

**Harvard Pilgrim Health Care  
Stride<sup>SM</sup> Basic Rx (HMO),  
Stride<sup>SM</sup> Value Rx (HMO),  
Stride<sup>SM</sup> Value Rx Plus (HMO),  
Stride<sup>SM</sup> Choice Rx (HMO-POS) and  
Stride<sup>SM</sup> Gain Rx<sup>SM</sup> (HMO)**

**Prior Authorization  
Requirements**

Effective 09/01/2021

Updated 8/2/2021

Harvard Pilgrim Health Care includes Harvard Pilgrim Health Care  
and Harvard Pilgrim Health Care of New England.



# ADEMPAS

## Products Affected

- ADEMPAS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Initial for PAH and CTEPH: Patient is concurrently taking nitrates or nitric oxide donors (e.g. amyl nitrate), phosphodiesterase inhibitors (e.g. sildenafil, tadalafil, or vardenafil), or non-specific PDE inhibitors (e.g. dipyridamole, theophylline).
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. Chronic thromboembolic pulmonary hypertension (CTEPH) (Initial): One of the following: A) Both of the following: 1) Diagnosis of inoperable or persistent/recurrent CTEPH and 2) CTEPH is symptomatic OR B) Patient is currently on any therapy for the diagnosis of CTEPH.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH, CTEPH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH, CTEPH: Initial: 12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# AFINITOR

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention but patient is not a candidate for curative surgical resection. Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma AND trial and failure, contraindication, or intolerance to SUTENT (sunitinib) or NEXAVAR (sorafenib). Neuroendocrine tumors of pancreatic origin (pNET): Diagnosis of progressive pNET that are unresectable, locally advanced, or metastatic. Renal angiomyolipoma: Diagnosis of renal angiomyolipoma and TSC AND Patient does not require immediate surgery. Breast Cancer: Patient is a postmenopausal woman AND Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole) AND Afinitor (everolimus) will be used in combination with AROMASIN (exemestane). Neuroendocrine tumors of gastrointestinal (GI) or lung origin: Diagnosis of progressive, well-differentiated, non-functional NET of GI or lung origin AND patient has unresectable, locally advanced or metastatic disease. TSC-associated partial-onset seizures: Diagnosis of TSC-associated partial-onset seizures. Used as adjunctive therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	TSC-associated partial-onset seizures: Prescribed by or in consultation with a neurologist. All other uses: Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	All uses: 12 months
<b>Other Criteria</b>	All Indications: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# ALECENSA

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**Products Affected**

- ALECENSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): A) Diagnosis of metastatic NSCLC AND B) Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# ALUNBRIG

## Products Affected

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# AMPYRA

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## Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient is ambulatory and is on concomitant therapy with a disease-modifying agent (e.g. interferon beta agents, copaxone, gilenya, tecfidera, etc.).
Age Restrictions	
Prescriber Restrictions	MS (initial): Prescribed by or in consultation with a neurologist or multiple sclerosis specialist.
Coverage Duration	MS (initial): 12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# APTIOM

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**Products Affected**

- APTIOM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of partial-onset seizures and has had an insufficient response or intolerance to two or more medications indicated for adjunct partial seizures (e.g. felbamate, fycompa, gabapentin, lamotrigine, lyrica, leviteracetam, oxcarbazepine, tiagabine, topiramate, vimpat, and/or zonisamide).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# ARANESP

## Products Affected

- ARANESP (ALBUMIN FREE)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with chemo (Initial): Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Part D member receiving dialysis or identified as a Part D end stage renal disease member: pays under Part B.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021



# ARCALYST

## Products Affected

- ARCALYST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Cryopyrin-Associated Periodic Syndromes (CAPS) (Initial): Diagnosis of CAPS, including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS). The medication will not be used in combination with another biologic.
<b>Age Restrictions</b>	CAPS (Initial): 12 years of age or older
<b>Prescriber Restrictions</b>	CAPS (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist.
<b>Coverage Duration</b>	CAPS (initial, reauth): 12 months
<b>Other Criteria</b>	CAPS (Reauth): Patient has experienced disease stability or improvement in clinical symptoms while on therapy as evidence by one of the following: A) improvement in rash, fever, joint pain, headache, conjunctivitis, B) decreased number of disease flare days, C) normalization of inflammatory markers (CRP, ESR, SAA), D) corticosteroid dose reduction, OR E) improvement in MD global score or active joint count.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# AUBAGIO

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## Products Affected

- AUBAGIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease which includes active disease with new brain lesions).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or multiple sclerosis specialist.
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# AUSTEDO

## Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chorea associated with Huntington's disease (initial): Diagnosis of Chorea associated with Huntington's disease. Tardive dyskinesia (initial): Diagnosis of moderate to severe tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication or 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Huntington's disease chorea (initial): Prescribed by a neurologist. Tardive dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist.
<b>Coverage Duration</b>	Initial: 12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# AYVAKIT

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## Products Affected

- AYVAKIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Gastrointestinal stromal tumor (GIST): Diagnosis of GIST. Disease is one of the following: unresectable or metastatic. Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# BALVERSA

## Products Affected

- BALVERSA ORAL TABLET 3 MG, 4 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Urothelial Carcinoma: Diagnosis of urothelial carcinoma (UC). One of the following: Locally advanced or Metastatic AND Patient has fibroblast growth factor receptor (FGFR) 3 or FGFR2 genetic alterations as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). One of the following: 1) Cancer 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 or 2) Cancer has progressed during or following immunotherapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# BENLYSTA

## Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Monotherapy for diagnosis of severe active lupus nephritis or severe active central nervous system lupus, or for members who are autoantibody negative or when used in combination with other biologics or intravenous cyclophosphamide.
<b>Required Medical Information</b>	Systemic lupus erythematosus (SLE) (init): Diagnosis of active SLE. Autoantibody positive (ie, anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL). Currently receiving at least one standard of care treatment for active SLE (eg, antimalarials [eg, Plaquenil (hydroxychloroquine)], corticosteroids [eg, prednisone], or immunosuppressants [eg, methotrexate, Imuran (azathioprine)]).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	SLE (init): Prescribed by or in consultation with a rheumatologist
<b>Coverage Duration</b>	SLE (initial, reauth): 12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# BOSULIF

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## Products Affected

- BOSULIF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic myelogenous/myeloid leukemia (CML): Diagnosis of Philadelphia chromosome-positive (Ph+) CML.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# BRAFTOVI

## Products Affected

- BRAFTOVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Mektovi (binimetinib). Colorectal Cancer: One of the following diagnoses: Colon Cancer or Rectal Cancer. One of the following: 1) Unresectable or advanced disease or 2) Metastatic disease. Patient has received prior therapy. Cancer is BRAF V600E mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Erbitux (cetuximab).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021



# BRIVIACT

## Products Affected

- BRIVIACT ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of partial-onset seizures and has had an insufficient response or intolerance to two or more medications indicated for adjunct partial seizures (e.g. briviact, felbamate, fycompa, gabapentin, lamotrigine, lyrica, leviteracetam, oxcarbazepine, tiagabine, topiramate, vimpat, and/or zonisamide).
Age Restrictions	
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist.
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# BRUKINSA

## Products Affected

- BRUKINSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of relapsed or refractory mantle cell lymphoma (MCL). Trial and failure, contraindication, or intolerance to at least ONE combination treatment of rituximab and chemotherapy (e.g., BR, R-CHOP, R-CVP, R-FCM).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# C1 ESTERASE INHIBITORS

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## Products Affected

- HAEGARDA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For prophylaxis against HAE attacks.
Age Restrictions	
Prescriber Restrictions	HAE (prophylaxis): Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# CABOMETYX

## Products Affected

- CABOMETYX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Renal cell carcinoma (RCC): Diagnosis of RCC. RCC is advanced. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: a) Trial and failure or intolerance to Nexavar (sorafenib tosylate), or b) Patient has metastatic disease, or c) Patient has extensive liver tumor burden, or d) Patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or e) Disease is unresectable.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RCC: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with one of the following: oncologist, hepatologist, or gastroenterologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# CALQUENCE

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## Products Affected

- CALQUENCE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Mantle Cell Lymphoma: Diagnosis of mantle cell lymphoma (MCL) AND patient has received at least one prior therapy for MCL. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# CAPRELSA

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## Products Affected

- CAPRELSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Thyroid Cancer: Diagnosis of medullary thyroid cancer (MTC).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with oncologist or endocrinologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# CARBAGLU

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## Products Affected

- CARBAGLU

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Specialist in metabolic disorders.
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# CAYSTON

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## Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystic fibrosis (CF) (Initial, Reauth): Diagnosis of CF AND Patient has evidence of Pseudomonas aeruginosa in the lungs.
Age Restrictions	CF (Initial): 7 years of age or older
Prescriber Restrictions	
Coverage Duration	CF (Initial, reauth): 12 months
Other Criteria	CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021



# CERDELGA

## Products Affected

- CERDELGA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Gaucher disease (Initial): Diagnosis of Gaucher disease type 1. Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test.
<b>Age Restrictions</b>	Gaucher disease (initial): 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Gaucher disease (initial, reauth): 12 months
<b>Other Criteria</b>	Gaucher disease (Reauth): Patient's condition has not progressed, as defined by ALL of the following: A) Hemoglobin level decreased greater than 1.5 g/dL from baseline, AND B) Platelet count decreased greater than 25% from baseline, AND C) Spleen volume increased greater than 25% from baseline, AND D) Liver volume increased greater than 20% from baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# CGRPs

## Products Affected

- AIMOVIG SUBCUTANEOUS SOLUTION      • EMGALITY  
 AUTO-INJECTOR 140 MG/ML, 70 MG/ML      • EMGALITY (300 MG DOSE)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of episodic migraine, chronic migraine, or episodic cluster headache. Prescribed for the preventive treatment of migraines or treatment of episodic cluster headaches. The patient has had a previous trial of or contraindication to ONE alternative for preventive migraine treatment such as divalproex sodium, topiramate, propranolol, or timolol.
<b>Age Restrictions</b>	EM, CM, ECH (initial): 18 years of age or older.
<b>Prescriber Restrictions</b>	EM, CM, ECH (initial, reauth): Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
<b>Coverage Duration</b>	EM, CM, ECH (initial): 6 months. EM, CM, ECH (reauth): 12 months
<b>Other Criteria</b>	EM, CM (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency, severity, or duration. Or reduction in use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs], triptans) has decreased since the start of CGRP therapy. ECH (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# CHOLBAM

## Products Affected

- CHOLBAM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of peroxisomal disorder, 2) patient exhibits at least one of the following: a) liver disease (eg, jaundice, elevated serum transaminases), OR b) steatorrhea, OR c) complications from decreased fat-soluble vitamin absorption (eg, poor growth), AND 3) Cholbam will be used as an adjunctive treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses (initial): Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	All uses (reauth): documentation of positive clinical response to Cholbam therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# CIALIS

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## Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of benign prostatic hyperplasia (BPH).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Applies to the 2.5mg and 5mg strengths only.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# COMETRIQ

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## Products Affected

- COMETRIQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medullary thyroid cancer (MTC): Diagnosis of Metastatic MTC.
Age Restrictions	
Prescriber Restrictions	MTC: Prescribed by or in consultation with an oncologist/hematologist or endocrinologist.
Coverage Duration	All uses: 12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# COPIKTRA

## Products Affected

- COPIKTRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. Disease is relapsed or refractory. Trial and failure, contraindication, or intolerance to at least two prior therapies for CLL/SLL (e.g., Leukeran [chlorambucil], Gazyva [obinutuzumab], Arzerra [ofatumumab], Bendeka [bendamustine], Imbruvica [ibrutinib], Rituxan [rituximab], etc.). Follicular Lymphoma: Diagnosis of follicular lymphoma. Disease is relapsed or refractory. Trial and failure, contraindication, or intolerance to at least two prior systemic therapies for follicular lymphoma (e.g., Leukeran [chlorambucil], Gazyva [obinutuzumab], Arzerra [ofatumumab], Bendeka [bendamustine], Imbruvica [ibrutinib], Rituxan [rituximab], etc.).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# CORLANOR

## Products Affected

- CORLANOR ORAL SOLUTION
- CORLANOR ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chronic heart failure (CHF) (initial): Diagnosis of CHF. Patient has NYHA Class II, III, or IV symptoms. Patient has a left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm. Patient has a resting heart rate of greater than or equal to 70 beats per minute. Dilated Cardiomyopathy (DCM) (initial): Diagnosis of stable symptomatic heart failure due to DCM. Patient has NYHA Class II, III, or, IV symptoms. Patient is in sinus rhythm. Patient has an elevated heart rate.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CHF (initial): Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	CHF, DCM (initial, reauth): 12 months
<b>Other Criteria</b>	CHF (reauth): Documentation of positive clinical response to Corlanor therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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Formulary ID: 21386 Effective: 9/1/2021

# COSENTYX

## Products Affected

- COSENTYX (300 MG DOSE)
- COSENTYX 150 MG/ML SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 75 MG/0.5ML
- COSENTYX SENSOREADY (300 MG)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. TF/C/I to both Humira and Enbrel. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. TF/C/I to at least one of the following: Humira, Enbrel or Skyrizi. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. TF/C/I to both Humira and Enbrel.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS (initial): Prescribed by or in consultation with a rheumatologist.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to Cosentyx therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021



# COTELLIC

## Products Affected

- COTELLIC

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Melanoma: Diagnosis of unresectable or metastatic melanoma. Patient has a BRAF V600E or V600K mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with vemurafenib.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# DARAPRIM

## Products Affected

- *pyrimethamine oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Toxoplasmosis: 1) Patient is using pyrimethamine for the treatment of toxoplasmic encephalitis, secondary prophylaxis of toxoplasmic encephalitis, or treatment of congenital toxoplasmosis OR 2) Patient is using pyrimethamine for the primary prophylaxis of toxoplasmic encephalitis, patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX), and one of the following: patient has been re-challenged with TMP-SMX using a desensitization protocol and is still unable to tolerate, or evidence of life-threatening reaction to TMP-SMX in the past (eg, toxic epidermal necrolysis, Stevens-Johnson syndrome). Malaria: Patient is using pyrimethamine for the treatment of acute malaria or chemoprophylaxis of malaria. Patient does not have megaloblastic anemia due to folate deficiency. The provider acknowledges that pyrimethamine is not recommended by the Centers for Disease Control and Prevention (CDC) for the treatment and/or prophylaxis of malaria.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Toxoplasmosis only: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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Formulary ID: 21386 Effective: 9/1/2021

# DAURISMO

## Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Acute myeloid leukemia (AML): Diagnosis of newly-diagnosed acute myeloid leukemia (AML) AND Used in combination with low-dose cytarabine AND One of the following: 1) Patient is greater than or equal to 75 years old, or 2) Patient has comorbidities that preclude the use of intensive induction chemotherapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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Formulary ID: 21386 Effective: 9/1/2021

# DIACOMIT

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## Products Affected

- DIACOMIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of seizures associated with Dravet syndrome (DS). Used in combination with clobazam.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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Formulary ID: 21386 Effective: 9/1/2021

# DUPIXENT

## Products Affected

- DUPIXENT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Atopic dermatitis (initial): Diagnosis of moderate to severe atopic dermatitis. Patient has minimum body surface area (BSA) involvement of at least 10%, eczema area and severity index (EASI) score of at least 16, or physician global assessment (PGA) score of at least 3. Trial and failure, contraindication, or intolerance to one medium to high potency topical corticosteroid. Previous trial of or contraindication to the following: topical corticosteroids and topical calcineurin inhibitors [e.g., elidel (pimecrolimus), generic tacrolimus ointment]. Eosinophilic Asthma (initial): Diagnosis of moderate to severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter. One of the following: 1) Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months, 2) Any prior intubation for an asthma exacerbation, or 3) Prior asthma-related hospitalization within the past 12 months. Corticosteroid Dependent Asthma (initial): Diagnosis of moderate to severe asthma. Patient is currently dependent on oral corticosteroids for the treatment of asthma. Eosinophilic Asthma, Corticosteroid Dependent Asthma (initial): Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol)].</p>
<b>Age Restrictions</b>	<p>Asthma (initial): Age greater than or equal to 12 years. Atopic dermatitis/CRSwNP: no age restriction.</p>
<b>Prescriber Restrictions</b>	<p>Atopic dermatitis (Initial): Prescribed by or in consultation with one of the following: dermatologist, allergist/immunologist. Asthma (initial, reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CRSwNP (initial, reauth): Prescribed by or in consultation with an otolaryngologist or allergist/immunologist.</p>
<b>Coverage Duration</b>	<p>Atopic Derm, CRSwNP, and Asthma (Init): 6 mo. Atopic Derm, CRSwNP, and Asthma (Reauth): 12 mo.</p>

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PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Chronic rhinosinusitis with nasal polyposis (CRSwNP) (initial): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (eg, fluticasone, mometasone). Used in combination with another agent for CRSwNP (eg, intranasal corticosteroid). Atopic dermatitis (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity). Eosinophilic Asthma (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications). Patient is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications: 1) Inhaled corticosteroid (ICS) and additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline] OR 2) A combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]). Corticosteroid Dependent Asthma (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, reduction in oral corticosteroid dose). Patient is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications: 1) Inhaled corticosteroid (ICS) and additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline] OR 2) A combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol]). CRSwNP (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS, 0-8 scale], improvement in nasal congestion/obstruction score [NC, 0-3 scale]). Used in combination with another agent for CRSwNP (eg, intranasal corticosteroid).</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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Formulary ID: 21386 Effective: 9/1/2021

# EGRIFTA

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## Products Affected

- EGRIFTA SUBCUTANEOUS SOLUTION
- EGRIFTA SV RECONSTITUTED 1 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of HIV-associated lipodystrophy with excess abdominal fat.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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Formulary ID: 21386 Effective: 9/1/2021

# ENBREL

## Products Affected

- ENBREL
- ENBREL MINI
- ENBREL SURECLICK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Trial and failure, contraindication, or intolerance to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. TF/C/I to at least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, or sulfasalazine. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Trial and failure, contraindication, or intolerance to one NSAID.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RA (initial), PJIA (initial), AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to Enbrel therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# ENDARI

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## Products Affected

- ENDARI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Sickle cell disease (initial): Diagnosis of sickle cell disease. Used to reduce acute complications of sickle cell disease. One of the following: (a) Patient is using Endari with concurrent hydroxyurea therapy, OR (b) Patient has a contraindication or intolerance to hydroxyurea. Patient has had 2 or more painful sickle cell crises within the past 12 months or sickle cell associated symptoms which are interfering with activities of daily living or history of recurrent acute chest syndrome (ACS).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Sickle cell disease (reauth): Documentation of positive clinical response to Endari therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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Formulary ID: 21386 Effective: 9/1/2021

# EPCLUSA

## Products Affected

- EPCLUSA ORAL TABLET 200-50 MG
- *sofosbuvir-velpatasvir*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Provider attestation that patient has life expectancy less than 12 months due to non-liver related comorbid conditions (per AASLD/IDSA treatment guideline recommendation). Patient is concurrently taking any of the following medications not recommended by the manufacturer: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, HIV regimen that contains efavirenz, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan.
<b>Required Medical Information</b>	Criteria will be applied consistent with current AASLD/IDSA guideline. Diagnosis of chronic hepatitis C. Patient is not receiving Epclusa (sofosbuvir/velpatasvir) in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine.
<b>Coverage Duration</b>	12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# EPIDIOLEX

## Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Lennox-Gastaut syndrome (LGS): Diagnosis of seizures associated with LGS. Trial of, contraindication, or intolerance to two formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate). Dravet syndrome (DS): Diagnosis of seizures associated with DS.
Age Restrictions	
Prescriber Restrictions	LGS, DS: Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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Formulary ID: 21386 Effective: 9/1/2021

# EPOETIN ALFA

## Products Affected

- PROCRIT INJECTION SOLUTION 10000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML, 2000 UNIT/ML, 20000 UNIT/ML, 40000 UNIT/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with HIV (Initial): Anemia by lab values (Hgb less than 12 g/dL or Hct less than 36%) collected within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. Anemia with chemo (Initial): Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 mos, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon or peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 30% or Hgb less than 12 g/dL) collected within 30 days of request. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo. MDS:(init) 3mo,(reauth)12mo. Preop:1mo.

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PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Subject to ESRD review. CKD (Reauth): Dx of CKD. Most recent or average (avg) Hct over 3 months is 33% or less OR most recent or avg Hgb over 3 months is 11 g/dL or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Off-label uses (except MDS): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Verify iron evaluation for adequate iron stores.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ERIVEDGE

## Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Basal cell carcinoma: One of the following: A) Diagnosis of metastatic basal cell carcinoma OR B) Both of the following: 1) Diagnosis of locally advanced basal cell carcinoma AND 2) One of the following: a) Disease recurred following surgery or b) Patient is not a candidate for surgery and radiation.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# ERLEADA

## Products Affected

- ERLEADA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-metastatic castration-resistant prostate cancer (NM-CRPC): Diagnosis of non-metastatic, castration-resistant (chemical or surgical) prostate cancer. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog OR 2) Patient received a bilateral orchiectomy. Trial and failure or intolerance to Xtandi (enzalutamide). Metastatic castration-sensitive prostate cancer (M-CSPC): Diagnosis of metastatic, castration-sensitive prostate cancer. Trial and failure or intolerance to Xtandi (enzalutamide).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# ESBRIET

## Products Affected

- ESBRIET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Not approved for patients with known causes of interstitial lung disease (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus (HIV) infection, viral hepatitis, and cancer). Not approved if the patient has not obtained liver function tests.
<b>Required Medical Information</b>	Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity), AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	IPF (initial): Prescribed by a pulmonologist
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	IPF (reauth): Documentation of positive clinical response to Esbriet therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# FABRAZYME

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## Products Affected

- FABRAZYME INTRAVENOUS SOLUTION RECONSTITUTED 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Fabry Disease: Diagnosis of Fabry disease. Fabrazyme will not be used in combination with Galafold (migalastat).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Fabry Disease: 12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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# FARYDAK

## Products Affected

- FARYDAK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multiple Myeloma (MM): Diagnosis of MM. Used in combination with both of the following: Velcade (bortezomib) and dexamethasone. Patient has received at least two prior treatment regimens which included both of the following: Velcade (bortezomib) and an immunomodulatory agent [eg, Revlimid (lenalidomide), Thalomid (thalidomide)].
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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Formulary ID: 21386 Effective: 9/1/2021

# FASENRA

## Products Affected

- FASENRA
- FASENRA PEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Asthma (initial): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter. One of the following: 1) Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months, OR 2) Any prior intubation for an asthma exacerbation, OR 3) Prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), tiotropium], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)].
<b>Age Restrictions</b>	Asthma (Initial): Patient is 12 years of age or older
<b>Prescriber Restrictions</b>	Asthma (Initial/Reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist
<b>Coverage Duration</b>	Asthma (init): 6 months. Asthma (reauth): 12 months
<b>Other Criteria</b>	Asthma (Reauth): Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications). Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), tiotropium], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)].
<b>Indications</b>	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	

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# FINTEPLA

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## Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of seizures associated with Dravet syndrome
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# FIRAZYR

## Products Affected

- *icatibant acetate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
Age Restrictions	18 years of age or older
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist, allergist, hematologist or rheumatologist
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# FLECTOR

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## Products Affected

- *diclofenac patch*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acute pain due to minor strains, sprains and contusions.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# FORTEO

## Products Affected

- FORTEO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	History of hypercalcemia, hyperparathyroidism, skeletal malignancy (i.e. osteosarcoma), Paget's disease or radiation therapy.
<b>Required Medical Information</b>	Postmenopausal osteoporosis or osteopenia or men with primary or hypogonadal osteoporosis or osteopenia: Diagnosis of one of the following: a) postmenopausal osteoporosis or osteopenia or b) primary or hypogonadal osteoporosis or osteopenia. LOW BMD WITH A T-SCORE LESS THAN -2.5 AND AT HIGH RISK FOR FRACTURE AS DEFINED BY EITHER A HISTORY OF OSTEOPOROTIC FRACTURE OR MULTIPLE RISK FACTORS FOR FRACTURE (E.G. ADVANCED AGE, FRAILTY, INCREASED FALL RISK, GLUCOCORTICOID THERAPY) OR FAILED AT LEAST A 6 MONTH TRIAL OF, OR HAS CONTRAINDICATION TO, OR CANNOT TOLERATE BISPHOSPHONATES, CALCITONIN OR EVISTA. Glucocorticoid-Induced Osteoporosis: Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose greater than or equal to 5mg/day for greater than or equal to 3 months. LOW BMD WITH A T-SCORE LESS THAN -2.5 AND AT HIGH RISK FOR FRACTURE AS DEFINED BY EITHER A HISTORY OF OSTEOPOROTIC FRACTURE OR MULTIPLE RISK FACTORS FOR FRACTURE (E.G. ADVANCED AGE, FRAILTY, INCREASED FALL RISK, GLUCOCORTICOID THERAPY) OR FAILED AT LEAST A 6 MONTH TRIAL OF, OR HAS CONTRAINDICATION TO, OR CANNOT TOLERATE BISPHOSPHONATES.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	All uses (initial): 24 months. All uses (reauth): 12 months.
<b>Other Criteria</b>	Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021



# FOTIVDA

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## Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of renal cell carcinoma. Disease is one of the following: relapsed or refractory. Patient has received two or more prior systemic therapies (e.g., cabozantinib + nivolumab, lenvatinib + pembrolizumab, etc.).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or nephrologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# GALAFOLD

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## Products Affected

- GALAFOLD

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Fabry Disease (FD) (initial): Diagnosis of FD. Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data. FD (initial, reauthorization): Galafold will not be used in combination with Fabrazyme (agalsidase beta).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	FD (initial, reauth): 12 months
Other Criteria	FD (reauthorization): Documentation of positive clinical response to Galafold therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# GATTEX

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## Products Affected

- GATTEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Short Bowel Syndrome (SBS) (Initial) Diagnosis of SBS. Patient is dependent on parenteral nutrition/intravenous (PN/IV) support.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	SBS (initial, reauth): 12 months
Other Criteria	SBS (Reauth): Documentation of positive clinical response to Gattex therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

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# GAVRETO

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## Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Presence of rearranged during transfection (RET) gene fusion-positive tumor(s).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

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# GILENYA

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## Products Affected

- GILENYA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
Age Restrictions	
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or multiple sclerosis specialist
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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Formulary ID: 21386 Effective: 9/1/2021

# GILOTRIF

## Products Affected

- GILOTRIF

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): A) Diagnosis of advanced or metastatic (stage IIIB or IV) NSCLC AND B) One of the following: 1) Both of the following: a) Tumors have non-resistant epidermal growth factor (EGFR) mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND b) GILOTRIF will be used as first-line treatment, OR 2) All of the following: a) disease progressed after platinum-based chemotherapy and b) squamous NSCLC.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# GLATIRAMER ACETATE

## Products Affected

- *glatiramer acetate subcutaneous solution prefilled syringe 20 mg/ml, 40 mg/ml*
- *glatopa subcutaneous solution prefilled syringe 20 mg/ml, 40 mg/ml*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist or multiple sclerosis specialist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# GROWTH HORMONE

## Products Affected

- NORDITROPIN FLEXPRO
- OMNITROPE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Intrauterine growth retardation (IUGR) or small for gestational age (SGA): birth weight or length less than 2 standard deviations below the mean (or below the 3rd percentile) for gestational age and has failed to catch up by age 2. Growth hormone deficiency (childhood onset, idiopathic or acquired resulting from hypothalamic-pituitary disease, craniopharyngioma, head trauma, radiation or surgery): removal of pituitary gland or failed to respond to 1 standard growth hormone stimulation test (with insulin, levodopa, arginine, propranolol, clonidine or glucagon). Failure is defined as a peak measured growth hormone level of less than 5ng/ml after stimulation in adult patients and less than 10ng/ml after stimulation in pediatric patients.
<b>Age Restrictions</b>	Turner Syndrome, Chronic renal failure or Prader-Willi Syndrome: Less than 18 years of age. All other indications have no age requirement.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# HETLIOZ

## Products Affected

- HETLIOZ
- HETLIOZ LQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-24-Hour Sleep-Wake Disorder (Non-24) (initial): Both of the following: 1) Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernycthemeral syndrome), AND 2) patient is totally blind (has no light perception).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Non-24 (initial): Prescribed by or in consultation with a specialist in sleep disorders or neurologist
<b>Coverage Duration</b>	Non-24 (initial, reauth): 12 months
<b>Other Criteria</b>	Non-24 (reauth): Documentation of positive clinical response to HetlioZ therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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Formulary ID: 21386 Effective: 9/1/2021

# HRM ANTICHOLINERGICS

## Products Affected

- *ciproheptadine hcl oral*
- *diphenhydramine hcl oral elixir*
- *phenadoz rectal suppository 12.5 mg, 25 mg*
- *promethazine hcl oral syrup*
- *promethazine hcl oral tablet*
- *promethazine hcl rectal*
- *promethegan*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The drug is being prescribed for a medically accepted indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# HRM ANTIPARKINSONS AGENTS

## Products Affected

- *benztropine mesylate oral*
- *trihexyphenidyl hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The drug is being prescribed for a medically accepted indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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# HRM CARDIOVASCULAR AGENTS

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## Products Affected

- *guanfacine hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The drug is being prescribed for a medically accepted indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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Formulary ID: 21386 Effective: 9/1/2021

# HRM MEGESTROL ACETATE

## Products Affected

- *megestrol acetate oral suspension 40 mg/ml, 625 mg/5ml*
- *megestrol acetate oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The drug is being prescribed for a medically accepted indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# HRM PHENOBARBITAL

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## Products Affected

- *phenobarbital oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The drug is being prescribed for a medically accepted indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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# HRM SKELETAL MUSCLE RELAXANTS

## Products Affected

- *cyclobenzaprine hcl oral*
- *methocarbamol oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The drug is being prescribed for a medically accepted indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# HRM THIORIDAZINE

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## Products Affected

- *thioridazine hcl oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The drug is being prescribed for a medically accepted indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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# HUMIRA

## Products Affected

- HUMIRA
- HUMIRA PEDIATRIC CROHNS START
- HUMIRA PEN
- HUMIRA PEN-CD/UC/HS STARTER
- HUMIRA PEN-PEDIATRIC UC START
- HUMIRA PEN-PS/UV/ADOL HS START
- HUMIRA PEN-PSOR/UEIT STARTER

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)].</p> <p>Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. TF/C/I to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall).</p> <p>Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. TF/C/I to at least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, or sulfasalazine.</p> <p>Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. TF/C/I to at least one course of systemic therapy for psoriasis such as: acitretin, cyclosporine, methotrexate, or oral methoxsalen plus UVA light (PUVA).</p> <p>Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. TF/C/I to one NSAID.</p> <p>Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. TF/C/I to at least two of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall).</p> <p>Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to at least two of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol, Pentasa, Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)].</p> <p>Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III).</p> <p>Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>RA, AS, JIA (initial): Prescribed by or in consultation with a rheumatologist.</p> <p>PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.</p> <p>Plaque Psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist.</p> <p>CD, UC (initial): Prescribed by or in consultation with a gastroenterologist.</p> <p>Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.</p>

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PA Criteria	Criteria Details
<b>Coverage Duration</b>	All indications (initial, reauth): 12 months
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to Humira therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

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# IBRANCE

## Products Affected

- IBRANCE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Breast Cancer: Diagnosis of advanced or metastatic breast cancer. Disease is a) hormone receptor (HR)-positive, and b) human epidermal growth factor receptor 2 (HER2)-negative. One of the following: 1) used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) and one of the following: a) patient is a male, or b) patient is a postmenopausal woman, OR 2) both of the following: used in combination with Faslodex (fulvestrant) and disease has progressed following endocrine therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# ICLUSIG

## Products Affected

- ICLUSIG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documented diagnosis of chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (cml) or positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+all) for which no other tyrosine kinase inhibitor therapy is indicated or t315i-positive cml (chronic phase, accelerated phase, or blast phase) or t3151-positive Ph+all.
<b>Age Restrictions</b>	All Uses: 18 years of age or older
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	All uses: 12 months
<b>Other Criteria</b>	All uses: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# IDHIFA

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**Products Affected**

- IDHIFA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. Patient has an isocitrate dehydrogenase-2 (IDH2) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH2 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# IMATINIB MESYLATE

## Products Affected

- *imatinib mesylate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	One of the following: A) Diagnosis of Philadelphia chromosome positive (Ph+)/BCR ABL-positive chronic myelogenous leukemia (CML) OR B) Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL) OR C) Gastrointestinal stromal tumor (GIST) AND one of the following: 1) Patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST, OR 2) Patient had resection of c-KIT (CD117) positive GIST and imatinib will be used as adjuvant therapy OR D) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic OR E) Hypereosinophilic syndrome or chronic eosinophilic leukemia OR F) Myelodysplastic syndrome (MDS) or myeloproliferative disease associated with platelet-derived growth factor receptor gene rearrangements OR G) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	All uses: 12 months
<b>Other Criteria</b>	All uses: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# IMBRUVICA

## Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG, 560 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Mantle cell lymphoma (MCL): Diagnosis of MCL AND patient has relapsed or is refractory to at least one prior therapy for the treatment of MCL. Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Waldenstrom's macroglobulinemia: Diagnosis of Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma. Small lymphocytic lymphoma (SLL): Diagnosis of SLL. Marginal zone lymphoma (MZL): Diagnosis of MZL AND patient has received at least one prior anti-CD20-based therapy for MZL [e.g., Rituxan (rituximab), Zevalin (ibritumomab), Gazyva (obinutuzumab, etc.)]. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD AND trial and failure of one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses (except chronic graft versus host disease): Prescribed by or in consultation with an oncologist or hematologist. Chronic graft versus host disease: Prescribed by or in consultation with a hematologist, oncologist, or physician experienced in the management of transplant patients.
<b>Coverage Duration</b>	All Uses: 12 months
<b>Other Criteria</b>	All Uses: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# INCRELEX

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**Products Affected**

- INCRELEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Insulin-like Growth Factor-1 (IGF-1) deficiency (initial): Diagnosis of severe primary IGF-1 deficiency. GH gene deletion (initial): Diagnosis of GH gene deletion in patients who have developed neutralizing antibodies to GH.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with a pediatric endocrinologist
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	(Reauth): Evidence of positive response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# INGREZZA

## Products Affected

- INGREZZA ORAL CAPSULE 40 MG, 60 MG, 80 MG
- INGREZZA ORAL CAPSULE THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Tardive Dyskinesia (initial): Diagnosis of moderate to severe tardive dyskinesia.
Age Restrictions	
Prescriber Restrictions	Initial: Prescribed by or in consultation with a neurologist, psychiatrist, or movement disorder specialist.
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Tardive Dyskinesia (reauth): Documentation of positive clinical response to Ingrezza therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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Formulary ID: 21386 Effective: 9/1/2021

# INLYTA

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## Products Affected

- INLYTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of advanced RCC. One of the following: (1) for the first-line treatment of patients in combination with avelumab or (2) for the first-line treatment of patients in combination with pembrolizumab or (3) as a single agent, after failure of one prior systemic therapy.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# INQOVI

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## Products Affected

- INQOVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome. Patient has ONE of the following French- American-British subtypes: a) refractory anemia, b) refractory anemia with ringed sideroblasts, c) refractory anemia with excess blasts, or d) chronic myelomonocytic leukemia (CMML).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# INREBIC

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## Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Myelofibrosis: Diagnosis of one of the following: primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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Formulary ID: 21386 Effective: 9/1/2021

# IRESSA

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**Products Affected**

- IRESSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# JAKAFI

## Products Affected

- JAKAFI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Myelofibrosis: Diagnosis of primary myelofibrosis, OR post-polycythemia vera myelofibrosis, OR post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera, AND trial and failure, contraindication, or intolerance to hydroxyurea. Acute graft versus host disease (aGVHD): Diagnosis of aGVHD. Disease is steroid-refractory.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Myelofibrosis, Polycythemia vera: Prescribed by or in consultation with a hematologist/oncologist. Acute graft versus host disease: Prescribed by or in consultation with one of the following: hematologist, oncologist, physician experienced in the management of transplant patients.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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Formulary ID: 21386 Effective: 9/1/2021

# JYNARQUE

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**Products Affected**

- JYNARQUE ORAL TABLET
- JYNARQUE ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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Formulary ID: 21386 Effective: 9/1/2021

# KALYDECO

## Products Affected

- KALYDECO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Homozygous for F508del mutation in CFTR gene.
<b>Required Medical Information</b>	Cystic Fibrosis (CF) (Initial): Diagnosis of cystic fibrosis. Patient has one of the following mutations on at least one allele in the cystic fibrosis transmembrane conductance regulator gene as detected by an FDA-cleared cystic fibrosis mutation test or at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility: A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, E831X, F1052V, F1074L, G178R, G551D, G551S, G1069R, G1244E, G1349D, K1060T, L206W, P67L, R74W, R117C, R117H, R347H, R352Q, R1070Q, R1070W, S549N, S549R, S945L, S977F, S1251N, S1255P, 711+3A-G, 2789+5G-A, 3272-26A-G, or 3849+10kbC-T.
<b>Age Restrictions</b>	CF (Initial): 6 months of age or older
<b>Prescriber Restrictions</b>	CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
<b>Coverage Duration</b>	CF (initial, reauth): 12 months
<b>Other Criteria</b>	CF (Reauth): Documentation of positive clinical response (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations) to Kalydeco therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# KALYDECO GRANULE PACKETS

## Products Affected

- KALYDECO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Homozygous for F508del mutation in CFTR gene.
<b>Required Medical Information</b>	Cystic Fibrosis (CF) (Initial): Diagnosis of cystic fibrosis. Patient has one of the following mutations on at least one allele in the cystic fibrosis transmembrane conductance regulator gene as detected by an FDA-cleared cystic fibrosis mutation test or at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility: A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, E831X, F1052V, F1074L, G178R, G551D, G551S, G1069R, G1244E, G1349D, K1060T, L206W, P67L, R74W, R117C, R117H, R347H, R352Q, R1070Q, R1070W, S549N, S549R, S945L, S977F, S1251N, S1255P, 711+3A-G, 2789+5G-A, 3272-26A-G, or 3849+10kbC-T.
<b>Age Restrictions</b>	6 months of age or older
<b>Prescriber Restrictions</b>	CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
<b>Coverage Duration</b>	CF (initial, reauth): 12 months
<b>Other Criteria</b>	CF (Reauth): Documentation of positive clinical response (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations) to Kalydeco therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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Formulary ID: 21386 Effective: 9/1/2021

# KINERET

## Products Affected

- KINERET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance to at least one of the following DMARDs: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Kineret therapy. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RA (initial): Prescribed by or in consultation with a rheumatologist. NOMID (initial): Prescribed by or in consultation with allergist/immunologist or rheumatologist or pediatrician.
<b>Coverage Duration</b>	All Uses (initial, reauth): 12 months
<b>Other Criteria</b>	All Uses (Reauth): Documentation of positive clinical response to Kineret therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# KISQALI

## Products Affected

- KISQALI ORAL TABLET THERAPY  
PACK 200 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Breast cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: A) Kisqali is used in combination with an aromatase inhibitor [e.g., Femara (letrozole)] OR B) Both of the following: 1) Used in combination with Faslodex (fulvestrant) and 2) patient is a postmenopausal woman.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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Formulary ID: 21386 Effective: 9/1/2021

# KISQALI-FEMARA PAK

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## Products Affected

- KISQALI FEMARA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Breast cancer: Diagnosis of advanced or metastatic breast cancer. Cancer is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# KORLYM

## Products Affected

- KORLYM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cushing's syndrome (Initial): Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Diagnosis of either type 2 diabetes mellitus or diagnosis of glucose intolerance. Patient has either failed surgery or patient is not a candidate for surgery. Patient is not pregnant.
Age Restrictions	
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Reauth: Documentation of one of the following: patient has improved glucose tolerance while on Korlym therapy or patient has stable glucose tolerance while on Korlym therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# KOSELUGO

## Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Neurofibromatosis Type 1 (NF1): Diagnosis of NF1. Patient has plexiform neurofibromas that are both of the following: inoperable and causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment). Patient is able to swallow a capsule whole.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with one of the following: oncologist or neurologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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Formulary ID: 21386 Effective: 9/1/2021

# KUVAN

## Products Affected

- KUVAN
- *sapropterin dihydrochloride*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Phenylketonuria (PKU) (initial): DIAGNOSIS OF HYPERPHENYLALANINEMIA (HPA) DUE TO TETRAHYDROBIOPTERIN (BH4)-RESPONSIVE PHENYLKETONURIA (PKU).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by a specialist in metabolic disorders.
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	PKU (reauth): Patient has had an objective response to therapy, defined as a documented reduction in phenylalanine (Phe) blood levels from baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# KYNMOBI

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## Products Affected

- KYNMOBI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Parkinson's disease (PD) (Initial): Not used with any 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron)
<b>Required Medical Information</b>	Parkinson's disease (PD) (Initial): Diagnosis of PD. Patient is experiencing acute intermittent hypomobility (defined as "off" episodes characterized by muscle stiffness, slow movements, or difficulty starting movements). Used in combination with other medications for the treatment of PD (e.g., carbidopa/levodopa, pramipexole, ropinirole, etc.).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PD (Initial): Prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	PD (Initial, reauth): 12 months
<b>Other Criteria</b>	PD (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# LENVIMA

## Products Affected

- LENVIMA ORAL CAPSULE THERAPY                      MG, 2 X 10 MG, 2 X 10 MG & 4 MG, 2 X 4  
PACK 10 & 4 MG, 10 MG, 10 MG & 2 X 4                      MG, 3 X 4 MG, 4 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Differentiated thyroid cancer (DTC): Diagnosis of DTC. Disease is locally recurrent or metastatic. Patient has symptomatic or progressive disease. Disease is refractory to radioactive iodine treatment. Renal Cell Carcinoma (RCC): Diagnosis of advanced RCC. Treatment follows one prior anti-angiogenic therapy. Used in combination with everolimus. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or disease is unresectable.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	DTC/RCC: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with one of the following: oncologist, hepatologist, or gastroenterologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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Formulary ID: 21386 Effective: 9/1/2021

# LETAIRIS

## Products Affected

- *ambrisentan*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH Initial and reauth: 12 months
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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Formulary ID: 21386 Effective: 9/1/2021

# LIDOCAINE PATCH

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## Products Affected

- *lidocaine external patch 5 %*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Post-herpetic neuralgia: Diagnosis of post-herpetic neuralgia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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Formulary ID: 21386 Effective: 9/1/2021

# LONSURF

## Products Affected

- LONSURF

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Colorectal Cancer: Diagnosis of metastatic colorectal cancer AND trial and failure, contraindication, or intolerance to at least one component in the following: fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI) AND trial and failure, contraindication, or intolerance to at least one anti-VEGF therapy (e.g., Avastin) AND One of the following: A) patient has KRAS wild-type tumors and trial and failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Vectibix, Erbitux) OR Patient has KRAS mutant tumors. Gastric/Gastroesophageal Junction Adenocarcinoma: Diagnosis of metastatic gastric cancer or diagnosis of metastatic gastroesophageal junction adenocarcinoma. Trial and failure, contraindication or intolerance to at least two of the following: fluoropyrimidine-based chemotherapy (e.g. fluorouracil), Platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin), Taxane (e.g., docetaxel, paclitaxel) or irinotecan-based chemotherapy, HER2/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# LORBRENA

## Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic and anaplastic lymphoma kinase (ALK)-positive. Metastatic disease has progressed on one of the following: 1) Xalkori (crizotinib) and at least one other ALK inhibitor [e.g., Alunbrig (brigatinib)], 2) Alecensa (alectinib) as the first ALK inhibitor therapy, or 3) Zykadia (ceritinib) as the first ALK inhibitor therapy.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# LYNPARZA TABLET

## Products Affected

- LYNPARZA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Ovarian cancer, advanced disease with known or suspected BRCA mutation with 3 or more prior lines of chemotherapy: Diagnosis of advanced ovarian cancer. Presence of deleterious or suspected deleterious germline BRCA-mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Trial and failure, contraindication, or intolerance to three or more prior lines of chemotherapy (e.g., paclitaxel with cisplatin). Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Breast cancer: Diagnosis of metastatic breast cancer. Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease is human epidermal growth factor receptor 2 (HER2)-negative. Patient has been previously treated with chemotherapy (e.g., anthracycline, taxane) in the neoadjuvant, adjuvant, or metastatic setting. One of the following: a) Disease is hormone receptor (HR) negative, or b) Disease is hormone receptor (HR)-positive and one of the following: i) patient has been treated with prior endocrine therapy or ii) patient is considered an inappropriate candidate for endocrine therapy. See Other Criteria.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Maintenance treatment of BRCA-mutated advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: advanced epithelial ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Presence of deleterious

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PA Criteria	Criteria Details
	<p>or suspected deleterious BRCA-mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and/or genomic instability. Patient has had a complete or partial response to first-line platinum-based chemotherapy (e.g., carboplatin, cisplatin). Lynparza will be used in combination with bevacizumab. Prostate Cancer: Diagnosis of prostate cancer. Presence of a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease progression following prior treatment with enzalutamide or abiraterone. Pancreatic adenocarcinoma: Diagnosis of metastatic pancreatic adenocarcinoma. Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has not progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen. All indications: Approve for continuation of prior therapy.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# MAVYRET

## Products Affected

- MAVYRET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Provider attestation that patient has life expectancy less than 12 months due to non-liver related comorbid conditions (per AASLD/IDSA treatment guideline recommendation). moderate or severe hepatic impairment (child pugh b or c). Patient is concurrently taking any of the following: carbamazepine, rifampin, ethinyl estradiol-containing medication, atazanavir, darunavir, lopinavir, ritonavir, efavirenz, st. John's wort, atorvastatin, lovastatin, simvastatin, rosuvastatin at doses greater than 10mg, or cyclosporine at doses greater than 100mg per day. Prior failure of a DAA regimen with ns5a inhibitor and HCV protease inhibitor.
<b>Required Medical Information</b>	Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine.
<b>Coverage Duration</b>	8 to 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# MEKINIST

## Products Affected

- MEKINIST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Melanoma: Diagnosis of unresectable or metastatic melanoma AND cancer is BRAF V600E or V600K mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Tafinlar (dabrafenib). Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Tafinlar (dabrafenib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic ATC. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Tafinlar (dabrafenib).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# MEKTOVI

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## Products Affected

- MEKTOVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Braftovi (encorafenib).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# MS INTERFERONS

## Products Affected

- AVONEX PEN
- AVONEX PREFILLED
- REBIF
- REBIF REBIDOSE
- REBIF REBIDOSE TITRATION PACK
- REBIF TITRATION PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist or multiple sclerosis specialist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# MULPLETA

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**Products Affected**

- MULPLETA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Thrombocytopenia Prior to Planned Procedure (TPPP): Diagnosis (dx) of thrombocytopenia. Baseline platelet count is less than 50,000/mcL. Patient has chronic liver disease and is scheduled to undergo a procedure.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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# NATPARA

## Products Affected

- NATPARA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Hypocalcemia (Initial): Diagnosis of hypocalcemia due to chronic hypoparathyroidism. NATPARA is not being used in the setting of acute post-surgical hypoparathyroidism. Patient does not have a known calcium-sensing receptor mutation. Patient has a documented parathyroid hormone concentration that is inappropriately low for the level of calcium, recorded on at least two occasions within the previous 12 months. Patient has normal thyroid-stimulating hormone concentrations if not on thyroid hormone replacement therapy (or if on therapy, the dose had to have been stable for greater than or equal to 3 months). Patient has normal magnesium and serum 25-hydroxyvitamin D concentrations. NATPARA will be used as an adjunct treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Hypocalcemia (initial): Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	Initial and Reauth: 12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# NERLYNX

## Products Affected

- NERLYNX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Early Stage Breast cancer: Diagnosis (dx) of early stage breast cancer. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Patient has received adjuvant trastuzumab-based therapy. Advanced or Metastatic Breast Cancer: Dx of advanced or metastatic breast cancer. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Patient has received two or more prior anti-HER2 based regimens (e.g., trastuzumab + pertuzumab + docetaxel, ado-trastuzumab emtansine, etc.). Used in combination with capecitabine.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# NEXAVAR

## Products Affected

- NEXAVAR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Renal cell carcinoma (RCC): Diagnosis of RCC. One of the following: Relapsed disease OR both medically/surgically unresectable tumor and dx of Stage IV disease. Hepatocellular carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or disease is unresectable. Differentiated thyroid carcinoma (DTC): Diagnosis of DTC (ie, follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma). One of the following: locally recurrent disease or metastatic disease. One of the following: patient has symptomatic disease or patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment. Medullary thyroid carcinoma (MTC): Diagnosis of MTC. One of the following: 1) Disease is progressive or 2) Disease is symptomatic with distant metastases.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	DTC, MTC: Prescribed by or in consultation with an oncologist. RCC: Prescribed by or in consultation with an oncologist or nephrologist. HCC: Prescribed by or in consultation with an oncologist, hepatologist, or gastroenterologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# NEXLETOL/NEXLIZET

## Products Affected

- NEXLETOL
- NEXLIZET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: One of the following diagnoses: A) Heterozygous familial hypercholesterolemia (HeFH) as confirmed by Simon Broome Diagnostic Criteria OR B) Atherosclerotic cardiovascular disease (ASCVD). One of the following LDL-C values while on max tolerated statin tx within the last 120 days: (1) LDL-C greater than or equal to 70 mg/dL with ASCVD or (2) LDL-C greater than or equal to 100 mg/dL without ASCVD. One of the following: (1) Pt has been receiving at least 12 weeks of one high-intensity statin (HIS) therapy and will continue to receive a HIS at max tolerated dose, OR (2) Both of the following: a) Pt is unable to tolerate HIS AND b) Pt has been receiving at least 12 weeks of one moderate-intensity statin (MIS) or one low-intensity statin (LIS) and will continue to receive a MIS or LIS at max tolerated dose, OR (3) Pt is unable to tolerate low-, moderate-, or high-intensity statins as evidenced by intolerable and persistent (ie, more than 2 weeks) symptoms: myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times ULN), OR (4) Pt has a labeled contraindication to all statins AND Pt has been receiving at least 12 weeks of generic ezetimibe tx as adjunct to max tolerated statin tx or pt has a history of contraindication or intolerance to ezetimibe. Reauth: Documentation of positive clinical response to therapy (eg reduction in LDL-C levels).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 12 months. Reauth: 12 months.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# NINLARO

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**Products Affected**

- NINLARO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple myeloma: Diagnosis of multiple myeloma. Used in combination with Revlimid (lenalidomide) and dexamethasone. Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# NORTHERA

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**Products Affected**

- *droxidopa*
- NORTHERA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Neurogenic orthostatic hypotension (NOH) (init): Diagnosis of symptomatic NOH.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	NOH (init): Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist
<b>Coverage Duration</b>	NOH (initial and reauth): 12 months
<b>Other Criteria</b>	NOH (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# NUBEQA

## Products Affected

- NUBEQA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-metastatic castration-resistant or castration-recurrent prostate cancer (nmCRPC): Diagnosis of non-metastatic castration-resistant (chemical or surgical) or castration-recurrent prostate cancer. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog (e.g., Zoladex [goserelin], Vantas [histrelin], Lupron [leuprolide], Trelstar [triptorelin]) OR 2) Patient received bilateral orchiectomy. Trial and failure, contraindication, or intolerance to Xtandi (enzalutamide).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# NUCALA

## Products Affected

- NUCALA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Asthma (init): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by one of the following: baseline (pre-treatment) peripheral blood eosinophil level is greater than or equal to 150 cells/microliter or peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months. Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months or Patient has had any prior intubation for an asthma exacerbation or Patient has had a prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)].</p> <p>Eosinophilic Granulomatosis with Polyangiitis (EGPA) (init): Diagnosis of EGPA. Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy). Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>Asthma (init, reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. EGPA (init): Prescribed by or in consultation with a pulmonologist, rheumatologist or allergist/immunologist.</p>
<b>Coverage Duration</b>	<p>Asthma (init): 6 mo, Asthma (reauth): 12 months. EGPA (init, reauth): 12 months</p>
<b>Other Criteria</b>	<p>Asthma (reauth): Documentation of positive clinical response to therapy (eg, reduction in exacerbations, improvement in forced expiratory volume in 1 second (FEV1), decreased use of rescue medications). Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the</p>

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PA Criteria	Criteria Details
	<p>following: i) inhaled corticosteroid (ICS) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)]. EGPA (reauth): Documentation of positive clinical response to therapy (e.g., increase in remission time).</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# NUEDEXTA

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**Products Affected**

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pseudobulbar affect (PBA) (initial): Diagnosis of PBA. (Reauthorization): Documentation of clinical benefit from ongoing therapy with Nuedexta.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	PBA (initial/reauth): 12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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# NUPLAZID

## Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Parkinson's disease psychosis: Diagnosis of Parkinson's disease. Patient has at least one of the following: hallucinations or delusions.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist, geriatrician, or a behavioral health specialist (such as a psychiatrist)
<b>Coverage Duration</b>	Initial: 12 months. Reauth: 12 months.
<b>Other Criteria</b>	Renewal requires documentation that the patient has experienced an improvement in psychosis symptoms from baseline and demonstrates a continued need for treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# OCALIVA

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## Products Affected

- OCALIVA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with complete biliary obstruction.
<b>Required Medical Information</b>	Primary Biliary Cholangitis (PBC) (initial): Diagnosis of PBC (aka primary biliary cirrhosis). One of the following: a) patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) AND used in combination with UDCA, OR b) contraindication or intolerance to UDCA.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PBC (initial): Prescribed by or in consultation with a hepatologist or gastroenterologist.
<b>Coverage Duration</b>	PBC (initial): 6 months, (reauth): 12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# OCREVUS

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## Products Affected

- OCREVUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Relapsing forms of multiple sclerosis (initial): Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses). Primary progressive MS (initial): Diagnosis of primary progressive multiple sclerosis (PPMS).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months.
<b>Other Criteria</b>	All indications (reauth): Documentation of positive clinical response to Ocrevus therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# ODOMZO

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## Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma AND One of the following: 1) Cancer has recurred following surgery or radiation therapy or 2) Patient is not a candidate for surgery or radiation therapy.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# OFEV

## Products Affected

- OFEV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	IPF (initial): Prescribed by a pulmonologist
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	IPF (reauth): Documentation of positive clinical response to Ofev therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# ONUREG

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## Products Affected

- ONUREG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Acute Myeloid Leukemia (AML): Diagnosis of acute myeloid leukemia (AML). Patient has received previous treatment with an intensive induction chemotherapy regimen (e.g., cytarabine + daunorubicin, cytarabine + idarubicin, etc.). Patient has achieved one of the following: a) first complete remission (CR) or b) complete remission with incomplete blood count recovery (CRi). Patient is not able to complete intensive curative therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# OPSUMIT

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**Products Affected**

- OPSUMIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. Patient has NYHA-WHO functional class II-IV Symptoms. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# ORFADIN

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documented diagnosis of hereditary tyrosinemia type-1.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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# ORGOVYX

## Products Affected

- ORGOVYX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prostate Cancer: Diagnosis of advanced prostate cancer. Patient has required at least one year of androgen deprivation therapy (e.g., Brand Lupron formulations, generic leuprolide acetate, Nubeqa, Xtandi). Disease is one of the following: 1) Evidence of biochemical or clinical relapse following local primary intervention with curative intent or 2) Newly diagnosed androgen-sensitive metastatic disease or 3) Advanced localized disease unlikely to be cured by local primary intervention with curative intent.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an urologist or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# ORIAHNN

## Products Affected

- ORIAHNN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids). Patient is premenopausal. One of the following: 1) History of inadequate control of bleeding following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: combination (estrogen/progesterone) oral contraceptive, progestins, or tranexamic acid or 2) Patient has had a previous interventional therapy to reduce bleeding. Treatment duration of therapy has not exceeded a total of 24 months.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: Patient has improvement in bleeding associated with uterine leiomyomas (fibroids) (e.g., significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.). Treatment duration of therapy has not exceeded a total of 24 months.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# ORILISSA

## Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Endometriosis (EM) (initial - 150 mg): Diagnosis of moderate to severe pain associated with EM. One of the following: 1) History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: danazol, combination (estrogen/progesterone) oral contraceptive, or progestins, or 2) Patient has had surgical ablation to prevent recurrence. EM (200 mg): Diagnosis of moderate to severe pain associated with EM. One of the following: 1) History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: danazol, combination (estrogen/progesterone) oral contraceptive, or progestins, or 2) Patient has had surgical ablation to prevent recurrence.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	EM (init, reauth-150mg): 6 mo. EM (200mg): 6 mo.
<b>Other Criteria</b>	EM (reauthorization - 150 mg): Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain). Treatment duration of Orilissa has not exceeded a total of 24 months.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# ORKAMBI

## Products Affected

- ORKAMBI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Kalydeco therapy.
<b>Required Medical Information</b>	Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or at a Clinical Laboratory Improvement Amendments-approved facility. Baseline FEV1.
<b>Age Restrictions</b>	CF (Initial): Patient is 2 years of age or older
<b>Prescriber Restrictions</b>	CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
<b>Coverage Duration</b>	CF (initial, reauth): 12 months
<b>Other Criteria</b>	CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# OSPHENA

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## Products Affected

- OSPHENA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Dyspareunia (initial): Diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause. Vaginal dryness (initial): Diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	All uses (Initial, reauth): 12 months
Other Criteria	Dyspareunia, Vaginal dryness (reauth): Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# OTEZLA

## Products Affected

- OTEZLA ORAL TABLET
- OTEZLA ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	All cosmetic use indications.
<b>Required Medical Information</b>	Psoriatic arthritis (PsA, initial): Diagnosis of active PsA. Previous trial with one DMARD (disease-modifying antirheumatic drug) agent such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. Previous trial with one of the following conventional therapies such as PUVA (phototherapy ultraviolet light a), UVb (ultraviolet light b), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine. For all indications: TF/C/I to at least two of the following: Humira, Enbrel, Skyrizi, or Cosentyx.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.
<b>Coverage Duration</b>	Initial, Reauth: 12 months
<b>Other Criteria</b>	Reauth (all indications): Documentation of positive clinical response to Otezla therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# OXBRYTA

## Products Affected

- OXBRYTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of Sickle Cell Disease. Documentation of hemoglobin level that does not exceed 10.5 g/dL prior to therapy initiation. Trial and failure, contraindication, or intolerance to hydroxyurea.
<b>Age Restrictions</b>	Initial: Patient is 12 years of age or older.
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with one of the following: 1) Hematologist/Oncologist or 2) Specialist w/ expertise in the diagnosis and management of sickle cell disease.
<b>Coverage Duration</b>	Initial, Reauth: 12 months
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response to therapy (e.g., an increase in hemoglobin level of 1 g/dL or greater from baseline, decreased annualized incidence rate of vaso-occlusive crises [VOCs]). Documentation of hemoglobin level that does not exceed 10.5 g/dL.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# OXERVATE

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## Products Affected

- OXERVATE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Neurotrophic keratitis (NK): Diagnosis of NK.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or optometrist.
Coverage Duration	8 weeks
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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# PAH DRUGS

## Products Affected

- *alyq*
- *sildenafil citrate oral suspension reconstituted*
- *sildenafil citrate oral tablet 20 mg*
- *tadalafil (pah)*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH: (initial, reauth): 12 months
<b>Other Criteria</b>	PAH (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# PEMAZYRE

## Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of cholangiocarcinoma. Disease is one of the following: unresectable locally advanced or metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement. Patient has been previously treated.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# PIQRAY

## Products Affected

- PIQRAY ORAL TABLET THERAPY  
PACK 2 X 150 MG, 200 & 50 MG, 200  
MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Breast Cancer (BC): Diagnosis of advanced or metastatic BC. Disease is hormone receptor (HR)-positive, and human epidermal growth factor receptor 2 (HER2)-negative. Cancer is PIK3CA-mutated as detected by an FDA-approved test (therascreen PIK3CA RGQ PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient is a postmenopausal woman or male. Used in combination with fulvestrant. Disease has progressed on or after an endocrine-based regimen.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# POLIVY

## Products Affected

- POLIVY INTRAVENOUS SOLUTION RECONSTITUTED 30 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diffuse large B-cell lymphoma (DLBCL): Diagnosis of diffuse large B-cell lymphoma (DLBCL). Disease is relapsed or refractory. Used in combination with bendamustine and a rituximab product. Patient has received at least two prior therapies for DLBCL (e.g., RCHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone], HSCT [hematopoietic stem cell transplantation], CAR T [chimeric antigen receptor T-cell] therapy, RCEPP [rituximab, cyclophosphamide, etoposide, prednisone, procarbazine], GemOx [gemcitabine, oxaliplatin] with or without rituximab).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# POMALYST

## Products Affected

- POMALYST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple Myeloma (MM): Diagnosis of MM. Used in combination with dexamethasone. Patient has received two prior therapies, including Revlimid (lenalidomide) and a proteasome inhibitor [eg, Velcade (bortezomib) or Kyprolis (carfilzomib)] or has a contraindication or intolerance to Revlimid and proteasome inhibitors. Patient has experienced disease progression on or within 60 days of completion of last therapy. Kaposi sarcoma (KS): One of the following: 1) Both of the following: a) Diagnosis of AIDS-related KS and b) Patient has failed highly active antiretroviral therapy (HAART), OR 2) Both of the following: a) Diagnosis of KS and b) Patient is HIV-negative.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# PROLIA

## Products Affected

- PROLIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Osteoporosis: High risk of fracture defined as a history of osteoporotic fracture or multiple risk factors for fracture and a T score less than or equal to -2 as evidenced via bone density scan OR has had an inadequate response or intolerance to therapy with at least one traditional osteoporosis treatment (alendronate, calcitonin, ibandronate, raloxifene, risedronate, zoledronic acid). Glucocorticoid-induced osteoporosis: Patient is initiating or continuing systemic glucocorticoids at a daily dose equivalent to or greater than 7.5mg of prednisone for an anticipated duration of at least 6 months.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# PROMACTA

## Products Affected

- PROMACTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chronic immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Trial and failure, intolerance, contraindication to corticosteroids or immunoglobulins or splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C-associated thrombocytopenia. First-line for severe aplastic anemia (SAA): Diagnosis of SAA. Refractory SAA (initial): Diagnosis of refractory severe aplastic anemia. Insufficient response to immunosuppressive therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Chronic ITP and SAA: Prescribed by or in consultation with a hematologist/oncologist. Chronic hepatitis C associated thrombocytopenia: Prescribed by or in consultation with a hematologist/oncologist, gastroenterologist, hepatologist, infectious disease specialist, or HIV specialist certified through the American Academy of HIV Medicine.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# QINLOCK

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**Products Affected**

- QINLOCK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Gastrointestinal Stromal Tumor (GIST): Diagnosis of gastrointestinal stromal tumor (GIST). Disease is advanced. Patient has received prior treatment with three or more kinase inhibitors (e.g., sunitinib, regorafenib), one of which must include imatinib.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# QUALAQUIN

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## Products Affected

- *quinine sulfate oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Malaria: Diagnosis of uncomplicated malaria. One of the following: 1) Treatment in areas of chloroquine-sensitive malaria OR 2) Treatment in areas of chloroquine-resistant malaria. Not used for the treatment or prevention of nocturnal leg cramps.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 month
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# RAVICTI

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## Products Affected

- RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Urea cycle disorders (UCDs) (Initial): Diagnosis of UCDs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	UCDs (Initial, reauth): 12 months
Other Criteria	UCDs (reauth): Documentation of positive clinical response to Ravicti therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021



# REPATHA

## Products Affected

- REPATHA
- REPATHA SURECLICK
- REPATHA PUSHTRONEX SYSTEM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	HeFH/ASCVD/Primary HLD (initial): Must have LDL level within the past 6 months greater than 70mg/dl on maximal drug treatment (mdt) for at least 8 weeks and one of the following: (1) HeFH or HoFH determined by simon broome diagnostic (sbd) criteria or (2) ASCVD as substantiated by documentation submitted by requestor (e.g. on problem list, icd-9 or icd-10 code) or 3) Diagnosis of primary hyperlipidemia. No concurrent use of other pcsk9 inhibitors. Initial therapy: for statin tolerant pts: taking one of the following: (1) high dose high intensity statin such as atorvastatin (ator) 40 mg or 80 mg or rosuvastatin (rosuv) 20 mg or 40 mg or (2) max tolerated dose (mtd) of ator or rosuv with documentation of failed highest dose or (3) mtd of any statin given trial and failure of ator or rosuv with documentation of failure. For statin intolerant pts: physician must attest to statin intolerance (including but not limited to myopathy). Pts with contraindications to statins including active decompensated liver disease, nursing female, pregnancy or plans to become pregnant or hypersensitivity reactions will be approved for Repatha therapy without documented statin intolerance. If statin tolerant, patient must intend to continue on current maximal statin therapy once Repatha is started.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist
<b>Coverage Duration</b>	Initial and Reauth: 12 months
<b>Other Criteria</b>	All indications (reauth): Patient has been receiving prior Repatha therapy for at least 12 wks.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# RETEVMO

## Products Affected

- RETEVMO ORAL CAPSULE 40 MG, 80 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Lung Cancer: Diagnosis of metastatic non-small cell lung cancer (NSCLC). Disease has presence of RET gene fusion-positive tumor(s). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is advanced or metastatic. Disease has presence of RET gene mutation tumor(s). Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. Patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Lung Cancer, MTC: Prescribed by or in consultation with an oncologist. Thyroid Cancer: Prescribed by or in consultation with an endocrinologist or an oncologist.
<b>Coverage Duration</b>	Lung Cancer, MTC, Thyroid Cancer: 12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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Formulary ID: 21386 Effective: 9/1/2021

# REVLIMID

## Products Affected

- REVLIMID

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Relapsed/Refractory Multiple Myeloma (MM): Diagnosis of MM. Either used as 1) combination therapy with dexamethasone, or 2) maintenance therapy following autologous hematopoietic stem cell transplantation (auto-HSCT). Myelodysplastic syndromes (MDS): Diagnosis of transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q. Mantle cell lymphoma (MCL): Diagnosis of MCL. Disease has relapsed after, is refractory to, or progressed after at least one prior therapy (eg, bortezomib, bendamustine, cladribine, rituximab). Follicular Lymphoma (FL): Diagnosis of FL that has been previously treated. Used in combination with a rituximab product. Marginal Zone Lymphoma (MZL): Diagnosis of MZL that has been previously treated. Used in combination with a rituximab product.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist/hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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Formulary ID: 21386 Effective: 9/1/2021

# RINVOQ

## Products Affected

- RINVOQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Rheumatoid arthritis (RA) (initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Patient is not receiving Rinvoq in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RA (initial): Prescribed by or in consultation with a rheumatologist.
<b>Coverage Duration</b>	RA (initial, reauth): 12 months
<b>Other Criteria</b>	RA (reauth): Documentation of positive clinical response to therapy. Patient is not receiving Rinvoq in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# ROZLYTREK

## Products Affected

- ROZLYTREK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic non-small cell lung cancer (NSCLC). Patient has ROS1 rearrangement positive tumor(s). Solid Tumors: Patient has solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.). Disease is without a known acquired resistance mutation (e.g., TRKA G595R, TRKA G667C or TRKC G623R substitutions). Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: disease has progressed following previous treatment (e.g., surgery, radiation therapy, or systemic therapy) or disease has no satisfactory alternative treatments.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# RUBRACA

## Products Affected

- RUBRACA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Ovarian cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) Both of the following: a) Presence of deleterious BRCA mutation as detected by a U.S. Food and Drug Administration (FDA)-approved diagnostic test (e.g., FoundationFocus CDxBRCA Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and b) Trial and failure, contraindication, or intolerance to two or more chemotherapies (e.g., cisplatin, carboplatin), OR 2) Both of the following: a) Disease is recurrent and b) Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer. Presence of deleterious BRCA mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received previous treatment with both of the following: 1) Androgen receptor-directed therapy [e.g., Erleada (apalutamide), Xtandi (enzalutamide), Zytiga (abiraterone)], AND 2) A taxane-based chemotherapy [e.g., docetaxel, Jevtana (cabazitaxel)].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

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# RYDAPT

## Products Affected

- RYDAPT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Acute Myeloid Leukemia (AML): Newly diagnosed acute myeloid leukemia (AML), FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), Mast Cell Leukemia (MCL): Diagnosis of one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with a hematologist or oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# SECUADO

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**Products Affected**

- SECUADO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of schizophrenia. Both of the following: 1) Trial and failure of Saphris (asenapine) and 2) Trial and failure, contraindication, or intolerance to one of the following generic formulary atypical antipsychotic agents: aripiprazole, olanzapine, paliperidone, quetiapine, risperidone, or ziprasidone.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# SEROSTIM

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## Products Affected

- SEROSTIM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	HIV wasting (Initial): Diagnosis of HIV-associated wasting syndrome or cachexia, and anti-retroviral tx has been optimized to decrease the viral load.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial/Reauth: Prescribed by or in consultation with an infectious disease specialist.
<b>Coverage Duration</b>	Initial and Reauth: 12 months
<b>Other Criteria</b>	HIV wasting (reauth): Evidence of positive response to therapy. Patient is currently receiving treatment with antiretrovirals.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# SIGNIFOR

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**Products Affected**

- SIGNIFOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Cushing's disease (initial): Diagnosis of Cushing's disease AND failure to or patient is not a candidate for pituitary surgery.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or oncologist.
<b>Coverage Duration</b>	Initial: 12 months. Reauth: 12 months.
<b>Other Criteria</b>	Cushing's disease (reauth): a clinically meaningful reduction in 24-hour urinary free cortisol levels or improvement in signs or symptoms of the disease.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

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# SIRTURO

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## Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of pulmonary multi-drug resistant tuberculosis (mdr-tb) and sirturo is being used in combination with at least three other drugs to which the patient's mdr-tb isolate has been shown to be susceptible in vitro. If in vitro testing results are unavailable, treatment may be initiated with sirturo in combination with at least four other drugs to which the patient's mdr-tb isolate is likely to be susceptible.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# SKYRIZI

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**Products Affected**

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist.
<b>Coverage Duration</b>	Plaque psoriasis (Initial, reauth): 12 months
<b>Other Criteria</b>	Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

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# SOMAVERT

## Products Affected

- SOMAVERT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Acromegaly (initial): Diagnosis of acromegaly AND Failure to surgery and/or radiation therapy and/or other medical therapies (such as dopamine agonists [e.g., bromocriptine, cabergoline]) unless patient is not a candidate for these treatment options AND trial and failure or intolerance to generic octreotide (a somatostatin analogue).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an endocrinologist.
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	Acromegaly (reauth): Patient has experienced an objective response to therapy (biochemical control, decrease or normalization of IGF-1 levels).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# SPRAVATO

## Products Affected

- SPRAVATO (56 MG DOSE)
- SPRAVATO (84 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Treatment-resistant depression (TRD): Diagnosis of major depressive disorder (treatment-resistant). Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode. Used in combination with an oral antidepressant.
Age Restrictions	
Prescriber Restrictions	TRD: Prescribed by or in consultation with a psychiatrist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# SPRYCEL

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**Products Affected**

- SPRYCEL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Philadelphia chromosome positive (Ph+)/BCR ABL chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML. Ph+/BCR ABL acute lymphoblastic leukemia (ALL): Diagnosis of Ph+/BCR ABL ALL.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All Uses: Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	All Uses: 12 months
<b>Other Criteria</b>	All Uses: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# STELARA

## Products Affected

- STELARA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Plaque psoriasis: Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial): One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept), Humira (adalimumab), or Skyrizi (risankizumab) OR 2) for continuation of prior therapy. Psoriatic arthritis (PsA): Diagnosis of active PsA. PsA (Initial): One of the following: 1) TF/C/I Enbrel (etanercept) AND Humira (adalimumab) OR 2) for continuation of prior therapy. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active Crohn's disease. One of the following: 1) TF/C/I to Humira (adalimumab) OR 2) for continuation of prior therapy. Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: 1) TF/C/I to Humira (adalimumab) OR 2) for continuation of prior therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD and UC (initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	All uses (Initial, reauth): 12 months
<b>Other Criteria</b>	Reauth (all indications): Documentation of positive clinical response to Stelara therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# STIVARGA

## Products Affected

- STIVARGA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Metastatic colorectal cancer (mCRC): All of the following: 1) diagnosis of mCRC, AND 2) trial and failure, contraindication or intolerance to fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, AND 3) trial and failure, contraindication or intolerance to an anti-VEGF therapy (e.g., Avastin [bevacizumab]), AND 4) one of the following: a) RAS mutation, OR b) both of the following: RAS wild-type (RAS mutation negative tumor) and trial and failure, contraindication or intolerance to an anti-EGFR therapy [e.g., Vectibix (panitumumab), Erbitux (cetuximab)]. Gastrointestinal stromal tumor (GIST): All of the following: 1) diagnosis of locally advanced, unresectable or metastatic GIST, AND 2) trial and failure, contraindication or intolerance to both of the following: a) Gleevec (imatinib mesylate), AND b) Sutent (sunitinib malate). Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Trial and failure or intolerance to Nexavar (sorafenib tosylate).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	mCRC, GIST: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with an oncologist, hepatologist, or gastroenterologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# STRENSIQ

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**Products Affected**

- STRENSIQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Hypophosphatasia: Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia AND for patients requesting the 80 mg/0.8 mL vial only: Patient's weight is greater than or equal to 40 kg.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Hypophosphatasia: Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism or endocrinologist
<b>Coverage Duration</b>	Hypophosphatasia: 12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# SUTENT

## Products Affected

- SUTENT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma. Gastrointestinal stromal tumor (GIST): Diagnosis of GIST after disease progression on, or contraindication or intolerance to Gleevec (imatinib). Pancreatic neuroendocrine tumors: Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumor that is unresectable locally advanced or metastatic disease. Adjuvant treatment of renal cell carcinoma: Diagnosis of renal cell carcinoma (RCC). Used as adjuvant therapy. Patient is at high risk of recurrent RCC following nephrectomy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	All uses: 12 months
<b>Other Criteria</b>	All Indications: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# SYMDEKO

## Products Affected

- SYMDEKO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of cystic fibrosis. One of the following: 1) Patient is homozygous for the F508del mutation as detected by a FDA-cleared cystic fibrosis mutation test or at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility OR 2) Patient has one of the following mutations on at least one allele in the CF transmembrane conductance regulator (CFTR) gene as detected by FDA-cleared cystic fibrosis mutation test or at a Clinical Laboratory Improvement Amendments (CLIA) -approved facility: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3A-G, E831X, S945L, S977F, F1052V, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G-A, 3272-26A-G, 3849+10kbC-T.
<b>Age Restrictions</b>	Initial: Patient is 6 years of age or older
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	Reauth: Documentation of a positive clinical response to Symdeko (tezacaftor/ivacaftor) therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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Formulary ID: 21386 Effective: 9/1/2021

# TABRECTA

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**Products Affected**

- TABRECTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: recurrent, advanced, metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# TAFINLAR

## Products Affected

- TAFINLAR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Melanoma: Diagnosis of unresectable or metastatic melanoma AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) OR both of the following: cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and medication is used in combination with Mekinist (trametinib). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Mekinist (trametinib). Non-small Cell Lung Cancer (NSCLC): Diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Mekinist (trametinib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic anaplastic thyroid cancer. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Mekinist (trametinib) .</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	

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# TAGRISO

## Products Affected

- TAGRISO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC. One of the following: 1) Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), OR 2) Both of the following: a) Patient has known active EGFR T790M mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and b) Patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# TALZENNA

## Products Affected

- TALZENNA ORAL CAPSULE 0.25 MG, 1 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Breast cancer: Diagnosis of breast cancer. Disease is one of the following: a) locally advanced or b) metastatic. Presence of a deleterious or suspected deleterious germline BRCA-mutation (gBRCAm) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease is human epidermal growth factor receptor 2 (HER2)-negative.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# TARCEVA

## Products Affected

- *erlotinib hcl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): Diagnosis of locally advanced or metastatic (Stage III or IV) NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Pancreatic Cancer: Diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer AND erlotinib will be used in combination with gemcitabine.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	All uses: 12 months
<b>Other Criteria</b>	All Indications: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# TARGRETIN

## Products Affected

- TARGRETIN EXTERNAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cutaneous T-Cell Lymphoma (CTCL): Diagnosis of CTCL. Trial and failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [eg, corticosteroids {ie, clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}] or systemic therapies [eg, interferons]).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# TASIGNA

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## Products Affected

- TASIGNA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# TAVALISSE

## Products Affected

- TAVALISSE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chronic Idiopathic Thrombocytopenic Purpura (ITP) (initial): Diagnosis of chronic immune ITP or relapsed/refractory ITP. Baseline platelet count is less than 30,000/mcL. Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids, immunoglobulins, splenectomy, thrombopoietin receptor agonists (e.g., Nplate, Promacta), or Rituxan (rituximab). Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	ITP (initial): Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	ITP (initial, reauth): 12 months
<b>Other Criteria</b>	ITP (reauth): Documentation of positive clinical response to Tavalisse therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# TAZVERIK

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## Products Affected

- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.
Off Label Uses	

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# TECFIDERA

## Products Affected

- *dimethyl fumarate oral*
- *dimethyl fumarate starter pack*
- TECFIDERA ORAL
- TECFIDERA ORAL CAPSULE DELAYED RELEASE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or multiple sclerosis specialist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# TEGSEDI

## Products Affected

- TEGSEDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of hereditary transthyretin-mediated amyloidosis (HATTR) with polyneuropathy: physician attestation of diagnosis of HATTR as confirmed by either biopsy of tissue/organ to confirm amyloid presence and chemical typing to confirm presence of TTR protein or DNA genetic sequencing to confirm HATTR mutation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial: prescribed by or given in consultation with a neurologist, cardiologist, physician at an amyloidosis treatment center, or medical geneticist.
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	Initial: physician attestation that the patient has stage 1 or 2 polyneuropathy. Renewal: diagnosis of hereditary ttr amyloidosis (HATTR) and physician attestation that the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# TEPMETKO

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**Products Affected**

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# TERIPARATIDE

## Products Affected

- TERIPARATIDE (RECOMBINANT)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Postmenopausal osteoporosis or osteopenia or men with primary or hypogonadal osteoporosis or osteopenia: Diagnosis of one of the following: a) postmenopausal osteoporosis or osteopenia or b) primary or hypogonadal osteoporosis or osteopenia. One of the following: Set I) Both of the following: A) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) trial and failure, contraindication, or intolerance (TF/C/I) to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]), or Set II) Both of the following: A) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) TF/C/I to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and ii) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions. Treatment duration of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime. Glucocorticoid-Induced Osteoporosis: See Other Criteria section.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	All uses: 24 months (max 24 months of therapy per lifetime)
<b>Other Criteria</b>	<p>Glucocorticoid-Induced Osteoporosis: Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose greater than or equal to 5mg/day for greater than or equal to 3 months. One of the following: 1) BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius</p>

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PA Criteria	Criteria Details
	(one-third radius site), or 2) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions, or 3) History of one of the following fractures resulting from minimal trauma: vertebral compression fx, fx of the hip, fx of the distal radius, fx of the pelvis, or fx of the proximal humerus. TF/C/I to one bisphosphonate (e.g., alendronate). Treatment duration of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# TETRABENAZINE

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## Products Affected

- *tetrabenazine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of chorea associated with Huntington's disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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# THALOMID

## Products Affected

- THALOMID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multiple myeloma (MM): Diagnosis of MM. Used in combination with dexamethasone, unless the patient has an intolerance to steroids. Erythema nodosum leprosum (ENL): Diagnosis of moderate to severe ENL with cutaneous manifestations. Thalomid is not used as monotherapy if moderate to severe neuritis is present.
Age Restrictions	
Prescriber Restrictions	MM: Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# TIBSOVO

## Products Affected

- TIBSOVO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Relapsed or refractory Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Newly-Diagnosed AML: Diagnosis of newly-diagnosed AML. Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). One of the following: 1) patient is greater than or equal to 75 years old OR 2) patient has comorbidities that preclude use of intensive induction chemotherapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# TOPICAL LIDOCAINE

## Products Affected

- *glydo*
- *lidocaine external ointment 5 %*
- *lidocaine hcl external solution*
- *lidocaine hcl urethral/mucosal*
- *lidocaine-prilocaine external cream*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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# TOPICAL RETINOIDS

## Products Affected

- *adapalene external cream*
- *adapalene external gel*
- AVITA
- *tazarotene external cream*
- TAZORAC EXTERNAL CREAM 0.05 %
- TAZORAC EXTERNAL GEL
- *tretinoin external cream*
- *tretinoin external gel 0.025 %*
- *tretinoin microsphere*
- *tretinoin microsphere pump*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	All cosmetic use indications.
<b>Required Medical Information</b>	Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# TRACLEER

## Products Affected

- *bosentan*
- TRACLEER ORAL TABLET SOLUBLE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH (Initial and reauth) : 12 months
<b>Other Criteria</b>	PAH (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL

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## Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of cancer and breakthrough cancer pain, opioid tolerant and receiving concurrent therapy with a long-acting opioid.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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# TRIKAFTA

## Products Affected

- TRIKAFTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Cystic Fibrosis (CF) (initial): Diagnosis of CF. Patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility.
<b>Age Restrictions</b>	CF (initial): 12 years of age or older.
<b>Prescriber Restrictions</b>	CF (initial): Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center.
<b>Coverage Duration</b>	CF (initial, reauth): 12 months
<b>Other Criteria</b>	CF (reauth): Documentation of a positive clinical response to Trikafta therapy (e.g., improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}] or decreased number of pulmonary exacerbations).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# TUKYSA

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**Products Affected**

- TUKYSA ORAL TABLET 150 MG, 50 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases. Patient has received one or more prior antiHER2-based regimens in the metastatic setting. To be used in combination with trastuzumab and capecitabine.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hepatologist or oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# TURALIO

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**Products Affected**

- TURALIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Tenosynovial Giant Cell Tumor (TGCT): Diagnosis of TGCT. Patient is symptomatic. Patient is not a candidate for surgery due to worsening functional limitation or severe morbidity with surgical removal.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

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# TYKERB

## Products Affected

- *lapatinib ditosylate*
- TYKERB

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Breast Cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic or recurrent breast cancer. Used in combination with one of the following: Herceptin (trastuzumab), Xeloda (capecitabine), or aromatase inhibitors [eg, Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)].
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# TYMLOS

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**Products Affected**

- TYMLOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of postmenopausal osteoporosis or osteopenia. History of at least one recent osteoporotic fracture (i.e. Fragility or low trauma), or multiple risk factors for fracture (i.e. History of multiple recent low trauma fractures, BMD t-score less than or equal to -2.5, corticosteroid use, or use of GNRH analogs such as Nafarelin, etc.), or failed at least a 6 month trial of, or has contraindication to, or cannot tolerate bisphosphonates, calcitonin or Evista.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	24 months (max 24 months of therapy per lifetime).
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# UKONIQ

## Products Affected

- UKONIQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Relapsed or refractory marginal zone lymphoma (MZL): Diagnosis of Relapsed or refractory MZL. Received treatment with at least one prior anti-CD20-based regimen. Relapsed or refractory follicular lymphoma (FL): Diagnosis of relapsed or refractory FL. Received treatment with at least three prior lines of systemic therapy.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months.
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.
Off Label Uses	

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Formulary ID: 21386 Effective: 9/1/2021



# VALCHLOR

## Products Affected

- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) (initial): All of the following: 1) diagnosis of Stage IA MF-CTCL, OR diagnosis of Stage IB MF-CTCL, AND 2) patient has received at least one prior skin-directed therapy [e.g., topical corticosteroids, bexarotene topical gel (Targretin topical gel), etc.].
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# VENCLEXTA

## Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL): Diagnosis of CLL or SLL. Acute Myeloid Leukemia (AML): Diagnosis of newly diagnosed AML. Used in combination with azacitidine, or decitabine, or low-dose cytarabine. One of the following: 1) age 75 years or older OR 2) comorbidities that preclude use of intensive induction chemotherapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# VENTAVIS

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**Products Affected**

- VENTAVIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH (Initial and Reauth): 12 months
<b>Other Criteria</b>	Subject to Part B vs D review. PAH (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# VERZENIO

## Products Affected

- VERZENIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Breast Cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) used in combination with an aromatase inhibitor (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) and patient is a postmenopausal woman, OR b) used in combination with Faslodex (fulvestrant) and disease has progressed following endocrine therapy, OR c) used as monotherapy and disease has progressed following endocrine therapy and patient has already received at least one prior chemotherapy regimen.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# VIMPAT

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**Products Affected**

- VIMPAT ORAL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of partial-onset seizures and has had an insufficient response or intolerance to at least two (2) other medications indicated for adjunct partial seizures (e.g. aptiom, briviact, felbamate, fycompa, gabapentin, lamotrigine, lyrica, levetiracetam, oxcarbazepine, tiagabine, topiramate, and/or zonisamide).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# VITRAKVI

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Presence of solid tumors (e.g., salivary gland, soft tissue sarcoma, infantile fibrosarcoma, thyroid cancer, lung, melanoma, colon, etc.). Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.). Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]. Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy) OR Disease has no satisfactory alternative treatments.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# VIZIMPRO

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**Products Affected**

- VIZIMPRO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic. Disease is positive for one of the following epidermal growth factor receptor (EGFR) mutations: exon 19 deletion or exon 21 L858R substitution.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# VOTRIENT

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**Products Affected**

- VOTRIENT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Diagnosis of adipocytic soft tissue sarcoma or gastrointestinal stromal tumors.
<b>Required Medical Information</b>	Renal cell carcinoma (RCC): Diagnosis of advanced/metastatic RCC. Soft tissue sarcoma: Diagnosis of advanced soft tissue sarcoma and patient received at least one prior chemotherapy (e.g., ifosfamide, doxorubicin, cisplatin, dacarbazine, docetaxel, oxaliplatin, etc.).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# VYNDAMAX

## Products Affected

- VYNDAMAX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) (initial): Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM). One of the following: 1) Patient has a transthyretin (TTR) mutation (e.g., V122I), 2) Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits, OR 3) All of the following: i) echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis, ii) scintigraphy scan suggestive of cardiac TTR amyloidosis, and iii) absence of light-chain amyloidosis. One of the following: 1) History of heart failure (HF), with at least one prior hospitalization for HF, OR 2) Presence of clinical signs and symptoms of HF (e.g., dyspnea, edema). Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	ATTR-CM (initial, reauth): Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	ATTR-CM (initial, reauth): 12 months
<b>Other Criteria</b>	ATTR-CM (reauth): Documentation of positive clinical response to therapy. Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# VYNDAQEL

## Products Affected

- VYNDAQEL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) (initial): Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM). One of the following: 1) Patient has a transthyretin (TTR) mutation (e.g., V122I), 2) Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits, OR 3) All of the following: i) echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis, ii) scintigraphy scan suggestive of cardiac TTR amyloidosis, and iii) absence of light-chain amyloidosis. One of the following: 1) History of heart failure (HF), with at least one prior hospitalization for HF, OR 2) Presence of clinical signs and symptoms of HF (e.g., dyspnea, edema). Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	ATTR-CM (initial, reauth): Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	ATTR-CM (initial, reauth): 12 months
<b>Other Criteria</b>	ATTR-CM (reauth): Documentation of positive clinical response to therapy. Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# VYVANSE

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## Products Affected

- VYVANSE ORAL CAPSULE 10 MG, 20 MG, 30 MG, 40 MG, 50 MG, 60 MG, 70 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of attention deficit hyperactivity disorder (ADHD) or diagnosis of moderate to severe binge eating disorder (bed).
Age Restrictions	For moderate to severe binge eating disorder, 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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# WAKEFULNESS AGENTS

## Products Affected

- *armodafinil*
- *modafinil*
- SUNOSI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Generalized fatigue, travel-induced sleep disorder, sleep deprivation (i.e. military, academic).
<b>Required Medical Information</b>	Diagnosis of shift work sleep disorder (SWSD), obstructive sleep apnea (OSA)/hypopnea syndrome, or narcolepsy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# XALKORI

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**Products Affected**

- XALKORI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): Diagnosis of advanced or metastatic NSCLC AND One of the following: A) Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) or B) Patient has MET amplification- or ROS1 rearrangements-positive tumor as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	NSCLC: Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# XCOPRI

## Products Affected

- XCOPRI ORAL TABLET 100 MG, 150 MG, 200 MG, 50 MG X 25 MG, 14 X 150 MG & 14 X200 MG, 14 X 50 MG & 14 X100 MG, 150 & 200 MG, 50 & 200 MG
- XCOPRI ORAL TABLET THERAPY PACK 100 & 150 MG, 14 X 12.5 MG & 14

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of partial onset seizures.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# XELJANZ

## Products Affected

- XELJANZ
- XELJANZ XR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Xeljanz/Xeljanz XR: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Failure, contraindication, or intolerance to methotrexate, sulfasalazine, leflunomide or hydroxychloroquine. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. Failure, contraindication, or intolerance to Humira or Enbrel. Xeljanz only: Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Trial and failure, contraindication or intolerance to Humira.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. UC (initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# XERMELO

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## Products Affected

- XERMELO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Carcinoid syndrome diarrhea (Initial): Diagnosis of carcinoid syndrome diarrhea AND diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot]) for at least 3 months AND used in combination with SSA therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
<b>Coverage Duration</b>	Initial and Reauth: 12 months
<b>Other Criteria</b>	Carcinoid syndrome diarrhea (Reauthorization): Documentation of a positive clinical response to Xermelo therapy AND Xermelo will continue to be used in combination with SSA therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# XGEVA

## Products Affected

- XGEVA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple Myeloma (MM)/Bone metastasis from solid tumors (BMST): One of the following: 1) Diagnosis of multiple myeloma OR 2) diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) with documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Both of the following: 1) diagnosis of giant cell tumor of bone AND 2) One of the following: tumor is unresectable OR surgical resection is likely to result in severe morbidity. Hypercalcemia of malignancy (HCM): Both of the following: 1) diagnosis of hypercalcemia of malignancy, AND 2) TF/C/I to one intravenous bisphosphonate (eg, pamidronate, Zometa (zoledronic acid)).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	All uses: 6 months.
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# XIFAXAN

## Products Affected

- XIFAXAN ORAL TABLET 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prophylaxis of hepatic encephalopathy (HE) recurrence (550mg strength only): Used for the prophylaxis of hepatic encephalopathy recurrence, AND trial and failure, contraindication or intolerance to lactulose. Treatment of HE: Used for the treatment of HE. Trial and failure, contraindication, or intolerance to lactulose. Irritable bowel syndrome with diarrhea (IBS-D) (550mg strength only) (initial): Diagnosis of IBS-D.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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# XOLAIR

## Products Affected

- XOLAIR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Asthma (init): Diagnosis of moderate to severe persistent allergic asthma. Positive skin test or in vitro reactivity to a perennial aeroallergen. Pretreatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL for patients 12 years of age and older OR 30 to 1300 IU/mL for patients 6 years to less than 12 years of age. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)]. Chronic Idiopathic Urticaria (CIU) (init): Diagnosis of CIU. Persistent symptoms (itching and hives) for at least 4 consecutive weeks despite titrating to an optimal dose with a second generation H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines. Patient has tried and had an inadequate response or intolerance or contraindication to at least one of the following additional therapies: H2 antagonist, leukotriene receptor antagonist, H1 antihistamine, hydroxyzine, doxepin. Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>Asthma (init/reauth): Prescribed by or in consultation with an allergist/immunologist, or pulmonologist. CIU (init): Prescribed by or in consultation with an allergist/immunologist, or dermatologist</p>
<b>Coverage Duration</b>	<p>Asthma (init): 6 months, Asthma (reauth): 12 months. CIU (init): 3 months, (reauth) 6 months</p>
<b>Other Criteria</b>	<p>Asthma (reauth): Documentation of positive clinical response to therapy (e.g., Reduction in number of asthma exacerbations, improvement in forced expiratory volume in 1 second (FEV1), or decreased use of rescue medications). Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) inhaled corticosteroid (ICS) and ii) additional</p>

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PA Criteria	Criteria Details
	<p>asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)].</p> <p>CIU (reauth): Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment. Patient has experienced one or both of the following:  Reduction in itching severity from baseline or Reduction in the number of hives from baseline.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# XOSPATA

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**Products Affected**

- XOSPATA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of acute myeloid leukemia (AML). Disease is relapsed or refractory. Patient has a FMS-like tyrosine kinase (FLT3) mutation as determined by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# XPOVIO

## Products Affected

- XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 50 MG
- XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 40 MG
- XPOVIO (40 MG TWICE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 40 MG
- XPOVIO (60 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 60 MG
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 40 MG
- XPOVIO (80 MG TWICE WEEKLY)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple myeloma (MM): Diagnosis of relapsed or refractory multiple myeloma (RRMM). Patient has received at least four prior therapies. Disease is refractory to all of the following: 1) Two proteasome inhibitors (e.g., bortezomib, carfilzomib), 2) Two immunomodulatory agents (e.g., lenalidomide, thalidomide), and 3) An anti-CD38 monoclonal antibody (e.g. daratumumab). Used in combination with dexamethasone. Diffuse large B-cell lymphoma (DLBCL): Diagnosis of one of the following: 1) Relapsed or refractory DLBCL not otherwise specified OR 2) Relapsed or refractory DLBCL arising from follicular lymphoma. Patient has previously received at least two lines of systemic therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist/hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# XTANDI

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**Products Affected**

- XTANDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Castration-resistant or castration-recurrent prostate cancer (CRPC): Diagnosis of CRPC. Metastatic castration-sensitive prostate cancer (M-CSPC): Diagnosis of M-CSPC.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# XYREM

## Products Affected

- XYREM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are present, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are absent, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present, AND trial and failure, contraindication, or intolerance to one of the following: 1) amphetamine-based stimulant (eg, amphetamine, dextroamphetamine), OR 2) methylphenidate-based stimulant.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with Xyrem therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# YONSA

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**Products Affected**

- YONSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prostate Cancer: Diagnosis of metastatic castration-resistant (chemical or surgical) or recurrent prostate cancer. Used in combination with methylprednisolone. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient received a bilateral orchiectomy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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# ZAVESCA

## Products Affected

- *miglustat*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Gaucher disease: Diagnosis of mild to moderate type 1 Gaucher disease with at least one of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly. Patient is unable to receive enzyme replacement therapy due to one of the following conditions: allergy or hypersensitivity to enzyme replacement therapy, poor venous access, unavailability of enzyme replacement therapy (e.g., Cerezyme, VPRIV).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Gaucher disease: 12 months
Other Criteria	Member has tried and failed or has a contraindication to therapy with Cerdelga.
Indications	All Medically-accepted Indications.
Off Label Uses	

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# ZEJULA

## Products Affected

- ZEJULA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. Used for maintenance treatment in patients who are in complete or partial response to first-line platinum-based chemotherapy. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Treatment of advanced ovarian cancer after three or more chemotherapies: Diagnosis of advanced ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Patient has been treated with three or more prior chemotherapy regimens. Patient's cancer is associated with homologous recombination deficiency (HRD) positive status defined by one of the following: (a) a deleterious or suspected deleterious BRCA mutation or (b) both of the following: (1) genomic instability and (2) cancer has progressed more than 6 months after response to the last platinum-based chemotherapy (e.g., cisplatin, carboplatin).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# ZELBORAF

## Products Affected

- ZELBORAF

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (eg, cobas 4600 BRAFV600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Erdheim-Chester Disease: Diagnosis of Erdheim-Chester disease AND Disease is BRAFV600 mutant type (MT).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Melanoma: Prescribed by or in consultation with an oncologist. Erdheim-Chester Disease: Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	All indications: Approve for continuation of therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# ZELNORM

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## Products Affected

- ZELNORM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of irritable bowel syndrome with constipation (IBS-C). Patient is female. Trial and failure, contraindication, or intolerance to one of the following: Amitiza (lubiprostone) or Linzess (linaclotide).
Age Restrictions	Initial: Less than 65 years of age.
Prescriber Restrictions	
Coverage Duration	Initial: 6 weeks. Reauthorization: 12 months.
Other Criteria	Reauthorization: Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# ZOLEDRONIC ACID

## Products Affected

- *zoledronic acid*
- *zoledronic acid intravenous solution reconstituted 4 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Osteoporosis: High risk of fracture defined as a history of osteoporotic fracture or multiple risk factors for fracture and a T score less than or equal to -2 as evidenced via bone density scan OR has had an inadequate response or intolerance to therapy with at least one traditional osteoporosis treatment (alendronate, calcitonin, ibandronate, raloxifene, risedronate, zoledronic acid). Glucocorticoid-induced osteoporosis: Patient is initiating or continuing systemic glucocorticoids at a daily dose equivalent to or greater than 7.5mg of prednisone for an anticipated duration of at least 6 months.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# ZOLINZA

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**Products Affected**

- ZOLINZA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Progressive, persistent or recurrent disease on or contraindication or intolerance to two systemic therapies (e.g., bexarotene, romidepsin, etc.).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# ZORBTIVE

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**Products Affected**

- ZORBTIVE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Short Bowel Syndrome (SBS): Diagnosis of SBS. Patient is currently receiving specialized nutritional support (eg, intravenous parenteral nutrition, fluid, and micronutrient supplements).
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	SBS: 4 weeks
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021



# ZYDELIG

## Products Affected

- ZYDELIG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Used in combination with Rituxan (rituximab). The patient has relapsed on at least one prior therapy (eg, purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab]). Patient is a candidate for Rituxan (rituximab) monotherapy due to presence of other comorbidities (eg, coronary artery disease, peripheral vascular disease, diabetes mellitus, pulmonary disease [COPD]). Follicular Lymphoma (FL): Diagnosis of FL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]). Small lymphocytic lymphoma (SLL): Diagnosis of SLL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist/hematologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# ZYKADIA

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## Products Affected

- ZYKADIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC that is metastatic or recurrent. Tumor is anaplastic lymphoma kinase (ALK)-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

August 2021

Formulary ID: 21386 Effective: 9/1/2021

# ZYTIGA

## Products Affected

- *abiraterone acetate oral tablet 250 mg, 500 mg*
- ZYTIGA ORAL TABLET 500 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Metastatic Castration-Resistant Prostate Cancer (mCRPC): Diagnosis of metastatic castration-resistant (chemical or surgical) or recurrent prostate cancer. Used in combination with prednisone. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient received a bilateral orchiectomy. Metastatic Castration-Sensitive Prostate Cancer (mCSPC): Diagnosis of metastatic high-risk castration-sensitive prostate cancer. Used in combination with prednisone. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient received a bilateral orchiectomy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	mCRPC, mCSPC: Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	mCRPC, mCSPC: 12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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