOS

Products Affected

- TYMLOS

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of osteoporosis in men or postmenopausal women and one of the following A.) osteoporotic fracture or multiple risk factors for fracture, or B.) previous trial of/or contraindication to bisphosphonate
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Initial: 12 months, Renewal: 12 months (Maximum 24 month treatment per patient lifetime)
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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UBRELVY

Products Affected

- UBRELVY

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin)
Required Medical Information	Diagnosis of migraine disorder with or without aura and patient has documented trial, inadequate response, or contraindication to at least 1 generic formulary triptan
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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VALCHLOR

Products Affected

- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cutaneous T-cell lymphoma (stage IA and IB mycosis fungoides-type) and patient has received prior skin-directed therapy (e.g. Topical corticosteroids, phototherapy, or topical nitrogen mustard)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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VANFLYTA

Products Affected

- VANFLYTA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Patient must have all of the following A.) Newly diagnosed acute myeloid leukemia with FLT3-ITD mutation, B.) Used in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, and C.) Must be enrolled in the VANFLYTA REMS program
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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VENCLEXTA

Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with strong CYP3A inhibitor during the initial and titration phase in patients with CLL or SLL
Required Medical Information	Diagnosis of one of the following A.) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), or B.) Newly-diagnosed acute myeloid leukemia (AML) and used in combination with azacitidine, decitabine or low-dose cytarabine in patients 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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VERQUVO

Products Affected

- VERQUVO

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use of other soluble guanylate cyclase (sGC) stimulators, or B.) Pregnancy
Required Medical Information	Diagnosis of chronic heart failure (HF), NYHA Class II to IV and all of the following 1.) Left ventricular ejection fraction less than 45%, 2.) Previous hospitalization for HF within 6 months or outpatient IV diuretic treatment for HF within 3 months
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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VERZENIO

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer and ALL of the following: 1.) Patient is at high risk of recurrence, and 2.) Requested drug will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for adjuvant treatment, OR B.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and one of the following 1.) Used in combination with fulvestrant in a patient with disease progression following endocrine therapy, 2.) Used as monotherapy in a patient with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting, or 3.) For postmenopausal women, and men, used as initial endocrine-based treatment in combination with an aromatase inhibitor
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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VIGABATRIN

Products Affected

- *vigabatrin*
- VIGADRONE ORAL TABLET
- VIGPODER

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Infantile spasms, or B.) Refractory complex partial seizures and the drug is being used as adjunctive therapy in patients who have responded inadequately to two alternative treatments
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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VIJOICE

Products Affected

- VIJOICE ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) in patients who require systemic therapy
Age Restrictions	2 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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VITRAKVI

Products Affected

- VITRAKVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic or surgically unresectable neurotrophic receptor tyrosine kinase (NTRK) gene fusion positive solid tumors without a known acquired resistance mutation and used in patients with unsatisfactory alternative treatments or who have progressed following treatment
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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VIZIMPRO

Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic non-small cell lung cancer with confirmed epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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VONJO

Products Affected

- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of intermediate or high-risk primary or secondary myelofibrosis in adults AND a platelet count less than 50 X 10(9)/L
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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VORICONAZOLE

Products Affected

- *voriconazole intravenous*
- *voriconazole oral*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use of carbamazepine, CYP3A4 substrates (e.g., terfenadine, astemizole, cisapride, pimozide, or quinidine), B.) Concomitant use with high-dose ritonavir (400mg every 12 hours), C.) Concomitant use with ergot alkaloids, D.) Concomitant use with long-acting barbiturates, E.) Concomitant use with rifabutin or rifampin, F.) Concomitant use with sirolimus, or G.) Concomitant use with efavirenz at standard doses of 400mg/day or higher
Required Medical Information	Diagnosis of one of the following A.) Invasive aspergillosis, B.) Candidemia, C.) Esophageal Candidiasis, D.) Invasive candidiasis of the skin and abdomen, kidney, bladder wall, and wounds, or E.) Serious fungal infection due to <i>Scedosporium apiospermum</i> or <i>Fusarium</i> species
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	6 months
Other Criteria	IV formulation: B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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VYNDAMAX

Products Affected

- VYNDAMAX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of wild type or hereditary transthyretin related familial amyloid cardiomyopathy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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WELIREG

Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Von Hippel-Lindau (VHL) disease and therapy is required for any of the following disease associated tumors that do not require immediate surgery 1.) Renal cell carcinoma (RCC), 2.) Central nervous system (CNS) hemangioblastoma, or 3.) Pancreatic neuroendocrine tumor (pNET), or B.) Advanced renal cell carcinoma following a programmed death receptor-1 or programmed death-ligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
Last Updated: 07/24/2024
Effective: 08/01/2024

XALKORI

Products Affected

- XALKORI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive or ROS1-positive as detected by an FDA-approved test, B.) Relapsed or refractory systemic anaplastic large cell lymphoma that is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved test, or C.) Unresectable, recurrent, or refractory inflammatory myofibroblastic tumors that are anaplastic lymphoma kinase (ALK)-positive
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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XDEMVY

Products Affected

- XDEMVY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Demodex blepharitis
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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Effective: 08/01/2024

XGEVA

Products Affected

- XGEVA

PA Criteria	Criteria Details
Exclusion Criteria	Hypocalcemia (calcium less than 8.0 mg/dL)
Required Medical Information	Diagnosis of one of the following A.) Bone metastases from a solid tumor and used for the prevention of skeletal related events, B.) Multiple myeloma and used for the prevention of skeletal related events, C.) Hypercalcemia of malignancy refractory to bisphosphonate therapy, or D.) Giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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XOLAIR

Products Affected

- XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic idiopathic urticaria in patients who remain symptomatic despite H1 antihistamine therapy and patient will continue to receive concurrent H1 antihistamine therapy unless contraindicated or not tolerated, B.) Moderate to severe persistent asthma in patients with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms are inadequately controlled with inhaled corticosteroids and an additional controller medication (i.e. long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline) and patient has trial and failure, contraindication, or intolerance to Dupixent or Nucala, C.) Nasal polyps in patients with inadequate response to nasal corticosteroids, requested drug will be used as adjunctive treatment, and patient has trial and failure, contraindication, or intolerance to Dupixent, or D.) Reduction of allergic reactions (type I), including anaphylaxis, that may occur with accidental exposure to 1 or more foods in with IgE-mediated food allergy and is being used in conjunction with food allergen avoidance
Age Restrictions	1 year of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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Effective: 08/01/2024

XOSPATA

Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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XPOVIO

Products Affected

- XPOVIO (100 MG ONCE WEEKLY)
ORAL TABLET THERAPY PACK 50
MG
- XPOVIO (40 MG ONCE WEEKLY)
ORAL TABLET THERAPY PACK 40
MG
- XPOVIO (40 MG TWICE WEEKLY)
ORAL TABLET THERAPY PACK 40
MG
- XPOVIO (60 MG ONCE WEEKLY)
ORAL TABLET THERAPY PACK 60
MG
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY)
ORAL TABLET THERAPY PACK 40
MG
- XPOVIO (80 MG TWICE WEEKLY)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsed or refractory multiple myeloma being used in combination with dexamethasone in a patient who has received at least 4 prior therapies and is refractory to at least 2 proteasome inhibitors, at least 2 immunomodulatory agents, and an anti-CD38 monoclonal antibody, B.) Multiple myeloma being used in combination with bortezomib and dexamethasone in a patient who has received at least 1 prior therapy, C.) Relapsed or refractory diffuse large B-cell lymphoma not otherwise specified, or D.) Relapsed or refractory DLBCL arising from follicular lymphoma and patient has received at least 2 lines of systemic therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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PA Criteria	Criteria Details
Part B Prerequisite	No

Formulary ID: 24447 version 15
Last Updated: 07/24/2024
Effective: 08/01/2024

XTANDI

Products Affected

- XTANDI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Castration-resistant prostate cancer (CRPC), B.) Metastatic, castration-sensitive prostate cancer (mCSPC). For treatment of CRPC and mCSPC, one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient has received bilateral orchiectomy, or C.) Nonmetastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15

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XURIDEN

Products Affected

- XURIDEN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hereditary orotic aciduria
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
Last Updated: 07/24/2024
Effective: 08/01/2024

YONSA

Products Affected

- YONSA

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of metastatic, castration-resistant prostate cancer (mCRPC) and used in combination with methylprednisolone. For treatment of mCRPC, one of the following applies: 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient has received bilateral orchiectomy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
Last Updated: 07/24/2024
Effective: 08/01/2024

ZARXIO

Products Affected

- ZARXIO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chemotherapy induced febrile neutropenia (prophylaxis), B.) Severe chronic neutropenia, C.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, or D.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ZEJULA

Products Affected

- ZEJULA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Advanced or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and used as maintenance therapy in a patient who is in a complete or partial response to platinum-based chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ZELBORAF

Products Affected

- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Unresectable or metastatic melanoma and patient has positive BRAF-V600E mutation documented by an FDA-approved test, or B.) Erdheim-Chester disease and patient has documented BRAF V600 mutation
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ZIEXTENZO

Products Affected

- ZIEXTENZO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of a non-myeloid malignancy and drug is being used as prophylaxis for chemotherapy-induced neutropenia
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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ZILBRYSQ

Products Affected

- ZILBRYSQ

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of generalized myasthenia gravis in adults who are anti-acetylcholine receptor (AChR) antibody positive
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ZOKINVY

Products Affected

- ZOKINVY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Hutchinson-Gilford Progeria Syndrome or B.)Processing deficient progeroid laminopathy with documentation of either heterozygous LMNA mutation with progerin-like protein accumulation or homozygous or compound heterozygous ZMPSTE24 mutations
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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Last Updated: 07/24/2024
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ZOLINZA

Products Affected

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of primary cutaneous T-cell lymphoma (CTCL) in patients who have progressive, persistent or recurrent disease on or following two systemic therapies (e.g., bexarotene, romidepsin, etc)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ZTALMY

Products Affected

- ZTALMY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ZURZUVAE

Products Affected

- ZURZUVAE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of postpartum depression
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	14 days
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ZYDELIG

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	History of toxic epidermal necrosis with any drug
Required Medical Information	Diagnosis of Chronic lymphocytic leukemia, used in combination with rituximab and patient has relapsed on at least one prior therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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ZYKADIA

Products Affected

- ZYKADIA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Formulary ID: 24447 version 15
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PART B VERSUS PART D

Products Affected

- ABELCET INTRAVENOUS SUSPENSION 5 MG/ML
- *acetylcysteine inhalation solution 10 %, 20 %*
- *acyclovir sodium intravenous solution 50 mg/ml*
- *albuterol sulfate inhalation nebulization solution (2.5 mg/3ml) 0.083%, 0.63 mg/3ml, 1.25 mg/3ml, 2.5 mg/0.5ml*
- *amikacin sulfate injection solution 500 mg/2ml*
- *amphotericin b intravenous solution reconstituted 50 mg*
- *amphotericin b liposome intravenous suspension reconstituted 50 mg*
- *ampicillin sodium injection solution reconstituted 1 gm, 125 mg*
- *ampicillin sodium intravenous solution reconstituted 10 gm*
- *aprepitant oral capsule 125 mg, 40 mg, 80 & 125 mg, 80 mg*
- *azathioprine oral tablet 100 mg, 50 mg, 75 mg*
- *azithromycin intravenous solution reconstituted 500 mg*
- *aztreonam injection solution reconstituted 1 gm, 2 gm*
- *budesonide inhalation suspension 0.25 mg/2ml, 0.5 mg/2ml, 1 mg/2ml*
- *calcitonin (salmon) nasal solution 200 unit/act*
- *calcitriol oral capsule 0.25 mcg, 0.5 mcg*
- *calcitriol oral solution 1 mcg/ml*
- *cefotetan disodium injection solution reconstituted 1 gm, 2 gm*
- *cefoxitin sodium intravenous solution reconstituted 1 gm, 10 gm, 2 gm*
- *cefuroxime sodium injection solution reconstituted 750 mg*
- *cefuroxime sodium intravenous solution reconstituted 1.5 gm*
- *chlorpromazine hcl oral concentrate 100 mg/ml, 30 mg/ml*
- *chlorpromazine hcl oral tablet 10 mg, 100 mg, 200 mg, 25 mg, 50 mg*
- *cinacalcet hcl oral tablet 30 mg, 60 mg, 90 mg*
- *ciprofloxacin in d5w intravenous solution 200 mg/100ml*
- *clindamycin phosphate injection solution 900 mg/6ml*
- CLINIMIX E/DEXTROSE (2.75/5) INTRAVENOUS SOLUTION 2.75 %
- CLINIMIX E/DEXTROSE (4.25/10) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX E/DEXTROSE (4.25/5) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX E/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 %
- CLINIMIX E/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 %
- CLINIMIX/DEXTROSE (4.25/10) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX/DEXTROSE (4.25/5) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 %
- CLINIMIX/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 %
- *colistimethate sodium (cba) injection solution reconstituted 150 mg*
- *cromolyn sodium inhalation nebulization solution 20 mg/2ml*
- *cyclophosphamide oral capsule 25 mg, 50 mg*
- *cyclophosphamide oral tablet 25 mg, 50 mg*
- *cyclosporine modified oral capsule 100 mg, 25 mg, 50 mg*

Formulary ID: 24447 version XX

Last Updated: 07/24/2024

Effective: 08/01/2024

- *cyclosporine modified oral solution 100 mg/ml*
- *cyclosporine oral capsule 100 mg, 25 mg*
- *dextrose intravenous solution 10 %, 5 %*
- *dextrose-sodium chloride intravenous solution 10-0.2 %, 10-0.45 %, 2.5-0.45 %, 5-0.2 %, 5-0.45 %, 5-0.9 %*
- *diphtheria-tetanus toxoids dt intramuscular suspension 25-5 lfu/0.5ml*
- DOXY 100 INTRAVENOUS SOLUTION RECONSTITUTED 100 MG
- ENGERIX-B INJECTION SUSPENSION 20 MCG/ML
- ENGERIX-B INJECTION SUSPENSION PREFILLED SYRINGE 10 MCG/0.5ML, 20 MCG/ML
- ENVARSUS XR ORAL TABLET EXTENDED RELEASE 24 HOUR 0.75 MG, 1 MG, 4 MG
- ERAXIS INTRAVENOUS SOLUTION RECONSTITUTED 100 MG, 50 MG
- ERYTHROCIN LACTOBIONATE INTRAVENOUS SOLUTION RECONSTITUTED 500 MG
- *everolimus oral tablet 0.25 mg, 0.5 mg, 0.75 mg, 1 mg*
- *fluconazole in sodium chloride intravenous solution 200-0.9 mg/100ml-%, 400-0.9 mg/200ml-%*
- *furosemide injection solution 10 mg/ml*
- GENGRAF ORAL CAPSULE 100 MG, 25 MG
- GENGRAF ORAL SOLUTION 100 MG/ML
- *granisetron hcl oral tablet 1 mg*
- *heparin sodium (porcine) injection solution 1000 unit/ml, 10000 unit/ml, 20000 unit/ml, 5000 unit/ml*
- HEPLISAV-B INTRAMUSCULAR SOLUTION PREFILLED SYRINGE 20 MCG/0.5ML
- IMOVAX RABIES INTRAMUSCULAR SUSPENSION RECONSTITUTED 2.5 UNIT/ML
- INTRALIPID INTRAVENOUS EMULSION 20 %, 30 %
- *ipratropium bromide inhalation solution 0.02 %*
- *ipratropium-albuterol inhalation solution 0.5-2.5 (3) mg/3ml*
- ISOLYTE-P IN D5W INTRAVENOUS SOLUTION
- ISOLYTE-S PH 7.4 INTRAVENOUS SOLUTION
- *kcl in dextrose-nacl intravenous solution 10-5-0.45 meq/l-%-%, 20-5-0.2 meq/l-%-%, 20-5-0.45 meq/l-%-%, 20-5-0.9 meq/l-%-%, 30-5-0.45 meq/l-%-%, 40-5-0.45 meq/l-%-%, 40-5-0.9 meq/l-%-%*
- *kcl-lactated ringers-d5w intravenous solution 20 meq/l*
- *methotrexate sodium (pf) injection solution 50 mg/2ml*
- *methotrexate sodium injection solution 50 mg/2ml*
- *methotrexate sodium oral tablet 2.5 mg*
- *methylprednisolone oral tablet 16 mg, 32 mg, 4 mg, 8 mg*
- *metronidazole intravenous solution 500 mg/100ml*
- *moxifloxacin hcl in nacl intravenous solution 400 mg/250ml*
- *multiple electro type 1 ph 5.5 intravenous solution*
- *mycophenolate mofetil oral capsule 250 mg*
- *mycophenolate mofetil oral suspension reconstituted 200 mg/ml*
- *mycophenolate mofetil oral tablet 500 mg*
- *mycophenolate sodium oral tablet delayed release 180 mg, 360 mg*
- *nafcillin sodium injection solution reconstituted 1 gm, 2 gm*
- *nafcillin sodium intravenous solution reconstituted 10 gm*
- NUTRILIPID INTRAVENOUS EMULSION 20 %
- *ondansetron hcl oral solution 4 mg/5ml*

Formulary ID: 24447 version XX

Last Updated: 07/24/2024

Effective: 08/01/2024

- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet dispersible 4 mg, 8 mg*
- *oxacillin sodium in dextrose intravenous solution 1 gm/50ml, 2 gm/50ml*
- *oxacillin sodium injection solution reconstituted 1 gm, 2 gm*
- *oxacillin sodium intravenous solution reconstituted 10 gm*
- PANZYGA INTRAVENOUS SOLUTION 1 GM/10ML, 10 GM/100ML, 2.5 GM/25ML, 20 GM/200ML, 30 GM/300ML, 5 GM/50ML
- *paricalcitol oral capsule 1 mcg, 2 mcg, 4 mcg*
- *penicillin g potassium injection solution reconstituted 20000000 unit*
- *penicillin g sodium injection solution reconstituted 5000000 unit*
- *pentamidine isethionate inhalation solution reconstituted 300 mg*
- *pentamidine isethionate injection solution reconstituted 300 mg*
- *perphenazine oral tablet 4 mg, 8 mg*
- PLASMA-LYTE A INTRAVENOUS SOLUTION
- *potassium chloride in nacl intravenous solution 20-0.45 meq/l-%, 20-0.9 meq/l-%, 40-0.9 meq/l-%*
- *potassium chloride intravenous solution 10 meq/100ml, 2 meq/ml, 2 meq/ml (20 ml), 20 meq/100ml, 40 meq/100ml*
- *potassium cl in dextrose 5% intravenous solution 20 meq/l*
- *prednisolone oral solution 15 mg/5ml*
- *prednisolone sodium phosphate oral solution 10 mg/5ml, 20 mg/5ml, 25 mg/5ml, 6.7 (5 base) mg/5ml*
- *prednisolone sodium phosphate oral tablet dispersible 10 mg, 15 mg, 30 mg*
- PREDNISONE INTENSOL ORAL CONCENTRATE 5 MG/ML
- *prednisone oral solution 5 mg/5ml*
- *prednisone oral tablet 1 mg, 10 mg, 2.5 mg, 20 mg, 5 mg, 50 mg*
- PREHEVBRIO INTRAMUSCULAR SUSPENSION 10 MCG/ML
- PREMASOL INTRAVENOUS SOLUTION 10 %
- PRIVIGEN INTRAVENOUS SOLUTION 20 GM/200ML
- *prochlorperazine maleate oral tablet 10 mg, 5 mg*
- PROGRAF ORAL PACKET 0.2 MG, 1 MG
- PROSOL INTRAVENOUS SOLUTION 20 %
- PULMOZYME INHALATION SOLUTION 2.5 MG/2.5ML
- RABA VERT INTRAMUSCULAR SUSPENSION RECONSTITUTED
- RECOMBIVAX HB INJECTION SUSPENSION 10 MCG/ML, 40 MCG/ML, 5 MCG/0.5ML
- RECOMBIVAX HB INJECTION SUSPENSION PREFILLED SYRINGE 10 MCG/ML, 5 MCG/0.5ML
- *sirolimus oral solution 1 mg/ml*
- *sirolimus oral tablet 0.5 mg, 1 mg, 2 mg*
- *tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg*
- TDVAX INTRAMUSCULAR SUSPENSION 2-2 LF/0.5ML
- TEFLARO INTRAVENOUS SOLUTION RECONSTITUTED 400 MG, 600 MG
- TENIVAC INTRAMUSCULAR INJECTABLE 5-2 LFU, 5-2 LFU (INJECTION)
- *tigecycline intravenous solution reconstituted 50 mg*
- *tobramycin inhalation nebulization solution 300 mg/5ml*
- *tobramycin sulfate injection solution 10 mg/ml, 80 mg/2ml*
- TPN ELECTROLYTES INTRAVENOUS CONCENTRATE

Formulary ID: 24447 version XX

Last Updated: 07/24/2024

Effective: 08/01/2024

- TRAVASOL INTRAVENOUS SOLUTION 10 %
- TREXALL ORAL TABLET 10 MG, 15 MG, 5 MG, 7.5 MG
- TROPHAMINE INTRAVENOUS SOLUTION 10 %
- VARUBI (180 MG DOSE) ORAL TABLET THERAPY PACK 2 X 90 MG
- XATMEP ORAL SOLUTION 2.5 MG/ML

Details

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

Index

A

ABELCET INTRAVENOUS SUSPENSION 5 MG/ML.....	268
abiraterone acetate	1
acetylcysteine inhalation solution 10 %, 20 %	268
acitretin	2
ACTIMMUNE.....	3
acyclovir sodium intravenous solution 50 mg/ml	268
ADEMPAS	4
AKEEGA	5
albuterol sulfate inhalation nebulization solution (2.5 mg/3ml) 0.083%, 0.63 mg/3ml, 1.25 mg/3ml, 2.5 mg/0.5ml ..	268
ALECENSA.....	6
ALUNBRIG.....	8
ALVAIZ.....	9
ambrisentan	10
amikacin sulfate injection solution 500 mg/2ml	268
amphotericin b intravenous solution reconstituted 50 mg.....	268
amphotericin b liposome intravenous suspension reconstituted 50 mg	268
ampicillin sodium injection solution reconstituted 1 gm, 125 mg.....	268
ampicillin sodium intravenous solution reconstituted 10 gm.....	268
aprepitant oral capsule 125 mg, 40 mg, 80 & 125 mg, 80 mg	268
ARCALYST	11
ARIKAYCE.....	12
armodafinil	35
AUGTYRO.....	13
AURYXIA	14
AUSTEDO.....	15
AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HOUR 12 MG, 24 MG, 6 MG	15
AUSTEDO XR PATIENT TITRATION .	15

AVONEX PEN INTRAMUSCULAR AUTO-INJECTOR KIT.....	142
AVONEX PREFILLED INTRAMUSCULAR PREFILLED SYRINGE KIT.....	142
AYVAKIT	16
azathioprine oral tablet 100 mg, 50 mg, 75 mg	268
azithromycin intravenous solution reconstituted 500 mg.....	268
aztreonam injection solution reconstituted 1 gm, 2 gm	268
B	
BALVERSA	17
BENLYSTA SUBCUTANEOUS.....	18
BESREMI	19
BETASERON SUBCUTANEOUS KIT	142
bexarotene external	20
bexarotene oral.....	21
bosentan	22
BOSULIF.....	23
BRAFTOVI ORAL CAPSULE 75 MG ...	24
BRONCHITOL.....	25
BRUKINSA	26
budesonide inhalation suspension 0.25 mg/2ml, 0.5 mg/2ml, 1 mg/2ml	268
BYLVAY	27
BYLVAY (PELLETS).....	27
C	
CABLIVI	28
CABOMETYX	29
calcitonin (salmon) nasal solution 200 unit/act.....	268
calcitriol oral capsule 0.25 mcg, 0.5 mcg	268
calcitriol oral solution 1 mcg/ml.....	268
CALQUENCE	30
CAMZYOS	31
CAPRELSA	32
carglumic acid oral tablet soluble	33
CAYSTON.....	34

Formulary ID: 24447 version 15
Last Updated: 07/24/2024
Effective: 08/01/2024

cefotetan disodium injection solution
 reconstituted 1 gm, 2 gm..... 268
 cefoxitin sodium intravenous solution
 reconstituted 1 gm, 10 gm, 2 gm..... 268
 cefuroxime sodium injection solution
 reconstituted 750 mg..... 268
 cefuroxime sodium intravenous solution
 reconstituted 1.5 gm..... 268
 chlorpromazine hcl oral concentrate 100
 mg/ml, 30 mg/ml..... 268
 chlorpromazine hcl oral tablet 10 mg, 100
 mg, 200 mg, 25 mg, 50 mg 268
 cinacalcet hcl oral tablet 30 mg, 60 mg, 90
 mg 268
 ciprofloxacin in d5w intravenous solution
 200 mg/100ml 268
 clindamycin phosphate injection solution
 900 mg/6ml 268
 CLINIMIX E/DEXTROSE (2.75/5)
 INTRAVENOUS SOLUTION 2.75 % 268
 CLINIMIX E/DEXTROSE (4.25/10)
 INTRAVENOUS SOLUTION 4.25 % 268
 CLINIMIX E/DEXTROSE (4.25/5)
 INTRAVENOUS SOLUTION 4.25 % 268
 CLINIMIX E/DEXTROSE (5/15)
 INTRAVENOUS SOLUTION 5 % 268
 CLINIMIX E/DEXTROSE (5/20)
 INTRAVENOUS SOLUTION 5 % 268
 CLINIMIX/DEXTROSE (4.25/10)
 INTRAVENOUS SOLUTION 4.25 % 268
 CLINIMIX/DEXTROSE (4.25/5)
 INTRAVENOUS SOLUTION 4.25 % 268
 CLINIMIX/DEXTROSE (5/15)
 INTRAVENOUS SOLUTION 5 % 268
 CLINIMIX/DEXTROSE (5/20)
 INTRAVENOUS SOLUTION 5 % 268
 colistimethate sodium (cba) injection
 solution reconstituted 150 mg..... 268
 COMETRIQ (100 MG DAILY DOSE)
 ORAL KIT 80 & 20 MG 36
 COMETRIQ (140 MG DAILY DOSE)
 ORAL KIT 3 X 20 MG & 80 MG 36
 COMETRIQ (60 MG DAILY DOSE)..... 36

COPAXONE SUBCUTANEOUS
 SOLUTION PREFILLED SYRINGE .. 83
 COPIKTRA..... 37
 CORLANOR ORAL TABLET 38
 COSENTYX (300 MG DOSE)..... 39, 40
 COSENTYX SENSOREADY (300 MG) 39,
 40
 COSENTYX SUBCUTANEOUS
 SOLUTION PREFILLED SYRINGE 75
 MG/0.5ML 39, 40
 COSENTYX UNOREADY 39, 40
 COTELLIC 41
 cromolyn sodium inhalation nebulization
 solution 20 mg/2ml 268
 cyclophosphamide oral capsule 25 mg, 50
 mg 268
 cyclophosphamide oral tablet 25 mg, 50 mg
 268
 cyclosporine modified oral capsule 100 mg,
 25 mg, 50 mg 268
 cyclosporine modified oral solution 100
 mg/ml 269
 cyclosporine oral capsule 100 mg, 25 mg 269
 CYSTADROPS..... 43
 CYSTAGON..... 42
 CYSTARAN 43
D
 dalfampridine er 44
 DAURISMO 45
 DAYBUE..... 46
 deferasirox granules 47
 deferasirox oral tablet 47
 deferasirox oral tablet soluble 47
 deferiprone 48
 dextrose intravenous solution 10 %, 5 % 269
 dextrose-sodium chloride intravenous
 solution 10-0.2 %, 10-0.45 %, 2.5-0.45 %, 5-0.2 %, 5-0.45 %, 5-0.9 %..... 269
 DIACOMIT..... 49
 diclofenac sodium external gel 3 % 50
 DIFICID..... 51
 dimethyl fumarate oral 52
 dimethyl fumarate starter pack oral capsule
 delayed release therapy pack 52

Formulary ID: 24447 version 15
 Last Updated: 07/24/2024
 Effective: 08/01/2024

diphtheria-tetanus toxoids dt intramuscular suspension 25-5 Iu/0.5ml	269
DOJOLVI.....	53
DOXY 100 INTRAVENOUS SOLUTION RECONSTITUTED 100 MG	269
dronabinol	54
droxidopa	55
DUPIXENT.....	56
E	
ELIGARD.....	124
EMGALITY	57
ENBREL MINI.....	58
ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5ML	58
ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE	58
ENBREL SURECLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR	58
ENDARI	59
ENGERIX-B INJECTION SUSPENSION 20 MCG/ML	269
ENGERIX-B INJECTION SUSPENSION PREFILLED SYRINGE 10 MCG/0.5ML, 20 MCG/ML	269
ENSPRYNG	60
ENVARUSUS XR ORAL TABLET EXTENDED RELEASE 24 HOUR 0.75 MG, 1 MG, 4 MG	269
EPIDIOLEX.....	61
ERAXIS INTRAVENOUS SOLUTION RECONSTITUTED 100 MG, 50 MG	269
ERIVEDGE.....	63
ERLEADA	64
erlotinib hcl	65
ERYTHROCIN LACTOBIONATE INTRAVENOUS SOLUTION RECONSTITUTED 500 MG	269
everolimus oral tablet 0.25 mg, 0.5 mg, 0.75 mg, 1 mg	269
everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg	66
everolimus oral tablet soluble	67
EVRYSDI	68

F	
febuxostat.....	69
fentanyl	71
fentanyl citrate buccal lozenge on a handle	70
FERRIPROX ORAL SOLUTION.....	48
FERRIPROX TWICE-A-DAY.....	48
FILSPARI	72
fingolimod hcl.....	73
FINTEPLA.....	74
FIRMAGON (240 MG DOSE).....	75
FIRMAGON SUBCUTANEOUS SOLUTION RECONSTITUTED 80 MG	75
fluconazole in sodium chloride intravenous solution 200-0.9 mg/100ml-%, 400-0.9 mg/200ml-%	269
FOTIVDA	76
FRUZAQLA	77
furosemide injection solution 10 mg/ml .	269
G	
GALAFOLD	78
GATTEX.....	79
GAVRETO	80
gefitinib.....	81
GENGRAF ORAL CAPSULE 100 MG, 25 MG	269
GENGRAF ORAL SOLUTION 100 MG/ML.....	269
GILOTRIF	82
GLEOSTINE ORAL CAPSULE 10 MG, 100 MG, 40 MG.....	84
granisetron hcl oral tablet 1 mg	269
H	
heparin sodium (porcine) injection solution 1000 unit/ml, 10000 unit/ml, 20000 unit/ml, 5000 unit/ml	269
HEPLISAV-B INTRAMUSCULAR SOLUTION PREFILLED SYRINGE 20 MCG/0.5ML	269
HUMIRA (2 PEN)	89, 90
HUMIRA (2 SYRINGE) SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20	

Formulary ID: 24447 version 15
Last Updated: 07/24/2024
Effective: 08/01/2024

MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML	89, 90
HUMIRA-CD/UC/HS STARTER SUBCUTANEOUS PEN-INJECTOR KIT 80 MG/0.8ML	89, 90
HUMIRA-PED>/=40KG UC STARTER	89, 90
HUMIRA-PSORIASIS/UVEIT STARTER	89, 90
HYFTOR.....	91
I	
IBRANCE	92
icatibant acetate subcutaneous solution prefilled syringe	93
ICLUSIG.....	94
IDHIFA	95
imatinib mesylate	96
IMBRUVICA ORAL CAPSULE.....	97
IMBRUVICA ORAL SUSPENSION.....	97
IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG.....	97
IMOVAX RABIES INTRAMUSCULAR SUSPENSION RECONSTITUTED 2.5 UNIT/ML	269
INBRIJA	98
INCRELEX.....	99
INLYTA.....	100
INQOVI	101
INREBIC.....	102
INTRALIPID INTRAVENOUS EMULSION 20 %, 30 %	269
INTRAROSA.....	103
ipratropium bromide inhalation solution 0.02 %	269
ipratropium-albuterol inhalation solution 0.5-2.5 (3) mg/3ml	269
ISOLYTE-P IN D5W INTRAVENOUS SOLUTION.....	269
ISOLYTE-S PH 7.4 INTRAVENOUS SOLUTION.....	269
ISTURISA ORAL TABLET 1 MG, 5 MG	104
itraconazole oral.....	105, 106
ivermectin oral	107

IWILFIN	108
J	
JAKAFI.....	109
JAYPIRCA	110
JOENJA	111
JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 5 MG	112
K	
KALYDECO.....	113
kcl in dextrose-nacl intravenous solution 10- 5-0.45 meq/l-%-%, 20-5-0.2 meq/l-%-%, 20-5-0.45 meq/l-%-%, 20-5-0.9 meq/l-%- %, 30-5-0.45 meq/l-%-%, 40-5-0.45 meq/l-%-%, 40-5-0.9 meq/l-%-%	269
kcl-lactated ringers-d5w intravenous solution 20 meq/l.....	269
KESIMPTA.....	114
KINERET SUBCUTANEOUS SOLUTION PREFILLED SYRINGE	115
KISQALI (200 MG DOSE).....	116
KISQALI (400 MG DOSE).....	116
KISQALI (600 MG DOSE).....	116
KISQALI FEMARA (200 MG DOSE) ..	117
KISQALI FEMARA (400 MG DOSE) ..	117
KISQALI FEMARA (600 MG DOSE) ..	117
KOSELUGO	118
KRAZATI.....	119
L	
lapatinib ditosylate	120
lenalidomide.....	121
LENVIMA (10 MG DAILY DOSE)	122
LENVIMA (12 MG DAILY DOSE)	122
LENVIMA (14 MG DAILY DOSE)	122
LENVIMA (18 MG DAILY DOSE)	122
LENVIMA (20 MG DAILY DOSE)	122
LENVIMA (24 MG DAILY DOSE)	122
LENVIMA (4 MG DAILY DOSE)	122
LENVIMA (8 MG DAILY DOSE)	122
LEUKINE INJECTION SOLUTION RECONSTITUTED	123
leuprolide acetate (3 month)	124
leuprolide acetate injection	124
lidocaine external patch 5 %	125

Formulary ID: 24447 version 15
Last Updated: 07/24/2024
Effective: 08/01/2024

linezolid intravenous solution 600 mg/300ml	126
linezolid oral tablet	126
LIVMARLI	127
LIVTENCITY	128
LONSURF	129
LORBRENA	130
LUMAKRAS	131
LUPKYNIS	132
LUPRON DEPOT (1-MONTH)	124
LUPRON DEPOT (3-MONTH)	124
LUPRON DEPOT (4-MONTH)	124
LUPRON DEPOT (6-MONTH)	124
LUPRON DEPOT-PED (1-MONTH) INTRAMUSCULAR KIT 7.5 MG	124
LUPRON DEPOT-PED (3-MONTH) INTRAMUSCULAR KIT 11.25 MG	124
LUPRON DEPOT-PED (6-MONTH)	124
LYNPARZA ORAL TABLET	133, 134
LYTGOBI (12 MG DAILY DOSE)	135
LYTGOBI (16 MG DAILY DOSE)	135
LYTGOBI (20 MG DAILY DOSE)	135
M	
MATULANE	136
MAVYRET	88
MAYZENT	137
MAYZENT STARTER PACK	137
MEKINIST	138
MEKTOVI	139
methotrexate sodium (pf) injection solution 50 mg/2ml	269
methotrexate sodium injection solution 50 mg/2ml	269
methotrexate sodium oral tablet 2.5 mg	269
methylprednisolone oral tablet 16 mg, 32 mg, 4 mg, 8 mg	269
metronidazole intravenous solution 500 mg/100ml	269
mifepristone oral tablet 300 mg	140
miglustat	141
modafinil oral	35
MOUNJARO	85
moxifloxacin hcl in nacl intravenous solution 400 mg/250ml	269

multiple electro type 1 ph 5.5 intravenous solution	269
mycophenolate mofetil oral capsule 250 mg	269
mycophenolate mofetil oral suspension reconstituted 200 mg/ml	269
mycophenolate mofetil oral tablet 500 mg	269
mycophenolate sodium oral tablet delayed release 180 mg, 360 mg	269
N	
nafcillin sodium injection solution reconstituted 1 gm, 2 gm	269
nafcillin sodium intravenous solution reconstituted 10 gm	269
NAMZARIC	143
NERLYNX	144
NINLARO	145
nitisinone	146
NOXAFIL ORAL PACKET	171
NUBEQA	147
NUCALA	148
NUEDEXTA	149
NUPLAZID ORAL CAPSULE	150
NUPLAZID ORAL TABLET 10 MG ...	150
NUTRILIPID INTRAVENOUS EMULSION 20 %	269
O	
octreotide acetate injection solution 100 mcg/ml, 1000 mcg/ml, 200 mcg/ml, 50 mcg/ml, 500 mcg/ml	151
ODOMZO	152
OFEV	153
OGSIVEO ORAL TABLET 50 MG	154
OJJAARA	155
OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE	86, 87
OMNITROPE SUBCUTANEOUS SOLUTION RECONSTITUTED ...	86, 87
ondansetron hcl oral solution 4 mg/5ml ..	269
ondansetron hcl oral tablet 4 mg, 8 mg ...	270
ondansetron oral tablet dispersible 4 mg, 8 mg	270
ONUREG	156

Formulary ID: 24447 version 15
 Last Updated: 07/24/2024
 Effective: 08/01/2024

OPSUMIT	157	PIQRAY (300 MG DAILY DOSE).....	167
ORGOVYX.....	158	pirfenidone	168
ORKAMBI.....	159	PLASMA-LYTE A INTRAVENOUS	
ORSERDU.....	160	SOLUTION.....	270
OSPHENA	161	POMALYST.....	169
OTEZLA	162	posaconazole oral.....	170, 171
oxacillin sodium in dextrose intravenous		potassium chloride in nacl intravenous	
solution 1 gm/50ml, 2 gm/50ml.....	270	solution 20-0.45 meq/l-%, 20-0.9 meq/l-	
oxacillin sodium injection solution		%, 40-0.9 meq/l-%	270
reconstituted 1 gm, 2 gm.....	270	potassium chloride intravenous solution 10	
oxacillin sodium intravenous solution		meq/100ml, 2 meq/ml, 2 meq/ml (20 ml),	
reconstituted 10 gm.....	270	20 meq/100ml, 40 meq/100ml	270
OZEMPIC (0.25 OR 0.5 MG/DOSE)		potassium cl in dextrose 5% intravenous	
SUBCUTANEOUS SOLUTION PEN-		solution 20 meq/l.....	270
INJECTOR 2 MG/3ML	85	prednisolone oral solution 15 mg/5ml	270
OZEMPIC (1 MG/DOSE)		prednisolone sodium phosphate oral solution	
SUBCUTANEOUS SOLUTION PEN-		10 mg/5ml, 20 mg/5ml, 25 mg/5ml, 6.7 (5	
INJECTOR 4 MG/3ML	85	base) mg/5ml.....	270
OZEMPIC (2 MG/DOSE)	85	prednisolone sodium phosphate oral tablet	
P		dispersible 10 mg, 15 mg, 30 mg.....	270
PANRETIN.....	163	PREDNISONE INTENSOL ORAL	
PANZYGA INTRAVENOUS SOLUTION		CONCENTRATE 5 MG/ML.....	270
1 GM/10ML, 10 GM/100ML, 2.5		prednisone oral solution 5 mg/5ml	270
GM/25ML, 20 GM/200ML, 30		prednisone oral tablet 1 mg, 10 mg, 2.5 mg,	
GM/300ML, 5 GM/50ML	270	20 mg, 5 mg, 50 mg	270
paricalcitol oral capsule 1 mcg, 2 mcg, 4		PREHEVBRIO INTRAMUSCULAR	
mcg.....	270	SUSPENSION 10 MCG/ML	270
pazopanib hcl	164	PREMASOL INTRAVENOUS SOLUTION	
PEGASYS SUBCUTANEOUS SOLUTION		10 %	270
180 MCG/ML	165	PREVYMIS ORAL	172
PEGASYS SUBCUTANEOUS SOLUTION		PRIVIGEN INTRAVENOUS SOLUTION	
PREFILLED SYRINGE	165	20 GM/200ML.....	270
PEMAZYRE	166	prochlorperazine maleate oral tablet 10 mg,	
penicillin g potassium injection solution		5 mg	270
reconstituted 20000000 unit.....	270	PROGRAF ORAL PACKET 0.2 MG, 1 MG	
penicillin g sodium injection solution		270
reconstituted 5000000 unit.....	270	PROLASTIN-C INTRAVENOUS	
pentamidine isethionate inhalation solution		SOLUTION.....	7
reconstituted 300 mg.....	270	PROMACTA	173
pentamidine isethionate injection solution		PROSOL INTRAVENOUS SOLUTION 20	
reconstituted 300 mg.....	270	%	270
perphenazine oral tablet 4 mg, 8 mg.....	270	PULMOZYME INHALATION	
PIQRAY (200 MG DAILY DOSE).....	167	SOLUTION 2.5 MG/2.5ML	270
PIQRAY (250 MG DAILY DOSE).....	167		

Formulary ID: 24447 version 15
Last Updated: 07/24/2024
Effective: 08/01/2024

Q		
QINLOCK.....	174	
quinine sulfate oral.....	175	
R		
RABAVERT INTRAMUSCULAR		
SUSPENSION RECONSTITUTED... 270		
RAVICTI	176	
RECOMBIVAX HB INJECTION		
SUSPENSION 10 MCG/ML, 40		
MCG/ML, 5 MCG/0.5ML	270	
RECOMBIVAX HB INJECTION		
SUSPENSION PREFILLED SYRINGE		
10 MCG/ML, 5 MCG/0.5ML	270	
REGRANEX.....	177	
REPATHA	178	
REPATHA PUSHTRONEX SYSTEM..	178	
REPATHA SURECLICK.....	178	
RETACRIT INJECTION SOLUTION		
10000 UNIT/ML, 10000		
UNIT/ML(1ML), 2000 UNIT/ML, 20000		
UNIT/ML, 3000 UNIT/ML, 4000		
UNIT/ML, 40000 UNIT/ML	62	
RETEVMO	179	
REZLIDHIA	180	
REZUROCK.....	181	
riluzole	182	
RINVOQ.....	183	
RIVFLOZA.....	184	
ROZLYTREK.....	185	
RUBRACA	186	
RYBELSUS	85	
RYDAPT.....	187	
S		
sapropterin dihydrochloride oral packet .	188	
sapropterin dihydrochloride oral tablet...	188	
SCEMBLIX	189	
SIGNIFOR	190	
sildenafil citrate oral tablet 20 mg	191	
sirolimus oral solution 1 mg/ml	270	
sirolimus oral tablet 0.5 mg, 1 mg, 2 mg	270	
SIRTURO	192	
SKYRIZI PEN	193	
SKYRIZI SUBCUTANEOUS.....	193	
sodium oxybate	194	
		sofosbuvir-velpatasvir..... 88
		SOHONOS..... 195
		SOLTAMOX
		196
		SOMAVERT.....
		197
		sorafenib tosylate
		198
		SPRYCEL
		199
		STELARA SUBCUTANEOUS
		SOLUTION 45 MG/0.5ML
		200
		STELARA SUBCUTANEOUS
		SOLUTION PREFILLED SYRINGE
		200
		STIVARGA
		201
		sunitinib malate.....
		202
		SYMDEKO.....
		203
		SYMLINPEN 120 SUBCUTANEOUS
		SOLUTION PEN-INJECTOR.....
		204
		SYMLINPEN 60 SUBCUTANEOUS
		SOLUTION PEN-INJECTOR.....
		204
		SYNAREL
		205
		T
		TABLOID
		206
		TABRECTA
		207
		tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg
	
		270
		TAFINLAR.....
		208
		TAGRISO
		209
		TAKHZYRO.....
		210
		TALZENNA
		211
		TASIGNA.....
		212
		TAVNEOS
		213
		tazarotene external cream
		214
		tazarotene external gel
		214
		TAZORAC EXTERNAL CREAM 0.05 %
	
		214
		TAZVERIK.....
		215
		TDVAX INTRAMUSCULAR
		SUSPENSION 2-2 LF/0.5ML
		270
		TEFLARO INTRAVENOUS SOLUTION
		RECONSTITUTED 400 MG, 600 MG
	
		270
		TEGSEDI.....
		216
		TENIVAC INTRAMUSCULAR
		INJECTABLE 5-2 LFU, 5-2 LFU
		(INJECTION)
		270
		TEPMETKO
		217

Formulary ID: 24447 version 15
Last Updated: 07/24/2024
Effective: 08/01/2024

teriparatide (recombinant) subcutaneous solution pen-injector 620 mcg/2.48ml	218
tetrabenazine	219
THALOMID	220
TIBSOVO	221
tigecycline intravenous solution reconstituted 50 mg	270
TOBI PODHALER	222
tobramycin inhalation nebulization solution 300 mg/5ml	270
tobramycin sulfate injection solution 10 mg/ml, 80 mg/2ml	270
tolvaptan	223
toremifene citrate	225
TPN ELECTROLYTES INTRAVENOUS CONCENTRATE	270
TRAVASOL INTRAVENOUS SOLUTION 10 %	271
TRELSTAR MIXJECT	226
tretinoin external	224
TREXALL ORAL TABLET 10 MG, 15 MG, 5 MG, 7.5 MG	271
trientine hcl	227
TRIKAFTA	228
TROPHAMINE INTRAVENOUS SOLUTION 10 %	271
TRULICITY	85
TRUQAP	229
TUKYSA	230
TURALIO ORAL CAPSULE 125 MG..	231
TYMLOS	232
U	
UBRELVY	233
V	
VALCHLOR	234
VANFLYTA	235
VARUBI (180 MG DOSE) ORAL TABLET THERAPY PACK 2 X 90 MG	271
VENCLEXTA	236
VENCLEXTA STARTING PACK	236
VERQUVO	237
VERZENIO	238

VICTOZA SUBCUTANEOUS SOLUTION PEN-INJECTOR	85
vigabatrin	239
VIGADRONE ORAL TABLET	239
VIGPODER	239
VIJOICE ORAL TABLET THERAPY PACK	240
VITRAKVI	241
VIZIMPRO	242
VONJO	243
voriconazole intravenous	244
voriconazole oral	244
VOSEVI	88
VYNDAMAX	245
W	
WELIREG	246
X	
XALKORI	247
XATMEP ORAL SOLUTION 2.5 MG/ML	271
XDEMVY	248
XGEVA	249
XOLAIR	250
XOSPATA	251
XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 50 MG	252, 253
XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 40 MG.	252, 253
XPOVIO (40 MG TWICE WEEKLY) ORAL TABLET THERAPY PACK 40 MG	252, 253
XPOVIO (60 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 60 MG.	252, 253
XPOVIO (60 MG TWICE WEEKLY)..	252, 253
XPOVIO (80 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 40 MG.	252, 253
XPOVIO (80 MG TWICE WEEKLY)..	252, 253
XTANDI	254

Formulary ID: 24447 version 15
Last Updated: 07/24/2024
Effective: 08/01/2024

XURIDEN.....	255	ZIEXTENZO	260
Y		ZILBRYSQ	261
YARGESA.....	141	ZOKINVY	262
YONSA.....	256	ZOLINZA	263
Z		ZTALMY	264
ZARXIO	257	ZURZUVAE.....	265
ZEJULA.....	258	ZYDELIG	266
ZELBORAF.....	259	ZYKADIA ORAL TABLET	267