

MCS Classicare 2024 Formulary 2 Prior Authorization Criteria

MCS Classicare Del Caribe (HMO), MCS Classicare En Tu Hogar (HMO), MCS Classicare Efectivo (HMO), MCS Classicare Essential (HMO-POS), MCS Classicare Exacto (HMO), MCS Classicare Excede (HMO), MCS Classicare Firme (HMO), MCS Classicare Hero (HMO), MCS Classicare Intelicare
(HMO), MCS Classicare Primero (HMO C-SNP), MCS Classicare MAPD Group (HMO-POS), MCS Classicare Platino Del Sur (HMO D-SNP), MCS Classicare Platino Ideal (HMO D-SNP), MCS Classicare Platino MásCa\$h (HMO D-SNP),MCS Classicare Platino Maximo (HMO D-SNP), MCS Classicare Platino Progreso (HMO D-SNP), MCS Classicare Platino Total (HMO D-SNP)

MCS Classicare requires you (or your physician) to get prior authorization for certain drugs. This means that you will need to get approval from MCS Classicare before you fill your prescriptions. If you don't get approval, MCS Classicare may not cover the drug.

MCS Classicare is an HMO plan subscribed by MCS Advantage, Inc.

ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call 1.866.627.8183 (TTY: 1.866.627.8182).

ATENCIÓN: Si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.627.8183 (TTY: 1.866.627.8182). 注意:如果您使用繁體中文, 您可以免費獲得語言援助服務。請致電 1.866.627.8183 (TTY: 1.866.627.8182).



Last Updated 04/18/2024

Prior Authorization Requirements

ABIRATERONE

Products Affected

• abiraterone acetate oral tablet 250 mg, 500 mg

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

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

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

ADALIMUMAB-ADBM

Products Affected

• adalimumab-adbm (2 pen)

- adalimumab-adbm(cd/uc/hs strt)
- adalimumab-adbm(ps/uv starter)
- adalimumab-adbm (2 syringe) subcutaneous prefilled syringe kit 10 mg/0.2ml, 20 mg/0.4ml, 40 mg/0.8ml

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	Plan Year
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

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: Plan Year
Other Criteria	Continuation of therapy: patient is tolerating and responding to medication and has improved exercise capacity or a delay in clinical worsening.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AFINITOR

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 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 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

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

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	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

ALOSETRON

Products Affected

• alosetron hcl

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Constipation, B.) History of Chronic or severe constipation or sequelae from constipation, C.) History of ischemic colitis, intestinal obstruction, stricture, toxic megacolon, GI perforation, adhesions, diverticulitis, Crohns disease, ulcerative colitis, D.) History of severe hepatic impairment, E.) History of impaired intestinal circulation, thrombophlebitis, or hypercoagulable state, or F.) Coadministration with fluvoxamine
Required Medical Information	Diagnosis of irritable bowel syndrome, severe diarrhea-predominant
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ALPHA-1 PROTEINASE INHIBITOR

Products Affected

• PROLASTIN-C

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	Plan Year
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

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: Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AMJEVITA

Products Affected

• AMJEVITA

• AMJEVITA-PED 15KG TO <30KG

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	Plan Year
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

APTIOM

Products Affected

• APTIOM

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of partial-onset seizures
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

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	Plan Year
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ATYPICALS

	MTUFII. REXULTIJLAR PREFILLEDRISPERDAL CONSTAMG/2.4ML, 960. SECUADO• VERSACLOZ. VRAYLAR ORAL CAPSULE 1.5 MG, 3MG, 4.5 MG, 6 MG. VRAYLAR ORAL CAPSULE
PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Select atypical antipsychotics will be covered when one the following is met A.) Patient is using the requested drug for an FDA-Approved or compendia supported indication and the patient unable to take at least one generic oral atypical antipsychotic due to inadequate treatment response, intolerance, or contraindication, B.) Patient is using the requested drug for an FDA-Approved or compendia supported indication and patient has a clinical condition for which there is no generic alternative or the generic alternatives are not recommended based on published guidelines or clinical literature, or C.) Patient is using the requested drug for an FDA-Approved or compendia supported indication and patient medically requires use of a specific dosage form that is not available in the generic alternatives (examples: suspension, solution, injection).
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.

Prior Authorization Criteria

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

AUGTYRO

Products Affected

• AUGTYRO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of locally advanced or metastatic ROS1-positive non-small cell lung cancer
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

Products Affected

• AUSTEDO

• AUSTEDO XR PATIENT TITRATION

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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	Prescribed by or in consultation with an oncologist, allergist, or immunologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BALVERSA

Products Affected

BALVERSA ORAL TABLET 3 MG, 4
 MG, 5 MG

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

BANZEL

Products Affected

• rufinamide oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	Familial Short QT Syndrome
Required Medical Information	Diagnosis of 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

BENLYSTA

Products Affected

• BENLYSTA

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

BEXAROTENE GEL

Products Affected

• bexarotene

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

BEXAROTENE ORAL

Products Affected

• bexarotene

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 oncologist, hematologist, or dermatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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: Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Products Affected

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

MG, 500 MG

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

BRAFTOVI

Products Affected

• BRAFTOVI

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

BRIVIACT

Products Affected

• BRIVIACT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of partial-onset seizures, member must have history of inadequate response, contraindication, or intolerance to levetiracetam prior to approval.
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

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	Plan year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	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

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

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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CAPRELSA

Products Affected

• CAPRELSA ORAL TABLET 100 MG, 300 MG

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	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

CARGLUMIC ACID

Products Affected

• carglumic acid

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Products Affected

• clobazam oral suspension

• SYMPAZAN

• clobazam oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of 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

CNS STIMULANTS

Products Affected

• armodafinil

• modafinil

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

COMETRIQ

Products Affected

• COMETRIQ (100 MG DAILY DOSE)

• COMETRIQ (60 MG DAILY DOSE)

• COMETRIQ (140 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

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

Products Affected

CORLANOR ORAL SOLUTION
 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

Products Affected

- COSENTYX
- COSENTYX (300 MG DOSE) •
- COSENTYX SENSOREADY (300 MG)

COSENTYX UNOREADY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Ankylosing spondylitis, B.) Moderate to severe plaque psoriasis in adults, C.) Moderate to severe plaque psoriasis in patients 6 years to less than 18 years of age, D.) Active psoriatic arthritis in adult patients, E.) Active psoriatic arthritis in patients 2 years to less than 18 years of age, F.) Non-radiographic axial spondyloarthritis G.) Active enthesitis-related arthritis, or H.) Moderate to severe hidradenitis suppurativa in adults. Screening for latent tuberculosis infection is required prior to initiation of treatment
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Plan Year
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

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

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

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

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

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

DEFERASIROX

Products Affected

• deferasirox

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DEFERIPRONE

Products Affected

• deferiprone

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 $1.5 \ge 10(9)/L$
Age Restrictions	8 years of age and older
Prescriber Restrictions	None
Coverage Duration	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

DICLOFENAC PATCH

Products Affected

• diclofenac epolamine

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of acute mild to moderate pain due to minor strains, sprains and contusions
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	3 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DIMETHYL FUMARATE

Products Affected

• dimethyl fumarate

• *dimethyl fumarate starter 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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

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	Initial: 1 month, Renewal: 3 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	Prescribed by or in consultation with an allergist, dermatologist, gastroenterologist, immunologist, otolaryngologist, pulmonologist, or rheumatologist
Coverage Duration	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EMGALITY

Products Affected

• EMGALITY

• EMGALITY (300 MG DOSE)

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

EMSAM

Products Affected

• EMSAM

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use with any of the following: SSRIs, SNRIs, clomipramine, imipramine, meperidine, tramadol, methadone, pentazocine, propoxyphene, dextromethorphan, carbamazepine, or B.) Pheochromocytoma
Required Medical Information	Diagnosis of major depressive disorder and patient had trial of at least 2 generic oral antidepressants from differing classes (at least one should be from the following list: selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, mirtazapine, or bupropion unless contraindicated), unless unable to take any oral medication AND Patient had an adequate washout period (for patients previously on agents requiring a washout period)
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

ENBREL

- ENBREL
- ENBREL MINI

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	Plan Year
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

• ENBREL SURECLICK

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

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

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

EPOETIN THERAPY

Products Affected

• RETACRIT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Pretreatment hemoglobin levels of less than 10g/dL. Dose reduction or interruption if hemoglobin exceeds 10 g/dL (CKD not on dialysis-adult, cancer), 11 g/dL (CKD on dialysis), 12 g/dL (pediatric CKD) in addition to supporting statement of diagnosis from physician. Patients with perioperative hemoglobin more than 10 g/dL to 13 g/dL scheduled to undergo elective, noncardiac, nonvascular surgery
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	3 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

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

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

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

EVEROLIMUS SUSPENSION

Products Affected

 everolimus oral tablet soluble 2 mg, 3 mg, 5 mg

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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EXKIVITY

Products Affected

• EXKIVITY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations (as confirmed by an FDA-approved test) AND whose disease has progressed on or 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

FASENRA

Products Affected

• FASENRA

• FASENRA PEN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of severe asthma with an eosinophilic phenotype
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

FENTANYL ORAL

Products Affected

• *fentanyl citrate*

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

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

FIRMAGON

Products Affected

• FIRMAGON

• FIRMAGON (240 MG DOSE)

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

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

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

FULPHILA

Products Affected

• FULPHILA

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FYCOMPA

Products Affected

• FYCOMPA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Partial-onset seizures with or without secondary generalization, or B.) Primary generalized tonic-clonic seizure disorder as adjunctive therapy
Age Restrictions	4 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

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

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

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

GLATIRAMER

Products Affected

• glatiramer acetate

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GLEOSTINE

Products Affected

• GLEOSTINE

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

Products Affected

• OZEMPIC (0.25 OR 0.5 MG/DOSE)

RYBELSUS

OZEMPIC (1 MG/DOSE)OZEMPIC (2 MG/DOSE)

٠	TRULICITY	

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

GROWTH HORMONE

Products Affected

• OMNITROPE

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	Supporting statement of diagnosis from the physician
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or nephrologist
Coverage Duration	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HEPATITIS B

Products Affected

- adefovir dipivoxil
- BARACLUDE

- entecavir •
- VEMLIDY •

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of chronic hepatitis B and all of the following 1.) Patient has or had evidence of viral replication prior to initiation, 2.) Patient has evidence of persistent elevations in serum aminotransferase (ALT or AST) or histologically active disease, and 3.) Patient is receiving anti-retroviral therapy if the patient has HIV co-infection
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
Coverage Duration	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HEPATITIS C

Products Affected

• MAVYRET

• sofosbuvir-velpatasvir

• sojosbuvir-veipaiasvir	
PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must submit documentation of chronic hepatitis C genotype (confirmed by HCV RNA level within the last 6 months). Must submit laboratory results within 12 weeks prior to initiating therapy including: 1) CBC w Platelets, 2) AST/ALT, 3) Total Bilirubin, 4) Serum Albumin, and 5) PT/INR. Must include subtype, trial/failure, contraindication to, or intolerance to Sofosbuvir/Velpatasvir or Mavyret prior to 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

• VOSEVI

HRM - ANALGESICS

Products Affected

• butalbital-acetaminophen

• butalbital-apap-caffeine

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or 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

HRM - ANTI-ARRHYTHMICS

Products Affected

• digoxin oral solution

• digoxin oral tablet 250 mcg

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Formulary Non HRM alternatives: propranolol, sotalol, dofetilide, amiodarone, propafenone, mexiletine
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HRM - ANTICHOLINERGIC

Products Affected

• chlordiazepoxide-clidinium

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or 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

HRM - ANTIDEMENTIA

Products Affected

• ergoloid mesylates

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Formulary non-HRM alternatives: donepezil, galantamine, memantine, rivastigmine oral
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HRM - ANTIDEPRESSANTS

Products Affected

• chlordiazepoxide-amitriptyline

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Formulary non-HRM alternatives: mirtazapine, trazodone, fluoxetine, escitalopram, fluvoxamine, desvenlafaxine, duloxetine, sertraline, venlafaxine, bupropion
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HRM - ANTIHISTAMINES

Products Affected

- hydroxyzine hcl
- hydroxyzine pamoate

- promethazine hcl
- PROMETHEGAN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Formulary non-HRM alternatives FOR MANAGEMENT OF ALLERGIC CONDITIONS: desloratadine, cetirizine syp, levocetirizine. FOR MANAGEMENT OF ANXIETY/SEDATION: buspirone, trazodone. FOR MANAGEMENT OF NAUSEA/VOMITING: granisetron, ondansetron
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HRM - ANTIPARKINSON AGENTS

Products Affected

• *benztropine mesylate*

• trihexyphenidyl hcl

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Formulary non-HRM alternatives: amantadine, carbidopa/levodopa, entacapone, Neupro, pramipexole, ropinirole, selegiline
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HRM - BENZODIAZEPINES

Products Affected

alprazolam oral tablet 0.25 mg, 0.5 mg, 1
 mg, 2 mg

• chlordiazepoxide hcl

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or 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

estazolam

temazepam

HRM - CARDIOVASCULAR

Products Affected

• guanfacine hcl er

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Formulary Non HRM alternatives: atomoxetine, dexmethylphenidate, methylphenidate
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HRM - MEGESTROL

Products Affected

• megestrol acetate

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Formulary Non HRM alternatives: dronabinol
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HRM - SEDATIVE HYPNOTICS

Products Affected

• zaleplon

• *zolpidem tartrate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Formulary non-HRM alternatives: Belsomra, doxepin 3mg and 6mg tablets, trazodone
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HRM - SKELETAL MUSCLE RELAXANTS

Products Affected

• cyclobenzaprine hcl

• orphenadrine citrate er

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Formulary Non HRM alternatives: baclofen
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Products Affected

 HUMIRA (2 PEN) SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.4ML, 40 MG/0.8ML, 80 MG/0.8ML 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 HUMIRA-CD/UC/HS STARTER HUMIRA-PED>/=40KG UC STARTER HUMIRA-PED>/=40KG UC STARTER HUMIRA-PED>/=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	Plan Year
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment
Indications	All Medically-accepted Indications.

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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

ICATIBANT

Products Affected

• *icatibant acetate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hereditary angioedema AND medication will be used for the treatment of acute attacks
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist, hematologist, or immunologist
Coverage Duration	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Products Affected

• ICLUSIG ORAL TABLET 10 MG, 15 MG, 30 MG, 45 MG

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

Products Affected

IDHIFA ORAL TABLET 100 MG, 50 MG

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

IMATINIB

Products Affected

• *imatinib mesylate oral tablet 100 mg, 400 mg*

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

IMBRUVICA

Products Affected

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• IMBRUVICA ORAL CAPSULE 140 MG, 70 MG

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• IMBRUVICA ORAL SUSPENSION

• IMBRUVICA ORAL TABLET

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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INJECTABLE TESTOSTERONE

Products Affected

• testosterone cypionate

• testosterone enanthate

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Carcinoma of the breast (males only), B.) Known or suspected carcinoma of the prostate, C.) Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Hypogonadotropic hypogonadism, B.) Inoperable metastatic breast cancer in women who are postmenopausal (testosterone enanthate), C.) Primary hypogonadism, or D.) Delayed puberty (testosterone enanthate). Diagnosis of hypogonadism must be confirmed by a low-for-age serum testosterone (total or free) level defined by the normal laboratory reference value
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

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

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

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

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

Products Affected

INVEGA HAFYERA
 INTRAMUSCULAR SUSPENSION

PREFILLED SYRINGE 1092 MG/3.5ML, 1560 MG/5ML

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following A.) Diagnosis of schizophrenia, and B.) Adequate treatment has been established with Invega Sustenna for at least 4 months or Invega Trinza for at least one three-month injection cycle
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an psychiatrist
Coverage Duration	12 months
Other Criteria	For continuation of therapy member must be re-evaluated by the psychiatrist to assess clinical response. Treatment should be discontinued if failure to therapy or an adverse event is documented or the member does not demonstate adherence to treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Products Affected

 INVEGA SUSTENNA INTRAMUSCULAR SUSPENSION PREFILLED SYRINGE 117 MG/0.75ML, 156 MG/ML, 234 MG/1.5ML, 39 MG/0.25ML, 78 MG/0.5ML

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet one of the following A.) Diagnosis of schizophrenia and all of the following 1.) trial and failure, contraindication, or intolerance to two oral second-generation antipsychotics, 2.) Trial and failure to respond to haloperidol decanoate and fluphenazine decanoate, 3.)Member has established response and tolerability to oral paliperidone, and 4.) Patient presents history of noncompliance with oral medications and documentation is provided on the efforts to improve medication adherence, or B.) Diagnosis of schizoaffective disorder and both of the following 1.)Member has established response and tolerability to oral paliperidone and 2.) Patient presents history of noncompliance with oral medications and documentation is provided on the efforts to improve medication adherence
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an psychiatrist
Coverage Duration	12 months
Other Criteria	For continuation of therapy member must be re-evaluated by the psychiatrist to assess clinical response. Treatment should be discontinued if failure to therapy or an adverse event is documented or the member does not demonstate adherence to treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Prior Authorization Criteria

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INVEGA TRINZA

Products Affected

• INVEGA TRINZA INTRAMUSCULAR SUSPENSION PREFILLED SYRINGE

273 MG/0.88ML, 410 MG/1.32ML, 546 MG/1.75ML, 819 MG/2.63ML

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following A.) Diagnosis of schizophrenia, and B.) Adequate treatment has been established with Invega Sustenna for at least 4 months
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an psychiatrist
Coverage Duration	12months
Other Criteria	For continuation of therapy member must be re-evaluated by the psychiatrist to assess clinical response. Treatment should be discontinued if failure to therapy or an adverse event is documented or the member does not demonstate adherence to treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ITRACONAZOLE

Products Affected

• itraconazole

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

IVERMECTIN

Products Affected

• *ivermectin*

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

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

JAKAFI

Products Affected

• JAKAFI

PA Criteria	Criteria Details
I A CITTEITA	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

JAYPIRCA

Products Affected

JAYPIRCA ORAL TABLET 100 MG, 50 MG

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

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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KERENDIA

Products Affected

• KERENDIA

PA Criteria	Criteria Details
Exclusion Criteria	none
Required Medical Information	Diagnosis of Chronic kidney disease associated with Type 2 diabetes mellitus AND patient is currently receiving the following standard of care A.) A maximally tolerated dose of ACE inhibitor, ARB, or a combination medication containing an ACE or ARB AND B.) Antidiabetic agent (e.g., metformin or an agent containing metformin, SGLT2 inhibitor, GLP-1 RA)
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

KINERET

Products Affected

• KINERET

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, Orencia, Rinvoq), 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

Products Affected

- KISQALI (200 MG DOSE)
- KISQALI (400 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, an intolerable adverse event, or contraindication to Ibrance (palbociclib) or Verzenio (abemaciclib), C.) The patient is a postmenopausal woman or man and the requested drug is being used following disease progression on 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

• KISQALI (600 MG DOSE)

Prior Authorization Criteria

MCS Classicare Formulary 2 – Formulary ID: 24446 – Version 11 Effective date: 05/01/2024 Last Updated: 04/18/2024

KISQALI FEMARA

Products Affected

• KISQALI FEMARA (200 MG DOSE)

• KISQALI FEMARA (600 MG DOSE)

• KISQALI FEMARA (400 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

KORLYM

Products Affected

• KORLYM

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

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

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

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

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	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

LEUKINE

Products Affected

• LEUKINE

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LEUPROLIDE

Products Affected

MG, 30 MG, 45 <i>leuprolide aceta</i> <i>leuprolide aceta</i> LUPRON DEP	• LUPRON DEPOT-PED (1-MONTH)	
PA Criteria	Criteria Details	
Exclusion Criteria	Pregnancy	
Required Medical Information	Must meet one of the following: 1.) Eligard only: Advanced or metastatic prostate cancer, or 2.) For Lupron depot and leuprolide products only: A.) Advanced or metastatic prostate cancer and patient has failed or is intolerant to Eligard or Trelstar (7.5 mg 1-month, 22.5 mg 3-month, 30 mg	

Pregnancy
Must meet one of the following: 1.) Eligard only: Advanced or metastatic prostate cancer, or 2.) For Lupron depot and leuprolide products only: A.) Advanced or metastatic prostate cancer and patient has failed or is intolerant to Eligard or Trelstar (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
None
None
12 months
B vs D determination required per CMS guidance
All Medically-accepted Indications.
N/A
No

LIDOCAINE EXT

Products Affected

• lidocaine external ointment

• lidocaine hcl

PA Criteria	Criteria Details
Exclusion Criteria	Amide hypersensitivity
Required Medical Information	The requested drug will be used for or topical anesthesia of skin or mucous membranes
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

LINEZOLID

Products Affected

- linezolid intravenous
- linezolid oral suspension reconstituted

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	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

• linezolid oral tablet

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	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

LORBRENA

Products Affected

 LORBRENA ORAL TABLET 100 MG, 25 MG

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

LUMAKRAS

Products Affected

 LUMAKRAS ORAL TABLET 120 MG, 320 MG

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	This criteria applies to new starts only
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LYNPARZA

Products Affected

• LYNPARZA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	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
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist

Prior Authorization Criteria

MCS Classicare Formulary 2 – Formulary ID: 24446 – Version 11 Effective date: 05/01/2024 Last Updated: 04/18/2024

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

Products Affected

• LYTGOBI (12 MG DAILY DOSE)

• LYTGOBI (20 MG DAILY DOSE)

• LYTGOBI (16 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

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

MAYZENT

Products Affected

MAYZENT ORAL TABLET 0.25 MG, 1
 MAYZENT STARTER PACK
 MG, 2 MG

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 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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

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

MIFEPRISTONE

Products Affected

• mifepristone

DA Cuitaria	Critorio Dotoila
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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MIGLUSTAT

Products Affected

• miglustat

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NAYZILAM

Products Affected

• NAYZILAM

PA Criteria	Criteria Details
Exclusion Criteria	Acute narrow angle glaucoma
Required Medical Information	Diagnosis of epilepsy and documentation of acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures), that are distinct from a patient's usual seizure pattern
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	This criteria applies to new starts only
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

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	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

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

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	Prescribed by or in consultation with a neurologist
Coverage Duration	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NUPLAZID

Products Affected

• NUPLAZID

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

OCTREOTIDE

Products Affected

• octreotide acetate

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	Plan Year
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ODOMZO

Products Affected

• ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	None
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	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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OGSIVEO

Products Affected

• OGSIVEO

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

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

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

Products Affected

• ORENCIA CLICKJECT

ORENCIA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 125 MG/ML, 50 MG/0.4ML, 87.5 MG/0.7ML

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, or D.) Prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in patients undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor. Screening for latent tuberculosis infection is required prior to initiation of treatment.
Age Restrictions	None
Prescriber Restrictions	pJIA/PsA/RA: Prescribed by or in consultation with a dermatologist or rheumatologist. aGVHD: None
Coverage Duration	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Products Affected

ORSERDU ORAL TABLET 345 MG, 86
 MG

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 man 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

Products Affected

• OTEZLA ORAL TABLET

OTEZLA ORAL TABLET THERAPY PACK

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. Cosentyx, Enbrel, Humira, 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. Cosentyx, Enbrel, Humira, 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	18 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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

PEGYLATED INTERFERON

Products Affected

• PEGASYS

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

PENICILLAMINE

Products Affected

• penicillamine

l	
PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Breastfeeding, B.) During Pregnancy (except for treatment of Wilson's disease), C.) Hypersensitivity to penicillamine products, D.) Penicillamine-related aplastic anemia/agranulocytosis, E.) Rheumatoid arthritis patients with history or evidence of renal insufficiency
Required Medical Information	Diagnosis of one of the following A.) Cystinuria, B.) Severe, active rheumatoid arthritis, or C.) Wilson's disease
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Products Affected

• PIQRAY (200 MG DAILY DOSE)

• PIQRAY (300 MG DAILY DOSE)

• PIQRAY (250 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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

POMALYST

Products Affected

• POMALYST

PA Criteria	Criteria Details
ra 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	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

POSACONAZOLE

Products Affected

- NOXAFIL
- posaconazole oral suspension

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

• posaconazole oral tablet delayed release

PREVYMIS

Products Affected

• PREVYMIS

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use with pimozide 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

PROLIA

Products Affected

• PROLIA

PA Criteria	Criteria Details
Exclusion Criteria	Hypocalcemia (calcium less than 8.0 mg/dL)
Required Medical Information	Must meet all of the following A.) Diagnosis of one of the following 1.) Treatment of osteoporosis in postmenopausal females at high risk of fracture, 2.) Treatment of osteoporosis in males at high risk of fracture 3.) Treatment of bone loss in males receiving androgen-deprivation therapy for nonmetastatic prostate cancer, 4.) Treatment of bone loss in females receiving aromatase inhibitor therapy for breast cancer, or 5.) Treatment of glucocorticoid-induced osteoporosis in patients at high risk of fracture who are initiating or continuing systemic glucocorticoids at a daily dose greater than or equal to 7.5 mg of prednisone for an anticipated duration of at least 6 months B.) Bone density scan (DEXA) documenting a T-score less than - 1.0 at lumbar spine, total hip, femoral neck, or 33% radius and member has high risk factors (high risk defined as osteoporotic fracture history, multiple risk factors for fracture, or failure of or intolerance to other available osteoporosis therapy) or T-score less than or equal to -2.5 in the lumbar spine, total hip, femoral neck, or 33% radius
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

Prior Authorization Criteria

MCS Classicare Formulary 2 – Formulary ID: 24446 – Version 11 Effective date: 05/01/2024 Last Updated: 04/18/2024

PROMACTA

Products Affected

PROMACTA ORAL PACKET 12.5 MG,
 PROMACTA ORAL TABLET 25 MG

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PULMOZYME

Products Affected

• PULMOZYME

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis (CF)
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	Plan Year
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PURIXAN

Products Affected

• PURIXAN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) Diagnosis of acute lymphocytic leukemia, 2.) Using in combination with methotrexate, 3.) Patient has tried/failed or has contraindication/intolerance to mercaptopurine tablets
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

PYRIMETHAMINE

Products Affected

• pyrimethamine

PA Criteria	Criteria Details
Exclusion Criteria	Documented megaloblastic anemia due to folate deficiency
Required Medical Information	Diagnosis of Toxoplasmosis and treatment in combination with a sulfonamide
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	10 weeks
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	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

QUININE SULFATE

Products Affected

• quinine sulfate

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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REPATHA

Products Affected• REPATHA• 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

RETEVMO

Products Affected

RETEVMO ORAL CAPSULE 40 MG, 80
MG

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

REVLIMID

Products Affected

• REVLIMID

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	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

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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

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	Plan Year
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

Products Affected

- RIVFLOZA SUBCUTANEOUS
 SOLUTION
- RIVFLOZA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 128 MG/0.8ML, 160 MG/ML

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	Prescribed by or in consultation with a NEPHROLOGIST
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ROZLYTREK

Products Affected

• ROZLYTREK ORAL CAPSULE 100 • ROZLYTREK ORAL PACKET

MG, 200 MG

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	Verify the pregnancy status of females of reproductive potential prior to initiating ROZLYTREK
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

RUFINAMIDE

Products Affected

• rufinamide oral suspension

PA Criteria	Criteria Details
Exclusion Criteria	Familial Short QT Syndrome
Required Medical Information	Diagnosis of seizures associated with Lennox-Gastaut syndrome and used as adjunctive treatment
Age Restrictions	1 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

RYDAPT

Products Affected

• RYDAPT

PA Criteria	Criteria Details
r A Uniterna	
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

SAPROPTERIN

Products Affected

• sapropterin dihydrochloride

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: Plan year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SCEMBLIX

Products Affected

• SCEMBLIX

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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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 riocguat 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	Continuation of therapy: patient is tolerating and responding to medication and has improved exercise capacity or a delay in clinical worsening.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

Products Affected

- SKYRIZI PEN
- SKYRIZI SUBCUTANEOUS SOLUTION CARTRIDGE 180 MG/1.2ML, 360 MG/2.4ML

SKYRIZI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

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. Screening for latent tuberculosis infection is required prior to initiation of treatment.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist, gastroenterologist, or rheumatologist
Coverage Duration	Plan Year
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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Products Affected

• SOHONOS ORAL CAPSULE 1 MG, 1.5 MG, 10 MG, 2.5 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
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

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

Products Affected

• SOMAVERT SUBCUTANEOUS SOLUTION RECONSTITUTED 10 MG, 15 MG, 20 MG, 25 MG, 30 MG

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

Products Affected

• SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

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

Products Affected

- STELARA SUBCUTANEOUS
 SOLUTION
- STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 45 MG/0.5ML, 90 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severely active Crohn's disease, B.) Moderate to severe plaque psoriasis, C.) Active psoriatic arthritis, or D.) Moderate to severe active ulcerative colitis. Screening for latent tuberculosis infection is required prior to initiation of treatment.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist
Coverage Duration	Plan Year
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

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	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

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	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

Products Affected

• SYMLINPEN 120

• SYMLINPEN 60

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

TADALAFIL

Products Affected

• tadalafil

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) concurrent use of nitrates, including intermittent use, or B.) diagnosis of erectile dysfunction without signs and symptoms of BPH
Required Medical Information	Diagnosis of benign prostatic hyperplasia (BPH) and patient has experienced intolerance to or treatment failure to ONE alpha-blocker (e.g., doxazosin, prazosin, tamsulosin) AND to ONE 5-alpha reductase inhibitor (e.g., dutasteride, finasteride).
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

TAGRISSO

Products Affected

• TAGRISSO

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

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 enzulatamide
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

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

TAZAROTENE

Products Affected

• tazarotene external cream

• TAZORAC

• tazarotene external gel

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

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

ТЕРМЕТКО

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

TERIPARATIDE

Products Affected

• *teriparatide (recombinant)*

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, 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	Plan year (Maximum 24 month treatment per patient lifetime)
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TETRABENAZINE

Products Affected

• *tetrabenazine oral tablet 12.5 mg, 25 mg*

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

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

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 Pseudomonas aeruginosa infection in the lungs
Age Restrictions	6 years of age and older
Prescriber Restrictions	None
Coverage Duration	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TOPICAL RETINOIDS

Products Affected

• adapalene

• tretinoin external

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of mild to moderate acne vulgaris
Age Restrictions	PA applies to patients older than 26 years of age
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TOPICAL TESTOSTERONE

Products Affected

PA Criteria

Exclusion

 testosterone transdermal gel 10 mg/act (2%), 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%) testosterone transdermal solution

Criteria Details Any of the following A.) Carcinoma of the breast (males only), B.) Known or suspected carcinoma of the prostate (C) Pregnancy

Criteria	or suspected carcinoma of the prostate, C.) Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Hypogonadotropic hypogonadism, or B.) Primary hypogonadism. Diagnosis of hypogonadism must be confirmed by a low-for-age serum testosterone (total or free) level defined by the normal laboratory reference value
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

•

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

Products Affected

TRELSTAR MIXJECT
 INTRAMUSCULAR SUSPENSION

RECONSTITUTED 11.25 MG, 22.5 MG, 3.75 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TRIKAFTA

Products Affected

• TRIKAFTA ORAL TABLET THERAPY • PACK

TRIKAFTA ORAL THERAPY PACK 100-50-75 & 75 MG, 80-40-60 & 59.5 MG

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 elexacaftor/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

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

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

TURALIO

Products Affected

• TURALIO

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. Liver function tests prior to initiation.
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

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	Plan year (Maximum 24 month treatment per patient lifetime)
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

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

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

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

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

VIGABATRIN

Products Affected

- vigabatrin
- VIGADRONE

• VIGADRONE	
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

• VIGPODER

VIJOICE

Products Affected

• VIJOICE

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VITRAKVI

Products Affected

VITRAKVI ORAL CAPSULE 100 MG,
 VITRAKVI ORAL SOLUTION 25 MG

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

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

• 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

VORICONAZOLE

Products Affected

- voriconazole intravenous
- voriconazole oral suspension reconstituted

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 Scedosporium apiospermum or Fusarium species
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	6 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

•

voriconazole oral tablet 200 mg, 50 mg

VOTRIENT

Products Affected

• VOTRIENT

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

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

• XALKORI ORAL CAPSULE

• XALKORI ORAL CAPSULE SPRINKLE 150 MG, 20 MG, 50 MG

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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Products Affected

- XCOPRI (250 MG DAILY DOSE)
- XCOPRI (350 MG DAILY DOSE)
 - DOSE) PACK 00 MG, 150

• XCOPRI ORAL TABLET THERAPY

• XCOPRI ORAL TABLET 100 MG, 150 MG, 200 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	Familial short QT syndrome
Required Medical Information	Diagnosis of partial-onset seizures
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

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

• XELJANZ ORAL SOLUTION

XELJANZ XR

XELJANZ ORAL TABLET 10 MG, 5 •

MG

MG	
PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis (RA), B.) Active psoriatic arthritis, C.) Moderate to severe ulcerative colitis (UC), D.) Polyarticular course juvenile idiopathic arthritis (pcJIA), or E.) Active ankylosing spondylitis. Screening for latent tuberculosis infection is required prior to initiation of treatment.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Plan Year
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

XERMELO

Products Affected

• XERMELO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of carcinoid syndrome diarrhea and both of the following 1.) Diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide, lanreotide) for at least 3 months, and 2.) Used in combination with SSA therapy
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
Coverage Duration	Plan year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

• 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, used for the prevention of skeletal related events and must have an inadequate treatment response, adverse event, or contraindication to zoledronic acid, B.) Multiple myeloma, used for the prevention of skeletal related events and must have an inadequate treatment response, adverse event, or contraindication to zoledronic acid, C.) Hypercalcemia of malignancy refractory to bisphosphonate therapy and must have an inadequate treatment response, adverse event, or contraindication to zoledronic acid, 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	Plan Year
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	Yes

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, 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 or Dupixent, C.) Nasal polyps in patients with inadequate response to nasal corticosteroids, 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	Prescribed by or in consultation with an allergist, dermatologist, immunologist, otolaryngologist, or pulmonologist
Coverage Duration	Initial: 6 months, Renewal: Plan Year
Other Criteria	B vs D coverage determination per CMS guidelines
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

- XPOVIO (100 MG ONCE WEEKLY)
- XPOVIO (40 MG ONCE WEEKLY)
- XPOVIO (40 MG TWICE WEEKLY)
- XPOVIO (60 MG ONCE 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
Part B Prerequisite	No

• XPOVIO (60 MG TWICE WEEKLY)

• XPOVIO (80 MG ONCE WEEKLY)

• XPOVIO (80 MG TWICE WEEKLY)

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

• YONSA

PA Criteria	Criteria Details
Exclusion Criteria	None
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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

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

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	Plan Year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

• ZILBRYSQ SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 23 MG/0.574ML, 32.4 MG/0.81ML

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	Plan year
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

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	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

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

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

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

ZYDELIG

Products Affected

ZYDELIG ORAL TABLET 100 MG, 150 MG

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

ZYKADIA

Products Affected

• ZYKADIA

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

PART B VERSUS PART D

Products Affected

- 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
- amphotericin b intravenous solution reconstituted 50 mg
- amphotericin b liposome intravenous suspension reconstituted 50 mg
- ampicillin sodium injection solution reconstituted 1 gm, 125 mg
- aprepitant oral capsule 125 mg, 40 mg, 80 & 125 mg, 80 mg
- azathioprine oral tablet 50 mg
- azithromycin intravenous solution reconstituted 500 mg
- 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
- 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
- cinacalcet hcl oral tablet 30 mg, 60 mg, 90 mg
- CINRYZE INTRAVENOUS SOLUTION RECONSTITUTED 500 UNIT
- ciprofloxacin in d5w intravenous solution 200 mg/100ml
- clindamycin phosphate injection solution 600 mg/4ml, 900 mg/6ml
- CLINIMIX/DEXTROSE (4.25/5)
 INTRAVENOUS SOLUTION 4.25 %

Prior Authorization Criteria

- 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
- cyclosporine modified oral solution 100 mg/ml
- cyclosporine oral capsule 100 mg, 25 mg
- dextrose intravenous solution 10 %, 5 %
- dextrose-nacl intravenous solution 10-0.2
 %, 10-0.45 %, 2.5-0.45 %
- 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
- 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-%
- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA INTRAVENOUS SOLUTION RECONSTITUTED 10 GM, 5 GM

- GAMMAPLEX INTRAVENOUS
 SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 5 GM/50ML
- GAMUNEX-C INJECTION SOLUTION
 1 GM/10ML
- granisetron hcl oral tablet 1 mg
- heparin sodium (porcine) injection solution 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
- 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-%-%, 40-5-0.9 meq/l-%-%
- *kcl-lactated ringers-d5w intravenous solution 20 meq/l*
- levalbuterol hcl inhalation nebulization solution 0.31 mg/3ml, 0.63 mg/3ml, 1.25 mg/0.5ml, 1.25 mg/3ml
- *methotrexate sodium (pf) injection solution 50 mg/2ml*
- *methotrexate sodium injection solution 50 mg/2ml*
- *metronidazole intravenous solution 500 mg/100ml*
- *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
- NUTRILIPID INTRAVENOUS EMULSION 20 %
- ondansetron hcl oral solution 4 mg/5ml
- ondansetron hcl oral tablet 4 mg, 8 mg
- ondansetron oral tablet dispersible 4 mg, 8 mg
- 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
- 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
- PREHEVBRIO INTRAMUSCULAR SUSPENSION 10 MCG/ML
- PROGRAF ORAL PACKET 0.2 MG, 1
 MG
- RABAVERT 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

- SANDIMMUNE ORAL SOLUTION 100 MG/ML
- 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
- TEFLARO INTRAVENOUS SOLUTION RECONSTITUTED 400 MG, 600 MG
- 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
- TRAVASOL INTRAVENOUS SOLUTION 10 %
- TROPHAMINE INTRAVENOUS SOLUTION 10 %
- 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.

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%
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XPOVIO (60 MG TWICE WEEKLY)	
XPOVIO (80 MG ONCE WEEKLY)	
XPOVIO (80 MG TWICE WEEKLY)	
XTANDI	
Y	200
YONSA	267
Z	_0,
zaleplon	102
ZARXIO	
ZEJULA	
ZELBORAF	
ZIEXTENZO	
	<i>_</i> /1

ZILBRYSQ SUBCUTANEOUS

SOLUTION PREFILLED SYRING	GE 23
MG/0.574ML, 32.4 MG/0.81ML	272
ziprasidone mesylate	. 17, 18
ZOKINVY	273
ZOLINZA	274
zolpidem tartrate	102

ZTALMY
ZURZUVAE ORAL CAPSULE 20 MG, 25
MG, 30 MG 276
ZYDELIG ORAL TABLET 100 MG, 150
MG
ZYKADIA 278