

# ABIRATERONE

---

## Products Affected

- *abiraterone acetate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Castration-resistant metastatic prostate cancer and used in combination with prednisone, or B.) High risk, castration-sensitive metastatic prostate cancer and used in combination with prednisone
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ACITRETIN

---

## Products Affected

- *acitretin*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	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)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# ACTIMMUNE

---

## Products Affected

- ACTIMMUNE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ADEMPAS

---

## Products Affected

- ADEMPAS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	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)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	Initial: 6 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# AFINITOR DISPERZ

---

## Products Affected

- AFINITOR DISPERZ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Hypersensitivity to everolimus or excipients, or B.) Hypersensitivity to rapamycin derivatives (e.g. sirolimus)
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ALECENSA

---

## Products Affected

- ALECENSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer as detected by an FDA-approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# ALPHA-1 PROTEINASE INHIBITOR

---

## Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Immunoglobulin A (IgA) deficiency with antibodies against IgA
<b>Required Medical Information</b>	Diagnosis of alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency in adult patients with emphysema
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ALUNBRIG

---

## Products Affected

- ALUNBRIG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of anaplastic lymphoma kinase-positive (ALK) metastatic non-small cell lung cancer (NSCLC)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# AMBRISENTAN

---

## Products Affected

- *ambrisentan*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Pregnancy, or B.) Idiopathic pulmonary fibrosis (IPF), including those with pulmonary hypertension
<b>Required Medical Information</b>	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.)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	Initial: 6 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ARCALYST

---

## Products Affected

- ARCALYST

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# ARIKAYCE

---

## Products Affected

- ARIKAYCE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Known sensitivity to any aminoglycoside
<b>Required Medical Information</b>	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)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist or pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# AURYXIA

---

## Products Affected

- AURYXIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Iron overload syndrome (e.g. hemochromatosis)
<b>Required Medical Information</b>	Diagnosis of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or nephrologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Ferric Citrate is NOT approvable for iron deficiency anemia per Part D law
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# AUSTEDO

---

## Products Affected

- AUSTEDO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Suicidal ideation and/or untreated or inadequately treated depression, B.) Hepatic impairment, C.) Taking MAOIs, reserpine, or tetrabenazine
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chorea associated with Huntington's disease (Huntington's chorea), or B.) Tardive dyskinesia
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or psychiatrist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# AYVAKIT

---

## Products Affected

- AYVAKIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# BALVERSA

---

## Products Affected

- BALVERSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 or FGFR2 genetic alterations and 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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# BENLYSTA

---

## Products Affected

- BENLYSTA SUBCUTANEOUS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist or rheumatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# BEXAROTENE ORAL

---

## Products Affected

- *bexarotene*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# BOSENTAN

---

## Products Affected

- *bosentan*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant cyclosporine A or glyburide therapy, or B.) Pregnancy
<b>Required Medical Information</b>	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.)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	Initial: 6 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# BOSULIF

---

## Products Affected

- BOSULIF

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# BRAFTOVI

---

## Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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, or 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.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# BRUKINSA

---

## Products Affected

- BRUKINSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of mantle cell lymphoma (MCL) and patient has received at least one prior therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# CABLIVI

---

## Products Affected

- CABLIVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) and used in combination with plasma exchange and immunosuppression therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# CABOMETYX

---

## Products Affected

- CABOMETYX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Advanced hepatocellular carcinoma (HCC) and patient has been previously treated with sorafenib, or C.) Advanced renal cell carcinoma and used as first line treatment in combination with nivolumab
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# CALQUENCE

---

## Products Affected

- CALQUENCE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# CAPRELSA

---

## Products Affected

- CAPRELSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Congenital long QT syndrome
<b>Required Medical Information</b>	Diagnosis of metastatic or unresectable locally advanced medullary thyroid cancer (MTC) AND disease is symptomatic or progressive
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# CARBAGLU

---

## Products Affected

- CARBAGLU

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) N-acetyl glutamate synthase (NAGS) deficiency with acute or chronic hyperammonemia, or B.) Propionic or methylmalonic acidemia with acute hyperammonemia
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# CAYSTON

---

## Products Affected

- CAYSTON

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (confirmed by appropriate diagnostic or genetic testing) and patient has suspected or confirmed <i>Pseudomonas aeruginosa</i> lung infection
<b>Age Restrictions</b>	7 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# CNS STIMULANTS

---

## Products Affected

- *armodafinil*
- *modafinil*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# COMETRIQ

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of progressive, metastatic medullary thyroid cancer
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# COPIKTRA

---

## Products Affected

- COPIKTRA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsed or refractory chronic lymphocytic leukemia, B.) Small lymphocytic lymphoma, or C.) Relapsed or refractory follicular lymphoma and patient has history of at least 2 prior therapies
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# CORLANOR

---

## Products Affected

- CORLANOR ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	Diagnosis of one of the following A.) 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.) stable, symptomatic heart failure due to dilated cardiomyopathy in patients who are in sinus rhythm with an elevated heart rate
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# COSENTYX

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Ankylosing spondylitis and patient has trial and failure, contraindication, or intolerance to two preferred products, (i.e. Humira, Enbrel), B.) Moderate to severe plaque psoriasis and patient has trial and failure, contraindication, or intolerance to two preferred products, (i.e. Humira, Enbrel, Skyrizi, Stelara), C.) Active psoriatic arthritis and patient has trial and failure, contraindication, or intolerance to two preferred products, (i.e. Humira, Enbrel, Stelara), or D.) Non-radiographic axial spondyloarthritis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Screening for latent tuberculosis infection is required prior to initiation of treatment
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# COTELLIC

---

## Products Affected

- COTELLIC

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of unresectable or metastatic malignant melanoma with BRAF V600E OR V600K mutation, and documentation of combination therapy with vemurafenib (Zelboraf)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# CYSTAGON

---

## Products Affected

- CYSTAGON

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Known serious hypersensitivity to penicillamine or cysteamine
<b>Required Medical Information</b>	Diagnosis of nephropathic cystinosis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# CYSTEAMINE OPHTH

---

## Products Affected

- CYSTADROPS
- CYSTARAN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cystinosis and patient has corneal cystine crystal accumulation
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# DALFAMPRIDINE

---

## Products Affected

- *dalfampridine er*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) History of seizure. B.) Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute)
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# DAURISMO

---

## Products Affected

- DAURISMO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# DEFERASIROX

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Creatinine clearance less than 40 mL/min, B.) Poor performance status, C.) Platelet count less than 50 x 10 <sup>9</sup> /L, D.) Advanced malignancy, E.) High-risk myelodysplastic syndrome (MDS)
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# DEFERIPRONE

---

## Products Affected

- *deferiprone*
- FERRIPROX ORAL SOLUTION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) Diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease, or other anemias, 2.) Patient has failed prior chelation therapy, and 3.) Patient has an absolute neutrophil count greater than $1.5 \times 10^9/L$
<b>Age Restrictions</b>	8 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# DIACOMIT

---

## Products Affected

- DIACOMIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of severe myoclonic epilepsy in infancy (Dravet syndrome) in patients taking clobazam
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# DICLOFENAC TOPICAL

---

## Products Affected

- *diclofenac sodium external gel 3 %*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Actinic keratosis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# DIMETHYL FUMARATE

---

## Products Affected

- *dimethyl fumarate oral*
- *dimethyl fumarate starter pack*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# DOJOLVI

---

## Products Affected

- DOJOLVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Long-chain fatty acid oxidation disorder (LC-FAOD)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# DRONABINOL

---

## Products Affected

- *dronabinol*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Sesame oil hypersensitivity
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Anorexia associated to AIDS, or B.) Chemotherapy-induced nausea and vomiting
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# DROXIDOPA

---

## Products Affected

- *droxidopa*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# DUPIXENT

---

## Products Affected

- DUPIXENT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) 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, 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
<b>Age Restrictions</b>	6 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# ENBREL

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Screening for latent tuberculosis infection is required prior to initiation of treatment
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ENDARI

---

## Products Affected

- ENDARI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	5 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# ENSPRYNG

---

## Products Affected

- ENSPRYNG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Active Hepatitis B infection, or B.) Active or untreated latent tuberculosis
<b>Required Medical Information</b>	Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist, immunologist, or ophthalmologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ENTRESTO

---

## Products Affected

- ENTRESTO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) History of angioedema related to previous ACE inhibitor or ARB therapy, B.) Concomitant use or use within 36 hours of ACE inhibitors, or C.) Concomitant use of aliskiren in patients with diabetes
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic heart failure, NYHA Class II to IV, reduced ejection fraction in adult patients, or B.) Symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients (1 year and older)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# EPIDIOLEX

---

## Products Affected

- EPIDIOLEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# EPOETIN THERAPY

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Non-myeloid neoplastic disease and utilized for the treatment of chemotherapy induced anemia, B.) HIV infection and utilized for the treatment of zidovudine induced anemia, C.) Chronic kidney disease resulting in anemia, or D.) High risk surgical candidate status at risk for perioperative blood loss and undergoing elective, noncardiac, or nonvascular surgery
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# ERIVEDGE

---

## Products Affected

- ERIVEDGE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ERLEADA

---

## Products Affected

- ERLEADA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Nonmetastatic, castration-resistant prostate cancer, or B.) Metastatic, castration-sensitive prostate cancer
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# ERLOTINIB

---

## Products Affected

- *erlotinib hcl*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ESBRIET

---

## Products Affected

- ESBRIET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of idiopathic pulmonary fibrosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# EVEROLIMUS

## Products Affected

- AFINITOR ORAL TABLET 10 MG
- *everolimus oral tablet 2.5 mg, 5 mg, 7.5 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Hypersensitivity to everolimus or excipients, or B.) Hypersensitivity to rapamycin derivatives (e.g. sirolimus)
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery, B.) Advanced hormone receptor-positive, HER2 negative breast cancer in postmenopausal women and taken in combination with exemestane, after failure with letrozole or anastrozole, C.) Progressive, well-differentiated, nonfunctional neuroendocrine tumors of gastrointestinal or lung origin and disease is unresectable, locally advanced, or metastatic, D.) Pancreatic progressive neuroendocrine tumors and disease is unresectable, locally advanced, or metastatic, E.) Advanced renal cell carcinoma (RCC) after failure with sunitinib or sorafenib, F.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# EVRYSDI

---

## Products Affected

- EVRYSDI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of spinal muscular atrophy (SMA)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# FARYDAK

---

## Products Affected

- FARYDAK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) Diagnosis of multiple myeloma, 2.) Medication is being used in combination with Velcade (bortezomib) and dexamethasone, 3.) Patient has received at least two prior treatment regimens, including Velcade (bortezomib) and an immunomodulatory agent [e.g., Revlimid (lenalidomide), Thalomid (thalidomide)]
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# FENTANYL ORAL

---

## Products Affected

- *fentanyl citrate buccal lozenge on a handle*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	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)
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	16 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# FENTANYL PATCH

---

## Products Affected

- *fentanyl*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Management of acute or postoperative pain (including headache/migraine, dental pain, and use in the emergency room), B.) Mild or intermittent pain management, C.) Use in opioid non-tolerant patients, D.) Known or suspected gastrointestinal obstruction, including paralytic ileus, E.) Acute or severe bronchial asthma and used in an unmonitored setting (absence of resuscitative equipment)
<b>Required Medical Information</b>	Must meet all of the following 1.) Patient is opioid tolerant (taking for one week or longer at least 60mg of morphine or equivalent daily) and 2.) Patient has tried at least one extended release oral opioids or is unable to take extended release oral opioids secondary to allergy, adverse events, swallowing difficulty, or uncontrollable nausea/vomiting
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# FINTEPLA

---

## Products Affected

- FINTEPLA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI
<b>Required Medical Information</b>	Diagnosis of Severe myoclonic epilepsy in infancy (Dravet syndrome)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# FOTIVDA

---

## Products Affected

- FOTIVDA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of relapsed or refractory advanced renal cell cancer (RCC) following 2 or more prior systemic therapies
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# GALAFOLD

---

## Products Affected

- GALAFOLD

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Fabry disease with an amenable galactosidase alpha gene (GLA) mutation
<b>Age Restrictions</b>	16 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# GATTEX

---

## Products Affected

- GATTEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of short bowel syndrome and patient is dependent on parenteral support
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# GAVRETO

---

## Products Affected

- GAVRETO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# GILENYA

---

## Products Affected

- GILENYA ORAL CAPSULE 0.5 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure, B.) History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker, C.) Baseline QTC interval greater than or equal to 500 milliseconds, D.) Receiving concurrent treatment with Class Ia or Class III anti-arrhythmic drugs (quinidine, procainamide, amiodarone, sotalol)
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	10 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# GILOTRIF

---

## Products Affected

- GILOTRIF

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have nonresistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test, or B.) Metastatic squamous NSCLC with progression after platinum-based chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# GLATIRAMER

---

## Products Affected

- COPAXONE SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- *glatiramer acetate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# GROWTH HORMONE

## Products Affected

- OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE
- OMNITROPE SUBCUTANEOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	<p>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</p>
<b>Required Medical Information</b>	<p>Diagnosis of pediatric indication: A.) GHD and bone age at least 1 year or 2 standard deviations (SD) delayed compared with chronological age and 2 stim tests with peak GH secretion below 10 ng/mL or IGF-1/IGFBP3 level more than 2 SDS below mean if CNS pathology, h/o irradiation, or proven genetic cause, B.) SGA and birth weight or length 2 or more SDS below mean for gestational age and fails to manifest catch up growth by age 2 (height 2 or more SDS below mean for age and gender), C.) CRI and nutritional status has been optimized, metabolic abnormalities have been corrected, and patient has not had renal transplant D.) SHOX deficiency or Noonan syndrome E.) PWS confirmed by genetic testing, F.) Turner Syndrome confirmed by chromosome analysis. For GHD, CRI, SHOX deficiency, Noonan syndrome, and PWS one of the following height more than 3 SDS below mean for age and gender, or height more than 2 SDS below mean with GV more than 1 SDS below mean, or GV over 1 year 2 SDS below mean. OR Diagnosis of an adult indication: A.) childhood- or adult-onset GHD confirmed by 2 standard GH stim tests (provide assay): 1 test must be insulin tolerance test (ITT) with blood glucose nadir less than 40 mg/dL (2.2 mmol/L). If contraindicated, use a standardized stim test (i.e. arginine plus GH releasing hormone [preferred], glucagon, arginine), B.) GHD with at least 1 other pituitary hormone deficiency and failed at least 1 GH stim test (ITT preferred), C.) GHD with panhypopituitarism (3 or more pituitary hormone deficiencies), D.) GHD with irreversible hypothalamic-pituitary structural lesions due to tumors, surgery or radiation of pituitary or hypothalamus region AND a subnormal IGF-1 (after at least 1 month off GH therapy) AND Objective evidence of GHD complications, such as: low bone density, increased visceral fat mass, or cardiovascular complications AND Completed linear growth (GV less than</p>

Under CMS Review

<b>PA Criteria</b>	<b>Criteria Details</b>
	2 cm/year) AND GH has been discontinued for at least 1 month (if previously receiving GH)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an Endocrinologist or Nephrologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# HEPATITIS B

---

## Products Affected

- *adefovir dipivoxil*
- BARACLUDGE ORAL SOLUTION
- *entecavir*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of chronic hepatitis B and all of the following 1.) Patient has evidence of viral replication, 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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# HEPATITIS C

---

## Products Affected

- MAVYRET
- *sofosbuvir-velpatasvir*
- VOSEVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of HCV genotype, subtype and quantitative HCV RNA (viral load) testing any time prior to therapy. Must document cirrhosis status, prior treatment history (if any), and planned duration of treatment. All genotypes will require trial/failure, contraindication to, or intolerance to Mavyret or Sofosbuvir-Velpatasvir prior to the approval of Vosevi.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
<b>Coverage Duration</b>	Duration of approval per AASLD Guidelines
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# HETLIOZ

---

## Products Affected

- HETLIOZ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Non-24-hour-sleep-wake disorder (Non-24), or B.) Nighttime sleep disturbances associated with Smith-Magenis Syndrome (SMS)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 6 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# HUMIRA

## Products Affected

- HUMIRA PEDIATRIC CROHNS START SUBCUTANEOUS PREFILLED SYRINGE KIT 80 MG/0.8ML, 80 MG/0.8ML & 40MG/0.4ML
- HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT
- HUMIRA PEN-CD/UC/HS STARTER
- HUMIRA PEN-PEDIATRIC UC START
- HUMIRA PEN-PS/UV/ADOL HS START SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.8ML
- HUMIRA PEN-PSOR/UEIT STARTER
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Screening for latent tuberculosis infection is required prior to initiation of treatment
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# IBRANCE

---

## Products Affected

- IBRANCE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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 used in combination with an aromatase inhibitor in postmenopausal women or men
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# ICATIBANT

---

## Products Affected

- FIRAZYR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following and used as treatment for acute attacks A.) Hereditary angioedema (HAE) with C1 inhibitor deficiency (Type 1) confirmed by laboratory testing, or B.) HAE with C1 inhibitor dysfunction (Type 2) confirmed by laboratory testing, or C.) HAE with normal C1 inhibitor (Type 3) confirmed by laboratory testing and one of the following 1.) Positive test for an F12, angiotensin-1, or plasminogen gene mutation, or 2.) Family history of angioedema and the angioedema was refractory to a trial of an antihistamine for at least one month
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, hematologist, or immunologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ICLUSIG

---

## Products Affected

- ICLUSIG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# IDHIFA

---

## Products Affected

- IDHIFA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase 2 (IDH2) mutation as detected by an FDA approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# IMATINIB

---

## Products Affected

- *imatinib mesylate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# IMBRUVICA

---

## Products Affected

- IMBRUVICA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Mantle cell lymphoma (MCL) and patient has received at least one prior therapy, B.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL), C.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion, D.) Waldenstrom's macroglobulinemia (WM), E.) Marginal zone lymphoma (MZL) and patient requires systemic therapy and has received at least one prior anti-CD20-based therapy, or F.) Chronic graft vs host disease (cGVHD) after failure of a least one first-line corticosteroid therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# INBRIJA

---

## Products Affected

- INBRIJA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Concurrent use with nonselective monoamine oxidase inhibitors (MAOIs) (e.g. phenelzine and tranylcypromine), B.) Recent use (within 2 weeks) with a nonselective MAOI
<b>Required Medical Information</b>	Must meet all of the following A.) Diagnosis of Parkinson's disease, B.) Concurrent therapy with carbidopa/levodopa
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# INCRELEX

---

## Products Affected

- INCRELEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Active or suspected malignancy, B.) Use for growth promotion in patients with closed epiphyses, or C.) Intravenous administration
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# INLYTA

---

## Products Affected

- INLYTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# INQOVI

---

## Products Affected

- INQOVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# INREBIC

---

## Products Affected

- INREBIC

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# INTRAROSA

---

## Products Affected

- INTRAROSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Vaginal bleeding or dysfunctional uterine bleeding of an undetermined origin, or B.) Known or suspected estrogen-dependent neoplasia
<b>Required Medical Information</b>	Diagnosis of one of the following A.) moderate to severe dyspareunia due to menopause, or B.) atrophic vaginitis due to menopause
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 3 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# IRESSA

---

## Products Affected

- IRESSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# ISTURISA

---

## Products Affected

- ISTURISA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Cushing's disease in patients for whom pituitary surgery is not an option or has not been curative
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ITRACONAZOLE

---

## Products Affected

- *itraconazole oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ITRACONAZOLE SOLN

---

## Products Affected

- *itraconazole oral*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	Diagnosis of candidiasis (esophageal or oropharyngeal) that is refractory to treatment with fluconazole
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# JAKAFI

---

## Products Affected

- JAKAFI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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, OR C.) Acute graft versus host disease AND disease is refractory to steroid therapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# JUXTAPID

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Moderate to severe liver impairment or active liver disease including unexplained persistent abnormal liver function tests, B.) Pregnancy, or C.) Concomitant use with strong or moderate CYP3A4 inhibitors
<b>Required Medical Information</b>	Diagnosis of HoFH as confirmed by one of the following A.) Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (LDLRAP1 or ARH), or B.) Both of the following 1.) Either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL, and 2.) Either xanthoma before 10 years of age or evidence of heterozygous FH in both parents
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 6 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# KALYDECO

---

## Products Affected

- KALYDECO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# KESIMPTA

---

## Products Affected

- KESIMPTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Active Hepatitis B infection
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# KISQALI

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Hormone receptor (HR)-positive, HER-2 negative advanced or metastatic breast cancer in pre/perimenopausal or postmenopausal women and used in combination with an aromatase inhibitor, or B.) Hormone receptor (HR)-positive, HER-2 negative advanced or metastatic breast cancer in postmenopausal women and used in combination with fulvestrant
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# KISQALI FEMARA

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of hormone receptor (HR)-positive, HER-2 negative advanced or metastatic breast cancer in pre/perimenopausal or postmenopausal women
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# KORLYM

---

## Products Affected

- KORLYM

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# KOSELUGO

---

## Products Affected

- KOSELUGO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of neurofibromatosis type 1 (NF1) in a patient who has symptomatic, inoperable plexiform neurofibromas (PN)
<b>Age Restrictions</b>	2 years of age to 17 years of age
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# KYNMOBI

---

## Products Affected

- KYNMOBI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with 5-HT(3) receptor antagonists (e.g.. ondansetron, granisetron, dolasetron, palonosetron, alosetron etc.)
<b>Required Medical Information</b>	Diagnosis of Parkinson's disease (PD) and patient is experiencing acute intermittent hypomobility (defined as off episodes characterized by muscle stiffness, slow movements, or difficulty starting movements)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# LAPATINIB

---

## Products Affected

- *lapatinib ditosylate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# 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)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# LEUKINE

---

## Products Affected

- LEUKINE INJECTION SOLUTION RECONSTITUTED

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# LEUPROLIDE

---

## Products Affected

- ELIGARD
- *leuprolide acetate injection*
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced or metastatic prostate cancer and patient has failed or is intolerant to Eligard (7.5 mg 1-month, 22.5 mg 3-month, 30 mg 4-month, & 45 mg 6-month depots only), B.) Endometriosis (3.75 mg 1-month & 11.25 mg 3-month depots only), C.) Anemia due to uterine leiomyomata (Fibroids) (3.75 mg 1-month & 11.25 mg 3-month depots only) and patient is preoperative, or D.) Central precocious puberty (idiopathic or neurogenic) in children
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# LIDOCAINE PATCH

---

## Products Affected

- *lidocaine external patch 5 %*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Pain associated with diabetic neuropathy, B.) Pain associated with cancer-related neuropathy, C.) Post-herpetic neuralgia, D.) Chronic back pain, or E.) Osteoarthritis of the knee or hip
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# LINEZOLID

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use of MAOI therapy
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# LONSURF

---

## Products Affected

- LONSURF

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# LORBRENA

---

## Products Affected

- LORBRENA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use with strong CYP3A4 inducers
<b>Required Medical Information</b>	Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# LUMAKRAS

---

## Products Affected

- LUMAKRAS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# LUPKYNIS

---

## Products Affected

- LUPKYNIS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin)
<b>Required Medical Information</b>	Initial: Diagnosis of systemic lupus erythematosus (SLE) with active lupus nephritis (LN) Classes III, IV, V (alone or in combination), and all of the following: 1.) Baseline renal function of 45 mL/min/1.73 m <sup>2</sup> or greater, 2.) Will be used in combination with a background immunosuppressive therapy regimen (e.g. mycophenolate, oral steroids, etc). Renewal: Improvement in urine protein to creatinine ratio (UPCR) (i.e. less than or equal to 0.5 mg/mg) AND estimated glomerular filtration rate (eGFR) of 60 mL/min/1.73 m <sup>2</sup> or greater, or no confirmed decrease from baseline in eGFR of greater than 20%
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a rheumatologist or nephrologist
<b>Coverage Duration</b>	Initial: 12 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# LYNPARZA

## Products Affected

- LYNPARZA ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	<p>Diagnosis of one of the following A.) HER2-negative, deleterious or suspected deleterious germline BRCA mutated metastatic breast cancer and patient has been previously treated with chemotherapy in neoadjuvant, adjuvant, or metastatic setting, B.) Advanced ovarian cancer with known or suspected BRCA mutation as detected by an FDA-approved test AND patient has trial and failure, contraindication, or intolerance to 3 or more prior lines of chemotherapy, C.) 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), D.) 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, E.) 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, F.) 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, or G.) 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</p>
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# MATULANE

---

## Products Affected

- MATULANE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Inadequate marrow reserve
<b>Required Medical Information</b>	Diagnosis of Hodgkin's Disease, Stages III and IV and used in combination with other anticancer drugs
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# MAYZENT

---

## Products Affected

- MAYZENT
- MAYZENT STARTER PACK ORAL TABLET THERAPY PACK 12 X 0.25 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	Diagnosis of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease and the following A.) Patients with relapsing forms of multiple sclerosis have history of/or contraindication to Avonex, Betaseron, Glatiramer, Gilenya, or Dimethyl Fumarate
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# MEKINIST

---

## Products Affected

- MEKINIST

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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, or D.) Metastatic non-small cell lung cancer, with BRAF V600E mutation, in combination with dabrafenib.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# MEKTOVI

---

## Products Affected

- MEKTOVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of 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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# METHOXSALLEN

---

## Products Affected

- *methoxsalen rapid*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# MIGLUSTAT

---

## Products Affected

- *miglustat*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of mild to moderate type 1 Gaucher disease and patient is not a candidate for enzyme replacement therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# MS INTERFERONS

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# NATPARA

---

## Products Affected

- NATPARA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of hypoparathyroidism and used to control hypocalcemia
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# NERLYNX

---

## Products Affected

- NERLYNX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# NEXAVAR

---

## Products Affected

- NEXAVAR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Squamous cell lung cancer being treated with carboplatin and paclitaxel
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# NINLARO

---

## Products Affected

- NINLARO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of multiple myeloma, used in combination with lenalidomide and dexamethasone, AND patient has history of at least 1 prior therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# NITISINONE

---

## Products Affected

- *nitisinone*
- ORFADIN ORAL CAPSULE 20 MG
- ORFADIN ORAL SUSPENSION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of hereditary tyrosinemia type 1
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# NUBEQA

---

## Products Affected

- NUBEQA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of non-metastatic, castration-resistant prostate cancer
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# NUCALA

---

## Products Affected

- NUCALA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# NUEDEXTA

---

## Products Affected

- NUEDEXTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	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, pimozone), 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
<b>Required Medical Information</b>	Diagnosis of pseudobulbar affect
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# NUPLAZID

---

## Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of hallucinations and delusions associated with Parkinson disease psychosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# OCTREOTIDE

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Acromegaly and patient has inadequate response to or is ineligible for surgery, radiation, or bromocriptine mesylate, or B.) Metastatic carcinoid syndrome, or C.) Vasoactive intestinal peptide-secreting tumors (VIPomas) with associated diarrhea
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ODOMZO

---

## Products Affected

- ODOMZO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# OFEV

---

## Products Affected

- OFEV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ONUREG

---

## Products Affected

- ONUREG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# OPSUMIT

---

## Products Affected

- OPSUMIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	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.)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	Initial: 6 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ORGOVYX

---

## Products Affected

- ORGOVYX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced prostate cancer
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# ORKAMBI

---

## Products Affected

- ORKAMBI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (CF) with documented homozygous F508del mutation confirmed by FDA-approved CF mutation test
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# OSPHENA

---

## Products Affected

- OSPHENA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Undiagnosed abnormal genital bleeding, B.) Known or suspected estrogen-dependent neoplasia, C.) Active deep vein thrombosis (DVT), pulmonary embolism (PE), or a history of these conditions, D.) Active arterial thromboembolic disease (e.g. stroke, myocardial infarction) or a history of these conditions, or E.) Pregnancy
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause, or B.) Moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# OXANDROLONE

---

## Products Affected

- *oxandrolone oral*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Known or suspected carcinoma of the prostate or breast in males, B.) Carcinoma of the breast in females with hypercalcemia, C.) Pregnancy, D.) Nephrosis or nephrotic phase of nephritis, E.) Hypercalcemia
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Bone pain associated with osteoporosis, B.) Protein catabolism associated with chronic corticosteroid administration, or C.) Used as adjunctive therapy to promote weight gain after weight loss associated with one of the following 1.) Extensive surgery, 2.) Chronic infections, 3.) Severe trauma, or 4.) Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# PEGYLATED INTERFERON

---

## Products Affected

- PEGASYS SUBCUTANEOUS SOLUTION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# PEMAZYRE

---

## Products Affected

- PEMAZYRE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of 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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist, gastroenterologist, or hepatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# PHENYL BUTYRATE

---

## Products Affected

- *sodium phenylbutyrate oral tablet*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Management of acute hyperammonemia
<b>Required Medical Information</b>	Diagnosis of urea cycle disorders involving deficiencies of carbamoylphosphate synthetase, ornithine transcarbamoylase, or argininosuccinic acid
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# PIQRAY

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# POMALYST

---

## Products Affected

- POMALYST

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	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 demonstrate disease progression on or within 60 days of completion of the last therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# POSACONAZOLE

---

## Products Affected

- *posaconazole*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# POSACONAZOLE SUSPENSION

---

## Products Affected

- NOXAFIL ORAL SUSPENSION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# PREVYMIS

---

## Products Affected

- PREVYMIS ORAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	Must meet both of the following 1.) Patient is CMV-seropositive (R+) and 2.) Patient is receiving an allogeneic hematopoietic stem cell transplant (HSCT)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# PROMACTA

---

## Products Affected

- PROMACTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# PYRIMETHAMINE

---

## Products Affected

- *pyrimethamine oral*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Documented megaloblastic anemia due to folate deficiency
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Toxoplasmosis and treatment in combination with a sulfonamide, B.) Acute malaria and treatment in combination with a sulfonamide and the patient has had inadequate response/intolerance/contraindication to chloroquine or quinine, or C.) Chemoprophylaxis of malaria due to susceptible strains of plasmodia
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist
<b>Coverage Duration</b>	10 weeks
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# QINLOCK

---

## Products Affected

- QINLOCK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced gastrointestinal stromal tumor (GIST) and patient has received prior treatment with 3 or more kinase inhibitors, including imatinib
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# QUININE SULFATE

---

## Products Affected

- *quinine sulfate oral*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	Diagnosis of one of the following A.) uncomplicated Plasmodium falciparum malaria, B.) uncomplicated Plasmodium vivax malaria, or C.) babesiosis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# RAVICTI

---

## Products Affected

- RAVICTI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of urea cycle disorders
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# REGRANEX

---

## Products Affected

- REGRANEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Known neoplasm at the site of application
<b>Required Medical Information</b>	Diagnosis of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply
<b>Age Restrictions</b>	16 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# REPATHA

---

## Products Affected

- REPATHA
- REPATHA SURECLICK
- REPATHA PUSHTRONEX SYSTEM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	13 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 3 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# RETEVMO

---

## Products Affected

- RETEVMO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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), or C.) Advanced or metastatic RET fusion-positive thyroid cancer in patients who require systemic therapy and are refractory to radioactive iodine, if appropriate
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# REVLIMID

---

## Products Affected

- REVLIMID

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# REZUROCK

---

## Products Affected

- REZUROCK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# RILUZOLE

---

## Products Affected

- *riluzole*
- TIGLUTIK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of amyotrophic lateral sclerosis (ALS)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# RINVOQ

---

## Products Affected

- RINVOQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of moderate to severe rheumatoid arthritis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Screening for latent tuberculosis infection is required prior to initiation of treatment
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ROZLYTREK

---

## Products Affected

- ROZLYTREK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# RUBRACA

---

## Products Affected

- RUBRACA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Epithelial ovarian, fallopian tube, or primary peritoneal cancer with deleterious BRCA mutation (germline and/or somatic) as detected by an FDA-approved test and patient has been treated with 2 or more prior lines of chemotherapy, B.) 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 C.) 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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# RYDAPT

---

## Products Affected

- RYDAPT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# SAPROPTERIN

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of hyperphenylalaninemia (HPA) caused by tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 2 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# SIGNIFOR

---

## Products Affected

- SIGNIFOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 6 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# SILDENAFIL

---

## Products Affected

- *sildenafil citrate oral tablet 20 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Nitrate therapy, including intermittent use, B.) Concomitant use with riociguat or other guanylate cyclase stimulators, C.) Concomitant use with HIV protease inhibitors or elvitegravir/cobicistat/tenofovir/emtricitabine
<b>Required Medical Information</b>	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.)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# SKYRIZI

---

## Products Affected

- SKYRIZI
- SKYRIZI (150 MG DOSE)
- SKYRIZI PEN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of moderate to severe plaque psoriasis and patient is a candidate for systemic therapy or phototherapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Screening for latent tuberculosis infection is required prior to initiation of treatment
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# SOMAVERT

---

## Products Affected

- SOMAVERT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of acromegaly and patient has had an inadequate response to or is ineligible for surgery or radiation therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# SPRYCEL

---

## Products Affected

- SPRYCEL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	1 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# STELARA

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Moderate to severely active Crohn disease, B.) Moderate to severe plaque psoriasis, C.) Active psoriatic arthritis, or D.) Moderate to severe active ulcerative colitis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Screening for latent tuberculosis infection is required prior to initiation of treatment
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# STIVARGA

---

## Products Affected

- STIVARGA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# SUNITINIB

---

## Products Affected

- *sunitinib malate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# SUNOSI

---

## Products Affected

- SUNOSI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI
<b>Required Medical Information</b>	Diagnosis of one of the following A.) narcolepsy with excessive daytime drowsiness and has trial of/or contraindication to modafinil or armodafinil, or B.) obstructive sleep apnea (OSA) with excessive daytime drowsiness and has trial of/or contraindication to modafinil or armodafinil
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# SYMDEKO

---

## Products Affected

- SYMDEKO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (CF) and must meet one of the following 1.) Patient is homozygous for the F508del mutation, or 2.) Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor verified by an FDA-cleared CF mutation test
<b>Age Restrictions</b>	6 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
<b>Coverage Duration</b>	Initial: 6 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# SYMLIN

---

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Confirmed diagnosis of gastroparesis, B.) Hypoglycemia unawareness
<b>Required Medical Information</b>	Diagnosis of type 1 or type 2 diabetes mellitus and patient uses mealtime insulin therapy and has failed to achieve desired glucose control
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# SYNAREL

---

## Products Affected

- SYNAREL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) pregnancy, B.) breastfeeding, C.) undiagnosed abnormal vaginal bleeding
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Central precocious puberty, or B.) Endometriosis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# SYNRIBO

---

## Products Affected

- SYNRIBO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of chronic or accelerated phase chronic myeloid leukemia (CML) and patient has tried and failed or has a contraindication or intolerance to at least 2 tyrosine kinase inhibitors
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# TABRECTA

---

## Products Affected

- TABRECTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TAFINLAR

---

## Products Affected

- TAFINLAR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# TAGRISO

---

## Products Affected

- TAGRISO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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, or 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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TAKHZYRO

---

## Products Affected

- TAKHZYRO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following and used as routine prophylaxis A.) Hereditary angioedema (HAE) with C1 inhibitor deficiency (Type 1) confirmed by laboratory testing, or B.) HAE with C1 inhibitor dysfunction (Type 2) confirmed by laboratory testing, or C.) HAE with normal C1 inhibitor (Type 3) confirmed by laboratory testing and one of the following 1.) Positive test for an F12, angiotensin-1, or plasminogen gene mutation, or 2.) Family history of angioedema and the angioedema was refractory to a trial of an antihistamine for at least one month
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist, immunologist, or allergist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# TALZENNA

---

## Products Affected

- TALZENNA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of 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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TARGRETIN GEL

---

## Products Affected

- TARGRETIN EXTERNAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# TASIGNA

---

## Products Affected

- TASIGNA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	1 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TAZAROTENE

---

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	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)
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# TAZVERIK

---

## Products Affected

- TAZVERIK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	16 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TEGSEDI

---

## Products Affected

- TEGSEDI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Platelet count less than 100,000 per microliter, B.) Urinary protein to creatinine ratio (UPCR) of 1000 mg/g or higher
<b>Required Medical Information</b>	Diagnosis of Polyneuropathy of hereditary transthyretin-mediated amyloidosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# TEPMETKO

---

## Products Affected

- TEPMETKO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic non-small cell lung cancer (NSCLC) with mesenchymal-epithelial transition (MET) exon 14 skipping alterations
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TERIPARATIDE

---

## Products Affected

- *teriparatide (recombinant)*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 12 months, Renewal: 12 months (Maximum 24 month treatment per patient lifetime)
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# TESTOSTERONES

---

## Products Affected

- 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*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TETRABENAZINE

---

## Products Affected

- *tetrabenazine*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	Diagnosis of chorea associated with Huntington's disease
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# THALOMID

---

## Products Affected

- THALOMID

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Multiple myeloma that is newly diagnosed, or B.) Erythema nodosum leprosum (ENL)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or infectious disease specialist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TIBSOVO

---

## Products Affected

- TIBSOVO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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), or B.) 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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# TOBI

---

## Products Affected

- TOBI PODHALER

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Known sensitivity to any aminoglycoside
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (confirmed by appropriate diagnostic or genetic testing) and patient has suspected or confirmed <i>Pseudomonas aeruginosa</i> infection in the lungs
<b>Age Restrictions</b>	6 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TOLVAPTAN

---

## Products Affected

- *tolvaptan*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD), B.) Urgent need to raise serum sodium acutely, C.) Inability to sense or appropriately respond to thirst, D.) Hypovolemic hyponatremia, E.) Concomitant use of strong CYP 3A Inhibitors (e.g. clarithromycin, ketoconazole, ritonavir), or F.) Anuria
<b>Required Medical Information</b>	Diagnosis of clinically significant hypervolemic or euvolemic hyponatremia (serum sodium less than 125 mEq/L or less marks hyponatremia that is symptomatic and has resisted correction with fluid restriction), including in patients with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# TOPICAL RETINOIDS

---

## Products Affected

- *adapalene external cream*
- *adapalene external gel*
- *tretinoin external*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of mild to moderate acne vulgaris
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TOREMIFENE

---

## Products Affected

- *toremifene citrate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Acquired or congenital long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia
<b>Required Medical Information</b>	Diagnosis of metastatic breast cancer and patient must have previous inadequate response or intolerance to tamoxifen
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# TRIENTINE

---

## Products Affected

- *trientine hcl*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Wilson's disease in patients that are intolerant to penicillamine
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TRIKAFTA

---

## Products Affected

- TRIKAFTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# TUKYSA

---

## Products Affected

- TUKYSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of 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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TURALIO

---

## Products Affected

- TURALIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TYMLOS

---

## Products Affected

- TYMLOS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of postmenopausal osteoporosis and one of the following A.) osteoporotic fracture or multiple risk factors for fracture, or B.) previous trial of/or contraindication to bisphosphonate
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 12 months, Renewal: 12 months (Maximum 24 month treatment per patient lifetime)
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# UBRELVY

---

## Products Affected

- UBRELVY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin)
<b>Required Medical Information</b>	Diagnosis of migraine disorder with or without aura and patient has documented trial, inadequate response, or contraindication to at least 1 generic formulary triptan
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# UKONIQ

---

## Products Affected

- UKONIQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen, or B.) Relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# VALCHLOR

---

## Products Affected

- VALCHLOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# VARIZIG

---

## Products Affected

- VARIZIG INTRAMUSCULAR SOLUTION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	History of hypersensitivity (including anaphylaxis or severe systemic reaction) to immune globulin or any component of the preparation
<b>Required Medical Information</b>	Diagnosis of post-exposure varicella (chickenpox) infection prophylaxis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# VENCLEXTA

---

## Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use with strong CYP3A inhibitor during the initial and titration phase in patients with CLL or SLL
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# VERQUVO

---

## Products Affected

- VERQUVO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant use of other soluble guanylate cyclase (sGC) stimulators, or B.) Pregnancy
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# VERZENIO

---

## Products Affected

- VERZENIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced or metastatic, HER2-negative, hormone receptor-positive breast cancer AND one of the following: A.) For postmenopausal women must be used in combination with fulvestrant for the treatment of disease progression following endocrine therapy and patient has trial and failure or contraindication to Ibrance or Kisqali, B.) For premenopausal or perimenopausal women must be used in combination with fulvestrant for the treatment of disease progression following endocrine therapy and patient has trial and failure or contraindication to Ibrance, C.) Used as monotherapy for treatment of disease progression following endocrine therapy and patient has already received at least one prior chemotherapy regimen of Ibrance or Kisqali, D.) For postmenopausal women used as initial endocrine-based treatment in combination with an aromatase inhibitor and patient has trial and failure or contraindication to Kisqali or Ibrance, E.) For premenopausal or perimenopausal women used as initial endocrine-based treatment in combination with an aromatase inhibitor and patient has trial and failure or contraindication to Kisqali
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# VIGABATRIN

---

## Products Affected

- *vigabatrin*
- VIGADRONE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# VITRAKVI

---

## Products Affected

- VITRAKVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic or surgically unresectable neurotrophic receptor tyrosine kinase (NTRK) gene fusion positive solid tumors and used in patients with unsatisfactory alternative treatments or who have progressed following treatment
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# VIZIMPRO

---

## Products Affected

- VIZIMPRO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# VORICONAZOLE

## Products Affected

- *voriconazole intravenous*
- *voriconazole oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Invasive aspergillosis, B.) Candidemia, C.) Esophageal Candidiasis, D.) Invasive candidiasis of the skin and abdomen, kidney, bladder wall, and wounds, or E.) Serious fungal infection due to <i>Scedosporium apiospermum</i> or <i>Fusarium</i> species
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	IV formulation: B vs D determination required per CMS guidance
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# VOTRIENT

---

## Products Affected

- VOTRIENT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# VUMERITY

---

## Products Affected

- VUMERITY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# VYNDAMAX

---

## Products Affected

- VYNDAMAX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of wild type or hereditary transthyretin related familial amyloid cardiomyopathy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# XALKORI

---

## Products Affected

- XALKORI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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, or B.) Relapsed or refractory systemic anaplastic large cell lymphoma that is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved test
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# XGEVA

---

## Products Affected

- XGEVA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Hypocalcemia (calcium less than 8.0 mg/dL)
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Bone metastases from a solid tumor and used for the prevention of skeletal related events, B.) Multiple myeloma and used for the prevention of skeletal related events, C.) Hypercalcemia of malignancy refractory to bisphosphonate therapy, or D.) Giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# XOLAIR

---

## Products Affected

- XOLAIR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# XOSPATA

---

## Products Affected

- XOSPATA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# XPOVIO

---

## Products Affected

- XPOVIO (100 MG ONCE WEEKLY)
- XPOVIO (40 MG ONCE WEEKLY)
- XPOVIO (40 MG TWICE WEEKLY)
- XPOVIO (60 MG ONCE WEEKLY)
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY)
- XPOVIO (80 MG TWICE WEEKLY)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# XTANDI

---

## Products Affected

- XTANDI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Castration-resistant prostate cancer, or B.) Metastatic, castration-sensitive prostate cancer
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# XURIDEN

---

## Products Affected

- XURIDEN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of hereditary orotic aciduria
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# XYREM

---

## Products Affected

- XYREM

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# XYWAV

---

## Products Affected

- XYWAV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# YONSA

---

## Products Affected

- YONSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	Diagnosis of metastatic, castration-resistant prostate cancer and use in combination with methylprednisolone
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ZARXIO

---

## Products Affected

- ZARXIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review



# ZEJULA

---

## Products Affected

- ZEJULA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) 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, or B.) Advanced ovarian, fallopian tube, or primary peritoneal cancer and patient has been treated with 3 or more prior chemotherapy regimens, and cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA mutation, or genomic instability, and disease has progressed more than 6 months after response to the last platinum-based chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or gynecologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ZELBORAF

---

## Products Affected

- ZELBORAF

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# ZIEXTENZO

---

## Products Affected

- ZIEXTENZO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of a non-myeloid malignancy and drug is being used as prophylaxis for chemotherapy-induced neutropenia
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ZOLINZA

---

## Products Affected

- ZOLINZA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	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)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Under CMS Review

# ZYDELIG

---

## Products Affected

- ZYDELIG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	History of toxic epidermal necrosis with any drug
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic lymphocytic leukemia, used in combination with rituximab and patient has relapsed on at least one prior therapy, B.) Non-Hodgkins lymphoma (Follicular, B-Cell) and the patient has relapsed on at least two prior systemic therapies, or C.) Small lymphocytic lymphoma and the patient has relapsed on at least two prior systemic therapies
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ZYKADIA

---

## Products Affected

- ZYKADIA ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

## PART B VERSUS PART D

---

### Products Affected

- ABELCET INTRAVENOUS SUSPENSION 5 MG/ML
- *acetylcysteine inhalation solution 10 %, 20 %*
- *acyclovir sodium intravenous solution 50 mg/ml*
- *albuterol sulfate inhalation nebulization solution (2.5 mg/3ml) 0.083%, 0.63 mg/3ml, 1.25 mg/3ml, 2.5 mg/0.5ml*
- AMBISOME INTRAVENOUS SUSPENSION RECONSTITUTED 50 MG
- AMINOSYN-PF INTRAVENOUS SOLUTION 7 %
- *amphotericin b intravenous solution reconstituted 50 mg*
- *aprepitant oral capsule 125 mg, 40 mg, 80 & 125 mg, 80 mg*
- AZASAN ORAL TABLET 100 MG, 75 MG
- *azathioprine oral tablet 50 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*
- *caspofungin acetate intravenous solution reconstituted 50 mg, 70 mg*
- *cefoxitin sodium injection solution reconstituted 10 gm*
- *cefoxitin sodium intravenous solution reconstituted 1 gm, 2 gm*
- *chlorpromazine hcl oral tablet 10 mg, 25 mg*
- *cinacalcet hcl oral tablet 30 mg, 60 mg, 90 mg*
- CLINIMIX E/DEXTROSE (2.75/5) INTRAVENOUS SOLUTION 2.75 %
- CLINIMIX E/DEXTROSE (4.25/10) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX E/DEXTROSE (4.25/5) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX E/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 %
- CLINIMIX E/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 %
- CLINIMIX/DEXTROSE (4.25/10) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX/DEXTROSE (4.25/5) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 %
- CLINIMIX/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 %
- CLINISOL SF INTRAVENOUS SOLUTION 15 %
- *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 %*
- *diphtheria-tetanus toxoids dt intramuscular suspension 25-5 lfu/0.5ml*
- ENGERIX-B INJECTION SUSPENSION 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*
- FIRMAGON (240 MG DOSE) SUBCUTANEOUS SOLUTION RECONSTITUTED 120 MG/VIAL
- FIRMAGON SUBCUTANEOUS SOLUTION RECONSTITUTED 80 MG

- GAMUNEX-C INJECTION SOLUTION 1 GM/10ML
- GENGRAF ORAL CAPSULE 100 MG, 25 MG
- GENGRAF ORAL SOLUTION 100 MG/ML
- *granisetron hcl oral tablet 1 mg*
- HEPATAMINE INTRAVENOUS SOLUTION 8 %
- IMOVAX RABIES INTRAMUSCULAR INJECTABLE 2.5 UNIT/ML
- INTRALIPID INTRAVENOUS EMULSION 20 %, 30 %
- INTRON A INJECTION SOLUTION 10000000 UNIT/ML, 6000000 UNIT/ML
- INTRON A INJECTION SOLUTION RECONSTITUTED 10000000 UNIT, 18000000 UNIT, 50000000 UNIT
- *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
- *levolbuterol hcl inhalation nebulization solution 0.31 mg/3ml, 0.63 mg/3ml, 1.25 mg/0.5ml, 1.25 mg/3ml*
- *levocarnitine oral solution 1 gm/10ml*
- *levocarnitine oral tablet 330 mg*
- *methotrexate oral tablet 2.5 mg*
- *methotrexate sodium (pf) injection solution 50 mg/2ml*
- *methotrexate sodium injection solution 50 mg/2ml*
- *methylprednisolone oral tablet 16 mg, 32 mg, 4 mg, 8 mg*
- *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 %
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 2 GM/20ML
- *ondansetron hcl oral solution 4 mg/5ml*
- *ondansetron hcl oral tablet 24 mg, 4 mg, 8 mg*
- *ondansetron oral tablet dispersible 4 mg, 8 mg*
- *paricalcitol oral capsule 1 mcg, 2 mcg, 4 mcg*
- *pentamidine isethionate inhalation solution reconstituted 300 mg*
- *pentamidine isethionate injection solution reconstituted 300 mg*
- PLASMA-LYTE 148 INTRAVENOUS SOLUTION
- PLASMA-LYTE A INTRAVENOUS SOLUTION
- PLENAMINE INTRAVENOUS SOLUTION 15 %
- *prednisolone oral solution 15 mg/5ml*
- *prednisolone sodium phosphate oral solution 10 mg/5ml, 20 mg/5ml, 25 mg/5ml, 6.7 (5 base) mg/5ml*
- *prednisolone sodium phosphate oral tablet dispersible 10 mg, 15 mg, 30 mg*
- PREDNISONE INTENSOL ORAL CONCENTRATE 5 MG/ML
- *prednisone oral solution 5 mg/5ml*
- *prednisone oral tablet 1 mg, 10 mg, 2.5 mg, 20 mg, 5 mg, 50 mg*
- PREMASOL INTRAVENOUS SOLUTION 10 %
- PRIVIGEN INTRAVENOUS SOLUTION 20 GM/200ML
- PROCALAMINE INTRAVENOUS SOLUTION 3 %
- PROGRAF ORAL PACKET 0.2 MG, 1 MG
- PROSOL INTRAVENOUS SOLUTION 20 %
- PULMOZYME INHALATION SOLUTION 1 MG/ML
- RABAVERT INTRAMUSCULAR SUSPENSION RECONSTITUTED



- RECOMBIVAX HB INJECTION SUSPENSION 10 MCG/ML, 10 MCG/ML (1ML SYRINGE), 40 MCG/ML, 5 MCG/0.5ML
- *sirolimus oral solution 1 mg/ml*
- *sirolimus oral tablet 0.5 mg, 1 mg, 2 mg*
- *tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg*
- TDVAX INTRAMUSCULAR SUSPENSION 2-2 LF/0.5ML
- TENIVAC INTRAMUSCULAR INJECTABLE 5-2 LFU
- *tigecycline intravenous solution reconstituted 50 mg*
- *tobramycin inhalation nebulization solution 300 mg/5ml*
- TPN ELECTROLYTES INTRAVENOUS CONCENTRATE
- TRAVASOL INTRAVENOUS SOLUTION 10 %
- TRELSTAR MIXJECT INTRAMUSCULAR SUSPENSION RECONSTITUTED 11.25 MG, 22.5 MG, 3.75 MG
- TREXALL ORAL TABLET 10 MG, 15 MG, 5 MG, 7.5 MG
- TROPHAMINE INTRAVENOUS SOLUTION 10 %
- XATMEP ORAL SOLUTION 2.5 MG/ML
- ZORTRESS ORAL TABLET 1 MG

### **Details**

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

## Index

### A

ABELCET INTRAVENOUS SUSPENSION 5 MG/ML.....	231
abiraterone acetate .....	1
acetylcysteine inhalation solution 10 %, 20 % .....	231
acitretin .....	2
ACTIMMUNE.....	3
acyclovir sodium intravenous solution 50 mg/ml.....	231
adapalene external cream .....	193
adapalene external gel .....	193
adefovir dipivoxil.....	72
ADEMPAS.....	4
AFINITOR DISPERZ .....	5
AFINITOR ORAL TABLET 10 MG .....	57
albuterol sulfate inhalation nebulization solution (2.5 mg/3ml) 0.083%, 0.63 mg/3ml, 1.25 mg/3ml, 2.5 mg/0.5ml...	231
ALECENSA .....	6
ALUNBRIG .....	8
AMBISOME INTRAVENOUS SUSPENSION RECONSTITUTED 50 MG.....	231
ambrisentan .....	9
AMINOSYN-PF INTRAVENOUS SOLUTION 7 % .....	231
amphotericin b intravenous solution reconstituted 50 mg .....	231
aprepitant oral capsule 125 mg, 40 mg, 80 & 125 mg, 80 mg .....	231
ARCALYST.....	10
ARIKAYCE .....	11
armodafinil .....	28
AURYXIA .....	12
AUSTEDO .....	13
AVONEX PEN INTRAMUSCULAR AUTO-INJECTOR KIT .....	119
AVONEX PREFILLED INTRAMUSCULAR PREFILLED SYRINGE KIT .....	119
AYVAKIT.....	14
AZASAN ORAL TABLET 100 MG, 75 MG.....	231

azathioprine oral tablet 50 mg .....	231
--------------------------------------	-----

### B

BALVERSA .....	15
BARACLUDGE ORAL SOLUTION .....	72
BENLYSTA SUBCUTANEOUS .....	16
BETASERON SUBCUTANEOUS KIT .....	119
bexarotene.....	17
bosentan .....	18
BOSULIF.....	19
BRAFTOVI ORAL CAPSULE 75 MG ....	20
BRUKINSA .....	21
budesonide inhalation suspension 0.25 mg/2ml, 0.5 mg/2ml, 1 mg/2ml.....	231

### C

CABLIVI .....	22
CABOMETYX.....	23
calcitonin (salmon) nasal solution 200 unit/act .....	231
calcitriol oral capsule 0.25 mcg, 0.5 mcg	231
calcitriol oral solution 1 mcg/ml .....	231
CALQUENCE.....	24
CAPRELSA .....	25
CARBAGLU .....	26
casprofungin acetate intravenous solution reconstituted 50 mg, 70 mg .....	231
CAYSTON .....	27
cefoxitin sodium injection solution reconstituted 10 gm.....	231
cefoxitin sodium intravenous solution reconstituted 1 gm, 2 gm .....	231
chlorpromazine hcl oral tablet 10 mg, 25 mg .....	231
cinacalcet hcl oral tablet 30 mg, 60 mg, 90 mg.....	231
CLINIMIX E/DEXTROSE (2.75/5) INTRAVENOUS SOLUTION 2.75 %	231
CLINIMIX E/DEXTROSE (4.25/10) INTRAVENOUS SOLUTION 4.25 %	231
CLINIMIX E/DEXTROSE (4.25/5) INTRAVENOUS SOLUTION 4.25 %	231
CLINIMIX E/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 % .....	231
CLINIMIX E/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 % .....	231

CLINIMIX/DEXTROSE (4.25/10)	
INTRAVENOUS SOLUTION 4.25 %	231
CLINIMIX/DEXTROSE (4.25/5)	
INTRAVENOUS SOLUTION 4.25 %	231
CLINIMIX/DEXTROSE (5/15)	
INTRAVENOUS SOLUTION 5 %	231
CLINIMIX/DEXTROSE (5/20)	
INTRAVENOUS SOLUTION 5 %	231
CLINISOL SF INTRAVENOUS	
SOLUTION 15 %	231
colistimethate sodium (cba) injection	
solution reconstituted 150 mg	231
COMETRIQ (100 MG DAILY DOSE)	
ORAL KIT 80 & 20 MG	29
COMETRIQ (140 MG DAILY DOSE)	
ORAL KIT 3 X 20 MG & 80 MG	29
COMETRIQ (60 MG DAILY DOSE)	29
COPAXONE SUBCUTANEOUS	
SOLUTION PREFILLED SYRINGE	69
COPIKTRA	30
CORLANOR ORAL TABLET	31
COSENTYX (300 MG DOSE)	32
COSENTYX SENSOREADY (300 MG)	32
COTELLIC	33
cromolyn sodium inhalation nebulization	
solution 20 mg/2ml	231
cyclophosphamide oral capsule 25 mg, 50	
mg	231
cyclophosphamide oral tablet 25 mg, 50 mg	231
cyclosporine modified oral capsule 100 mg,	
25 mg, 50 mg	231
cyclosporine modified oral solution 100	
mg/ml	231
cyclosporine oral capsule 100 mg, 25 mg	231
CYSTADROPS	35
CYSTAGON	34
CYSTARAN	35
<b>D</b>	
dalfampridine er	36
DAURISMO	37
deferasirox oral tablet	38
deferasirox oral tablet soluble	38
deferiprone	39
dextrose intravenous solution 10 %, 5 %	231
DIACOMIT	40
diclofenac sodium external gel 3 %	41
dimethyl fumarate oral	42
dimethyl fumarate starter pack	42
diphtheria-tetanus toxoids dt intramuscular	
suspension 25-5 lfu/0.5ml	231
DOJOLVI	43
dronabinol	44
droxidopa	45
DUPIXENT	46
<b>E</b>	
ELIGARD	104
ENBREL MINI	47
ENBREL SUBCUTANEOUS SOLUTION	
25 MG/0.5ML	47
ENBREL SUBCUTANEOUS SOLUTION	
PREFILLED SYRINGE	47
ENBREL SUBCUTANEOUS SOLUTION	
RECONSTITUTED	47
ENBREL SURECLICK SUBCUTANEOUS	
SOLUTION AUTO-INJECTOR	47
ENDARI	48
ENGERIX-B INJECTION SUSPENSION	
10 MCG/0.5ML, 20 MCG/ML	231
ENSPRYNG	49
entecavir	72
ENTRESTO	50
ENVARUSUS XR ORAL TABLET	
EXTENDED RELEASE 24 HOUR 0.75	
MG, 1 MG, 4 MG	231
EPIDIOLEX	51
ERIVEDGE	53
ERLEADA	54
erlotinib hcl	55
ESBRIET	56
everolimus oral tablet 0.25 mg, 0.5 mg, 0.75	
mg	231
everolimus oral tablet 2.5 mg, 5 mg, 7.5 mg	57
EVRYSDI	58
<b>F</b>	
FARYDAK	59
fentanyl	61
fentanyl citrate buccal lozenge on a handle	60
FERRIPROX ORAL SOLUTION	39
FINTEPLA	62

FIRAZYR.....	77	IDHIFA .....	79
FIRMAGON (240 MG DOSE)		imatinib mesylate .....	80
SUBCUTANEOUS SOLUTION		IMBRUVICA .....	81
RECONSTITUTED 120 MG/VIAL ...	231	IMOVAX RABIES INTRAMUSCULAR	
FIRMAGON SUBCUTANEOUS		INJECTABLE 2.5 UNIT/ML.....	232
SOLUTION RECONSTITUTED 80 MG		INBRIJA .....	82
.....	231	INCRELEX .....	83
FOTIVDA .....	63	INLYTA.....	84
<b>G</b>		INQOVI .....	85
GALAFOLD .....	64	INREBIC .....	86
GAMUNEX-C INJECTION SOLUTION 1		INTRALIPID INTRAVENOUS	
GM/10ML .....	232	EMULSION 20 %, 30 % .....	232
GATTEX.....	65	INTRAROSA .....	87
GAVRETO.....	66	INTRON A INJECTION SOLUTION	
GENGRAF ORAL CAPSULE 100 MG, 25		1000000 UNIT/ML, 6000000 UNIT/ML	
MG.....	232	.....	232
GENGRAF ORAL SOLUTION 100		INTRON A INJECTION SOLUTION	
MG/ML .....	232	RECONSTITUTED 1000000 UNIT,	
GILENYA ORAL CAPSULE 0.5 MG .....	67	18000000 UNIT, 50000000 UNIT.....	232
GILOTRIF.....	68	ipratropium bromide inhalation solution	
glatiramer acetate.....	69	0.02 % .....	232
granisetron hcl oral tablet 1 mg .....	232	ipratropium-albuterol inhalation solution	
<b>H</b>		0.5-2.5 (3) mg/3ml .....	232
HEPATAMINE INTRAVENOUS		IRESSA.....	88
SOLUTION 8 % .....	232	ISOLYTE-P IN D5W INTRAVENOUS	
HETLIOZ.....	74	SOLUTION .....	232
HUMIRA PEDIATRIC CROHNS START		ISOLYTE-S PH 7.4 INTRAVENOUS	
SUBCUTANEOUS PREFILLED		SOLUTION .....	232
SYRINGE KIT 80 MG/0.8ML, 80		ISTURISA .....	89
MG/0.8ML & 40MG/0.4ML .....	75	itraconazole oral .....	90, 91
HUMIRA PEN SUBCUTANEOUS PEN-		<b>J</b>	
INJECTOR KIT .....	75	JAKAFI.....	92
HUMIRA PEN-CD/UC/HS STARTER....	75	JUXTAPID ORAL CAPSULE 10 MG, 20	
HUMIRA PEN-PEDIATRIC UC START	75	MG, 30 MG, 5 MG .....	93
HUMIRA PEN-PS/UV/ADOL HS START		<b>K</b>	
SUBCUTANEOUS PEN-INJECTOR		KALYDECO .....	94
KIT 40 MG/0.8ML .....	75	KESIMPTA .....	95
HUMIRA PEN-PSOR/UEVIT STARTER		KISQALI (200 MG DOSE).....	96
.....	75	KISQALI (400 MG DOSE).....	96
HUMIRA SUBCUTANEOUS PREFILLED		KISQALI (600 MG DOSE).....	96
SYRINGE KIT 10 MG/0.1ML, 20		KISQALI FEMARA (400 MG DOSE) .....	97
MG/0.2ML, 40 MG/0.4ML, 40		KISQALI FEMARA (600 MG DOSE) .....	97
MG/0.8ML .....	75	KISQALI FEMARA(200 MG DOSE) .....	97
<b>I</b>		KORLYM .....	98
IBRANCE .....	76	KOSELUGO.....	99
ICLUSIG .....	78	KYNMOBI .....	100

**L**

lapatinib ditosylate.....	101
LENVIMA (10 MG DAILY DOSE).....	102
LENVIMA (12 MG DAILY DOSE).....	102
LENVIMA (14 MG DAILY DOSE).....	102
LENVIMA (18 MG DAILY DOSE).....	102
LENVIMA (20 MG DAILY DOSE).....	102
LENVIMA (24 MG DAILY DOSE).....	102
LENVIMA (4 MG DAILY DOSE).....	102
LENVIMA (8 MG DAILY DOSE).....	102
LEUKINE INJECTION SOLUTION RECONSTITUTED .....	103
leuprolide acetate injection .....	104
levabuterol hcl inhalation nebulization solution 0.31 mg/3ml, 0.63 mg/3ml, 1.25 mg/0.5ml, 1.25 mg/3ml.....	232
levocarnitine oral solution 1 gm/10ml....	232
levocarnitine oral tablet 330 mg .....	232
lidocaine external patch 5 % .....	105
linezolid intravenous solution 600 mg/300ml .....	106
linezolid oral .....	106
LONSURF.....	107
LORBRENA .....	108
LUMAKRAS .....	109
LUPKYNIS.....	110
LUPRON DEPOT (1-MONTH).....	104
LUPRON DEPOT (3-MONTH).....	104
LUPRON DEPOT (4-MONTH).....	104
LUPRON DEPOT (6-MONTH).....	104
LYNPARZA ORAL TABLET.....	111, 112
<b>M</b>	
MATULANE .....	113
MAVYRET .....	73
MAYZENT .....	114
MAYZENT STARTER PACK ORAL TABLET THERAPY PACK 12 X 0.25 MG.....	114
MEKINIST.....	115
MEKTOVI .....	116
methotrexate oral tablet 2.5 mg .....	232
methotrexate sodium (pf) injection solution 50 mg/2ml .....	232
methotrexate sodium injection solution 50 mg/2ml .....	232
methoxsalen rapid.....	117

methylprednisolone oral tablet 16 mg, 32 mg, 4 mg, 8 mg.....	232
miglustat.....	118
modafinil.....	28
mycophenolate mofetil oral capsule 250 mg .....	232
mycophenolate mofetil oral suspension reconstituted 200 mg/ml .....	232
mycophenolate mofetil oral tablet 500 mg .....	232
mycophenolate sodium oral tablet delayed release 180 mg, 360 mg .....	232
<b>N</b>	
NATPARA .....	120
NERLYNX .....	121
NEXAVAR.....	122
NINLARO .....	123
nitisinone.....	124
NOXAFIL ORAL SUSPENSION .....	144
NUBEQA.....	125
NUCALA.....	126
NUEDEXTA .....	127
NUPLAZID ORAL CAPSULE .....	128
NUPLAZID ORAL TABLET 10 MG ....	128
NUTRILIPID INTRAVENOUS EMULSION 20 %.....	232
<b>O</b>	
OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 2 GM/20ML .....	232
octreotide acetate injection solution 100 mcg/ml, 1000 mcg/ml, 200 mcg/ml, 50 mcg/ml, 500 mcg/ml .....	129
ODOMZO .....	130
OFEV .....	131
OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE .....	70, 71
OMNITROPE SUBCUTANEOUS SOLUTION RECONSTITUTED ....	70, 71
ondansetron hcl oral solution 4 mg/5ml ..	232
ondansetron hcl oral tablet 24 mg, 4 mg, 8 mg.....	232
ondansetron oral tablet dispersible 4 mg, 8 mg.....	232
ONUREG.....	132
OPSUMIT.....	133
ORFADIN ORAL CAPSULE 20 MG ....	124

ORFADIN ORAL SUSPENSION .....	124
ORGOVYX.....	134
ORKAMBI .....	135
OSPHENA .....	136
oxandrolone oral .....	137
<b>P</b>	
paricalcitol oral capsule 1 mcg, 2 mcg, 4 mcg .....	232
PEGASYS SUBCUTANEOUS SOLUTION .....	138
PEMAZYRE .....	139
pentamidine isethionate inhalation solution reconstituted 300 mg .....	232
pentamidine isethionate injection solution reconstituted 300 mg .....	232
PIQRAY (200 MG DAILY DOSE) .....	141
PIQRAY (250 MG DAILY DOSE) .....	141
PIQRAY (300 MG DAILY DOSE) .....	141
PLASMA-LYTE 148 INTRAVENOUS SOLUTION.....	232
PLASMA-LYTE A INTRAVENOUS SOLUTION.....	232
PLENAMINE INTRAVENOUS SOLUTION 15 % .....	232
POMALYST .....	142
posaconazole .....	143
prednisolone oral solution 15 mg/5ml....	232
prednisolone sodium phosphate oral solution 10 mg/5ml, 20 mg/5ml, 25 mg/5ml, 6.7 (5 base) mg/5ml.....	232
prednisolone sodium phosphate oral tablet dispersible 10 mg, 15 mg, 30 mg.....	232
PREDNISON INTENSOL ORAL CONCENTRATE 5 MG/ML.....	232
prednisone oral solution 5 mg/5ml .....	232
prednisone oral tablet 1 mg, 10 mg, 2.5 mg, 20 mg, 5 mg, 50 mg.....	232
PREMASOL INTRAVENOUS SOLUTION 10 % .....	232
PREVYMIS ORAL .....	145
PRIVIGEN INTRAVENOUS SOLUTION 20 GM/200ML.....	232
PROCALAMINE INTRAVENOUS SOLUTION 3 % .....	232
PROGRAF ORAL PACKET 0.2 MG, 1 MG .....	232

PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED .....	7
PROMACTA .....	146
PROSOL INTRAVENOUS SOLUTION 20 % .....	232
PULMOZYME INHALATION SOLUTION 1 MG/ML.....	232
pyrimethamine oral .....	147
<b>Q</b>	
QINLOCK .....	148
quinine sulfate oral.....	149
<b>R</b>	
RABAVERT INTRAMUSCULAR SUSPENSION RECONSTITUTED....	232
RAVICTI .....	150
RECOMBIVAX HB INJECTION SUSPENSION 10 MCG/ML, 10 MCG/ML (1ML SYRINGE), 40 MCG/ML, 5 MCG/0.5ML.....	233
REGRANEX .....	151
REPATHA .....	152
REPATHA PUSHTRONEX SYSTEM...152	
REPATHA SURECLICK.....	152
RETACRIT INJECTION SOLUTION 10000 UNIT/ML, 10000 UNIT/ML(1ML), 2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML, 40000 UNIT/ML.....	52
RETEVMO .....	153
REVLIMID.....	154
REZUROCK.....	155
riluzole .....	156
RINVOQ.....	157
ROZLYTREK .....	158
RUBRACA .....	159
RYDAPT .....	160
<b>S</b>	
sapropterin dihydrochloride oral packet ..161	
sapropterin dihydrochloride oral tablet....161	
SIGNIFOR.....	162
sildenafil citrate oral tablet 20 mg.....	163
sirolimus oral solution 1 mg/ml.....	233
sirolimus oral tablet 0.5 mg, 1 mg, 2 mg .233	
SKYRIZI.....	164
SKYRIZI (150 MG DOSE) .....	164
SKYRIZI PEN.....	164

sodium phenylbutyrate oral tablet .....	140	tetrabenazine.....	188
sofosbuvir-velpatasvir .....	73	THALOMID .....	189
SOMAVERT .....	165	TIBSOVO .....	190
SPRYCEL .....	166	tigecycline intravenous solution	
STELARA SUBCUTANEOUS		reconstituted 50 mg.....	233
SOLUTION 45 MG/0.5ML .....	167	TIGLUTIK.....	156
STELARA SUBCUTANEOUS		TOBI PODHALER .....	191
SOLUTION PREFILLED SYRINGE	167	tobramycin inhalation nebulization solution	
STIVARGA.....	168	300 mg/5ml.....	233
sunitinib malate.....	169	tolvaptan.....	192
SUNOSI.....	170	toremifene citrate.....	194
SYMDEKO .....	171	TPN ELECTROLYTES INTRAVENOUS	
SYMLINPEN 120 SUBCUTANEOUS		CONCENTRATE .....	233
SOLUTION PEN-INJECTOR.....	172	TRAVASOL INTRAVENOUS SOLUTION	
SYMLINPEN 60 SUBCUTANEOUS		10 % .....	233
SOLUTION PEN-INJECTOR.....	172	TRELSTAR MIXJECT	
SYNAREL .....	173	INTRAMUSCULAR SUSPENSION	
SYNRIBO .....	174	RECONSTITUTED 11.25 MG, 22.5 MG,	
<b>T</b>		3.75 MG .....	233
TABRECTA.....	175	tretinoin external .....	193
tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg		TREXALL ORAL TABLET 10 MG, 15	
.....	233	MG, 5 MG, 7.5 MG .....	233
TAFINLAR.....	176	trientine hcl .....	195
TAGRISSO .....	177	TRIKAFTA .....	196
TAKHZYRO.....	178	TROPHAMINE INTRAVENOUS	
TALZENNA .....	179	SOLUTION 10 % .....	233
TARGRETIN EXTERNAL .....	180	TUKYSA .....	197
TASIGNA .....	181	TURALIO.....	198
tazarotene external cream.....	182	TYMLOS .....	199
TAZORAC EXTERNAL CREAM 0.05 %		<b>U</b>	
.....	182	UBRELVY .....	200
TAZORAC EXTERNAL GEL.....	182	UKONIQ.....	201
TAZVERIK.....	183	<b>V</b>	
TDVAX INTRAMUSCULAR		VALCHLOR .....	202
SUSPENSION 2-2 LF/0.5ML .....	233	VARIZIG INTRAMUSCULAR	
TEGSEDI .....	184	SOLUTION .....	203
TENIVAC INTRAMUSCULAR		VENCLEXTA .....	204
INJECTABLE 5-2 LFU .....	233	VENCLEXTA STARTING PACK .....	204
TEPMETKO .....	185	VERQUVO.....	205
teriparatide (recombinant).....	186	VERZENIO .....	206
testosterone transdermal gel 10 mg/act (2%),		vigabatrin .....	207
12.5 mg/act (1%), 20.25 mg/1.25gm		VIGADRONE .....	207
(1.62%), 20.25 mg/act (1.62%), 25		VITRAKVI .....	208
mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%),		VIZIMPRO .....	209
50 mg/5gm (1%).....	187	voriconazole intravenous .....	210
testosterone transdermal solution .....	187	voriconazole oral.....	210

VOSEVI .....	73	XPOVIO (80 MG TWICE WEEKLY)....	218
VOTRIENT.....	211	XTANDI .....	219
VUMERITY .....	212	XURIDEN .....	220
VYNDAMAX.....	213	XYREM .....	221
<b>X</b>		XYWAV .....	222
XALKORI.....	214	<b>Y</b>	
XATMEP ORAL SOLUTION 2.5 MG/ML		YONSA.....	223
.....	233	<b>Z</b>	
XGEVA .....	215	ZARXIO .....	224
XOLAIR.....	216	ZEJULA .....	225
XOSPATA .....	217	ZELBORAF.....	226
XPOVIO (100 MG ONCE WEEKLY) ...	218	ZIEXTENZO .....	227
XPOVIO (40 MG ONCE WEEKLY) .....	218	ZOLINZA .....	228
XPOVIO (40 MG TWICE WEEKLY) ...	218	ZORTRESS ORAL TABLET 1 MG .....	233
XPOVIO (60 MG ONCE WEEKLY) .....	218	ZYDELIG .....	229
XPOVIO (60 MG TWICE WEEKLY) ...	218	ZYKADIA ORAL TABLET .....	230
XPOVIO (80 MG ONCE WEEKLY) .....	218		