

# PRIOR AUTHORIZATION PROTOCOLS

## How do I request an exception to the Ultimate Health Plans' SNP Formulary?

You can ask Ultimate Health Plans to make an exception to our coverage rules. There are several types of exceptions that you can ask us to make.

- You can ask us to cover your drug even if it is not on our formulary. If approved, this drug will be covered at a pre-determined cost-sharing level, and you would not be able to ask us to provide the drug at a lower cost-sharing level.
- You can ask us to cover a formulary drug at a lower cost-sharing level if this drug is not on the specialty tier. If approved this would lower the amount you must pay for your drug.
- You can ask us to waive coverage restrictions or limits on your drug. For example, for certain drugs, Ultimate Health Plans limits the amount of the drug that we will cover. If your drug has a quantity limit, you can ask us to waive the limit and cover a greater amount.

Generally, Ultimate Health Plans will only approve your request for an exception if the alternative drugs included on the plan's formulary, the lower cost-sharing drug or additional utilization restrictions would not be as effective in treating your condition and/or would cause you to have adverse medical effects.

You should contact us to ask us for an initial coverage decision for a formulary, or utilization restriction exception. **When you request a formulary or utilization restriction exception you should submit a statement from your prescriber or physician supporting your request.** Generally, we must make our decision within 72 hours of getting your prescriber's supporting statement. You can request an expedited (fast) exception if you or your doctor believe that your health could be seriously harmed by waiting up to 72 hours for a decision. If your request to expedite is granted, we must give you a decision no later than 24 hours after we get a supporting statement from your doctor or other prescriber.

**Your prescriber must submit a statement supporting your coverage determination or exception request. In order to help us make a decision more quickly, you should include supporting medical information from your prescriber when you submit your exception request.**

### What if I have additional questions?

You can call us at: 1-800-311-7517 (seven days a week, 24 hours a day) if you have any additional questions. If you have a hearing or speech impairment, please call us at TTY 1-866-706-4757.

# ACTEMRA SC (s)

## Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS

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: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib) or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. Trial and failure, contraindication, or intolerance to a glucocorticoid (eg, prednisone). Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. Trial and failure, contraindication, or intolerance to one of the following: NSAID (eg, ibuprofen, naproxen), methotrexate, or systemic glucocorticoid (eg, prednisone). Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (Initial): Diagnosis of SSc-ILD as documented by the following: a) Exclusion of other known causes of ILD AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (eg, fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD, OR ii) In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RA, GC, SJIA, PJIA (initial): Prescribed by or in consultation with a rheumatologist. SSc-ILD (initial): Prescribed by or in consultation with a pulmonologist or rheumatologist.
<b>Coverage Duration</b>	RA, GC, SJIA, PJIA, SSc-ILD (initial, reauth): 12 months
<b>Other Criteria</b>	RA, GC, SJIA, PJIA, SSc-ILD (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	

# Actimmune (s)

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**Products Affected**

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of one of the following: 1) Chronic granulomatous disease (CGD), or 2) severe malignant osteopetrosis (SMO).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Adakveo (s)

## Products Affected

- ADAKVEO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of Sickle Cell Disease. Documentation of 2 vaso-occlusive events that required medical facility visits and treatments in the past 12 months (e.g., sickle cell crisis, acute pain episodes, acute chest syndrome, hepatic sequestration, splenic sequestration, priapism). Trial and failure or inadequate response, contraindication, or intolerance to one of the following: 1) Hydroxyurea or 2) L-glutamine (i.e., Endari).
<b>Age Restrictions</b>	
<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., reduction in annual rate of vaso-occlusive events, increased time between each vaso-occlusive event).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ADCIRCA (s)

## Products Affected

- *alyq*
- *tadalafil (pah)*

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: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ADEMPAS (s)

## Products Affected

- ADEMPAS

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. 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: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	PAH, CTEPH (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# AFINITOR (s)

## Products Affected

- AFINITOR ORAL TABLET 10 MG
- everolimus oral tablet 10 mg, 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 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.
<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>	



# AFINITOR DISPERZ (s)

## Products Affected

- AFINITOR DISPERZ
- everolimus oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Subependymal Giant Cell Astrocytoma (SEGA): Diagnosis of SEGA associated with tuberous sclerosis complex (TSC) that requires therapeutic intervention but patient is not a candidate for curative surgical resection. TSC-associated partial-onset seizures: Diagnosis of TSC-associated partial-onset seizures. Used as adjunctive therapy.
Age Restrictions	
Prescriber Restrictions	SEGA: Prescribed by or in consultation with an oncologist. TSC-associated partial-onset seizures: 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	

# AJOVY (s)

## Products Affected

- AJOVY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Episodic Migraines (EM) (initial): Diagnosis of EM. Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month. Chronic Migraines (CM) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months. All Indications (initial): Trial and failure, contraindication, or intolerance to Aimovig and Emgality. Medication will not be used in combination with another injectable CGRP inhibitor.
<b>Age Restrictions</b>	EM, CM (initial): 18 years of age or older.
<b>Prescriber Restrictions</b>	EM, CM (initial, reauth): Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
<b>Coverage Duration</b>	EM, CM (initial): 6 months. EM, CM (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 and/or intensity. Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. Medication will not be used in combination with another injectable CGRP inhibitor. CM (reauth): Patient continues to be monitored for medication overuse headache.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Alecensa (s)

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**Products Affected**

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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).
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	

# ALPHA-1 PROTEINASE INHIBITOR, NON-PREFERRED (s)

## Products Affected

- ARALAST NP INTRAVENOUS SOLUTION RECONSTITUTED 1000 MG
- GLASSIA
- PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED
- ZEMAIRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Alpha-1 antitrypsin (AAT) deficiency: Diagnosis of congenital AAT deficiency. Diagnosis of emphysema. Continued optimal conventional treatment for emphysema (e.g., bronchodilators). One of the following: 1) PiZZ, PiZ(null), or Pi(null)(null) protein phenotypes (homozygous) OR 2) other rare AAT disease genotypes associated with pre-treatment serum AAT level less than 11 µM/L [e.g., Pi(Malton, Malton), Pi(SZ)]. One of the following: Circulating pre-treatment serum AAT level less than 11 µM/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry) OR the patient has a concomitant diagnosis of necrotizing panniculitis. Trial and failure, or intolerance to Prolastin.
<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>	

# ALUNBRIG (s)

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<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>	

# AMPYRA (s)

## Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple Sclerosis (MS) (initial): Diagnosis of MS. Physician confirmation that patient has difficulty walking (eg, timed 25 foot walk test). One of the following: expanded disability status scale (EDSS) score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial): Prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	MS (Initial): 6 months. (Reauth): 12 months.
<b>Other Criteria</b>	MS (Reauth): Physician confirmation that the patient's walking improved with therapy. One of the following: EDSS score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ANADROL-50 (s)

## Products Affected

- ANADROL-50 ORAL TABLET 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Anemia (initial): Diagnosis of anemia caused by deficient red cell production AND trial and failure or intolerance to two standard therapies for anemia (i.e., erythropoiesis-stimulating agents, immunosuppressants) AND Treatment will not replace other supportive measures (e.g., transfusion, correction of iron, folic acid, vitamin B12 or pyridoxine deficiency, antibacterial therapy, corticosteroids).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Anemia (reauth): Documentation of a positive clinical response to therapy as evidenced by an improvement in anemia (e.g., increased hemoglobin, increased reticulocyte count, reduction/elimination for need of blood transfusions).
Indications	All Medically-accepted Indications.
Off Label Uses	

# APOKYN (s)

## Products Affected

- APOKYN
- apomorphine hcl subcutaneous*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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>	



# Aranesp (s)

## 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): 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 receiving chemo. CKD (init, reauth), Chemo (init), MDS (init): Verify iron evaluation for adequate iron stores. 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>	CKD (Init): 6 mo. CKD (reauth): 12 mo. Chemo(init, reauth): 3 mo. MDS: (init) 3 mo,(reauth) 12 mo.
<b>Other Criteria</b>	Subject to ESRD review. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 mo is 33% or less (Hgb 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or avg Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. 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 receiving chemo. 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.

PA Criteria	Criteria Details
	Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Arcalyst (s)

## 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. Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA. Patient weighs at least 10 kg. Patient is currently in remission (e.g., no fever, skin rash, and bone pain/no radiological evidence of active bone lesions/C-reactive protein [CRP] less than 5 mg/L). Recurrent Pericarditis (Initial): Diagnosis of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart. Trial and failure, contraindication, or intolerance (TF/C/I) to at least one of the following: nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen), colchicine, or corticosteroids (e.g., prednisone).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CAPS (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist. Recurrent Pericarditis (initial): Prescribed by or in consultation with a cardiologist.
<b>Coverage Duration</b>	CAPS, Recurrent Pericarditis (initial, reauth): 12 months. DIRA: 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. Recurrent Pericarditis (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# AUBAGIO (s)

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**Products Affected**

- AUBAGIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multiple Sclerosis (MS) (initial): 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	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
Indications	All Medically-accepted Indications.
Off Label Uses	

# Austedo (s)

## 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: 3 months. Reauth: 12 months
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Avastin (s)

## Products Affected

- AVASTIN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Non-Small Cell Lung Cancer: Excluded if squamous cell histology.
<b>Required Medical Information</b>	<p>Colorectal Cancer: Diagnosis of metastatic colorectal cancer. One of the following: 1) Both of the following: a) used as first- or second-line treatment and b) used in combination with an intravenous 5-fluorouracil-based chemotherapy, OR 2) All of the following: a) used as second-line treatment, b) used in combination with fluoropyrimidine-irinotecan-based chemotherapy or fluoropyrimidine-oxaliplatin-based chemotherapy, and c) patient has progressed on a first-line bevacizumab-containing regimen.</p> <p>Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is unresectable, locally advanced, recurrent, or metastatic. Used as first-line treatment. Used in combination with paclitaxel and carboplatin.</p> <p>Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with interferon-alpha.</p> <p>Cervical Cancer: Diagnosis of carcinoma of the cervix. Disease is persistent, recurrent, or metastatic. Used in combination with one of the following: a) paclitaxel and cisplatin or b) paclitaxel and topotecan.</p> <p>Glioblastoma: Diagnosis of recurrent glioblastoma.</p> <p>Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) All of the following: a) disease is stage 3 or 4, b) patient has been treated with bevacizumab as a single agent, c) treatment is following surgical resection, and d) used in combination with carboplatin and paclitaxel, OR 2) All of the following: a) disease is platinum-resistant recurrent, b) patient has received no more than 2 prior chemotherapy regimens, and c) used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, OR 3) All of the following: a) disease is platinum-sensitive recurrent, b) patient has been treated with bevacizumab as a single agent, and c) used in combination with one of the following: i) carboplatin and paclitaxel or ii) carboplatin and gemcitabine.</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>	Hepatocellular Carcinoma (HCC): Dx of hepatocellular carcinoma. Disease is unresectable or metastatic. Used in combination with

PA Criteria	Criteria Details
	Tecentriq (atezolizumab). Patient has not received prior systemic therapy. All indications: Trial and failure, or intolerance to Mvasi (bevacizumab-awwb) and Zirabev (bevacizumab-bvzr), OR approve for continuation of prior therapy. Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ayvakit (s)

## Products Affected

- AYVAKIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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. Advanced Systemic Mastocytosis (AdvSM): Diagnosis of AdvSM. Patient has one of the following: a) aggressive systemic mastocytosis (ASM), b) systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or c) mast cell leukemia (MCL).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	GIST: Prescribed by or in consultation with an oncologist. AdvSM: Prescribed by or in consultation with an oncologist/hematologist, allergist, or immunologist.
<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>	



# Balversa (s)

## 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 (therascreen FGFR RGQ RT-PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). One of the following: 1) Patient has progressed during or following at least one line of prior chemotherapy or immunotherapy OR 2) Patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.
<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>	

# Benlysta (s)

## Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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)]). Lupus Nephritis (init): Diagnosis of active lupus nephritis. Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	SLE (init): Prescribed by or in consultation with a rheumatologist. Lupus Nephritis (init): Prescribed by or in consultation with a nephrologist or rheumatologist.
<b>Coverage Duration</b>	SLE, Lupus Nephritis (init, reauth): 6 months
<b>Other Criteria</b>	SLE, Lupus Nephritis (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# BEOVU (s)

## Products Affected

- BEOVU INTRAVITREAL SOLUTION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of neovascular (wet) age-related macular degeneration. Trial and failure, contraindication or intolerance to compounded bevacizumab [e.g., Avastin, Mvasi (bevacizumab-awwb), Zirabev (bevacizumab-bvzr)] prepared by a 503(B) Outsourcing Facility OR Lucentis (ranibizumab)
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases
<b>Coverage Duration</b>	Initial, Reauth: 12 months
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response to therapy
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# BERINERT (s)

## Products Affected

- BERINERT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
Age Restrictions	
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist or an allergist
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Besremi (s)

## Products Affected

- BESREMI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of polycythemia vera as confirmed by all of the following: 1) One of the following: a) Hemoglobin greater than 16.5 g/dL for men or hemoglobin greater than 16.0 g/dL for women, b) Hematocrit greater than 49% for men or hematocrit greater than 48% for women, or c) Increased red cell mass, AND 2) Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis) including prominent erythroid, granulocytic and megakaryocytic proliferation with pleomorphic, mature megakaryocytes, AND 3) One of the following: a) Presence of JAK2 or JAK2 exon 12 mutation or b) Subnormal serum erythropoietin level. Both of the following: 1) Trial and failure, contraindication or intolerance (TF/C/I) to hydroxyurea, AND 2) TF/C/I to one interferon therapy (e.g., Intron A, Pegasys, 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>	

# Bosulif (s)

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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	

# Braftovi (s)

## 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>	

# BRIVIACT (s)

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**Products Affected**

- BRIVIACT ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Partial-onset seizures: 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	



# Brukina (s)

## Products Affected

- BRUKINSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Mantle Cell Lymphoma (MCL): Diagnosis of relapsed or refractory 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). Waldenstrom's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL. Disease is relapsed or refractory. Patient has received at least one prior anti-CD20-based regimen for MZL (e.g., rituximab, obinutuzumab).
<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>	

# CABLIVI (s)

## Products Affected

- CABLIVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Acquired thrombotic thrombocytopenic purpura (aTTP): Diagnosis of aTTP. First dose was/will be administered by a healthcare provider as a bolus intravenous injection. Used in combination with immunosuppressive therapy (e.g. rituximab, glucocorticoids). One of the following: 1) Used in combination with plasma exchange or 2) both of the following: patient has completed plasma exchange and less than 59 days have or will have elapsed beyond the last plasma exchange.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist.
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Cabometyx (s)

## 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, contraindication, 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. Differentiated Thyroid Cancer (DTC): Diagnosis of DTC. Disease is one of the following: a) locally advanced or b) metastatic. Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib]). Disease or patient is refractory to radioactive iodine treatment or ineligible.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RCC: Prescribed by or in consultation with one of the following: an oncologist or nephrologist. HCC: Prescribed by or in consultation with one of the following: oncologist, hepatologist, or gastroenterologist. DTC: 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>	

# Calquence (s)

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**Products Affected**

- CALQUENCE ORAL CAPSULE
- CALQUENCE ORAL TABLET

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	

# CAPRELSA (s)

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**Products Affected**

- CAPRELSA ORAL TABLET 100 MG, 300 MG

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	

# CARISOPRODOL (s)

## Products Affected

- *carisoprodol oral tablet 350 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The drug is being prescribed for an FDA-approved indication. If the patient is 65 years of age or older, 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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Cayston (s)

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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	

# Cerdelga (s)

## 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 continues to need requested medication.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Chenodal (s)

## Products Affected

- *chenodal*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Radiolucent stones (RS) (initial): Diagnosis of radiolucent stones. Patient has a well-opacifying gallbladder visualized by oral cholecystography. Trial and failure, contraindication or intolerance to ursodiol. Patient is not a candidate for surgery. Stones are not calcified (radiopaque) or radiolucent bile pigment stones.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	RS (initial, reauth): 12 months.
<b>Other Criteria</b>	RS (reauth): Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment as evidenced by oral cholecystograms or ultrasonograms.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Cholbam (s)

## 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) 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 therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# CIALIS (s)

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**Products Affected**

- *tadalafil oral tablet 2.5 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of nitrates.
Required Medical Information	Diagnosis of benign prostatic hyperplasia (BPH). Trial and failure, contraindication, or intolerance to an alpha-blocker (e.g., doxazosin, prazosin, tamsulosin) or a 5-alpha reductase inhibitor (e.g., dutasteride, finasteride).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# CICLOPIROX (s)

## Products Affected

- *ciclodan*
- *ciclopirox external solution*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	All of the following: 1) Patient does not have lunula (matrix) involvement, 2) one of the following: a) Diagnosis of onychomycosis of the toenails, OR b) Diagnosis of onychomycosis of the fingernails, 3) Diagnosis of onychomycosis has been confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c) histology, 4) If toenail onychomycosis, patient has mild to moderate disease involving at least 1 target toenail, AND 5) Trial and failure, contraindication, or intolerance to oral terbinafine.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	48 weeks.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# CIMZIA (s)

## Products Affected

- CIMZIA
- CIMZIA PREFILLED KIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Rheumatoid Arthritis (RA, initial): Diagnosis (dx) of moderately to severely active RA. One of the following: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib) or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Crohn's Disease (CD, initial): Dx of moderately to severely active CD. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), Azathioprine (Imuran), Corticosteroid (eg, prednisone, methylprednisolone), Methotrexate (Rheumatrex, Trexall). TF/C/I to Humira or Skyrizi (risankizumab-rzaa), OR for continuation of prior therapy. Psoriatic Arthritis (PsA, initial): Dx of active PsA. One of the following: a) Either a TF/C/I to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER), OR b) for continuation of prior therapy. Ankylosing Spondylitis (AS, initial): Dx of active AS. TF/C/I to two of the following: Enbrel, Humira, Rinvoq, Xeljanz/Xeljanz XR, or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Plaque Psoriasis (initial): Dx of moderate to severe plaque psoriasis. TF/C/I to two of the following: Humira, Enbrel, Skyrizi (risankizumab), Cosentyx (secukinumab) OR for continuation of prior therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CD (init): Prescribed by or in consultation with a gastroenterologist. RA, AS, nr-axSpA (init): Prescribed by or in consultation with a rheumatologist. 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>	RA, PsA, AS, Plaque psoriasis, nr-axSpA (init, reauth): 12 mos. CD (init): 16 wks. (reauth): 12 mos.
<b>Other Criteria</b>	Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without

PA Criteria	Criteria Details
	definitive radiographic evidence of structural damage on sacroiliac joints.) TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen). Reauth (RA, CD, PsA, AS, nr-axSpA): Documentation of positive clinical response to therapy. Reauth (Plaque psoriasis): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Cinryze (s)

## Products Affected

- CINRYZE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For prophylaxis against HAE attacks.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HAE (prophylaxis): Prescribed by or in consultation with an immunologist or an allergist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Cometriq (s)

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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	



# Copiktra (s)

## 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.).
<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>	

# CORLANOR (s)

## 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. Patient has been hospitalized for worsening HF in the previous 12 months. Trial and failure, contraindication, or intolerance to two of the following at a maximally tolerated dose: A) One of the following: 1) ACE inhibitor (e.g., captopril, enalapril, lisinopril), 2) ARB (e.g., candesartan, losartan, valsartan), or 3) ARNI (e.g., Entresto [sacubitril and valsartan]), B) One of the following: 1) bisoprolol, 2) carvedilol, or 3) metoprolol succinate extended release, C) Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformin)], or D) Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]. Dilated Cardiomyopathy (DCM) (initial): Diagnosis of 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. Trial and failure, contraindication or intolerance to one of the following: 1) Beta blocker (e.g., bisoprolol, metoprolol succinate extended release), 2) Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), or 3) Diuretic Agent (e.g., spironolactone, furosemide).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CHF, DCM (initial): Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	CHF, DCM (initial, reauth): 12 months
<b>Other Criteria</b>	CHF, DCM (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Cortrophin (s)

## Products Affected

- CORTROPHIN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Infantile Spasms (IS) (West Syndrome) [off-label]: Diagnosis of IS (West Syndrome). Multiple Sclerosis (MS): Diagnosis of acute exacerbation of MS. One of the following: 1) Both of the following: a) Patient is new to therapy with corticotropin AND b) Trial and failure, contraindication, or intolerance (TF/C/I) to treatment with two high dose corticosteroid treatments (e.g., prednisone, IV methylprednisolone) OR 2) All of the following: a) Patient's MS exacerbations have been treated in the past with corticotropin AND b) Patient has benefitted from treatment with corticotropin for acute exacerbations of MS AND c) Medication is being used to treat a new exacerbation of MS. Other FDA-Approved Indications: Diagnosis of one of the following: 1) Rheumatic disorders: As adjunctive therapy for short-term administration in: psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis, or acute gouty arthritis, OR 2) Collagen diseases: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus or systemic dermatomyositis (polymyositis), OR 3) Dermatologic diseases: Severe erythema multiforme, Stevens-Johnson syndrome, or severe psoriasis, OR 4) Allergic states: Serum sickness or atopic dermatitis, OR 5) Ophthalmic diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, such as one of the following: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation, or allergic conjunctivitis, OR 6) Respiratory diseases: Symptomatic sarcoidosis, OR 7) Edematous state: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. TF/C/I to treatment with two corticosteroids (e.g., prednisone, methylprednisolone).</p>
<b>Age Restrictions</b>	IS: less than 2 years old
<b>Prescriber Restrictions</b>	IS, MS: neurologist. Rheumatic disorder, collagen disease: rheumatologist. Dermatologic: dermatologist. Allergic state: allergist, immunologist. Ophthalmic disease: optometrist, ophthalmologist. Respiratory diseases: pulmonologist. Edematous state: nephrologist, rheumatologist.
<b>Coverage Duration</b>	IS: 4 weeks. MS: 3 weeks. Other FDA-Approved Indications: 3 months.

PA Criteria	Criteria Details
<b>Other Criteria</b>	IS: Dosing for IS (West Syndrome) is in accordance with the United States Food and Drug Administration (FDA) approved labeling: not to exceed 150U/m <sup>2</sup> daily. MS: Dosing for MS is in accordance with the United States FDA approved labeling: not to exceed 120 units once daily. Other FDA-Approved Indications: Dosing is in accordance with the United States FDA approved labeling: not to exceed 80 units per day.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# COSENTYX (s)

## 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>	<p>Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication (eg, safety concerns, not indicated for patient's age/weight), or intolerance to one of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), OR for continuation of prior therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: a) Either trial and failure, contraindication (eg, safety concerns, not indicated for patient's age/weight), or intolerance to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER), OR b) for continuation of prior therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: a) Trial and failure, contraindication, or intolerance to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER), or attestation demonstrating a trial may be inappropriate, OR b) for continuation of prior therapy. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, meloxicam, naproxen). Enthesitis-Related Arthritis (ERA) (Initial): Diagnosis of active ERA. Trial and failure, contraindication, or intolerance to TWO non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, meloxicam, naproxen).</p>
<b>Age Restrictions</b>	ERA (initial): Patient is 4 years of age or older.
<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, nr-axSpA, ERA (initial): Prescribed by or in consultation with a rheumatologist.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months

PA Criteria	Criteria Details
<b>Other Criteria</b>	PsA, AS, nr-axSpA (Reauth): Documentation of positive clinical response to therapy. Psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. ERA (Reauth): Documentation of a positive clinical response to therapy as evidenced by at least one of the following: Reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Cotellic (s)

## Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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.
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	

# CRINONE (s)

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**Products Affected**

- CRINONE

PA Criteria	Criteria Details
Exclusion Criteria	All indications: Excluded if for fertility uses.
Required Medical Information	Secondary amenorrhea: Diagnosis of secondary amenorrhea (the absence of menses in women who have already started menstruation who are not pregnant, breastfeeding, or in menopause).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	



# CYSTARAN (s)

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**Products Affected**

- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystinosis: Diagnosis of cystinosis, confirmed by elevated leukocyte cystine levels (LCL), genetic analysis of the CTNS gene or corneal cystine crystal accumulation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Daliresp (s)

## Products Affected

- DALIRESP
- roflumilast*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD) (initial): Diagnosis of COPD. History of COPD exacerbations which required the use of systemic corticosteroids, antibiotics, or hospital admission. Trial and failure, intolerance, or contraindication to two prior therapies for COPD (e.g., Combivent, Spiriva).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	COPD (init, reauth): 12 months
Other Criteria	COPD (reauth): Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# DARAPRIM (s)

## 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>	

# Daurismo (s)

## Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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.
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	

# DEFERASIROX (s)

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Myelodysplastic Syndrome (MDS) (Initial): Diagnosis of MDS. Patient has Low or Intermediate-1 disease or is a potential transplant patient. Patient has received more than 20 red blood cell transfusions. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT) (Initial): Diagnosis of chronic iron overload due to NTDT. Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher. Serum ferritin level greater than 300 mcg/L.
<b>Age Restrictions</b>	Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Iron Overload Due to Blood Transfusions, MDS (initial, reauth):12 mo. NTDT (initial, reauth): 6mo.
<b>Other Criteria</b>	Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin level or LIC.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Diacomit (s)

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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	

# EGRIFTA (s)

## Products Affected

- EGRIFTA SUBCUTANEOUS SOLUTION  
RECONSTITUTED 1 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	HIV-associated lipodystrophy (initial): All of the following: 1) diagnosis of HIV-associated lipodystrophy, 2) one of the following: a) waist-circumference of greater than or equal to 95 cm (37.4 inches) in men, OR b) waist-circumference of greater than or equal to 94 cm (37 inches) for women, 3) one of the following: a) Waist-to-hip ratio of greater than or equal to 0.94 for men, OR b) waist-to-hip ratio of greater than or equal to 0.88 for women, 4) body mass index (BMI) greater than 20 kg/m <sup>2</sup> , AND 5) fasting blood glucose (FBG) levels less than or equal to 150 mg/dL (8.33 mmol/L), AND 6) patient has been on a stable regimen of antiretrovirals (eg, NRTIs, NNRTI, Protease Inhibitors, Integrase Inhibitors) for at least 8 weeks.
<b>Age Restrictions</b>	Initial: 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial, reauth: 6 months
<b>Other Criteria</b>	(reauth): documentation of clinical improvement (eg, improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance, etc) while on therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ELIGARD (s)

## Products Affected

- ELIGARD SUBCUTANEOUS KIT 22.5 MG, 30 MG, 45 MG, 7.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. Trial and failure, contraindication, or intolerance to any brand Lupron formulation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	



# Emgality (s)

## Products Affected

- EMGALITY SUBCUTANEOUS SOLUTION AUTO-INJECTOR 120 MG/ML
- EMGALITY SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 120 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Episodic Migraines (EM) (120 mg/mL strength only) (initial): Diagnosis of EM. Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month. Chronic Migraines (CM) (120 mg strength/mL only) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months.</p> <p>Episodic Cluster Headache (ECH) (100 mg/mL strength only) (initial): Diagnosis of episodic cluster headache. Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months.</p> <p>EM, CM (120 mg/mL strength only) (initial): Two of the following: a) History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine), OR patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine), b) History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate), OR patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate), c) History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, OR patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, or d) History of failure (after at least a two month trial) or intolerance to Atacand (candesartan), OR patient has a contraindication to Atacand (candesartan). All Indications (initial): Medication will not be used in combination with another injectable CGRP inhibitor.</p>
<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 (initial): 6 months. ECH (initial): 3 months. EM, CM, ECH (reauth): 12 months.
<b>Other Criteria</b>	EM, CM (120 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache

PA Criteria	Criteria Details
	frequency and/or intensity. Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. CM (120 mg/mL strength only) (reauth): Patient continues to be monitored for medication overuse headache. ECH (100 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. All Indications (reauthorization): Medication will not be used in combination with another injectable CGRP inhibitor.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Enbrel (s)

## Products Affected

- ENBREL
- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED
- 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 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. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, meloxicam, naproxen).
<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>	RA, PJIA, PsA, AS (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## EPCLUSA preferred (s)

### Products Affected

- *sofosbuvir-velpatasvir*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. Diagnosis of chronic hepatitis C. Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)].
Age Restrictions	
Prescriber Restrictions	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.
Coverage Duration	12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Epidiolex (s)

## Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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. Tuberous sclerosis complex (TSC): Diagnosis of seizures associated with TSC.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	LGS, DS, TSC: Prescribed by or in consultation with a neurologist
<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>	

# EPOETIN ALFA (s)

## Products Affected

- PROCRIT

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 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 receiving chemo. 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/peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 36% 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 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 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.
<b>Other Criteria</b>	<p>Subject to ESRD review. CKD, Chemo, MDS (init): History of use or unavailability of both Aranesp and Retacrit. HIV, Preop, HCV (init): History of use or unavailability of Retacrit. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 months</p>

PA Criteria	Criteria Details
	<p>is 33% or less (Hgb is 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or avg Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. 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 receiving chemo. 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, HCV): 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 (s)

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**Products Affected**

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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.
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	



# Erleada (s)

## Products Affected

- ERLEADA

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

# Esbriet (s)

## Products Affected

- ESBRIET ORAL CAPSULE
- *pirfenidone oral tablet 267 mg, 801 mg*

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 or in consultation with a pulmonologist
<b>Coverage Duration</b>	initial, reauth: 12 months
<b>Other Criteria</b>	IPF (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Evenity (s)

## Products Affected

- EVENITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Diagnosis of postmenopausal osteoporosis. 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 anti-resorptive 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 anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and ii) one of the following FRAX (Fracture Risk Assessment Tool) 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. Trial of, contraindication, or intolerance to one of the following: Forteo (teriparatide) or Tymlos (abaloparatide). Treatment duration of Evenity (romosozumab-aqqg) has not exceeded a total of 12 months during the patient's lifetime.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months (max 12 months of therapy per lifetime)
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Exkivity (s)

## Products Affected

- EXKIVITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: a) locally advanced or b) metastatic. Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation 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). Patient has progressed on or following prior treatment with a platinum-containing regimen (e.g., carboplatin, cisplatin).
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	

# FARYDAK (s)

## Products Affected

- FARYDAK ORAL CAPSULE 10 MG, 15 MG, 20 MG

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	

# Fasenra (s)

## 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 (e.g., prednisone) 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 (e.g., montelukast), long-acting beta-2 agonist (LABA) (e.g., salmeterol), tiotropium], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), 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 continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# FENTANYL (s)

## Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids: Morphine sulfate at doses of greater than or equal to 60 mg/day, Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ferriprox (s)

## Products Affected

- *deferiprone*
- FERRIPROX ORAL SOLUTION
- FERRIPROX ORAL TABLET 1000 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Transfusional iron overload (Initial): Diagnosis of transfusional iron overload due to one of the following: thalassemia syndromes, sickle cell disease, or other transfusion-dependent anemias. Patient has Absolute Neutrophil Count (ANC) greater than $1.5 \times 10^9/L$ . One of the following: A) Trial and failure, defined as serum ferritin greater than 2,500 mcg/L, to one chelation therapy (i.e., deferoxamine, deferasirox) OR B) History of contraindication or intolerance to one chelation therapy (i.e., deferoxamine, deferasirox).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	All uses (reauth): Documentation of positive clinical response to therapy (e.g., greater than or equal to 20% decline in serum ferritin levels from baseline, decrease in liver iron concentration). ANC greater than $1.5 \times 10^9/L$ .
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Fintepla (s)

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**Products Affected**

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	One of the following: 1) Diagnosis of seizures associated with Dravet syndrome, OR 2) Diagnosis of seizures associated with Lennox-Gastaut syndrome.
Age Restrictions	Lennox-Gastaut syndrome: Patient is 2 years of age or older.
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	

# Firazyr (s)

## Products Affected

- *icatibant acetate*
- *sajazir*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HAE: Prescribed by or in consultation with an immunologist or an allergist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Firdapse (s)

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**Products Affected**

- FIRDAPSE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Lambert-Eaton Myasthenic Syndrome (LEMS) (initial): Diagnosis of LEMS.
Age Restrictions	
Prescriber Restrictions	LEMS (initial): Prescribed by or in consultation with a neurologist.
Coverage Duration	LEMS (initial): 3 months. LEMS (reauth): 12 months.
Other Criteria	LEMS (reauth): Documentation of positive clinical response to therapy (e.g., improvement in dynamometry, Timed 25-Foot Walk Test, Timed Up and Go Test).
Indications	All Medically-accepted Indications.
Off Label Uses	

# FIRMAGON (s)

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**Products Affected**

- FIRMAGON
- FIRMAGON (240 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of advanced or metastatic prostate cancer.
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	

# Fotivda (s)

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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, nephrologist, or urologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Fulphila (s)

## Products Affected

- FULPHILA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of FN (off-label): Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications. Acute radiation syndrome (ARS) (off-label): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.
<b>Other Criteria</b>	All Indications: Trial and failure or intolerance to both of the following: Neulasta/Neulasta Onpro AND Udenyca.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Galafold (s)

## 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): 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 therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Gattex (s)

## Products Affected

- GATTEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Short Bowel Syndrome (SBS) (Initial): Diagnosis of SBS. Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 months.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	SBS (Init, reauth): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	SBS (Init): 6 months. SBS (Reauth): 12 months.
<b>Other Criteria</b>	SBS (Reauth): Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has had a reduction in weekly parenteral nutrition/intravenous (PN/IV) support from baseline while on therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Gavreto (s)

## Products Affected

- GAVRETO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Presence of metastatic rearranged during transfection (RET) gene fusion-positive tumor(s). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene mutation tumor(s). Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. One of the following: patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	NSCLC, 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>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# GILENYA (s)

## Products Affected

- *fingolimod hcl*
- GILENYA ORAL CAPSULE 0.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multiple Sclerosis (MS) (initial): 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	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
Indications	All Medically-accepted Indications.
Off Label Uses	

# GILOTRIF (s)

## 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>	

# Givlaari (s)

## Products Affected

- GIVLAARI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of acute hepatic porphyria (i.e., acute intermittent porphyria, hereditary coproporphyria, variegate porphyria, ALA dehydrase deficient porphyria). Patient has active disease with at least two documented porphyria attacks within the past 6 months. Provider attestation documenting elevated urinary or plasma levels of one of the following within the past 12 months: 1) porphobilinogen (PBG) or 2) delta-aminolevulinic acid (ALA). Patient has not had a liver transplant.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with a gastroenterologist or a specialist with expertise in the diagnosis and management of acute hepatic porphyria.
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response while on therapy as demonstrated by both of the following: 1) Reduction in hemin administration requirements and 2) Reduction in the rate or number of porphyria attacks. Patient has not had a liver transplant.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# GLATIRAMER ACETATE (s)

## 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) (initial): 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>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Gleevec (s)

## 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>	Hypereosinophilic syndrome or chronic eosinophilic leukemia, Aggressive systemic mastocytosis: Prescribed by or in consultation with an oncologist, hematologist, allergist, or immunologist. Dermatofibrosarcoma Protuberans: Prescribed by or in consultation with an oncologist, hematologist or dermatologist. GIST: Prescribed by or in consultation with an oncologist, hematologist or gastroenterologist. All other 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>	

# GROWTH HORMONE, NON-PREFERRED (s)

## Products Affected

- HUMATROPE
- HUMATROPE INJECTION SOLUTION RECONSTITUTED 5 MG
- NORDITROPIN FLEXPPO
- OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE
- SAIZEN
- SAIZENPREP

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>PGHD(initial):less than 4mo w/suspected GD based on clinical presentation (eg, persistent neonatal hypoglycemia, persistent/prolonged neonatal jaundice/elev bilirubin, male infant with microgenitalia, midline anatomical defects, failure to thrive),OR hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)]. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender assoc with growth rates unlikely to permit attainment of adult height in the normal range. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

PA Criteria	Criteria Details
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	<p>All uses (initial): Trial and failure or intolerance to Genotropin and Nutropin. AGHD(initial): dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg, damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1 GH stim test (insulin tolerance test [ITT], arginine/GHRH, glucagon, arginine, macimorelin) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m<sup>2</sup>, at or below 8mcg/L if BMI at or above 25 and below 30kg/m<sup>2</sup>, or at or below 4mcg/L if BMI at or above 30kg/m<sup>2</sup>], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin]) or doc deficiency of 3 anterior pituitary hormones (prolactin, ACTH, TSH, FSH/LH) and IGF-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab.</p> <p>AGHD, IGHDA(reauth): monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial): attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones: ACTH, TSH, prolactin, FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon, macimorelin) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m<sup>2</sup>, at or below 8mcg/L if BMI at or above 25 and below 30kg/m<sup>2</sup>, or at or below 4mcg/L if BMI at or above 30kg/m<sup>2</sup>], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon, macimorelin) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m<sup>2</sup>, at or below 8mcg/L if BMI at or above 25 and below 30kg/m<sup>2</sup>, or at or below 4mcg/L if BMI at or above 30kg/m<sup>2</sup>], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin]. TPAP(reauth): evidence of positive response to therapy (eg, incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3).</p> <p>IGHDA(initial): doc GHD after 2 GH stim tests(ITT, L-ARG, glucagon, macimorelin), w/ 2 corresponding peak GH values [ITT at or below 5mcg/L], [Arg at or below 5mcg/L], [glucagon at or below 3mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60, 90 mins after admin].</p>



PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	

# GROWTH HORMONE, PREFERRED (s)

## Products Affected

- GENOTROPIN
- GENOTROPIN MINQUICK
- NUTROPIN AQ NUSPIN 10
- NUTROPIN AQ NUSPIN 20
- NUTROPIN AQ NUSPIN 5

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>PGHD(initial):less than 4mo w/suspected GD based on clinical presentation (eg, persistent neonatal hypoglycemia, persistent/prolonged neonatal jaundice/elev bilirubin, male infant with microgenitalia, midline anatomical defects, failure to thrive),OR hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)]. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender assoc with growth rates unlikely to permit attainment of adult height in the normal range. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine,macimorelin) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L],[macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IGF-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab.</p> <p>AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial): attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones: ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon,macimorelin) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon, macimorelin) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3).</p> <p>IGHDA(initial):doc GHD after 2 GH stim tests(ITT,L-ARG,glucagon,macimorelin), w/ 2 corresponding peak GH values [ITT at or below 5mcg/L],[Arg at or below 5mcg/L],[glucagon at or below 3mcg/L],[macimorelin less than 2.8 ng/mL 30,45,60,90 mins after admin].</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# H.P. ACTHAR GEL (s)

## Products Affected

- ACTHAR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Infantile Spasm (IS) (West Syndrome): Diagnosis of infantile spasms (West Syndrome). Dosing for infantile spasms (West Syndrome) is in accordance with the United States Food and Drug Administration (FDA) approved labeling: not to exceed 150U/m<sup>2</sup> daily. Multiple Sclerosis (MS): Acute exacerbations of MS. Dosing for multiple sclerosis is in accordance with the United States FDA approved labeling: not to exceed 120 units once daily. Trial and failure, contraindication, or intolerance to treatment with two corticosteroids (e.g., prednisone, methylprednisolone). Rheumatic disorders: As adjunctive therapy for short-term administration in: psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis, or acute gouty arthritis. Collagen diseases: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis). Dermatologic diseases: Severe erythema multiforme, Stevens-Johnson syndrome, or severe psoriasis. Allergic states: Serum sickness or atopic dermatitis. Ophthalmic diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation, or allergic conjunctivitis. Respiratory diseases: Symptomatic sarcoidosis. Edematous state: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. All indications except for infantile spasms: Trial and failure, contraindication, or intolerance to treatment with two corticosteroids. All indications (except infantile spasms, multiple sclerosis): Dosing is in accordance with the United States FDA approved labeling: not to exceed 80 units per day.</p>
<b>Age Restrictions</b>	Infantile spasms: less than 2 years old
<b>Prescriber Restrictions</b>	<p>Infantile Spasm, MS: neurologist. Rheumatic disorder, collagen disease: rheumatologist. Dermatologic: dermatologist. Allergic state: allergist, immunologist. Ophthalmic disease: optometrist, ophthalmologist. Respiratory diseases: pulmonologist. Edematous state: nephrologist, rheumatologist.</p>
<b>Coverage Duration</b>	Infantile Spasms: 4 weeks. MS: 3 weeks. All other FDA-approved uses: 3 months.

PA Criteria	Criteria Details
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# HARVONI (s)

## Products Affected

- HARVONI ORAL PACKET
- HARVONI ORAL TABLET 45-200 MG
- *ledipasvir-sofosbuvir*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Criteria will be applied consistent with current AASLD/IDSA guideline. All (including patients with genotype 5 or 6 infection AND decompensated cirrhosis): A) Diagnosis of chronic hepatitis C, B) Patient is not receiving ledipasvir/sofosbuvir in combination with another HCV direct acting antiviral agent [eg, Sovaldi (sofosbuvir)]. ONE of the following: Trial and failure, intolerance, or contraindication (eg, safety concerns, not indicated for patient's age/weight) to a) Mavyret (except patients with decompensated cirrhosis, and b) sofosbuvir/velpatasvir, OR for continuation of prior ledipasvir/sofosbuvir therapy.
<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>	

# HETLIOZ (s)

## Products Affected

- HETLIOZ

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). Smith-Magenis Syndrome (SMS) (initial): Diagnosis of Smith-Magenis Syndrome (SMS). Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking).
<b>Age Restrictions</b>	SMS (initial): 16 years of age or older
<b>Prescriber Restrictions</b>	Non-24 (initial): Prescribed by or in consultation with a specialist in sleep disorders or neurologist. SMS (initial): Prescribed by or in consultation with a specialist in sleep disorders or neurologist.
<b>Coverage Duration</b>	Non-24, SMS (initial): 6 mo. (reauth): 12 mo
<b>Other Criteria</b>	Non-24 (reauth): Documentation of positive clinical response to therapy. SMS (reauth): Documentation of positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality)
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# HRM - Megestrol Suspension

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The drug is being prescribed for an FDA-approved 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	



# HRM - Megestrol Tablet

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## Products Affected

- *megestrol acetate oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The drug is being prescribed for an FDA-approved 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	Applies to New Starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Humira (s)

## 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. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. TF/C/I to two NSAIDs (e.g., diclofenac, ibuprofen, meloxicam, naproxen).</p> <p>Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. TF/C/I to one 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 one 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>
<b>Coverage Duration</b>	<p>UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial, reauth): 12 mo.</p>

PA Criteria	Criteria Details
<b>Other Criteria</b>	RA, JIA, PsA, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ibrance (s)

## 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>	

# ICLUSIG (s)

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chronic myelogenous leukemia: Diagnosis of chronic myelogenous leukemia AND One of the following: A) Trial and failure, contraindication, or intolerance to at least TWO other tyrosine kinase inhibitors (e.g., Gleevec [imatinib], Sprycel, Tasigna, and Bosulif) or B) Patient has the T315I mutation. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) AND One of the following: A) Trial and failure, resistance relapse, contraindication, or intolerance to at least TWO other FDA-approved tyrosine kinase inhibitors (e.g., Gleevec [imatinib], Sprycel), or B) Patient has the T315I mutation.
<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>	

# Idhifa (s)

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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>	

# Ilumya (s)

## Products Affected

- ILUMYA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Plaque Psoriasis (initial): Diagnosis of moderate-to-severe plaque psoriasis. Trial and failure, contraindication, or intolerance to two of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Cosentyx (secukinumab), or for continuation of prior therapy.
Age Restrictions	
Prescriber Restrictions	Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Plaque Psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Imbruvica (s)

## Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL SUSPENSION
- 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 like prednisone or methylprednisolone, 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>	



# Inbrija (s)

## Products Affected

- INBRIJA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Parkinson's disease (PD) (initial): Diagnosis of PD. Patient is experiencing intermittent OFF episodes. Used in combination with carbidopa/levodopa. Trial and failure, contraindication or intolerance to two of the following: MAO-B inhibitor (e.g., rasagiline, selegiline), dopamine agonist (e.g., pramipexole, ropinirole), or COMT Inhibitor (e.g., entacapone).
Age Restrictions	
Prescriber Restrictions	PD (initial): Prescribed by or in consultation with a neurologist
Coverage Duration	PD (initial, reauth): 12 months
Other Criteria	PD (reauth): Documentation of positive clinical response to therapy. Used in combination with carbidopa/levodopa.
Indications	All Medically-accepted Indications.
Off Label Uses	

# INCRELEX (s)

## Products Affected

- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Insulin-like Growth Factor-1 (IGF-1) deficiency (initial): Diagnosis of severe primary IGF-1 deficiency. Height standard deviation score of -3.0 or less. Basal IGF-1 standard deviation score of -3.0 or less. Normal or elevated growth hormone (GH). GH gene deletion (initial): Diagnosis of GH gene deletion in patients who have developed neutralizing antibodies to GH.
Age Restrictions	
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	(Reauth): Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Inlyta (s)

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**Products Affected**

- INLYTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. One of the following: (1) disease has relapsed or (2) diagnosis of stage IV disease.
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	

# Inqovi (s)

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**Products Affected**

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome.
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	

# Inrebic (s)

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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	

# Intron A (s)

## Products Affected

- INTRON A
- INTRON A INJECTION SOLUTION  
10000000 UNIT/ML, 6000000 UNIT/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Diagnosis of chronic hepatitis C, patient without decompensated liver disease, patient has not previously been treated with interferon, and one of the following - 1) used in combination with ribavirin or 2) contraindication or intolerance to ribavirin. Metastatic renal cell carcinoma (RCC): diagnosis of metastatic RCC, used in combination with Avastin (bevacizumab). Other: diagnosis of condylomata acuminata (genital or perianal), diagnosis of hairy cell leukemia, diagnosis of AIDS-related Kaposi's sarcoma, diagnosis of malignant melanoma, diagnosis of Stage III or IV follicular Non-Hodgkin's Lymphoma.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RCC: Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	HepB, HepC: 48 wks. Condylomata acuminata (genital or perianal): 6 wks. Other: 12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Iressa (s)

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**Products Affected**

- IRESSA

PA Criteria	Criteria Details
<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>	

# ISOTRETINOIN (s)

## Products Affected

- *accutane*
- *amnesteam*
- *claravis*
- *isotretinoin oral capsule 10 mg, 20 mg, 30 mg, 40 mg*
- *myorisan*
- *zenatane*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Acne (initial): Diagnosis of acne. One of the following: A) Prescribed by a dermatologist or, B) Trial and failure, contraindication or intolerance to an adequate trial (at least 6 weeks) on two of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin-A/Retin-A Micro (tretinoin)], b) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)], c) topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Acne (initial): 5 months. Acne (reauth): Retreatment - 5 months, Dose Titration - 1 month
<b>Other Criteria</b>	Acne, Retreatment (reauth): After more than 2 months off therapy, persistent or recurring acne is still present. Acne, Dose Titration (reauth): Confirmation that the total cumulative dose is less than 150 mg/kg.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# IVIG (s)

## Products Affected

- FLEBOGAMMA DIF INTRAVENOUS SOLUTION 10 GM/200ML, 5 GM/50ML
- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA
- GAMMAKED INJECTION SOLUTION 1 GM/10ML
- GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/200ML
- GAMUNEX-C INJECTION SOLUTION 1 GM/10ML
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 10 GM/200ML, 2 GM/20ML
- PRIVIGEN INTRAVENOUS SOLUTION 20 GM/200ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. Gammaplex only: Hereditary intolerance to fructose. Infants for whom sucrose or fructose tolerance has not been established.
<b>Required Medical Information</b>	Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG - Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than $10 \times 10^9/L$ . 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm <sup>3</sup> . Continued in Other Criteria Section.
<b>Age Restrictions</b>	HIV (initial): patient is less than or equal to 12 years of age.

PA Criteria	Criteria Details
<b>Prescriber Restrictions</b>	All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist).
<b>Coverage Duration</b>	4 months: Solid organ transplant. 12 months: all other diagnoses.
<b>Other Criteria</b>	<p>[D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-Barré syndrome. 3) Inflammatory myopathies (dermatomyositis or polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants).</p> <p>[E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapson, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# JAKAFI (s)

## 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. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD. Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Myelofibrosis, Polycythemia vera: Prescribed by or in consultation with a hematologist/oncologist. aGVHD, cGVHD: 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>	

# Jatenzo (s)

## Products Affected

- JATENZO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab, OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reauth): 12 mo.
<b>Other Criteria</b>	HG (Reauth): 1) Follow-up total serum T level within or below the normal limits of the reporting lab, or 2) Follow-up total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Follow-up calculated free or bioavailable T level within or below the normal limits of the reporting lab, or follow-up calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# JUXTAPID (s)

## Products Affected

- JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 40 MG, 5 MG, 60 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Homozygous familial hypercholesterolemia (HoFH) (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the following: 1) either untreated/pre-treatment LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. One of the following: a) patient is receiving other lipid-lowering therapy, or b) patient has an inability to take other lipid-lowering therapy. Trial and failure, contraindication, or intolerance to Repatha therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HoFH (initial, reauth): Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.
<b>Coverage Duration</b>	HoFH (initial): 6 months. (reauth): 12 months
<b>Other Criteria</b>	HoFH (reauthorization): One of the following: a) patient continues to receive other lipid-lowering therapy, or b) patient has an inability to take other lipid-lowering therapy. Submission of medical records (eg, chart notes, laboratory values) documenting LDL-C reduction from baseline while on therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Kalydeco (s)

## Products Affected

- KALYDECO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Cystic Fibrosis (CF) (Initial): Diagnosis of cystic fibrosis. Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
<b>Age Restrictions</b>	CF (Initial): 4 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 [percent predicted forced expiratory volume in one second (PPFEV1)], decreased number of pulmonary exacerbations) while on therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# KEVEYIS (s)

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**Products Affected**

- KEVEYIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Periodic paralysis (Initial): Diagnosis of one of the following: Primary hyperkalemic periodic paralysis, Primary hypokalemic periodic paralysis, or Paramyotonia Congenita with periodic paralysis.
Age Restrictions	
Prescriber Restrictions	All uses (initial): Prescribed by or in consultation with a neurologist
Coverage Duration	All uses (Initial): 3 months. (Reauth): 12 months
Other Criteria	All uses (Reauth): Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# KINERET (s)

## 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: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID AND dx of NOMID has been confirmed by one of the following: 1) NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3) gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation OR 2) Both of the following: a) two of the following clinical symptoms: urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia), chronic aseptic meningitis, or skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing) AND b) elevated acute phase reactants (eg, erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA]). Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA.
<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>	RA, NOMID (initial, reauth): 12 months. DIRA: 12 months.
<b>Other Criteria</b>	RA, NOMID (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Kisqali (s)

## Products Affected

- KISQALI ORAL TABLET THERAPY  
PACK 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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., Femara (letrozole)] OR B) Used in combination with Faslodex (fulvestrant).
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	

# KISQALI-FEMARA PACK (s)

## Products Affected

- KISQALI FEMARA ORAL TABLET  
THERAPY PACK 200 & 2.5 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) Patient is postmenopausal OR B) Both of the following: a) Patient is pre/perimenopausal or male AND b) Treated with a Luteinizing Hormone-Releasing Hormone (LHRH) agonist (e.g. leuprolide).
<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>	

# KORLYM (s)

## Products Affected

- KORLYM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	Initial, reauth: 6 months
<b>Other Criteria</b>	Reauth: Documentation of one of the following: patient has improved glucose tolerance while on therapy or patient has stable glucose tolerance while on therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Koselugo (s)

## 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	

# Kuvan (s)

## Products Affected

- *sapropterin dihydrochloride*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Phenylketonuria (PKU) (initial): Diagnosis of PKU. Patient will have blood Phe levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	PKU (Init): 2 months (Reauth): 12 months
Other Criteria	PKU (reauth): Documentation of a positive clinical response to therapy. Patient will continue to have blood Phe levels measured periodically during therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Lenvima (s)

## 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. One of the following: 1) Both of the following: a) Used as first-line treatment and b) Used in combination with Keytruda (pembrolizumab), or 2) Both of the following: a) Treatment follows one prior anti-angiogenic therapy and b) 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. Endometrial Carcinoma (EC): Diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR). Patient has disease progression following systemic therapy. Used in combination with Keytruda (pembrolizumab) therapy. Patient is not a candidate for curative surgery or radiation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	DTC/RCC/EC: 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>	

# LETAIRIS (s)

## 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): 6 months. PAH (Reauth): 12 months
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Leukine (s)

## Products Affected

- LEUKINE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Bone marrow/stem cell transplant (BMSCT): One of the following: 1) patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT, OR 2) used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, OR 3) patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy. Acute myeloid leukemia (AML): Diagnosis of AML. Patient has completed induction or consolidation chemotherapy. Age greater than or equal to 55 years. Febrile Neutropenia (FN) Prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with a greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). Treatment of High-Risk FN: Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications. HIV-related neutropenia (HIVN): Patient is infected with HIV, and ANC less than or equal to 1000 (cells/mm <sup>3</sup> ).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HIVN: Prescribed by or in consultation with a hematologist/oncologist or infectious disease specialist. All other uses: Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	BMSCT, AML, FN (prophylaxis, treatment): 3mo or duration of tx. HIVN: 6mo. ARS: 1 mo.
<b>Other Criteria</b>	



PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	

# LIDOCAINE TOPICAL (s)

## 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	

# Lidoderm (s)

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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	

# LONSURF (s)

## Products Affected

- LONSURF ORAL TABLET 15-6.14 MG, 20-8.19 MG

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., bevacizumab) AND One of the following: A) patient has RAS wild-type tumors and trial and failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Vectibix, Erbitux) OR Patient has RAS 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>	

# Lorbrena (s)

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**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 metastatic NSCLC. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor 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	

# LOTRONEX (s)

## Products Affected

- *alosetron hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women (initial): All of the following: 1) diagnosis of severe diarrhea-predominant IBS, 2) symptoms for at least 6 months, 3) female patient, AND 4) trial and failure, contraindication, or intolerance to an antidiarrheal agent [eg, loperamide].
Age Restrictions	Initial: 18 years of age or older
Prescriber Restrictions	
Coverage Duration	IBS (initial): 12 weeks. IBS (reauth): 6 mo.
Other Criteria	IBS (reauthorization): Symptoms of IBS continue to persist, AND documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Lumakras (s)

## Products Affected

- LUMAKRAS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: a) locally advanced or b) metastatic. Tumor is KRAS G12C-mutated 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). Patient has received at least one prior systemic therapy (e.g., cisplatin/pemetrexed, atezolizumab, nivolumab, capmatinib).
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	

# LUPANETA PACK (s)

## Products Affected

- LUPANETA PACK COMBINATION KIT  
11.25 & 5 MG, 3.75 & 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Endometriosis (initial): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID (e.g., diclofenac, ibuprofen, meloxicam, naproxen) and one oral contraceptive (e.g., norethindrone-ethinyl estradiol, estradiol and norethindrone).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Endomet (init, reauth): 6 months
Other Criteria	Endometriosis (reauthorization): Patient is experiencing recurrence of symptoms after an initial course of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	



# LUPRON (s)

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**Products Affected**

- *leuprolide acetate injection*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Prostate CA: 12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# LUPRON DEPOT (s)

## Products Affected

- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)  
INTRAMUSCULAR KIT 30MG
- LUPRON DEPOT (6-MONTH)  
INTRAMUSCULAR KIT 45MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prostate Cancer (7.5 mg, 22.5 mg, 30 mg, 45 mg): Diagnosis of advanced or metastatic prostate cancer. Endometriosis (3.75 mg, 11.25 mg): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID (e.g., diclofenac, ibuprofen, meloxicam, naproxen) and one oral contraceptive (e.g., norethindrone-ethinyl estradiol, estradiol and norethindrone). Uterine Leiomyomata (UL) (3.75 mg, 11.25 mg): a) For use prior to surgery to reduce size of fibroids to facilitate a surgical procedure (eg, myomectomy, hysterectomy) OR b) all of the following: treatment of anemia, anemia is caused by uterine leiomyomata (fibroids), and for use prior to surgery.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Prostate CA: 12 mo. Endomet:6mo. UL (anemia):3 mo (fibroids):4 mo
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Lynparza tablet (s)

## Products Affected

- LYNPARZA ORAL TABLET 100 MG, 150 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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). High risk early breast cancer: Diagnosis of high risk early 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 CLIA. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Patient has been previously treated with neoadjuvant and adjuvant chemotherapy (e.g., anthracycline, taxane). Metastatic 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 CLIA. Disease is 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 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses (except prostate cancer): Prescribed by or in consultation with an oncologist. Prostate cancer: Prescribed by or in consultation with an oncologist or urologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	First-line 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 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).

PA Criteria	Criteria Details
	<p>Patient has had a complete or partial response to first-line platinum-based chemotherapy (e.g., carboplatin, cisplatin). Will be used as first-line maintenance treatment. 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 (e.g., FOLFIRINOX, FOLFOX, etc.). First-line maintenance treatment of HRD-positive advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with bevacizumab: Diagnosis of advanced epithelial ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Cancer is associated with homologous recombination deficiency (HRD)-positive status (defined by either: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability) 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). Patient has had a complete or partial response to first-line platinum-based chemotherapy (e.g., carboplatin, cisplatin). Used in combination with bevacizumab (e.g., Avastin, Mvasi). Will be used as first-line maintenance treatment. Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer. Presence of deleterious or suspected deleterious homologous recombination repair (HRR) gene 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). Disease has progressed following prior treatment with one of the following: a) enzalutamide (Xtandi) or b) abiraterone (e.g., Zytiga, Yonsa). All indications: Approve for continuation of prior therapy.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# MAKENA (s)

## Products Affected

- *hydroxyprogesterone caproate*  
*intramuscular oil*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Preterm birth prophylaxis: Patient had a previous singleton (single offspring) spontaneous preterm birth. Patient is having a singleton pregnancy. Therapy will be started between 16 weeks, 0 days and 20 weeks, 6 days of gestation. Therapy will be continued until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Preterm birth prophylaxis: Prescribed by or in consultation with a specialist in obstetrics and gynecology
<b>Coverage Duration</b>	Preterm birth prophylaxis: 21 weeks
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# MARINOL (s)

## Products Affected

- *dronabinol*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Nausea and Vomiting Associated with Cancer Chemotherapy (CINV): Patient is receiving cancer chemotherapy. Trial and failure, contraindication, or intolerance to one 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). Trial and failure, contraindication, or intolerance to one of the following: Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Zyprexa (olanzapine). AIDS anorexia: Diagnosis of anorexia with weight loss in patients with AIDS. Patient is on antiretroviral therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	CINV: 6 months. AIDS anorexia: 3 months.
<b>Other Criteria</b>	Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B when patient is receiving cancer chemotherapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Mavenclad (s)

## Products Affected

- MAVENCLAD

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Patient has not been previously treated with cladribine AND Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: A) Aubagio (teriflunomide), B) Lemtrada (alemtuzumab), C) Plegridy (peginterferon beta-1a), D) Tysabri (natalizumab), E) Any one of the interferon beta-1a injections (eg, Avonex), F) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), G) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), H) Any one of the glatiramer acetates (eg, Copaxone, Glatopa, generic glatiramer acetate), I) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya [fingolimod], Mayzent [siponimod], Zeposia [ozanimod]), J) Any one of the B-cell targeted therapies (eg, Ocrevus [ocrelizumab], Kesimpta [ofatumumab]), OR 2) Patient has previously received treatment with cladribine AND Patient has not already received the FDA-recommended lifetime limit of 2 treatment courses (or 4 treatment cycles total) of cladribine. Not used in combination with another disease-modifying therapy for MS.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS: Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS: 1 month
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Mavyret (s)

## Products Affected

- MAVYRET ORAL PACKET
- MAVYRET ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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 not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].
Age Restrictions	
Prescriber Restrictions	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.
Coverage Duration	8 to 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	



# MAYZENT (s)

## Products Affected

- MAYZENT ORAL TABLET 0.25 MG, 1 MG, 2 MG
- MAYZENT STARTER PACK ORAL TABLET THERAPY PACK 0.25 MG, 12 X 0.25 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple Sclerosis (MS) (initial): 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>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Mekinist (s)

## 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 Tafenlar (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 Tafenlar (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 Tafenlar (dabrafenib).</p>
<b>Age Restrictions</b>	Solid tumors: Patient is 6 years of age or older.
<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. Solid tumors: Diagnosis of solid tumors. Disease is unresectable or metastatic. Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options. 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). Medication is used in combination with Tafenlar (dabrafenib).

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	

# Mektovi (s)

## Products Affected

- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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).
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	

# METHYLTESTOSTERONE (s)

## Products Affected

- *methitest*
- *methyltestosterone oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab, OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted. Delayed puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Dysphoria (GD)/Gender Incongruence (off-label): Dx of GD/Gender Incongruence.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC, GD: 12 mo. DP: 6 mo.
<b>Other Criteria</b>	HG (Reauth): 1) Follow-up total serum T level within or below the normal limits of the reporting lab, or 2) Follow-up total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Follow-up calculated free or bioavailable T level within or below the normal limits of the reporting lab, or follow-up calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	

# Migranal (s)

## Products Affected

- *dihydroergotamine mesylate nasal*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of migraine headaches with or without aura. Will be used for the acute treatment of migraine. One of the following: Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or contraindication to all triptans.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
<b>Coverage Duration</b>	Initial: 3 months. Reauth: 12 months.
<b>Other Criteria</b>	Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# MIRVASO (s)

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**Products Affected**

- MIRVASO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rosacea (init): Diagnosis of rosacea. Patient has moderate to severe persistent (nontransient) facial erythema.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Rosacea (init, reauth): 12 months
Other Criteria	Rosacea (reauth) Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	



# MS INTERFERONS (non-preferred) (s)

## Products Affected

- 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) (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following: Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Extavia (interferon beta-1b), Plegridy (peginterferon beta-1a), or 2) for continuation of prior therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# MS INTERFERONS (preferred) (s)

## Products Affected

- AVONEX PEN
- AVONEX PREFILLED
- BETASERON
- EXTAVIA
- PLEGRIDY STARTER PACK  
SUBCUTANEOUS SOLUTION PEN-  
INJECTOR
- PLEGRIDY SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple Sclerosis (MS) (initial): 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>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Mulpleta (s)

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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	1 month
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Myalept (s)

## Products Affected

- MYALEPT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Lipodystrophy (initial): Diagnosis of congenital or acquired generalized lipodystrophy AND one of the following: 1) Diabetes mellitus or insulin resistance despite optimized insulin therapy at maximum tolerated doses OR 2) Hypertriglyceridemia despite optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	Lipodystrophy (reauth): Patient has experienced an objective response to therapy, such as A) Sustained reduction in hemoglobin A1c (HbA1c) level from baseline OR B) Sustained reduction in triglyceride (TG) levels from baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# NATPARA (s)

## 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. Not 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. 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: 6 months. Reauth: 12 months
<b>Other Criteria</b>	Hypocalcemia (Reauth): One of the following: A) Patient has achieved and maintained serum calcium levels in the ideal range (7.5 - 10.6 mg/dL ), OR B) Patient has experienced a 50% or greater reduction from baseline in oral calcium intake, OR C) Patient has experienced a 50% or greater reduction from baseline in oral vitamin D intake.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Nerlynx (s)

## Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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.
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	

# Neulasta (s)

## Products Affected

- NEULASTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis).</p> <p>Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). Treatment of FN: Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia.</p> <p>Diagnosis of FN. Patient is at high risk for infection-associated complications.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Nexavar (s)

## Products Affected

- NEXAVAR
- sorafenib tosylate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Renal cell carcinoma (RCC): Diagnosis of RCC. 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, metastatic disease, or unresectable 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. Trial and failure, contraindication, or intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib).
<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>	



# NINLARO (s)

## Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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)].
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	

## NON-PREFERRED TIRF (s)

### Products Affected

- ABSTRAL SUBLINGUAL TABLET  
SUBLINGUAL 400 MCG, 600 MCG, 800 MCG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids: Morphine sulfate at doses of greater than or equal to 60 mg/day, Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day). Trial and failure or intolerance to generic fentanyl lozenge.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Northera (s)

## Products Affected

- *droxidopa*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Neurogenic orthostatic hypotension (NOH) (init): Diagnosis of symptomatic NOH. NOH is caused by one of the following conditions: primary autonomic failure (eg, Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, non-diabetic autonomic neuropathy. Trial and failure, contraindication, or intolerance to one of the following agents: fludrocortisone acetate, midodrine.
<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 (init): 1 month (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>	

# NOURIANZ (s)

## Products Affected

- NOURIANZ ORAL TABLET 20 MG, 40 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Parkinson's disease (PD) (initial): Diagnosis of PD. Patient is experiencing "off" episodes. Used in combination with carbidopa/levodopa. Trial and failure, contraindication or intolerance to two of the following: MAO-B Inhibitor (e.g., rasagiline, selegiline), Dopamine Agonist (e.g., pramipexole, ropinirole), or COMT Inhibitor (e.g., entacapone).
<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. Used in combination with carbidopa/levodopa.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Nubeqa (s)

## Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-metastatic castration-resistant or castration-recurrent prostate cancer (NM-CRPC): Diagnosis of non-metastatic castration-resistant (chemical or surgical) or castration-recurrent prostate cancer. Metastatic hormone-sensitive prostate cancer (mHSPC): Diagnosis of mHSPC. Used in combination with docetaxel.
Age Restrictions	
Prescriber Restrictions	NM-CRPC, mHSPC: Prescribed by or in consultation with an oncologist or urologist.
Coverage Duration	NM-CRPC, mHSPC: 12 months
Other Criteria	NM-CRPC, mHSPC: Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Nuedexta (s)

## Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Pseudobulbar affect (PBA) (initial): Diagnosis of PBA. Patient does not have any of the following contraindications: a) Concomitant use with other drugs containing quinidine, quinine, or mefloquine, b) History of Nuedexta, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression, or lupus-like syndrome, c) Known hypersensitivity to dextromethorphan (e.g., rash, hives), d) Taking monoamine oxidase inhibitors (MAOIs) (e.g., phenelzine, selegiline, tranylcypromine) or have taken MAOIs within the preceding 14 days, e) Has prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, or has heart failure, f) Receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), g) Has complete atrioventricular (AV) block without implanted pacemakers, or at high risk of complete AV block. PBA (reauth): Documentation of clinical benefit from ongoing therapy as demonstrated by a decrease in inappropriate laughing or crying episodes.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PBA (initial): Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist.
<b>Coverage Duration</b>	PBA (initial/reauth): 12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Nuplazid (s)

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**Products Affected**

- NUPLAZID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Parkinson's disease psychosis: Diagnosis of Parkinson's disease. Patient has at least one of the following: hallucinations or delusions.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# NUVIGIL (s)

## Products Affected

- armodafinil oral tablet 150 mg, 200 mg, 250 mg, 50 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Obstructive sleep apnea (OSA) (Initial): Diagnosis (dx) of OSA defined by one of the following: a) 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or b) both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), AND 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work disorder (SWD) (Initial):Dx of SWD confirmed by one of the following: 1) symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia. Narcolepsy (initial): Dx of narcolepsy as confirmed by sleep study (unless prescriber provides justification confirming that a sleep study is not feasible).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	OSA, SWD: Initial, Reauth: 6 mo. Narcolepsy: Initial, Reauth: 12 mo
<b>Other Criteria</b>	OSA, Narcolepsy (Reauth): Documentation of positive clinical response to armodafinil therapy. SWD (Reauth): Documentation of positive clinical response to armodafinil therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# OCALIVA (s)

## Products Affected

- OCALIVA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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. Patient does not have evidence of advanced cirrhosis (i.e., cirrhosis with current or prior evidence of hepatic decompensation including encephalopathy or coagulopathy). Patient does not have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia).
<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>	PBC (reauthorization): Submission of medical records (eg, laboratory values) documenting a reduction in ALP level from pre-treatment baseline (ie, prior obeticholic acid therapy) while on therapy. Patient does not have evidence of advanced cirrhosis (i.e., cirrhosis with current or prior evidence of hepatic decompensation including encephalopathy or coagulopathy). Patient does not have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Odomzo (s)

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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	

# Ofev (s)

## 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. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (initial): Diagnosis of SSc-ILD as documented by all of the following: a) exclusion of other known causes of 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 idiopathic interstitial pneumonia (eg, fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on HRCT revealing SSc-ILD or probable SSc-ILD, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD. Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype (initial): 1) diagnosis of chronic fibrosing interstitial lung disease, AND 2) patient has a high-resolution computed tomography (HRCT) showing at least 10% of lung volume with fibrotic features, AND 3) disease has a progressive phenotype as observed by one of the following: decline of forced vital capacity (FVC), worsening of respiratory symptoms, or increased extent of fibrosis seen on imaging.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (initial): Prescribed by or in consultation with a pulmonologist
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	

# Onureg (s)

## 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>	

# OPSUMIT (s)

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**Products Affected**

- OPSUMIT

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: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ORENCIA SC (s)

## Products Affected

- ORENCIA CLICKJECT
- ORENCIA SUBCUTANEOUS

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: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. One of the following: a) Either a trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR b) for continuation of prior therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: a) Either a trial and failure, contraindication, or intolerance to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER), OR b) for continuation of prior therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Orenitram (s)

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**Products Affected**

- ORENITRAM

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: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	



# Orgovyx (s)

## Products Affected

- ORGOVYX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prostate Cancer: Diagnosis of advanced prostate cancer. 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an urologist 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>	

# Orilissa (s)

## 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 has not exceeded a total of 24 months.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ORKAMBI (s)

## Products Affected

- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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 a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
<b>Age Restrictions</b>	CF (Initial): Patient is 6 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>	

# OTEZLA (s)

## Products Affected

- OTEZLA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Psoriatic arthritis (PsA, initial): Diagnosis of active PsA. One of the following: a) Either a trial and failure, contraindication, or intolerance to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER), OR b) for continuation of prior therapy. Plaque psoriasis (Initial): Diagnosis of plaque psoriasis. One of the following: 1) Patient has mild plaque psoriasis, OR 2) Both of the following: a) Patient has moderate to severe plaque psoriasis AND b) Trial and failure, contraindication, or intolerance to two of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Cosentyx (secukinumab), or 3) for continuation of prior therapy. Oral ulcers associated with Behcet's Disease (Initial): Diagnosis of Behcet's Disease. Patient has active oral ulcers.
<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 (PsA): Documentation of positive clinical response to therapy. Reauth (plaque psoriasis): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. Reauth (oral ulcers associated with Behcet's Disease): Documentation of positive clinical response to therapy (eg, reduction in pain from oral ulcers or reduction in number of oral ulcers).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Oxandrin (s)

## Products Affected

- oxandrolone oral tablet 10 mg, 2.5 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Promote weight gain (initial): Used as adjunctive therapy to promote weight gain AND Diagnosis of one of the following: Extensive surgery, Chronic infections, Severe trauma, Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons AND a nutritional consult was performed. Counterbalance protein catabolism (initial): Used to counterbalance protein catabolism associated with chronic corticosteroid administration. Bone pain: Diagnosis of bone pain associated with osteoporosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	bone pain: 1 month. Others (initial, reauth): 3 months
<b>Other Criteria</b>	All diagnoses except bone pain (reauth): Documentation of a positive clinical response to therapy as evidenced by an improvement in weight gain or increase in lean body mass.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Oxbryta (s)

## Products Affected

- OXBRYTA ORAL TABLET
- OXBRYTA ORAL TABLET SOLUBLE

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 or inadequate response, contraindication, or intolerance to hydroxyurea.
<b>Age Restrictions</b>	
<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>	

# Padcev (s)

## Products Affected

- PADCEV INTRAVENOUS SOLUTION RECONSTITUTED 20 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Urothelial Cancer: Diagnosis of locally advanced or metastatic urothelial cancer. Both of the following: 1) Patient has received prior treatment with one immune checkpoint inhibitor (CPI) in the neoadjuvant/adjuvant, locally advanced or metastatic setting, unless contraindicated: a) Programmed death receptor-1 (PD-1) inhibitor [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab)] or b) Programmed death-ligand 1 (PD-L1) inhibitor [e.g., Tecentriq (atezolizumab), Imfinzi (durvalumab), Bavencio (avelumab)] and 2) Patient has received prior treatment with a platinum-based chemotherapy (e.g., carboplatin, cisplatin) in the neoadjuvant/adjuvant, locally advanced or metastatic setting.
<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>	

# Palforzia (s)

## Products Affected

- PALFORZIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Initial: Excluded if any of the following: 1) history of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease, OR 2) history of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 2 months, OR 3) severe or poorly controlled asthma
<b>Required Medical Information</b>	Initial: Diagnosis and clinical history of peanut allergy as documented by both of the following: a) a serum peanut-specific IgE level of greater than or equal to 0.35 kUA/L, AND b) a mean wheal diameter that is at least 3mm larger than the negative control on skin-prick testing for peanut. One of the following: 1) patient is 4 to 17 years of age and is in the initial dose escalation phase of therapy, OR 2) patient is 4 years of age and older and is in the up-dosing or maintenance phase of therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with an allergist/immunologist.
<b>Coverage Duration</b>	Initial, Reauth: 12 months.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Palynziq (s)

## Products Affected

- PALYNZIQ SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 10 MG/0.5ML, 2.5 MG/0.5ML, 20 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Phenylketonuria (PKU) (initial): Diagnosis of PKU. Patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management (e.g., Kuvan [sapropterin]). One of the following: Patient has had a trial and failure or intolerance to Kuvan (sapropterin) or patient is not a candidate for Kuvan (sapropterin) therapy due to the presence of two null mutations in trans. Patient will have phenylalanine blood levels measured every 4 weeks until a maintenance dose is established and periodically thereafter.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	PKU (initial, reauth): 12 months
<b>Other Criteria</b>	PKU (reauth): Documentation of a positive clinical response to therapy. Patient will continue to have phenylalanine blood levels measured periodically during therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Pegasys (s)

## Products Affected

- PEGASYS
- PEGASYS PROCLICK  
SUBCUTANEOUS SOLUTION AUTO-  
INJECTOR 180 MCG/0.5ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Criteria will be applied consistent with current AASLD-IDSA guidance.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	HepB: 48 wks. HepC: Initial: 28 wks. Reauth: 20 wks.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Pemazyre (s)

## Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Cholangiocarcinoma: 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. Myeloid/lymphoid neoplasm: Diagnosis of myeloid/lymphoid neoplasms (MLNs). Disease is relapsed or refractory. Disease has presence of a fibroblast growth factor receptor 1 (FGFR1) rearrangement.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Cholangiocarcinoma: Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist. MLNs: 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>	

# PENNSAID (s)

## Products Affected

- *diclofenac sodium external solution 1.5 %*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Osteoarthritis of the knees (initial): Diagnosis of osteoarthritis of the knees. Patient meets one of the following: 1) Treatment failure with at least two prescription strength topical or oral non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) OR 2) History of peptic ulcer disease/gastrointestinal bleed OR 3) Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	Osteoarthritis of the knees (reauth): Documentation of positive clinical response to therapy (e.g., improvement in pain symptoms of osteoarthritis).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Piqray (s)

## 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>	

# Pomalyst (s)

## 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) [e.g., Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide), Dovato (dolutegravir/lamivudine), Triumeq (dolutegravir/abacavir/lamivudine)], OR 2) Both of the following: a) Diagnosis of KS and b) Patient is HIV-negative.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All indications: Prescribed by or in consultation with an oncologist or 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>	

# Posaconazole (s)

## Products Affected

- NOXAFIL ORAL SUSPENSION
- *posaconazole*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prophylaxis of systemic fungal infections (SFI): Used as prophylaxis of invasive fungal infections caused by Aspergillus or Candida for one of the following conditions: 1) Patient is at high risk of infections due to severe immunosuppression from hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD) or hematologic malignancies with prolonged neutropenia from chemotherapy OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Treatment (Tx) of SFI: Used as treatment of systemic fungal infections caused by Aspergillus. Oropharyngeal Candidiasis (OPC): Diagnosis of OPC. One of the following: 1) Candidiasis is refractory or resistant to treatment with fluconazole OR 2) Trial and failure, contraindication, or intolerance to fluconazole.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Prophylaxis of SFI: 6 months. Tx of SFI: 3 months. OPC: 1 month.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# PRALUENT (s)

## Products Affected

- PRALUENT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>HeFH/ASCVD/Primary HLD (init): One of the following dx: A)HeFH as confirmed by one of the following: 1)Both of the following: a)Untreated/pre-treatment LDL greater than 190 mg/dL in an adult, AND b)One of the following: i) Family hx of tendinous xanthomas and/or arcus cornealis in 1st degree relative, or 2nd degree relative, ii)Hx of myocardial infarction (MI) in 1st-degree relative less than 60 years of age, iii)Family hx of MI in 2nd-degree relative less than 50 years of age, iv)Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, v)Family hx of FH in 1st- or 2nd-degree relative, or 2)Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult AND one of the following: presence of tendinous xanthoma in pt, arcus cornealis before age 45, or functional mutation in the LDL receptor, ApoB, or PCSK9 gene. OR B)ASCVD as confirmed by ACS, hx of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic origin OR C)Primary hyperlipidemia (HLD). HoFH (init): Dx of HoFH as confirmed by one of the following: 1)Gen confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2)either untreated LDL greater than 500 or treated LDL greater than 300, AND either xanthoma before 10 yo or evidence of HeFH in both parents. HeFH/ASCVD/Primary HLD (init): One of the following: set A)Both of the following: a)One of the following LDL values while on max tolerated lipid lowering regimen w/in the last 120 days: 1)LDL greater than or equal to 100 mg/dL w/ASCVD, or 2)LDL greater than or equal to 130 mg/dL w/o ASCVD. AND b)One of the following: 1)Pt has been receiving at least 12 wks of one high-intensity (HI) statin therapy (tx) and will continue to receive a HI statin [ie, atorvastatin 40-80 mg, rosuvastatin 20-40 mg] at max tolerated dose.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months
<b>Other Criteria</b>	Set A (cont, initial): OR (2) Both of the following: A) Pt unable to tolerate HI statin as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle



PA Criteria	Criteria Details
	<p>symptoms w/ CK elevations less than 10 times ULN) AND B) One of the following: a) Pt has been receiving at least 12 wks of one moderate-intensity (MI) or low-intensity (LI) statin tx and will continue to receive a MI or LI statin [ie, atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at max tolerated dose, OR b) Pt is unable to tolerate MI or LI statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN), OR (3) Pt has a labeled contraindication to all statins, OR (4) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin treatment w/ CK elevations greater than 10 times ULN on one statin tx. OR set B) Both of the following: a) One of the following LDL values while on max tolerated lipid lowering regimen w/in the last 120 days: (1) LDL b/t 70 and 99 mg/dL w/ ASCVD. (2) LDL b/t 100 and 129 mg/dL w/o ASCVD. AND b) Both of the following: (1) One of the following: i) Pt has been receiving at least 12 wks of one max-tolerated statin tx and will continue to receive a statin at max tolerated dose, ii) pt is unable to tolerate statin tx as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN, iii) Patient has a labeled contraindication to all statins, or iv) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin tx w/ CK elevations greater than 10 times ULN on one statin tx and (2) Pt has been receiving at least 12 weeks of ezetimibe (Zetia) tx as adjunct to max tolerated statin tx OR Pt has a hx of contraindication or intolerance to ezetimibe. HoFH (init): One of the following: 1)Pt is receiving other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD (reauth): Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) at max tolerated dose (unless pt has documented inability to take these medications). HoFH (reauth): One of the following: 1)Pt continues to receive other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD/HoFH (reauth): Documentation of LDL reduction while on Praluent therapy.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Promacta (s)

## Products Affected

- PROMACTA ORAL PACKET 12.5 MG, 25 MG
- PROMACTA ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of one of the following: relapsed/refractory ITP, persistent ITP, or chronic ITP. Baseline platelet count is less than 30,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. Trial and failure, intolerance, contraindication to corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C-associated thrombocytopenia. One of the following: 1) Planning to initiate and maintain interferon-based treatment, or 2) currently receiving interferon-based treatment. First-line for severe aplastic anemia (SAA): Diagnosis of SAA. Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy). Used in combination with standard immunosuppressive therapy. Patient meets at least two of the following: 1) absolute neutrophil count less than 500/mcL, 2) platelet count less than 20,000/mcL, 3) absolute reticulocyte count less than 60,000/mcL. Refractory SAA (initial): Diagnosis of refractory severe aplastic anemia. Patient has a platelet count less than 30,000/mcL. Insufficient response to immunosuppressive therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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>	ITP(init, reauth):12mo.HepC:3mo(init), 12mo(reauth).1stline SAA:6mo.RefractSAA:16wk-init, 12mo-reauth
<b>Other Criteria</b>	ITP (reauth): Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding. Hepatitis C (reauth): One of the following: 1) For patients that started treatment with eltrombopag prior to initiation of treatment with interferon, eltrombopag will be approved when both of the following are met: a) Currently on antiviral interferon therapy for treatment of chronic hepatitis C and b) Documentation that the patient reached a threshold platelet count that allows initiation of antiviral interferon therapy

PA Criteria	Criteria Details
	with eltrombopag treatment by week 9, OR 2) For patients that started treatment with eltrombopag while on concomitant treatment with interferon, eltrombopag will be approved based on the following: Currently on antiviral interferon therapy for treatment of chronic hepatitis C. Refractory SAA (reauth): Documentation of positive clinical response to therapy as evidenced by an increase in platelet count.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# PROVIGIL (s)

## Products Affected

- *modafinil*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Obstructive sleep apnea (OSA) (Initial): Diagnosis (dx) of OSA defined by one of the following: 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), and 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work disorder (SWD) (Initial): Dx of SWD confirmed by one of the following: 1) Symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia. Narcolepsy (initial): Dx of narcolepsy as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). MS Fatigue (initial): Dx of multiple sclerosis (MS). Patient is experiencing fatigue. Depression (initial): Treatment-resistant depression defined as diagnosis of major depressive disorder (MDD) or bipolar depression, AND trial and failure, contraindication, or intolerance to at least two antidepressants from different classes (eg, SSRIs, SNRIs, bupropion). Used as adjunctive therapy. Idiopathic Hypersomnia (Initial): Diagnosis of idiopathic hypersomnia as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Narcolepsy: Init, Reauth: 12 mo. All other indications: Init, Reauth: 6 mo.
<b>Other Criteria</b>	OSA, Narcolepsy, Idiopathic Hypersomnia (Reauth): Documentation of positive clinical response to modafinil therapy. SWD (Reauth):

PA Criteria	Criteria Details
	Documentation of positive clinical response to modafinil therapy. MS Fatigue (reauth): Patient is experiencing relief of fatigue with modafinil therapy. Depression (reauth): Documentation of positive clinical response to modafinil therapy. Used as adjunctive therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Pulmozyme (s)

## Products Affected

- PULMOZYME

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis (CF) (Initial, Reauth): Diagnosis of CF.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	Part B vs D determination applies. 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	

# Qinlock (s)

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**Products Affected**

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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.
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	

# QUALAQUIN (s)

## Products Affected

- *quinine sulfate oral*

PA Criteria	Criteria Details
Exclusion Criteria	Excluded if used solely for the treatment or prevention of nocturnal leg cramps.
Required Medical Information	Malaria: Diagnosis of uncomplicated malaria. One of the following: 1) Treatment in areas of chloroquine-sensitive malaria, and trial and failure, contraindication, or intolerance to chloroquine or hydroxychloroquine, OR 2) Treatment in areas of chloroquine-resistant malaria.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	7 days
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	



# RAVICTI (s)

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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 therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Reblozyl (s)

## Products Affected

- REBLOZYL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Beta Thalassemia (initial): One of the following: a) Diagnosis of beta thalassemia major AND patient requires regular red blood cell (RBC) transfusions, OR b) Diagnosis of transfusion-dependent beta thalassemia. MDS-RS, MDS/MPN-RS-T (initial): One of the following diagnoses: a) Very low-to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS), OR b) Myelodysplastic or myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T). Patient has failed an erythropoiesis stimulating agent [e.g., Epogen (epoetin alfa), Aranesp (darbepoetin)]. Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with a hematologist or oncologist.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	Beta Thalassemia (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in RBC transfusion burden). MDS-RS, MDS/MPN-RS-T (reauth): Documentation of a positive clinical response to therapy (e.g., RBC transfusion independence, improvement in hemoglobin levels).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# REGRANEX (s)

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**Products Affected**

- REGRANEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diabetic neuropathic ulcers: Patient has a lower extremity diabetic neuropathic ulcer. Treatment will be given in combination with ulcer wound care (eg, debridement, infection control, and/or pressure relief).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	5 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# REPATHA (s)

## Products Affected

- REPATHA
- REPATHA SURECLICK
- REPATHA PUSHTRONEX SYSTEM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>HeFH/ASCVD/Primary HLD (init): One of the following dx: A)HeFH as confirmed by one of the following: 1)Both of the following: a)Untreated/pre-treatment LDL greater than 190 mg/dL in an adult, AND b)One of the following: i) Family hx of tendinous xanthomas and/or arcus cornealis in 1st degree relative, or 2nd degree relative, ii)Hx of myocardial infarction (MI) in 1st-degree relative less than 60 years of age, iii)Family hx of MI in 2nd-degree relative less than 50 years of age, iv)Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, v)Family hx of FH in 1st- or 2nd-degree relative, or 2)Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult AND one of the following: presence of tendinous xanthoma in pt, arcus cornealis before age 45, or functional mutation in the LDL receptor, ApoB, or PCSK9 gene. OR B)ASCVD as confirmed by ACS, hx of MI, stable or unstable angina, coronary or other arterial revascularization, stroke,TIA, or peripheral arterial disease presumed to be of atherosclerotic origin. OR C)Primary hyperlipidemia (HLD). HoFH (init): Dx of HoFH as confirmed by one of the following: 1)Gen confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2)either untreated LDL greater than 500 or treated LDL greater than 300, AND either xanthoma before 10 yo or evidence of HeFH in both parents. HeFH/ASCVD/Primary HLD (init): One of the following: set A)Both of the following: a)One of the following LDL values while on max tolerated lipid lowering regimen w/in the last 120 days: 1)LDL greater than or equal to 100 mg/dL w/ASCVD, or 2)LDL greater than or equal to 130 mg/dL w/o ASCVD. AND b)One of the following: 1)Pt has been receiving at least 12 wks of one high-intensity (HI) statin therapy (tx) and will continue to receive a HI statin [ie, atorvastatin 40-80 mg, rosuvastatin 20-40 mg] at max tolerated dose.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months
<b>Other Criteria</b>	Set A (cont, initial): OR (2) Both of the following: A) Pt unable to tolerate HI statin as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle

PA Criteria	Criteria Details
	<p>symptoms w/ CK elevations less than 10 times ULN) AND B) One of the following: a) Pt has been receiving at least 12 wks of one moderate-intensity (MI) or low-intensity (LI) statin tx and will continue to receive a MI or LI statin [ie, atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at max tolerated dose, OR b) Pt is unable to tolerate MI or LI statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN), OR (3) Pt has a labeled contraindication to all statins, OR (4) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin treatment w/ CK elevations greater than 10 times ULN on one statin tx. OR set B) Both of the following: a) One of the following LDL values while on max tolerated lipid lowering tx w/in the last 120 days: (1) LDL b/t 70 and 99 mg/dL w/ ASCVD. (2) LDL b/t 100 and 129 mg/dL w/o ASCVD. AND b) Both of the following: (1) One of the following: i) Pt has been receiving at least 12 wks of one max-tolerated statin tx and will continue to receive a statin at max tolerated dose, ii) pt is unable to tolerate statin tx as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN, iii) Patient has a labeled contraindication to all statins, or iv) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin tx w/ CK elevations greater than 10 times ULN on one statin tx and (2) Pt has been receiving at least 12 weeks of ezetimibe (Zetia) tx as adjunct to max tolerated statin tx OR Pt has a hx of contraindication or intolerance to ezetimibe. HoFH (init): One of the following: 1)Pt is receiving other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD (reauth): Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) at max tolerated dose (unless pt has documented inability to take these medications). HoFH (reauth): One of the following: 1)Pt continues to receive other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD/HoFH (reauth): Documentation of LDL reduction while on Repatha tx.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# RETACRIT (s)

## Products Affected

- RETACRIT

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 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 receiving chemo. 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/peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 36% 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 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 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.
<b>Other Criteria</b>	Subject to ESRD review. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 months is 33% or less (Hgb is 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on

PA Criteria	Criteria Details
	<p>dialysis, OR 3) Most recent or avg Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. 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 receiving chemo. 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. Other Off-label uses (except MDS, HCV): 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>	

# Retevmo (s)

## Products Affected

- RETEVMO

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>	



# Revatio (s)

## Products Affected

- *sildenafil citrate oral tablet 20 mg*

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: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# REVATIO SUSPENSION (s)

## Products Affected

- *sildenafil citrate oral suspension reconstituted*

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. One of the following: A) Intolerance to generic Revatio tablets, OR B) Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following: age, oral-motor difficulties, or dysphagia.
<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: 6 months. 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>	

# REVCOVI (s)

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**Products Affected**

- REVCOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency (SCID).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Revlimid (s)

## Products Affected

- lenalidomide
- REVLIMID

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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>	

# Rilutek (s)

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**Products Affected**

- *riluzole*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Amyotrophic lateral sclerosis (ALS): Diagnosis of amyotrophic lateral sclerosis (ALS).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	ALS: 12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Rinvoq (s)

## Products Affected

- RINVOQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Rheumatoid arthritis (RA) (initial - 15 mg): 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)], OR for continuation of prior therapy. Psoriatic arthritis (PsA) (initial - 15 mg): Diagnosis of active PsA. Ankylosing spondylitis (AS) (initial - 15 mg): Diagnosis of active AS. RA, PsA, AS (initial - 15 mg): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Enbrel, Humira). Not used in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine). Atopic dermatitis (AD) (initial - 15 mg and 30 mg): Diagnosis of moderate to severe AD. TF/C/I to at least one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment. One of the following: 1) Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of AD (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.), OR 2) Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved AD therapies: Adbry (tralokinumab-ldrm) and Dupixent (dupilumab). Not used in combination with biologic immunomodulators (eg, Dupixent, Adbry) or other immunosuppressants (eg, azathioprine, cyclosporine). Ulcerative colitis (UC) (initial): Diagnosis of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, or corticosteroids (eg, prednisone). Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Humira). Not used in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine)</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>RA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. AD (initial): Prescribed by or in consultation with a dermatologist or allergist/immunologist. UC (initial): Prescribed by or in consultation with a gastroenterologist.</p>

PA Criteria	Criteria Details
<b>Coverage Duration</b>	RA, PsA, AS, UC, AD (initial, reauth): 12 months.
<b>Other Criteria</b>	RA, PsA, AS, UC (reauth): Documentation of positive clinical response to therapy. Not used in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine). AD (reauth): Documentation of a positive clinical response to therapy (eg, reduction in body surface area involvement, reduction in pruritus severity). Not used in combination with biologic immunomodulators (eg, Dupixent, Adbry) or other immunosuppressants (eg, azathioprine, cyclosporine).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Rozlytrek (s)

## Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

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>	



# Rubraca (s)

## 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. Both of the following: 1) Disease is recurrent, and 2) 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>	Ovarian cancer: Prescribed by or in consultation with an oncologist. Prostate cancer: 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>	

# RUCONEST (s)

## Products Affected

- RUCONEST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
Age Restrictions	
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist or an allergist
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# RUXIENCE (s)

## Products Affected

- RUXIENCE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-Hodgkin's Lymphoma (NHL): One of the following: 1) Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma. Used as first-line treatment in combination with chemotherapy, 2) Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma. Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy. Used as monotherapy for maintenance therapy, 3) Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma. One of the following: a) Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy or, b) Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy, 4) Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma OR, 5) Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma. Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens. Chronic Lymphocytic Leukemia (CLL): Diagnosis of chronic lymphocytic leukemia. Used in combination with fludarabine and cyclophosphamide. Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): Diagnosis of WG or MPA. Patient is concurrently on glucocorticoids (eg, prednisone) OR contraindication or intolerance to glucocorticoids (eg, prednisone).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	NHL, CLL: Prescribed by or in consultation with a hematologist/oncologist. WG, MPA: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist.
<b>Coverage Duration</b>	NHL, CLL: 12 months. WG, MPA: 3 months.
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ruzurgi (s)

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**Products Affected**

- RUZURGI ORAL TABLET 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Lambert-Eaton Myasthenic Syndrome (LEMS) (initial): Diagnosis of LEMS.
Age Restrictions	
Prescriber Restrictions	LEMS (initial): Prescribed by or in consultation with a neurologist.
Coverage Duration	LEMS (initial): 3 months. LEMS (reauth): 12 months.
Other Criteria	LEMS (reauth): Documentation of positive clinical response to therapy (e.g., improvement in dynamometry, Timed 25-Foot Walk Test, Timed Up and Go Test).
Indications	All Medically-accepted Indications.
Off Label Uses	

# Rydapt (s)

## 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>	

# SABRIL (s)

## Products Affected

- *vigabatrin*
- *vigadrone*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Complex Partial Seizures (CPS): For use as adjunctive therapy. Failure, contraindication, or intolerance to two formulary anticonvulsants [eg, Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)]. Infantile Spasms (IS): Diagnosis of infantile spasms.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Sandostatin (s)

## Products Affected

- *octreotide acetate injection*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Acromegaly (initial): Diagnosis of acromegaly. One of the following: A) Inadequate response to surgical resection and/or pituitary irradiation OR B) Patient is not a candidate for surgical resection or pituitary irradiation. Trial and failure, contraindication or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses.</p> <p>Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes.</p> <p>Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	<p>Acromegaly (reauth): Documentation of positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): Patient has improvement in number of diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (reauth): Patient has improvement in number of diarrhea episodes.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Scemblix (s)

## Products Affected

- SCEMBLIX ORAL TABLET 20 MG, 40 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of chronic myelogenous/myeloid leukemia (CML). Disease is Philadelphia chromosome-positive (Ph+). Disease is in chronic phase. One of the following: 1) Patient has been previously treated with two or more alternative tyrosine kinase inhibitors (TKI) [e.g., Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tassigna (nilotinib), Iclusig (ponatinib)], OR 2) Disease is T315I mutation positive.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or 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>	



# Serostim (s)

## 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 one of the following: unintentional weight loss greater than 10% over the last 12 months, or unintentional weight loss greater than 7.5% over the last 6 months, or loss of 5% body cell mass (BCM) within 6 months, or body mass index (BMI) less than 20 kg/m <sup>2</sup> , or patient is male and has BCM less than 35% of total body weight (TBW) and BMI less than 27 kg/m <sup>2</sup> , or patient is female and has BCM less than 23% of TBW and BMI less than 27 kg/m <sup>2</sup> . Nutritional evaluation since onset of wasting first occurred. Anti-retroviral tx has been optimized to decrease the viral load. Patient has not had weight loss as a result of other underlying treatable conditions (eg, depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes). Patient has tried and had an inadequate response or intolerance to dronabinol or megestrol acetate.
<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: 3 months. Reauth: 6 months
<b>Other Criteria</b>	HIV wasting (reauth): Evidence of positive response to therapy. One of the following targets or goals has not been achieved: weight, BCM, BMI. Patient is currently receiving treatment with antiretrovirals.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# SIGNIFOR (s)

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**Products Affected**

- SIGNIFOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Cushing's disease (initial): Diagnosis of Cushing's disease. One of the following: a) Pituitary surgery has not been curative for the patient or b) Patient is not a candidate for pituitary surgery.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	Cushing's disease (initial, reauth): 12 months
<b>Other Criteria</b>	Cushing's disease (reauth): Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Siklos (s)

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**Products Affected**

- SIKLOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Sickle Cell Anemia: Diagnosis of sickle cell anemia. Patient has moderate to severe painful crises. One of the following: 1) Patient is less than 18 years of age or 2) Trial and failure, or intolerance to Droxia.
Age Restrictions	Patient is 2 years of age or older
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# SILIQ (s)

## Products Affected

- SILIQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Plaque Psoriasis (initial): Diagnosis of moderate-to-severe plaque psoriasis. Trial and failure, contraindication, or intolerance to two of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Cosentyx (secukinumab), or for continuation of prior therapy.
<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 as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# SIMPONI (s)

## Products Affected

- SIMPONI

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: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: a) Either TF/C/I to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER), OR b) for continuation of prior therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: a) TF/C/I to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) for continuation of prior therapy. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. UC (initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	UC (Initial): 12 weeks. UC (Reauth): 12 months. RA, AS, PsA (Initial, reauth): 12 months
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Skyrizi (s)

## Products Affected

- SKYRIZI (150 MG DOSE)
- SKYRIZI SUBCUTANEOUS SOLUTION CARTRIDGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active CD. Will be used as a maintenance dose following the intravenous induction doses.
<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 (Initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	Plaque psoriasis, PsA, CD (Initial, reauth): 12 months
<b>Other Criteria</b>	Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. PsA, CD (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Soliris (S)

## Products Affected

- SOLIRIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Paroxysmal Nocturnal Hemoglobinuria (PNH) (initial): Diagnosis of PNH. Trial and failure, contraindication, or intolerance (TF/C/I) to Ultomiris (ravulizumab). Prescribed medication is used for induction therapy and will not exceed 600 mg weekly for the first 4 weeks OR Prescribed medication is used for maintenance therapy and will not exceed 900 mg weekly at week 5, then 900 mg every 2 weeks thereafter. Atypical Hemolytic Uremic Syndrome (aHUS) (initial): Diagnosis of aHUS. TF/C/I to Ultomiris (ravulizumab). One of the following: A) For patients 18 years of age and older, prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks OR Prescribed medication is used for maintenance therapy and will not exceed 1200 mg weekly at week 5, then 1200 mg every 2 weeks thereafter or B) For patients less than 18 years of age, dosing is in accordance with the United States (US) Food and Drug Administration (FDA) approved labeled dosing for aHUS. Generalized Myasthenia Gravis (gMG) (initial): Diagnosis of gMG. Patient is anti-acetylcholine (AChR) antibody positive. One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus), or 2) TF/C/I to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus), and TF/C/I to chronic plasmapheresis/plasma exchange (PE) or intravenous immunoglobulin (IVIG). Neuromyelitis Optica Spectrum Disorder (NMOSD) (initial): Diagnosis of NMOSD. Patient is anti-aquaporin-4 (AQP4) antibody positive. gMG, NMOSD (initial): Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks OR Prescribed medication is used for maintenance therapy and will not exceed 1200 mg weekly at week 5, then 1200 mg every 2 weeks thereafter.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>NMOSD (initial): Prescribed by or in consultation with a neurologist or ophthalmologist. gMG (initial): Prescribed by or in consultation with a neurologist.</p>
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>PNH (reauth): Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy. Prescribed medication is used for maintenance therapy and will not exceed 900 mg every 2 weeks. aHUS (reauth): Documentation of positive clinical response (e.g., increase in mean platelet counts, hematologic normalization) to therapy. One of the following: A) For patients 18 years of age and older, prescribed medication is used for maintenance therapy and will not exceed 1200 mg every 2 weeks or B) For patients less than 18 years of age, dosing is in accordance with the United States (US) Food and Drug Administration (FDA) approved labeled dosing for aHUS. gMG, NMOSD (reauth): Documentation of positive clinical response to therapy. Prescribed medication is used for maintenance therapy and will not exceed 1200 mg every 2 weeks.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Somatuline Depot (s)

## Products Affected

- SOMATULINE DEPOT  
SUBCUTANEOUS SOLUTION 120  
MG/0.5ML, 60 MG/0.2ML, 90 MG/0.3ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Acromegaly: Diagnosis of acromegaly. One of the following: A) Inadequate response to one of the following: surgery or radiotherapy, OR B) Not a candidate for one of the following: surgery or radiotherapy. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (120mg/0.5mL strength only): Diagnosis of GEP-NETs. Disease is one of the following: (a) unresectable, locally advanced or (b) metastatic. Carcinoid syndrome (120mg/0.5mL strength only): Diagnosis of carcinoid syndrome. Used to reduce the frequency of short-acting somatostatin analog rescue therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<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>	

# Somavert (s)

## Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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)
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial and reauth: 12 months
Other Criteria	Acromegaly (reauth): Patient has experienced a positive clinical response to therapy (biochemical control, decrease or normalization of IGF-1 levels).
Indications	All Medically-accepted Indications.
Off Label Uses	

# SOVALDI (s)

## Products Affected

- SOVALDI ORAL PACKET
- SOVALDI ORAL TABLET 400 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Criteria will be applied consistent with current AASLD/IDSA guideline. Diagnosis of chronic hepatitis C. All GT1 and GT4: 1) trial and failure, intolerance or contraindication (TF/I/C) (eg, safety concerns, not indicated for patient's age/weight) to both of the following: a) sofosbuvir/velpatasvir and b) Mavyret OR 2) For continuation of prior therapy. For GT2 or GT3 patients using sofosbuvir plus ribavirin: TF/I/C (eg, safety concerns, not indicated for patient's age/weight) to a) sofosbuvir/velpatasvir AND Mavyret OR b) for continuation of prior therapy.
<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 48 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>	

# Sporanox (s)

## Products Affected

- *itraconazole oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	One of the following: 1) patient has a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), OR 2) all of the following: a) patient has a diagnosis of onychomycosis confirmed by one of the following (CAPSULE ONLY): i) positive potassium hydroxide (KOH) preparation, OR ii) fungal culture, OR iii) nail biopsy, AND b) patient has had a trial and failure, contraindication, or intolerance to oral terbinafine, OR 3) both of the following (ORAL SOLUTION ONLY): a) patient has a diagnosis of candidiasis (esophageal or oropharyngeal), AND b) one of the following: i) candidiasis is refractory or resistant to treatment with fluconazole OR ii) trial and failure, contraindication, or intolerance to fluconazole.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Systemic fungal infxn:6mo.Candidiasis:1mo.Fingernail onycho:5wks.Toenail onycho, other:3mo.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Sprycel (s)

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**Products Affected**

- SPRYCEL

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

# STELARA (s)

## Products Affected

- STELARA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Plaque psoriasis (Initial): Trial and failure, contraindication (eg, safety concerns, not indicated for patient's age/weight), or intolerance to two of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Cosentyx (secukinumab), OR for continuation of prior therapy. Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial): Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER), OR for continuation of prior therapy. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active Crohn's disease. Both of the following: a) TF/C/I to one of the following: Humira or Skyrizi, and b) TF/C/I to treatment with at least one immunomodulator or corticosteroid [e.g., Purinethol (6-mercaptopurine), Imuran (azathioprine), Sandimmune (cyclosporine A), Prograf (tacrolimus), MTX (methotrexate), prednisone, methylprednisolone], OR for continuation of prior therapy. Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to two of the following, or attestation demonstrating a trial may be inappropriate: Humira (adalimumab), Rinvoq (upadacitinib), or Xeljanz/Xeljanz XR (tofacitinib), OR for continuation of prior therapy.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>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.</p>
<b>Coverage Duration</b>	All uses (Initial, reauth): 12 months
<b>Other Criteria</b>	<p>Reauth (PsA, CD, UC): Documentation of positive clinical response to therapy. Reauth (plaque psoriasis): Documentation of positive clinical</p>

PA Criteria	Criteria Details
	response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Stivarga (s)

## 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 (e.g., FOLFOX, FOLFIRI, FOLFOXIRI), AND 3) trial and failure, contraindication or intolerance to an anti-VEGF therapy (e.g., 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>	



# Sunosi (s)

## Products Affected

- SUNOSI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Narcolepsy (initial): Diagnosis (Dx) of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible). Obstructive Sleep Apnea (OSA) (initial): Dx of OSA defined by one of the following: a) 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), or b) both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND one of the following signs/symptoms are present: daytime sleepiness, nonrestorative sleep, fatigue, insomnia, waking up with breath holding/gasping/choking, habitual snoring noted by a bed partner or other observer, or observed apnea. All uses (initial): Trial and failure, contraindication or intolerance to both generic modafinil and generic armodafinil.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Narcolepsy (initial): 6 mo, (reauth): 12 mo. OSA (initial, reauth): 6 mo.
<b>Other Criteria</b>	Narcolepsy (reauth): Documentation of positive clinical response to therapy. OSA (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Sutent (s)

## Products Affected

- sunitinib malate*
- 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>	

# Sylatron (s)

## Products Affected

- SYLATRON SUBCUTANEOUS KIT 200 MCG, 300 MCG, 600 MCG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Melanoma: Diagnosis of melanoma with microscopic or gross nodal involvement AND The prescribed medication will be used as adjuvant therapy within 84 days of definitive surgical resection, including complete lymphadenectomy.
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	

# Symlin (s)

## Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: One of the following diagnoses: A) Type 1 diabetes OR B) Type 2 diabetes. Patient has failed to achieve desired glucose control despite optimal insulin therapy. Patient is taking concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: Patient has experienced an objective response to therapy demonstrated by an improvement in HbA1c from baseline. Patient is receiving concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Synribo (s)

## Products Affected

- SYNRIBO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic myelogenous leukemia (CML): Diagnosis of CML in the chronic or accelerated phase AND Patient has tried and has had resistance, relapse, inadequate response, intolerance or is contraindicated to TWO tyrosine kinase inhibitors (i.e., Gleevec [imatinib], Sprycel, Tasigna, and Bosulif, Iclusig).
Age Restrictions	
Prescriber Restrictions	CML: 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	

# SYPRINE (s)

## Products Affected

- *clovique oral capsule 250 mg*
- *trientine hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration). Trial and failure, contraindication, or intolerance to a penicillamine product (e.g., Depen, Cuprimine)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Reauth: Documentation of a positive clinical response to therapy
Indications	All Medically-accepted Indications.
Off Label Uses	

# Tabrecta (s)

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**Products Affected**

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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).
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	

# TAFAMIDIS (s)

## Products Affected

- VYNDAMAX
- 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>	



# Tafinlar (s)

## 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>	Solid tumors: Patient is 6 years of age or older.
<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. Solid tumors: Diagnosis of solid tumors. Disease is unresectable or metastatic. Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved

PA Criteria	Criteria Details
	by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Mekinist (trametinib).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Tagrisso (s)

## Products Affected

- TAGRISSO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): One of the following: A) All of the following: 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), or Vizimpro (dacomitinib). OR B) All of the following: Diagnosis of NSCLC. 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). Both of the following: 1) Patient is receiving as adjuvant therapy, and 2) Patient has had a complete surgical resection of the primary NSCLC tumor.
<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>	

# Takhzyro (s)

## Products Affected

- TAKHZYRO SUBCUTANEOUS SOLUTION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For prophylaxis against HAE attacks.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HAE (prophylaxis): Prescribed by or in consultation with an immunologist or an allergist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# TALTZ (s)

## Products Affected

- TALTZ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. Trial and failure, contraindication (eg, safety concerns, not indicated for patient's age/weight), or intolerance to two of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Cosentyx (secukinumab), OR for continuation of prior therapy. Psoriatic Arthritis (PsA) (initial): Diagnosis of active PsA. Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Rinvoq (upadacitinib), or Xeljanz/XR (tofacitinib/ER), OR for continuation of prior therapy. Ankylosing spondylitis (AS) (initial): Diagnosis of active AS. One of the following: a) Either TF/C/I to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER), or attestation demonstrating a trial may be inappropriate, OR b) for continuation of prior therapy. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) TF/C/I to one non-steroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, meloxicam, naproxen). One of the following: a) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab), OR b) for continuation of prior therapy.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. AS, nr-axSpA (initial): Prescribed by or in consultation with a rheumatologist.</p>
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	<p>PsA, AS, nr-axSpA (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the</p>

PA Criteria	Criteria Details
	body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Talzenna (s)

## Products Affected

- TALZENNA ORAL CAPSULE 0.25 MG, 0.5 MG, 0.75 MG, 1 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<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>	

# TARCEVA (s)

## Products Affected

- erlotinib hcl oral tablet 100 mg, 150 mg, 25 mg

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>	



# Targretin (s)

## Products Affected

- *bexarotene*
- TARGRETIN EXTERNAL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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]).
<b>Age Restrictions</b>	
<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>	

# Tasigna (s)

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**Products Affected**

- TASIGNA ORAL CAPSULE 150 MG, 200 MG, 50 MG

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	

# Tazverik (s)

## Products Affected

- TAZVERIK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Epithelioid sarcoma: Diagnosis of epithelioid sarcoma. Disease is one of the following: metastatic or locally advanced. Patient is not eligible for complete resection. Follicular lymphoma: Diagnosis of follicular lymphoma. Disease is one of the following: relapsed or refractory.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Epithelioid sarcoma: Prescribed by or in consultation with an oncologist. Follicular lymphoma: Prescribed by or in consultation with an oncologist or 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>	

# TECFIDERA (s)

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple Sclerosis (MS) (initial): 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>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Tegsedi (s)

## Products Affected

- TEGSEDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) (initial): Diagnosis of hATTR amyloidosis with polyneuropathy. Patient has a transthyretin (TTR) mutation (e.g., V30M). One of the following: 1) Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb, 2) Patient has baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2, OR 3) Patient has a baseline neuropathy impairment score (NIS) between 10 and 130. Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	hATTR amyloidosis (initial): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	hATTR amyloidosis (initial, reauth): 12 months
<b>Other Criteria</b>	hATTR amyloidosis (reauth): Patient has demonstrated a benefit from therapy (e.g., improved neurologic impairment, slowing of disease progression, quality of life assessment). One of the following: 1) Patient continues to have a PND score less than or equal to IIIb, 2) Patient continues to have a FAP stage of 1 or 2, OR 3) Patient continues to have a NIS between 10 and 130.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Tepmetko (s)

## 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	

# TERIPARATIDE (s)

## Products Affected

- FORTEO

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 (initial): 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.</p> <p>Glucocorticoid-Induced Osteoporosis: See Other Criteria section.</p>
<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>	<p>Glucocorticoid-Induced Osteoporosis (initial): 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 (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</p>

PA Criteria	Criteria Details
	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). All uses (initial, reauth): One of the following: 1) Treatment duration of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime, or 2) Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)].
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Testosterone (s)

## Products Affected

- ANDRODERM
- STRIANT BUCCAL 30 MG
- *testosterone transdermal gel 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 40.5 mg/2.5gm (1.62%)*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab, OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted. Gender Dysphoria (GD)/Gender Incongruence (off-label): Dx of GD/Gender Incongruence.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reauth): 12 mo. GD: 12 mo.
<b>Other Criteria</b>	HG (Reauth): 1) Follow-up total serum T level within or below the normal limits of the reporting lab, or 2) Follow-up total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Follow-up calculated free or bioavailable T level within or below the normal limits of the reporting lab, or follow-up calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	

# Thalomid (s)

## Products Affected

- THALOMID

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MM: 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>	

# Tibsovo (s)

## 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. Newly-Diagnosed AML: Diagnosis of newly-diagnosed AML. 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. Locally Advanced or Metastatic Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is locally advanced or metastatic. Patient has been previously treated. All indications: 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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Relapsed or refractory AML, Newly-Diagnosed AML: Prescribed by or in consultation with a hematologist/oncologist. Locally Advanced or Metastatic Cholangiocarcinoma: Prescribed by or in consultation with a hepatologist, gastroenterologist, 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>	

# TOPICAL RETINOID (s)

## Products Affected

- AVITA
- *tretinoin external*
- *tretinoin microsphere*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne).
Age Restrictions	PA applies to members 26 years of age or older
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# TRELSTAR (s)

## Products Affected

- TRELSTAR MIXJECT INTRAMUSCULAR  
SUSPENSION RECONSTITUTED 11.25  
MG, 22.5 MG, 3.75 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. Trial and failure, contraindication, or intolerance to any brand Lupron formulation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Tremfya (s)

## Products Affected

- TREMFYA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Cosentyx (secukinumab), OR for continuation of prior therapy. Psoriatic Arthritis (PsA) (initial): Diagnosis of active PsA. Either TF/C/I to two of the following, or attestation that a trial may be inappropriate: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Rinvoq (upadacitinib), or Xeljanz/XR (tofacitinib/ER), OR 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.
<b>Coverage Duration</b>	All Indications (Initial, reauth): 12 months
<b>Other Criteria</b>	Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Trikafta (s)

## 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 of the following mutations 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: F508del mutation OR a mutation in the CFTR gene that is responsive based on in vitro data.
<b>Age Restrictions</b>	CF (initial): 6 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 positive clinical response to 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>	



# Triptodur (s)

## Products Affected

- TRIPTODUR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range. Trial and failure or intolerance to Lupron Depot-Ped.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
<b>Coverage Duration</b>	CPP (Initial, reauth): 12 months
<b>Other Criteria</b>	CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Truseltiq (s)

## Products Affected

- TRUSELTIQ (100MG DAILY DOSE)
- TRUSELTIQ (125MG DAILY DOSE)
- TRUSELTIQ (50MG DAILY DOSE)
- TRUSELTIQ (75MG DAILY DOSE)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of cholangiocarcinoma. Disease is one of the following: a) unresectable locally advanced or b) metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has been previously treated.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hepatologist, gastroenterologist, 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>	

# Tukysa (s)

## Products Affected

- TUKYSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Breast cancer: Diagnosis of breast cancer. Disease is one of the following: a) advanced unresectable or b) metastatic. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Used in combination with trastuzumab and capecitabine. Patient has received one or more prior anti-HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine).
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	

# Turalio (s)

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**Products Affected**

- TURALIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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.
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	

# Tykerb (s)

## Products Affected

- *lapatinib ditosylate*

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: 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	

# TYSABRI (s)

## Products Affected

- TYSABRI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following disease-modifying therapies for MS: A) Aubagio (teriflunomide), B) Lemtrada (alemtuzumab), C) Mavenclad (cladribine), D) Plegridy (peginterferon beta-1a), E) Any one of the inteferon beta-1a injections (eg, Avonex), F) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), G) Any one of the glatiramer acetate injections (eg, Copaxone, Glatopa, generic glatiramer acetate), H) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), I) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya, Mayzent, Zeposia), J) Any one of the B-cell targeted therapies (eg, Ocrevus, Kesimpta), 2) Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their MS, or 3) for continuation of prior therapy. MS (init, reauth): Not used in combination with another disease-modifying therapy for MS. Crohn's Disease (CD) (initial): Diagnosis of moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes). TF/C/I to one of the following conventional therapies: corticosteroids (eg, prednisone, methylprednisolone), 6-mercaptopurine (6MP [Purinethol], azathioprine (Imuran), methotrexate (Rheumatrex, Trexall), aminosalicylates (eg, sulfasalazine, mesalamine, olsalazine). TF/C/I to a TNF-inhibitor (eg, Humira [adalimumab], infliximab). CD (initial and reauth): Not used in combination with an immunosuppressant (eg, 6-MP, azathioprine, cyclosporine, or methotrexate). Not used in combination with a TNF-inhibitor (eg, Enbrel [etanercept], Humira [adalimumab], or infliximab).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>MS (init, reauth): Prescribed by or in consultation with a neurologist. CD (initial): Prescribed by or in consultation with a gastroenterologist.</p>
<b>Coverage Duration</b>	<p>MS (init, reauth): 12mo. CD (Init): 3 mo. CD (Reauth): 6 mo if not on steroids. Otherwise, 3 mo.</p>

PA Criteria	Criteria Details
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). CD (reauth): Documentation of positive clinical response (eg, improved disease activity index) to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ubrelvy (s)

## Products Affected

- UBRELVY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Will not be used for preventive treatment of migraine. Patient has fewer than 15 headache days per month. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. Medication will not be used in combination with another oral CGRP inhibitor.
Age Restrictions	Initial: 18 years of age or older.
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
Coverage Duration	Initial: 3 months. Reauth: 12 months.
Other Criteria	Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea). Will not be used for preventive treatment of migraine. Medication will not be used in combination with another oral CGRP inhibitor.
Indications	All Medically-accepted Indications.
Off Label Uses	



# Udenyca (s)

## Products Affected

- UDENYCA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of FN (off-label): Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications. Acute radiation syndrome (ARS) (off-label): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ukoniq (s)

## Products Affected

- UKONIQ ORAL TABLET 200 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Marginal zone lymphoma (MZL): Diagnosis of MZL. Disease is one of the following: relapsed or refractory. Patient has received at least one prior anti-CD20-based regimen (e.g., bendamustine + rituximab, bendamustine + obinutuzumab, etc.). Follicular lymphoma (FL): Diagnosis of FL. Disease is one of the following: relapsed or refractory. Patient has received at least three prior lines of systemic therapy (e.g., bendamustine + rituximab, bendamustine + obinutuzumab, etc.).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MZL/FL: 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>	

# UPTRAVI (s)

## Products Affected

- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) (initial): Diagnosis of PAH AND Patient 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. One of the following: a) trial and failure, contraindication, or intolerance to a PDE5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)] or Adempas (riociguat), and trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g. Letairis (ambrisentan), Opsumit (macitentan), or Tracleer (bosentan)] OR b) For continuation of prior therapy. Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months
<b>Other Criteria</b>	PAH (Reauth): Documentation of positive clinical response to therapy. Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)].
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Valchlor (s)

## Products Affected

- VALCHLOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.].
<b>Age Restrictions</b>	
<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>	

# Varizig (s)

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**Products Affected**

- VARIZIG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Presence of contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).
<b>Required Medical Information</b>	Immune globulin is being used intramuscularly. The immune globulin is being used for passive immunization or post exposure-prophylaxis of varicella. Patient is considered a high risk individual (i.e., immune compromised, pregnant woman, newborn of mother with varicella, premature infant, and infant less than 1 year old).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months (approve one dose only)
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Venclexta (s)

## 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>	

# VENTAVIS (s)

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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): 6 months. (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>	

# Verzenio (s)

## Products Affected

- VERZENIO ORAL TABLET 100 MG, 150 MG, 200 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Advanced or Metastatic 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 male or 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. Early Breast Cancer: Diagnosis of early breast cancer at high risk of recurrence. Disease is hormone receptor (HR)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Disease is node-positive. Used as adjunctive therapy. Used in combination with one of the following endocrine therapies: 1) tamoxifen or 2) aromatase inhibitor (e.g., anastrozole, letrozole, exemestane). Patient has a Ki-67 score of greater than or equal to 20% as determined by 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>	



# Vitrakvi (s)

## 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>	

# Vizimpro (s)

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**Products Affected**

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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.
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	

# Vonjo (s)

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**Products Affected**

- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of ONE of the following: a) Primary myelofibrosis, b) Post-polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Disease is intermediate or high risk. Pre-treatment platelet count below $50 \times 10^9/L$ .
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Voriconazole Injection (s)

## Products Affected

- *voriconazole intravenous*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Invasive aspergillosis: Diagnosis of invasive aspergillosis (IA). Candidemia: Diagnosis of candidemia. One of the following: (1) patient is non-neutropenic or (2) infection is located in skin, abdomen, kidney, bladder wall, or wounds. Esophageal Candidiasis: Diagnosis of esophageal candidiasis. Mycosis: Diagnosis of fungal infection caused by <i>Scedosporium apiospermum</i> (asexual form of <i>Pseudallescheria boydii</i> ) or <i>Fusarium</i> spp. including <i>Fusarium solani</i> . For fusariosis: Patient is intolerant of, or refractory to, other therapy (e.g., liposomal amphotericin B, amphotericin B lipid complex).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 weeks
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Votrient (s)

## Products Affected

- VOTRIENT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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.).
Age Restrictions	
Prescriber Restrictions	All uses: 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	

# Vumerity (s)

## Products Affected

- VUMERITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Vyondys (s)

## Products Affected

- VYONDYS 53

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following: diagnosis of Duchenne muscular dystrophy (DMD) and documentation of a confirmed mutation of the dystrophin gene amenable to exon 53 skipping. Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly. Submission of medical records (e.g., chart notes, laboratory values) documenting the patient is ambulatory, as evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with a neurologist who has experience treating children.
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	Reauth: One of the following: 1) All of the following: Patient has been on therapy for less than 12 months, patient is tolerating therapy, dose will not exceed 30 mg/kg of body weight infused once weekly, and submission of medical records (e.g., chart notes, laboratory values) documenting the patient is maintaining ambulatory status, as evaluated via the 6MWT or NSAA OR 2) All of the following: Patient has been on therapy for 12 months or more, patient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients), patient is tolerating therapy, dose will not exceed 30 mg/kg of body weight infused once weekly, and submission of medical records (e.g., chart notes, laboratory values) documenting the patient is maintaining ambulatory status, as evaluated via the 6MWT or NSAA.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Wakix (s)

## Products Affected

- WAKIX

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). Symptoms of cataplexy are present. Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2) (initial): Diagnosis (Dx) of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible). Symptoms of cataplexy are absent. Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present. Trial and failure, contraindication or intolerance to both generic modafinil and generic armodafinil.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses (initial): Prescribed by or in consultation with one of the following: neurologist, psychiatrist, or sleep medicine specialist.
<b>Coverage Duration</b>	All uses (initial): 6 months. All uses (reauth): 12 months.
<b>Other Criteria</b>	Narcolepsy with cataplexy (Narcolepsy Type 1) (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy. Narcolepsy without cataplexy (Narcolepsy Type 2) (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Welireg (s)

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**Products Affected**

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of von Hippel-Lindau (VHL) disease. Patient requires therapy for one of the following: a) renal cell carcinoma (RCC), b) central nervous system (CNS) hemangioblastoma, or c) pancreatic neuroendocrine tumor (pNET). Patient does not require immediate surgery.
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	

# Xalkori (s)

## 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 rearrangement-positive tumor as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Anaplastic Large Cell Lymphoma (ALCL): Diagnosis of systemic ALCL. Disease is relapsed or refractory. 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). Inflammatory Myofibroblastic Tumor (IMT): Diagnosis of IMT. Disease is one of the following: a) unresectable, b) recurrent, or c) refractory. 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).
<b>Age Restrictions</b>	IMT: Patient is 1 year of age or older.
<b>Prescriber Restrictions</b>	NSCLC, IMT: Prescribed by or in consultation with an oncologist. ALCL: Prescribed by or in consultation with an oncologist or 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>	

# Xcopri (s)

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**Products Affected**

- XCOPRI

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	

# XELJANZ (s)

## Products Affected

- XELJANZ
- XELJANZ XR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Xeljanz tab/Xeljanz XR tab: 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)]. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. RA, PsA, AS (Initial): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Enbrel, Humira). Ankylosing spondylitis (AS) (Initial): Diagnosis of active AS. Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Trial and failure, contraindication or intolerance to one of the following conventional therapies: 6-mercaptopurine (Purinethol), aminosalicylate [e.g., mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)], azathioprine (Imuran), or corticosteroids (e.g., prednisone, methylprednisolone). Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Humira). All indications: Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RA, PJI, AS (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>	RA/PJI/PSA/AS (initial, reauth): 12 months. UC (init): 4 mo. UC (reauth): 12 mo.
<b>Other Criteria</b>	Xeljanz: Polyarticular course juvenile idiopathic arthritis (PJI) (Initial): Diagnosis of active polyarticular course juvenile idiopathic arthritis. One of the following: TF/C/I to Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29/F40.2 for specific phobia diagnostic criteria), OR for continuation of prior therapy. All Indications (Reauth): Documentation of positive clinical response to therapy. Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	

# Xenazine (s)

## Products Affected

- tetrabenazine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chorea associated with Huntington's Disease (HD) (Initial): Diagnosis of chorea in patients with Huntington's disease. Tardive dyskinesia (Initial): Diagnosis of 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. Tourette's syndrome (Initial): Patient has tics associated with Tourette's syndrome. Trial and failure, contraindication, or intolerance to Haldol (haloperidol).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HD (Initial): Prescribed by or in consultation with a neurologist. Tardive dyskinesia, Tourette's syndrome (Initial): Prescribed by or in consultation with neurologist or psychiatrist.
<b>Coverage Duration</b>	All uses: (initial) 3 months. (Reauth) 12 months.
<b>Other Criteria</b>	All indications (Reauth): Documentation of clinical response and benefit from therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# XERMELO (s)

## Products Affected

- XERMELO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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.
Age Restrictions	
Prescriber Restrictions	Initial: Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
Coverage Duration	Initial: 6 months. Reauth: 12 months
Other Criteria	Carcinoid syndrome diarrhea (Reauthorization): Documentation of a positive clinical response to therapy AND drug will continue to be used in combination with SSA therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Xgeva (s)

## 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) Both of the following: a) Diagnosis of multiple myeloma and b) Trial and failure, intolerance, or contraindication to one bisphosphonate (eg, zoledronic acid), OR 2) Both of the following: a) Diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) and b) 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: a) tumor is unresectable, OR b) 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) Trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (eg, pamidronate, Zometa (zoledronic acid)).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	GCTB, HCM: Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	MM/BMST, GCTB: 12 mo. HCM: 2 mo.
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Xifaxan (s)

## Products Affected

- XIFAXAN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Travelers' diarrhea (TD) (200 mg strength only): Diagnosis of travelers' diarrhea, AND one of the following: a) Trial and failure, contraindication, or intolerance to one of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin) OR b) resistance to all of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin). 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, AND trial and failure, contraindication or intolerance to an antidiarrheal agent [eg, loperamide].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	TD: 14 days. HE (prophylaxis, treatment): 12 months. IBS-D (initial, reauth): 2 weeks.
<b>Other Criteria</b>	IBS-D (reauth): Patient experiences IBS-D symptom recurrence.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Xolair (s)

## 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 [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium), OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)]. 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 (e.g., cetirizine, fexofenadine), 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 (e.g., famotidine, cimetidine), leukotriene receptor antagonist (e.g., montelukast), H1 antihistamine, hydroxyzine, doxepin. Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines. Nasal polyps (NP) (init): Diagnosis of NP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone). Used in combination with another agent for nasal polyps.</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. NP (init/reauth): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist.</p>
<b>Coverage Duration</b>	<p>Asthma, init: 6 mo, reauth: 12 mo. CIU, init: 3 mo, reauth: 6 mo. NP, init/reauth: 12 mo.</p>

PA Criteria	Criteria Details
<b>Other Criteria</b>	Asthma (reauth): Documentation of positive clinical response to therapy (e.g., Reduction in asthma exacerbations, improvement in forced expiratory volume in 1 second (FEV1), decreased use of rescue medications). Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. 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. NP (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 [NCS: 0-3 scale]). Used in combination with another agent for nasal polyps.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Xospata (s)

## Products Affected

- XOSPATA

PA Criteria	Criteria Details
<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>	

# Xpovio (s)

## Products Affected

- XPOVIO (100 MG ONCE WEEKLY)
- XPOVIO (40 MG ONCE WEEKLY)
- XPOVIO (40 MG TWICE WEEKLY) ORAL  
TABLET THERAPY PACK 20 MG, 40 MG
- XPOVIO (60 MG ONCE WEEKLY)
- 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 multiple myeloma. Patient has received at least one prior therapy (e.g., lenalidomide, bortezomib, daratumumab, pomalidomide). Used in combination with bortezomib and dexamethasone. Relapsed/Refractory Multiple Myeloma (RRMM): Diagnosis of relapsed or refractory multiple myeloma (RRMM). Patient has received at least four prior therapies (e.g., lenalidomide, bortezomib, daratumumab, pomalidomide). 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 (e.g., CHOP: cyclophosphamide, doxorubicin, vincristine, and prednisone plus rituximab).
<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>	

# Xtandi (s)

## Products Affected

- XTANDI

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

# XYREM (s)

## 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>	All uses (initial): Prescribed by or in consultation with one of the following: neurologist, psychiatrist, or sleep medicine specialist.
<b>Coverage Duration</b>	All uses (initial): 6 months. All uses (reauth): 12 months
<b>Other Criteria</b>	Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Yonsa (s)

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**Products Affected**

- YONSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prostate Cancer: Diagnosis of metastatic castration-resistant (chemical or surgical) or recurrent prostate cancer. Used in combination with methylprednisolone. Trial and failure or intolerance to Xtandi (enzalutamide).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.
Off Label Uses	



# Zavesca (s)

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**Products Affected**

- *miglustat*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Gaucher disease: Diagnosis of mild to moderate type 1 Gaucher disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Gaucher disease: 12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Zejula (s)

## Products Affected

- ZEJULA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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. Used for maintenance treatment in patients who are in a complete or partial response to first-line platinum-based chemotherapy (e.g., cisplatin, carboplatin). 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).
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	

# Zelboraf (s)

## 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>	

# Zeposia (s)

## Products Affected

- ZEPOSIA
- ZEPOSIA 7-DAY STARTER PACK
- ZEPOSIA STARTER KIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy. Ulcerative Colitis (UC) (init): Diagnosis of moderately to severely active UC. One of the following: a) Trial and failure, contraindication, or intolerance to two of the following, or attestation demonstrating a trial may be inappropriate: Humira (adalimumab), Rinvoq (upadacitinib), or Xeljanz IR (tofacitinib IR)/Xeljanz XR (tofacitinib XR), OR b) for continuation of prior therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial, reauth): Prescribed by or in consultation with a neurologist. UC (init): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	MS (initial, reauth): 12 months. UC (init): 12 weeks, (reauth): 12 months.
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). UC (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ziextenzo (s)

## Products Affected

- ZIEXTENZO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis).</p> <p>Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). Treatment of FN: Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia.</p> <p>Diagnosis of FN. Patient is at high risk for infection-associated complications.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.
<b>Other Criteria</b>	All Indications: Trial and failure or intolerance to both of the following: Neulasta/Neulasta Onpro AND Udenyca.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Zolinza (s)

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**Products Affected**

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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.).
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	

# Zorbtive (s)

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**Products Affected**

- ZORBTIVE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Short Bowel Syndrome (SBS): Diagnosis of SBS. Patient is currently receiving specialized nutritional support (eg, intravenous parenteral nutrition, fluid, and micronutrient supplements). Patient has not previously received 4 weeks of treatment with Zorbtive (somatropin).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	SBS: 4 weeks.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Zydelig (s)

## 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]).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CLL: 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>	



# Zykadia (s)

## 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	

## ZYTIGA (preferred) (s)

### Products Affected

- *abiraterone acetate*

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. Metastatic Castration-Sensitive Prostate Cancer (mCSPC): Diagnosis of metastatic high-risk castration-sensitive prostate cancer. Used in combination with prednisone.
<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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