



## **2020 Prior Authorization (PA) Criteria**

Certain drugs require prior authorization from ConnectiCare Medicare Advantage Plans. This means that your doctor must contact us to get approval before prescribing the drug to you. If your doctor does not get prior approval, the drug may not be covered.

This list also includes drugs that may be covered under Medicare Part B or Part D depending on how the drugs are used or administered. If your drug is on this list, your doctor should call us and provide information describing the use and administration of the drug so we can advise on whether the drug will be covered.

To see if your drug is on the list, refer to the index located at the end of this document for the medication you are looking for or click this [\[SEARCH\]](#) button and enter the name of your drug in the pop-up task pane.

## ACTHAR

### Products Affected

- Acthar

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Use in patients with multiple sclerosis (MS) as pulse therapy on a monthly basis. Use as maintenance therapy in patients with psoriatic arthritis, rheumatoid arthritis, or ankylosing spondylitis. Treatment of proteinuria in diabetic nephropathy.
<b>Required Medical Information</b>	MS exacerbation, rheumatic disorder exacerbation, history of corticosteroid use
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Infantile spasms, prescribed by or in consultation with a neurologist or an epileptologist. MS exacerbation, prescribed by or in consultation with a neurologist or physician that specializes in the treatment of MS. Rheumatic disorder exacerbation, prescribed by or in consultation with a rheumatologist.
<b>Coverage Duration</b>	One month
<b>Other Criteria</b>	For MS exacerbation and rheumatic disorder exacerbation, approve if the patient cannot use high-dose IV corticosteroids because IV access is not possible or if the patient has tried high-dose corticosteroids administered IV for an acute exacerbation and has experienced a severe or limiting adverse effect. (Applies only to beneficiaries enrolled in an MA-PD plan.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# ACTIMMUNE

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## Products Affected

- Actimmune

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ADEMPAS

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### Products Affected

- Adempas

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH and CTEPH- must be prescribed by or in consultation with a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Right heart catheterization is not required in pts who are currently receiving Adempas or another agent indicated for WHO group 1.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# AFINITOR

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## Products Affected

- Afinitor
- Afinitor Disperz oral tablet for suspension  
2 mg, 3 mg, 5 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an Oncologist or a Neurologist.
Coverage Duration	3 years
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## ALECENSA

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### Products Affected

- Alecensa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Confirmed ALK-positive NSCLC as detected by an FDA-approved test and prior therapies tried
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC): The patient has metastatic ALK-positive NSCLC as detected by an FDA-approved test AND The patient has progressed on or are intolerant to Xalkori (crizotinib)
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ALOSETRON

## Products Affected

- alosetron

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient has a history of any of the following conditions: Chronic or severe constipation or sequelae from constipation. Intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions. Ischemic colitis. Impaired intestinal circulation, thrombophlebitis or hypercoagulable state. Crohn's disease or ulcerative colitis. Diverticulitis. Severe hepatic impairment.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) alosetron is being prescribed for a woman AND chronic IBS symptoms have lasted at least 6 months AND gastrointestinal tract abnormalities have been ruled out AND the patient has had inadequate response to conventional therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ALUNBRIG

### Products Affected

- Alunbrig oral tablet 180 mg, 30 mg, 90 mg
- Alunbrig oral tablets, dose pack

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with other chemotherapy, patients with ALK-negative NSCLC, pediatric patients less than 18 years of age
<b>Required Medical Information</b>	Diagnosis, prior therapies, ALK-positive NSCLC confirmed by an FDA-approved test
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For NSCLC, patient has metastatic or recurrent disease that is ALK-positive as detected by an FDA-approved test AND patient has progressed on Xalkori (crizotinib)
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## AMBRISENTAN

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### Products Affected

- ambrisentan

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, idiopathic pulmonary fibrosis, including idiopathic pulmonary fibrosis patients with pulmonary hypertension (WHO group 3).
<b>Required Medical Information</b>	PAH WHO group, right heart catheterization
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Pulmonary arterial hypertension (PAH) WHO Group 1 patients not currently on ambrisentan or another agent indicated for WHO Group 1 PAH are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment. PAH WHO Group 1 patients currently on ambrisentan or another agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## ANTICONVULSANTS

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### Products Affected

- topiramate oral capsule, sprinkle
- topiramate oral capsule, sprinkle, ER 24hr
- topiramate oral tablet
- zonisamide

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

## APOKYN

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### Products Affected

- APOKYN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# APTIOM

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## Products Affected

- Aptiom

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# ARCALYST

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## Products Affected

- Arcalyst

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Riloncept should not be given in combination with biologic therapy (e.g. tumor necrosis factor (TNF) blocking agents (eg, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), anakinra, or canakinumab).
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a rheumatologist, geneticist, dermatologist or immunologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ARIKAYCE

### Products Affected

- Arikayce

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with a known hypersensitivity to any aminoglycoside. Patients with non-refractory MAC lung disease.
<b>Required Medical Information</b>	Diagnosis. Previous therapies tried. Current therapy regimen.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an infectious disease specialist or pulmonologist.
<b>Coverage Duration</b>	Initial approval: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Initial: The patient must have a diagnosis of Mycobacterium avium complex (MAC) lung disease as confirmed by a MAC-positive sputum culture AND the patient must have a positive sputum culture obtained after at least 6 months of a multi-drug regimen for MAC lung disease with a macrolide (clarithromycin or azithromycin), rifampin, and ethambutol AND Arikayce must be used as part of a multi-drug regimen and will not be approved for use as a single agent. Renewal: Patient has demonstrated response to therapy with the addition of Arikayce, defined as a negative sputum culture obtained within the last 30 days of renewal. Patients that have had negative cultures for 1 year will not be approved for continued treatment. Treatment beyond the first recertification approval (after 18 months) will require documentation of a positive sputum culture to demonstrate the need for continued treatment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ARMODAFINIL

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### Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients with known hypersensitivity to modafinil
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	17 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For excessive sleepiness due to SWSD, the patient is working at least 5 overnight shifts per month.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## AURYXIA

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### Products Affected

- Auryxia

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## BALVERSA

### Products Affected

- Balversa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies tried, presence of susceptible FGFR genetic alterations in tumor specimens as detected by an FDA-approved companion diagnostic.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For locally advanced or metastatic urothelial carcinoma, patient must have susceptible FGFR3 or FGFR2 genetic alterations AND must have progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## BANZEL

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### Products Affected

- Banzel

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# BENLYSTA

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## Products Affected

- Benlysta subcutaneous

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients with severe lupus nephritis or severe active central nervous system lupus, concurrent use with other biologics or intravenous cyclophosphamide
<b>Required Medical Information</b>	Diagnosis, patient has active, autoantibody-positive, systemic lupus erythematosus and is receiving standard therapy
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a rheumatologist, or a physician that specializes in diseases of joints and muscles
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## BEXAROTENE

### Products Affected

- bexarotene
- Targretin topical

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	Diagnosis, prior therapies tried. For female patients of child bearing potential, a negative pregnancy test will be obtained within one week prior to bexarotene gel therapy, and the pregnancy test will be repeated at monthly intervals while the patient remains on therapy.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For oral bexarotene, for a diagnosis of primary cutaneous T cell lymphoma, patient is refractory to one prior systemic therapy. For bexarotene gel, for the topical treatment of cutaneous lesions, patients have refractory or persistent CTCL (Stage IA and IB) after other therapies or have not tolerated other therapies.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## BOSULIF

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### Products Affected

- Bosulif oral tablet 100 mg, 400 mg, 500 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Bosulif is being used. For chronic myelogenous leukemia (CML), the Philadelphia chromosome (Ph) status of the leukemia must be reported. For CML, prior therapies tried must be reported to confirm resistance or intolerance.
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For Chronic phase, accelerated phase (AP), or blast phase (BP) Ph+ CML, must have resistance or intolerance to any one prior therapy for approval.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## BRAFTOVI

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### Products Affected

- Braftovi oral capsule 75 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Wild-type BRAF melanoma
<b>Required Medical Information</b>	Diagnosis, BRAF mutation status as detected by an FDA-approved test, current treatment regimen
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For melanoma, patient has unresectable or metastatic disease AND the presence of the BRAF V600E or V600K mutation as detected by an FDA-approved test AND Braftovi will be used in combination with Mektovi.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# BRIVIACT

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## Products Affected

- Briviact oral

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CABOMETYX

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## Products Affected

- Cabometyx

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, medication history
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For hepatocellular carcinoma (HCC), patient has been previously treated with sorafenib.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# CALQUENCE

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## Products Affected

- Calquence

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Previous treatment with a BTK inhibitor (e.g. Imbruvica)
<b>Required Medical Information</b>	Diagnosis, previous therapies tried
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For mantle cell lymphoma (MCL), patient has received at least one prior therapy
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CHOLBAM

## Products Affected

- Cholbam

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	baseline liver function tests
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with hepatologist, metabolic specialist, or GI
<b>Coverage Duration</b>	Initial approval for 3 months, continuation approval for 12 months
<b>Other Criteria</b>	For continuation of therapy to be approved patient must meet 2 of the 3 following lab criteria or meet 1 of the 3 follow lab criteria and have body weight increased by 10% or stable at greater than the 50th percentile. Lab criteria: (1) patient alanine aminotransferase (ALT) or aspartate aminotransferase (AST) less than 50 U/L or the baseline levels reduced by 80%, (2) patient total bilirubin level must be reduced to less than or equal to 1 mg/dL, (3) patient must not have evidence of cholestasis on liver biopsy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CINRYZE

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## Products Affected

- Cinryze

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CLOBAZAM

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## Products Affected

- clobazam

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The patient will receive clobazam for the treatment of seizures associated with Lennox-Gastaut syndrome.
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# COMETRIQ

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## Products Affected

- Cometriq

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of progressive, metastatic medullary thyroid cancer.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## COPIKTRA

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### Products Affected

- Copiktra

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, Previous therapies tried and failed.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For relapsed or refractory chronic lymphocytic leukemia (CLL), small lymphocytic leukemia (SLL), or follicular lymphoma (FL), patient must have been previously treated with two prior therapies.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## CORLANOR

### Products Affected

- Corlanor

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Previous use of a Beta-blocker, LVEF, sinus rhythm, and resting HR
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	HF in pts not currently receiving Corlanor - must all of the following 1. have LVEF of less than or equal 35 percent, 2. have sinus rhythm and a resting HR of greater than or equal to 70 BPM, AND 3. tried or is currently receiving a Beta-blocker for HF (e.g., metoprolol succinate sustained-release, carvedilol, bisoprolol, carvedilol ER) unless the patient has a contraindication to the use of beta blocker therapy (e.g., bronchospastic disease such as COPD and asthma, severe hypotension or bradycardia). HF in pts currently receiving Corlanor - had a LVEF of less than or equal to 35 percent prior to initiation of Corlanor therapy AND has tried or is currently receiving a Beta-blocker for HF unless the patient has a contraindication to the use of beta blocker therapy. For the treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, patient is in sinus rhythm with an elevated heart rate.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# COSENTYX

## Products Affected

- Cosentyx (2 Syringes)
- Cosentyx Pen (2 Pens)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	For Psoriatic Arthritis (PsA), must be prescribed by or in consultation with a dermatologist or rheumatologist. For Ankylosing Spondylitis (AS), must be prescribed by, or in consultation with, a rheumatologist. For Plaque Psoriasis (PP), must be prescribed by or in consultation with a dermatologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For PP, approve if the patient has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant. Patients who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first. For PsA, patient has tried at least one conventional systemic DMARD (eg, MTX, leflunomide, sulfasalazine) for at least 3 months, unless intolerant. Patients who have already tried a biologic are not required to step back and try a conventional DMARD first.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# COTELLIC

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## Products Affected

- Cotellic

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Presence of BRAF V600E or V600K mutation confirmed by an FDA approved test
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Unresectable or metastatic melanoma - being prescribed in combination with vemurafenib
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## CRINONE

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### Products Affected

- Crinone

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Use in patients to supplement or replace progesterone in the management of infertility.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Secondary amenorrhea, 12 months. Support of an established pregnancy, 9 months.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## DALFAMPRIDINE ER

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### Products Affected

- dalfampridine

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	MS. If prescribed by, or in consultation with, a neurologist or MS specialist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## DARAPRIM

### Products Affected

- Daraprim

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	hypersensitivity to pyrimethamine, documented megaloblastic anemia due to folate deficiency
<b>Required Medical Information</b>	Medication history, patient's immune status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Toxoplasma gondii Encephalitis, Chronic Maintenance and Prophylaxis (Primary)-prescribed by or in consultation with an infectious diseases specialist. Toxoplasmosis Treatment-prescribed by or in consultation with an infectious diseases specialist, a maternal-fetal medicine specialist, or an ophthalmologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Malaria Prophylaxis, approve if the patient has tried at least two other antimalarials (eg, atovaquone-proguanil, chloroquine phosphate, hydroxychloroquine sulfate, doxycycline, mefloquine, and primaquine). Malaria Treatment, approve if the patient has tried at least two other antimalarials (eg, Coartem [artemether-lumefantrine tablets], quinine sulfate or quinidine gluconate in combination with doxycycline, tetracycline, or clindamycin, quinine sulfate in combination with primaquine and either doxycycline or tetracycline, or the following medications as monotherapy or in combination with primaquine: atovaquone-proguanil, mefloquine, chloroquine phosphate, and hydroxychloroquine). Toxoplasma gondii Encephalitis, Chronic Maintenance, approve if the patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary), approve if the patient is immunosuppressed and the patient has tried one other recommended therapy, unless contraindicated (eg, trimethoprim-sulfamethoxazole [TMP-SMX], atovaquone).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis



## DAURISMO

### Products Affected

- Daurismo oral tablet 100 mg, 25 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Patient is newly-diagnosed with acute myeloid leukemia (AML), Medical history, Current medication regimen
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Patient has newly-diagnosed acute myeloid leukemia (AML) AND the patient is using Daurismo in combination with low-dose cytarabine AND the patient is 75 years of age or older OR according to the prescribing physician, the patient has comorbidities that preclude the use of intensive induction chemotherapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## DEMSEER

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### Products Affected

- Demser

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## DICLOFENAC GEL

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### Products Affected

- diclofenac sodium topical gel 3 %

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## DIGOXIN

### Products Affected

- Digitek oral tablet 250 mcg (0.25 mg)
- Digox oral tablet 250 mcg (0.25 mg)
- digoxin oral solution 50 mcg/mL (0.05 mg/mL)
- digoxin oral tablet 250 mcg (0.25 mg)
- Lanoxin oral tablet 250 mcg (0.25 mg)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The physician has documented the indication for the continued use of the HRM (high risk medication) with an explanation of the specific benefit established with the medication and how that benefit outweighs the potential risk, AND the physician will continue to monitor for side effects, AND the physician has documented that the patient has tried and failed digoxin 0.125mg daily or provided clinical rationale as to why the lower dose is not appropriate for the patient.
<b>Age Restrictions</b>	This prior authorization only applies to members 65 years of age or older to ensure safe use of a potentially high risk medication in the elderly population. Members under 65 years of age are not subject to the prior authorization requirements.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## DUPIXENT

### Products Affected

- Dupixent

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Treatment naive patients
<b>Required Medical Information</b>	Diagnosis, previous therapies tried and lengths of trials, percentage of body surface area affected (atopic dermatitis only), documentation confirming eosinophilic asthma phenotype or oral corticosteroid-dependent asthma (asthma only)
<b>Age Restrictions</b>	Atopic dermatitis: 12 years of age and older. Asthma: 12 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an allergist, immunologist, dermatologist, pulmonologist, or an ENT specialist.
<b>Coverage Duration</b>	Initiation 16 weeks, Continuation 12 months
<b>Other Criteria</b>	<p>For atopic dermatitis initial therapy, patient has atopic dermatitis involvement estimated to be over 10% of the body surface area (BSA), AND patient has used at least one medium, medium-high, high, and/or super-high-potency prescription topical corticosteroid for at least 30 days AND the patient has tried tacrolimus ointment for at least 30 days AND inadequate efficacy was demonstrated with topical therapy, according to the prescribing physician. For atopic dermatitis continuation, approve if the patient has responded to Dupixent therapy as determined by the prescribing physician (e.g., marked improvements in erythema, induration, papulation, edema, excoriations, and lichenification, reduced pruritus, decreased requirement for other topical or systemic therapies, reduced body surface area (BSA) affected with atopic dermatitis, or other responses observed).</p> <p>For asthma initial therapy, approve if the patient has moderate to severe asthma with an eosinophilic phenotype OR is dependent on oral corticosteroids AND Dupixent is being used as add-on maintenance treatment in patients receiving BOTH high-dose inhaled corticosteroids AND an additional controller medication (e.g. long-acting beta agonist, etc.) AND the patient has had two or more exacerbations in the previous year OR requires daily oral corticosteroids (for at least 3 days in addition to the regular maintenance therapies). For asthma continuation, approve if the</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	patient has decreased use of oral corticosteroids OR has an increase in forced expiratory volume (FEV1) from pretreatment baseline OR decreased use of inhaled corticosteroids.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## EMSAM

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### Products Affected

- Emsam

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients less than 12 years of age. Concurrent use of SSRIs, SNRIs, clomipramine, imipramine, meperidine, tramadol, methadone, pentazocine, propoxyphene, dextromethorphan, and carbamazepine. Patients with pheochromocytoma.
<b>Required Medical Information</b>	Diagnosis, previous therapies tried, current therapy regimen
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a psychiatrist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least one of the following antidepressants: bupropion, trazodone, mirtazapine, serotonin norepinephrine reuptake inhibitors (e.g., venlafaxine), selective serotonin reuptake inhibitors (e.g., citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), tricyclic or tetracyclic antidepressants (e.g., amitriptyline, nortriptyline) AND the patient is unable to swallow oral formulations due to oral or motor difficulties, dysphagia, etc.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ENBREL

### Products Affected

- Enbrel Mini
- Enbrel subcutaneous recon soln
- Enbrel subcutaneous syringe 25 mg/0.5 mL (0.5), 50 mg/mL (1 mL)
- Enbrel SureClick

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried.
<b>Age Restrictions</b>	Juvenile idiopathic arthritis (JIA)- 2 years or older. Plaque psoriasis (PP)- 4 years or older. Ankylosing spondylitis (AS), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA)- 18 years and older.
<b>Prescriber Restrictions</b>	For RA, AS, and JIA, must be prescribed by, or in consultation with, a rheumatologist. PsA, must be prescribed by, or in consultation with, a rheumatologist or dermatologist. PP, must be prescribed by, or in consultation with, a dermatologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For RA, patient has tried one conventional synthetic DMARD for at least 3 months. Patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD. For JIA, patient has tried another agent (e.g MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD) or will be starting on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or if patient has aggressive disease. For PP, approve if the patient has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant. Patients who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first. For PsA, patient has tried at least one conventional systemic DMARD (eg, MTX, leflunomide, sulfasalazine) for at least 3 months, unless intolerant. Patients who have already tried a biologic are not required to step back and try a conventional DMARD first.
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A

## ENDARI

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### Products Affected

- Endari

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	5 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a physician who specializes in SCD (e.g., a hematologist).
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For Sickle Cell Disease, patient will be using Endari to reduce acute complications.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## EPCLUSA

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### Products Affected

- Epclusa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin.
<b>Required Medical Information</b>	Documentation from the medical record of diagnosis including genotype, HCV RNA viral levels prior to treatment, history of previous HCV therapies, and presence/absence of cirrhosis. For patients with cirrhosis, cirrhosis must be documented by FibroScan, FibroTest ActiTest, liver biopsy, or radiological imaging.
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.
<b>Coverage Duration</b>	12 weeks, based on indication and current AASLD/IDSA guidance.
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# EPIDIOLEX

## Products Affected

- Epidiolex

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, Previous therapies tried
<b>Age Restrictions</b>	2 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist, specializing in seizure therapy.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For approval of Epidiolex, patient has a diagnosis of Lennox-Gastaut syndrome OR Dravet syndrome AND patient has refractory epilepsy after treatment with two prior therapies (e.g. lamotrigine, clobazam, clonazepam).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ERIVEDGE

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### Products Affected

- Erivedge

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Metastatic or Locally advanced basal cell carcinoma (LABCC), approve if the patients BCC has recurred following surgery or the patient is not a candidate for surgery or radiation therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ESBRIET

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### Products Affected

- Esbriet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination use with Nintedanib
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in combination with a pulmonologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## FARYDAK

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### Products Affected

- Farydak oral capsule 10 mg, 15 mg, 20 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	History of previous therapies tried
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist or Hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Must be used in combination with Velcade and dexamethasone AND previously tried Velcade and one immunomodulatory drug (i.e., Thalomid, Revlimid, or Pomalyst).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# FERRIPROX

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## Products Affected

- Ferriprox oral tablet 500 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## FIRAZYR

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### Products Affected

- Firazyr
- icatibant

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## FYCOMPA

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### Products Affected

- Fycompa oral suspension
- Fycompa oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a Neurologist
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# GALAFOLD

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## Products Affected

- Galafold

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of Fabry disease with an amenable galactosidase alpha gene (GLA) variant.
<b>Age Restrictions</b>	16 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, nephrologist, or a physician who specializes in the treatment of Fabry disease.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Patient has a documented diagnosis of Fabry disease with an amenable galactosidase alpha gene (GLA) variant.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# GATTEX

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## Products Affected

- Gattex 30-Vial

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# GILOTRIF

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## Products Affected

- Gilotrif

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For metastatic non-small cell lung cancer (NSCLC) documentation of non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test. For metastatic squamous NSCLC, documentation of prior platinum-based chemotherapy.
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# GRANIX

## Products Affected

- Granix

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with a history of serious allergic reactions to filgrastim or pegfilgrastim products. Administration within 24 hours preceding or following chemotherapy or radiotherapy.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	For cancer patients receiving chemotherapy, the patient must be receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen) OR the patient must be receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen AND the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (e.g., at least 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, HIV infection) OR the patient must have had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a CSF (e.g., filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment OR the patient has received chemotherapy, has febrile neutropenia, and has at least one risk factor for poor clinical outcomes or for developing infection-associated complications according to the prescribing physician (e.g., sepsis syndrome, older than 65 years, severe neutropenia - ANC less than 100 cells/mm <sup>3</sup> , neutropenia expected to be more than 10 days in duration,

<b>PA Criteria</b>	<b>Criteria Details</b>
	invasive fungal infection, other clinically documented infections, or prior episode of febrile neutropenia).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## GROWTH HORMONE

### Products Affected

- Norditropin FlexPro

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>For pediatric GHD in neonate with hypoglycemia: patient has a randomly assessed GH level less than 20 ng/mL, other causes of hypoglycemia have been ruled out, and other treatments have been ineffective. For all pediatric patients: patients have short stature or slow growth velocity and have been evaluated for other causes of growth failure. For pediatric GHD, patient has delayed bone age. For pediatric GHD without pituitary disease, patient failed 2 stimulation tests. For pediatric GHD with a pituitary or CNS disorder, patient has clinical evidence of GHD and low IGF-1/IGFBP3. For TS and SHOX patients: diagnosis confirmed by genetic testing. For CRI patients: metabolic, endocrine and nutritional abnormalities have been treated or stabilized and patient has not had a kidney transplant. For SGA: patient has a low birth weight or length for gestational age. For ISS: pediatric GHD has been ruled out with one stimulation test. For adult GHD, patient was assessed for other causes of GHD-like symptoms. For adult GHD without pituitary disease, patient failed 2 stimulation tests. For adult GHD with at least 3 pituitary hormone deficiencies (PHD) or panhypopituitarism: have a low IGF-1. For adult GHD with less than 3 PHD, low IGF-1 and failed one stimulation test. For renewal: patient has seen clinical improvement.</p>
<b>Age Restrictions</b>	For Turner syndrome and SGA, 2 years of age and older. For Noonan syndrome and SHOX, 3 years of age and older.
<b>Prescriber Restrictions</b>	Endocrinologist, Pediatric Nephrologist, Gastroenterologist, Nutritional Support Specialist, Infectious Disease Specialist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Short stature homeobox-gene (SHOX) deficiency

# HARVONI

## Products Affected

- Harvoni oral tablet 90-400 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin.
<b>Required Medical Information</b>	Documentation from the medical record of diagnosis including genotype, HCV RNA viral levels prior to treatment, history of previous HCV therapies, and presence/absence of cirrhosis. For patients with cirrhosis, cirrhosis must be documented by FibroScan, FibroTest ActiTest, liver biopsy, or radiological imaging.
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.
<b>Coverage Duration</b>	12 to 24 weeks, based on indication and current AASLD/IDSA guidance.
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# HETLIOZ

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## Products Affected

- HetlioZ

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For the indication of Non-24-Hour Sleep-Wake Disorder (Non-24), approval will only be granted for patients who are totally blind.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## HRM

### Products Affected

- butalbital-acetaminop-caff-cod
- butalbital-acetaminophen oral tablet 50-325 mg
- butalbital-acetaminophen-caff oral capsule
- butalbital-acetaminophen-caff oral tablet 50-325-40 mg
- butalbital-aspirin-caffeine oral capsule
- clemastine oral tablet 2.68 mg
- cyclobenzaprine oral tablet
- cyproheptadine
- metaxalone
- methyldopa-hydrochlorothiazide
- promethazine oral tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve when the provider has assessed the risk versus benefit in using this High Risk Medication (HRM) in the patient and has confirmed that they would still like to initiate or continue therapy
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



## HRM - BENZODIAZEPINES

### Products Affected

- alprazolam oral tablet extended release 24 hr
- lorazepam oral
- oxazepam

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Procedure-related sedation = 1mo. All other conditions = 12 months
<b>Other Criteria</b>	All medically accepted indications other than insomnia, authorize use. Insomnia, approve lorazepam or oxazepam if the patient has had a trial with two of the following: ramelteon, doxepin 3mg or 6 mg, eszopiclone, zolpidem, or zaleplon.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

## HRM BENZODIAZEPINES/ANTICONVULSANTS

### Products Affected

- clonazepam oral tablet, disintegrating
- clorazepate dipotassium
- diazepam oral concentrate
- diazepam oral solution 5 mg/5 mL (1 mg/mL)
- diazepam oral tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve when the provider has assessed the risk versus benefit in using this High Risk Medication (HRM) in the patient and has confirmed that they would still like to initiate or continue therapy
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

## HRM PD

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### Products Affected

- amitriptyline
- clomipramine
- doxepin oral
- estradiol oral
- imipramine HCl
- imipramine pamoate
- megestrol oral tablet
- perphenazine-amitriptyline
- phenobarbital
- trimipramine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve when the provider has assessed the risk versus benefit in using this High Risk Medication (HRM) in the patient and has confirmed that they would still like to initiate or continue therapy
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# HUMIRA

## Products Affected

- Humira
- Humira Pediatric Crohns Start subcutaneous syringe kit 40 mg/0.8 mL, 40 mg/0.8 mL (6 pack)
- Humira Pen
- Humira Pen Crohns-UC-HS Start
- Humira Pen Psor-Uveits-Adol HS
- Humira(CF)
- Humira(CF) Pedi Crohns Starter subcutaneous syringe kit 80 mg/0.8 mL, 80 mg/0.8 mL-40 mg/0.4 mL
- Humira(CF) Pen Crohns-UC-HS
- Humira(CF) Pen Psor-Uv-Adol HS
- HUMIRA(CF) SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.4 ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried.
<b>Age Restrictions</b>	Crohn's disease (CD)- 6 years or older. Juvenile idiopathic arthritis (JIA), Uveitis - 2 years or older. Hidradenitis suppurativa (HS) - 12 years or older. Ulcerative colitis (UC), Ankylosing spondylitis (AS), Plaque psoriasis (PP), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA) - 18 years and older.
<b>Prescriber Restrictions</b>	For RA, JIA, and AS, must be prescribed by, or in consultation with, a rheumatologist. For PsA, must be prescribed by, or in consultation with, a rheumatologist or dermatologist. For PP and HS, must be prescribed by, or in consultation with, a dermatologist. UC and CD, must be prescribed by, or in consultation with, a gastroenterologist. For UV, must be prescribed by, or in consultation with, an ophthalmologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For RA, patient has tried one conventional synthetic DMARD for at least 3 months. Patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD. For JIA, patient has tried another agent (e.g MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD) or will be starting on Humira concurrently with MTX, sulfasalazine, or leflunomide or if patient has aggressive disease. For PP, approve if the patient has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3

PA Criteria	Criteria Details
	<p>months, unless intolerant. Patients who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first. For CD, approve if patient has tried corticosteroids (CS) or if patient is currently on CS or if patient has tried one other agent for CD (eg, azathioprine, 6-mercaptopurine, MTX, infliximab, or ustekinumab) or patient had ileocolonic resection or enterocutaneous (perianal or abdominal) or rectovaginal fistulas. For UC, patient has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab or a corticosteroid such as prednisone or methylprednisolone) or was intolerant to one of these agents, or the patient has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. For HS, patient has tried one other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). For PsA, patient has tried at least one conventional systemic DMARD (eg, MTX, leflunomide, sulfasalazine) for at least 3 months, unless intolerant. Patients who have already tried a biologic are not required to step back and try a conventional DMARD first. Clinical criteria incorporated into the Humira quantity limit edit, approve additional quantity (to allow for 40 mg every week) if the patient has a diagnosis of HS OR a diagnosis of RA in patients not receiving concomitant methotrexate.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## IBRANCE

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### Products Affected

- Ibrance

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of HER2-negative, hormone receptor-positive, advanced or metastatic breast cancer
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For HER2-negative, hormone receptor-positive, advanced or metastatic breast cancer, must be used in combination with fulvestrant for progression following endocrine therapy OR in postmenopausal women or in men as initial therapy in combination with an aromatase inhibitor.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ICLUSIG

## Products Affected

- Iclusig oral tablet 15 mg, 45 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	CML T315I-positive or has tried TWO other TKIs indicated for use in CML (e.g., imatinib, Sprycel, Tassigna). ALL Ph+, T315I-positive or has tried TWO other TKIs indicated for use in Ph+ ALL (e.g. imatinib, Sprycel).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## IDHIFA

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### Products Affected

- Idhifa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Acute myeloid leukemia without the presence of the isocitrate dehydrogenase-2 (IDH2) mutation
<b>Required Medical Information</b>	Diagnosis, documentation of the presence of the isocitrate dehydrogenase-2 (IDH2) mutation in the blood or bone marrow as detected by an FDA-approved test
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For relapsed or refractory acute myeloid leukemia, patient has the isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## IMATINIB

### Products Affected

- imatinib oral tablet 100 mg, 400 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL) must be positive for the Philadelphia chromosome or BCR-ABL gene. For CML, patient meets one of the following: 1) newly diagnosed, 2) resistance or intolerance to prior therapy, or 3) recurrence after stem cell transplant. For ALL, patient meets one of the following: 1) newly diagnosed and imatinib is used in combination with chemotherapy, or 2) ALL is relapsed or refractory. For GIST, patient meets one of the following: 1) unresectable, recurrent, or metastatic disease, or 2) use of imatinib for adjuvant therapy following resection, or 3) use of imatinib for pre-operative therapy and patient is at risk for significant surgical morbidity.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

## IMBRUVICA

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### Products Affected

- Imbruvica

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For patients with mantle cell lymphoma (MCL)-history of prior treatment. For patients with marginal zone lymphoma-history of prior treatment with at least one anti-CD20-based therapy.
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist or a transplant specialist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# INGREZZA

## Products Affected

- Ingrezza
- Ingrezza Initiation Pack

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies tried
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist or psychiatrist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Patient has a diagnosis of moderate to severe tardive dyskinesia AND a history of current or previous chronic use of conventional neuroleptics, anticholinergics, toxins, substances of abuse, and other agents.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## INLYTA

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### Products Affected

- Inlyta oral tablet 1 mg, 5 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Advanced renal cell carcinoma, approve if the patient has failed at least one prior systemic therapy (eg, Torisel, Avastin, Sutent, IFN-alpha, IL-2, Votrient, Nexavar).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## INREBIC

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### Products Affected

- Inrebic

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist or hematologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF), approve if the patient has intermediate-2 or high-risk disease.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## IRESSA

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### Products Affected

- Iressa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Metastatic NSCLC - The patient has epidermal growth factor receptor (EGFR) exon 19 deletions OR has exon 21 (L858R) substitution mutations as detected by an FDA-approved test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## IVIG

### Products Affected

- Gammagard Liquid
- Gamunex-C injection solution 1 gram/10 mL (10 %)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Part B versus D determination per CMS guidance to establish if drug used for PID in pts home.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

## JAKAFI

### Products Affected

- Jakafi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Steroid-refractory acute GVHD: 12 years or older. All other indications: 18 years or older.
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist or Hematologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For polycythemia vera patients must have tried hydroxyurea
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## JUXTAPID

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### Products Affected

- Juxtapid

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# JYNARQUE

## Products Affected

- Jynarque oral tablet
- Jynarque oral tablets, sequential

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pediatric patients less than 18 years of age, patients with uncorrected abnormal blood sodium concentrations.
<b>Required Medical Information</b>	Diagnosis, Serum sodium, ALT, AST and bilirubin laboratory results
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a nephrologist or a health care provider specializing in kidney health.
<b>Coverage Duration</b>	Initiation 3 months, Continuation 6 months
<b>Other Criteria</b>	For initiation, patient has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) AND is at risk of rapidly-progressing ADPKD. Patient has baseline serum sodium within the normal range. For continuation, patient has serum sodium laboratory results within the normal range.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## KALYDECO

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### Products Affected

- Kalydeco

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients with cystic fibrosis who are homozygous for the F508del mutation in the CFTR gene.
<b>Required Medical Information</b>	CF mutation test documenting one mutation in the CFTR gene.
<b>Age Restrictions</b>	6 months of age and older for packets. 6 years of age and older for tablets.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## KEVEYIS

### Products Affected

- Keveyis

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient with history of hypersensitivity to diclorphenamide or other sulfonamides, Patient on high dose aspirin, Patient with severe pulmonary disease, Patient with hepatic insufficiency
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial therapy - 2 months, Continuing therapy - 12 months
<b>Other Criteria</b>	<p>Hyperkalemic Periodic Paralysis (HyperPP) and Related Variants: Patient has a confirmed diagnosis of primary hyperkalemic periodic paralysis by meeting at least ONE of the following criteria: Patient has had an increase from baseline in serum potassium concentration of greater than or equal to 1.5 mEq/L during a paralytic attack OR Patient has had a serum potassium concentration during a paralytic attack of greater than 5.0 mEq/L OR Patient has a family history of the condition OR Patient has a genetically confirmed skeletal muscle sodium channel mutation AND The prescribing physician has excluded other reasons for acquired hyperkalemia (e.g., drug abuse, renal and adrenal dysfunction) For Continuation of treatment a patient has decrease in the frequency or severity of paralytic attacks with treatment as determined by the prescribing physician. For Hypokalemic Periodic Paralysis (HypoPP) and Related Variants for Initiation of treatment: Patient has a confirmed diagnosis of primary hypokalemic periodic paralysis by meeting at least ONE of the following: Patient has had a serum potassium concentration of less than 3.5 mEq/L during a paralytic attack OR Patient has a family history of the condition OR Patient has a genetically confirmed skeletal muscle calcium or sodium channel mutation AND Patient has had improvements in paralysis attack symptoms with potassium intake. For Continuation of treatment: Patient has decrease</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	in the frequency or severity of paralytic attacks with treatment as determined by the prescribing physician
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# KISQALI

## Products Affected

- Kisqali Femara Co-Pack oral tablet 200 mg/day(200 mg x 1)-2.5 mg, 400 mg/day(200 mg x 2)-2.5 mg, 600 mg/day(200 mg x 3)-2.5 mg
- Kisqali oral tablet 200 mg/day (200 mg x 1), 400 mg/day (200 mg x 2), 600 mg/day (200 mg x 3)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Use as monotherapy, pregnancy
<b>Required Medical Information</b>	Hormone receptor (HR) status, human epidermal growth factor receptor 2 (HER2) status, menopause status, previous therapies tried
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For pre/perimenopausal or postmenopausal women, patient has hormone-receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer and Kisqali is being used in combination with an aromatase inhibitor as initial endocrine-based therapy. For postmenopausal women with HR-positive, HER-2 negative advanced or metastatic breast cancer, Kisqali (single agent) is being used in combination with fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## KORLYM

### Products Affected

- Korlym

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy. Patients taking simvastatin, lovastatin, and CYP3A substrates with narrow therapeutic ranges, such as cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, and tacrolimus. Concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses. Women with a history of unexplained vaginal bleeding. Women with endometrial hyperplasia with atypia or endometrial carcinoma.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## KUVAN

### Products Affected

- Kuvan oral tablet, soluble

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Blood phenylalanine (Phe) levels. Pretreatment blood phenylalanine (Phe) levels greater than 10mg/dL if the patient is older than 12 years of age or greater than 6mg/dL if less than or equal to 12 years of age. Response to a therapeutic trial (greater than or equal to a 30% reduction in blood Phe levels) is required for long-term authorization.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	2 months initial, 12 months on renewal
<b>Other Criteria</b>	Blood Phe levels should be checked after 1 week of therapy and periodically up to one month during a therapeutic trial.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## LENVIMA

### Products Affected

- Lenvima

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Differentiated Thyroid Cancer - must be locally recurrent or metastatic, progressive refractory to radioactive iodine treatment for approval. Advanced Renal Cell Carcinoma - must be used in combination with everolimus following one prior anti-angiogenic therapy (eg, Inlyta, Votrient, Sutent, Nexavar). For hepatocellular carcinoma (HCC), patient's disease is unresectable.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## LEUKINE

### Products Affected

- Leukine injection recon soln

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Administration within 24 hours preceding or following chemotherapy or radiotherapy, hypersensitivity to yeast-derived products. For prophylaxis of febrile neutropenia: use to increase the chemotherapy dose intensity or dose schedule above established regimens. For treatment of febrile neutropenia, when patient receives Neulasta during the current chemotherapy cycle. For AML only, excessive (greater than or equal to 10%) leukemic myeloid blasts in the bone marrow or peripheral blood.
<b>Required Medical Information</b>	For patients with nonmyeloid malignancies receiving myelosuppressive chemotherapy: Leukine may be used for the prevention of chemotherapy-induced febrile neutropenia if the patient experienced febrile neutropenia with a prior chemotherapy cycle OR the patient is at risk of developing febrile neutropenia. Leukine is allowable for the treatment of febrile neutropenia in patients who have received prophylaxis with Leukine (or Neupogen) OR in patients at risk for infection-related complications.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# LEUPROLIDE

## Products Affected

- Eligard
- Eligard (3 month)
- Eligard (4 month)
- Eligard (6 month)
- leuprolide subcutaneous kit
- Lupron Depot
- Lupron Depot (3 month)
- Lupron Depot (4 month)
- Lupron Depot (6 Month)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	For abnrml uterine bleeding, uterine leiomyomata,endometriosis-6 mo.All other=12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



## LIDOCAINE PATCH

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### Products Affected

- lidocaine topical adhesive patch, medicated

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For diabetic neuropathic pain: the patient must have previous use and inadequate response or intolerance to any ONE medication that is FDA-labeled for diabetic peripheral neuropathy, including (but not limited to) duloxetine and Lyrica.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Diabetic neuropathic pain, neuropathic pain associated with cancer

# LINEZOLID

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## Products Affected

- linezolid
- linezolid in dextrose 5%

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Culture and sensitivity and CBC within normal limits
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	28 days
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## LONG ACTING OPIOIDS

### Products Affected

- KADIAN ORAL CAPSULE, EXTENDED RELEASE PELLETS 200 MG
- methadone oral solution 10 mg/5 mL, 5 mg/5 mL
- methadone oral tablet 10 mg, 5 mg
- morphine oral capsule, ER multiphase 24 hr 120 mg, 30 mg, 45 mg, 60 mg, 75 mg, 90 mg
- morphine oral capsule, extend. release pellets 10 mg, 100 mg, 20 mg, 30 mg, 50 mg, 60 mg, 80 mg
- morphine oral tablet extended release 100 mg, 15 mg, 200 mg, 30 mg, 60 mg
- Nucynta ER
- oxycodone oral tablet extended release 12 hr 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 5 mg, 7.5 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute (ie, non-chronic) pain
<b>Required Medical Information</b>	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	For pain severe enough to require daily, around-the-clock, long-term opioid treatment (with no cancer diagnosis, not in long term care facility and not in hospice), approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) at least two non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), unless unavailable in the state, AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is

<b>PA Criteria</b>	<b>Criteria Details</b>
	intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# LONSURF

## Products Affected

- Lonsurf

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Treatment-naive patients
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For Metastatic colorectal cancer, patient must have previously been treated with a fluoropyrimidine (e.g., capecitabine, 5-FU)-, AND oxaliplatin-, AND irinotecan based chemotherapy AND an anti-VEGF therapy AND if RAS wild-type, an anti-EGFR therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## LORBRENA

### Products Affected

- Lorbrena

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant treatment with strong CYP3A inducers.
<b>Required Medical Information</b>	Confirmed ALK-positive NSCLC as detected by an FDA-approved test, Previous therapies tried
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC), patient has metastatic ALK-positive NSCLC as detected by an FDA-approved test AND the patient has had disease progression on Xalkori (crizotinib) and at least one other ALK inhibitor for metastatic disease OR disease progression on Alecensa (alectinib) as the first ALK inhibitor therapy for metastatic disease OR disease progression on Zykadia (ceritinib) as the first ALK inhibitor therapy for metastatic disease.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## LUCEMYRA

### Products Affected

- Lucemyra

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, Medication history.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a physician specializing in pain management or addiction psychiatry.
<b>Coverage Duration</b>	14 days
<b>Other Criteria</b>	Patient has a diagnosis of opioid dependence (physiologic dependence/tolerance) or opioid use disorder AND the patient is currently or will be undergoing abrupt opioid discontinuation AND Lucemyra is being used for mitigation of opioid withdrawal symptoms AND Lucemyra is being initiated during the period of peak withdrawal symptoms (i.e. the first 5 to 7 days following the last use of opioid) AND Lucemyra will only be used for up to 14 days.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## LYNPARZA

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### Products Affected

- Lynparza oral tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies, A deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer as detected by an FDA-approved test.
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	A documented diagnosis of advanced ovarian cancer which has been treated with at least three prior lines of chemotherapy. Maintenance treatment of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, in patients who are in a complete or partial response to platinum-based chemotherapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## MEGESTROL

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### Products Affected

- megestrol oral suspension 400 mg/10 mL (40 mg/mL), 625 mg/5 mL

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

## MEKINIST

### Products Affected

- Mekinist oral tablet 0.5 mg, 2 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	For a diagnosis of melanoma, patients who have progressed on prior BRAF-inhibitor therapy
<b>Required Medical Information</b>	Documentation of the detected BRAFV600E or BRAFV600K mutation
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For Unresectable or metastatic, malignant melanoma, with BRAF V600E or V600K mutation, Mekinist will be used as monotherapy or in combination with Tafinlar. For the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, must be used in combination with Tafinlar following complete resection (with lymph node involvement). For metastatic NSCLC with BRAF V600E mutation, must be used in combination with Tafinlar. For locally advanced or metastatic anaplastic thyroid carcinoma with BRAF V600E mutation and no satisfactory locoregional treatment options, must be used in combination with Tafinlar.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# MEKTOVI

## Products Affected

- Mektovi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, BRAF mutation status as detected by an FDA-approved test, current treatment regimen
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For melanoma, patient has unresectable or metastatic disease AND the presence of the BRAF V600E or V600K mutation as detected by an FDA-approved test AND patient has a left ventricular ejection fraction greater than or equal to 50% AND Mektovi will be used in combination with Braftovi.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# METHAMPHETAMINE

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## Products Affected

- methamphetamine

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## MODAFINIL

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### Products Affected

- modafinil

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients must be greater than or equal to 17 years of age.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Excessive sleepiness due to SWSD if the patient is working at least 5 overnight shifts per month.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



## MULPLETA

### Products Affected

- Mulpleta

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, Chart notes documenting scheduled procedure, Baseline platelet count
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a gastroenterologist, hepatologist, or hematologist.
<b>Coverage Duration</b>	14 days
<b>Other Criteria</b>	For the treatment of thrombocytopenia, approve if patient has a diagnosis of chronic liver disease AND is scheduled to undergo an invasive procedure AND the patient has a documented baseline platelet count less than 50,000 taken within the last 14 days AND Mulpleta will be initiated 8 to 14 days prior to the procedure AND the procedure will occur 2 to 8 days following the last dose of Mulpleta AND Mulpleta is not being administered to normalize platelet counts.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## NATPARA

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### Products Affected

- Natpara

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Hypoparathyroidism caused by calcium-sensing receptor mutations. Patients with acute post-surgical hypoparathyroidism.
<b>Required Medical Information</b>	Serum calcium level
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## NERLYNX

### Products Affected

- Nerlynx

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Trastuzumab treatment naive patients, HER2-negative patients, ALT greater than 5-20 times the upper limit of normal, bilirubin greater than 3-10 times the upper limit of normal, concomitant use with proton pump inhibitors.
<b>Required Medical Information</b>	Diagnosis, human epidermal growth factor receptor 2 (HER2) status, previous therapies tried, patient has early stage breast cancer
<b>Age Restrictions</b>	18 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>	Nerlynx is being used for extended adjuvant treatment of early stage breast cancer with HER2 overexpression and patient has received adjuvant treatment with trastuzumab based therapy
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## NEXAVAR

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### Products Affected

- Nexavar

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapy
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC), patient must have history of refractory radioactive iodine treatment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## NINLARO

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### Products Affected

- Ninlaro oral capsule 2.3 mg, 3 mg, 4 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Previous therapies tried and failed, baseline CBC
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For multiple myeloma, patient has received at least one prior therapy AND will be used in combination with lenalidomide and dexamethasone.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## NORTHERA

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### Products Affected

- Northera

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation from the medical record of diagnosis and prior medication history
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a neurologist
<b>Coverage Duration</b>	Initial 4 weeks, renewal 6 months
<b>Other Criteria</b>	NOH, approve if the patient meets ALL of the following criteria: a) Patient has been diagnosed with symptomatic NOH due to primary autonomic failure (Parkinsons disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, AND b) Patient has tried midodrine
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# NUBEQA

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## Products Affected

- Nubeqa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Patient has a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC) AND the patient must have a history of failure, intolerance, or contraindication to Xtandi AND Erleada.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## NUEDEXTA

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### Products Affected

- Nuedexta

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# NUPLAZID

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## Products Affected

- Nuplazid oral capsule
- Nuplazid oral tablet 10 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# OCTREOTIDE

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## Products Affected

- octreotide acetate injection solution

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ODOMZO

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### Products Affected

- Odomzo

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For locally advanced basal cell carcinoma (BCC) has recurred following surgery or radiation therapy or if the patient is not a candidate for surgery and the patient is not a candidate for radiation therapy, according to the prescribing physician.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## OFEV

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### Products Affected

- Ofev

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with pirfenidone
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in combination with a pulmonologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## OPSUMIT

### Products Affected

- Opsumit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	PAH WHO group, right heart catheterization
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH - must be prescribed by or in consultation with a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Pulmonary arterial hypertension (PAH) WHO Group 1 patients not currently on Opsumit or another agent indicated for WHO Group 1 PAH are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment. PAH WHO Group 1 patients currently on Opsumit or another agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ORENCIA

### Products Affected

- Orenzia ClickJect
- Orenzia subcutaneous syringe 125 mg/mL, 50 mg/0.4 mL, 87.5 mg/0.7 mL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried.
<b>Age Restrictions</b>	Juvenile idiopathic arthritis (JIA)- 2 years or older. Psoriatic arthritis (PsA), Rheumatoid arthritis (RA)- 18 years and older. Orenzia ClickJect autoinjector- 18 years and older.
<b>Prescriber Restrictions</b>	For RA and JIA, must be prescribed by, or in consultation with, a rheumatologist. For PsA, must be prescribed by, or in consultation with, a rheumatologist or dermatologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For RA, patient has tried one conventional synthetic DMARD for at least 3 months. Patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD. For JIA, patient has tried another agent (e.g MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD) or will be starting on Orenzia concurrently with MTX, sulfasalazine, or leflunomide or if patient has aggressive disease. For PsA, patient has tried at least one conventional systemic DMARD (eg, MTX, leflunomide, sulfasalazine) for at least 3 months, unless intolerant. Patients who have already tried a biologic are not required to step back and try a conventional DMARD first.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ORILISSA

### Products Affected

- Orilissa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, Osteoporosis, Severe hepatic impairment (Child Pugh C), Concomitant use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine and gemfibrozil).
<b>Required Medical Information</b>	Diagnosis, Child Pugh score
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an OBGYN.
<b>Coverage Duration</b>	Initiation (150 mg or 200 mg): 6 months. Continuation (150 mg Only): 18 months.
<b>Other Criteria</b>	For initiation of therapy, patient has moderate to severe pain associated with endometriosis. For continuation of therapy, patient is being treated with Orilissa 150 mg and does not have the following coexisting conditions (dyspareunia, moderate hepatic impairment [Child Pugh Class B]). Maximum treatment duration 150 mg: 24 months, 200 mg: 6 months.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ORKAMBI

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### Products Affected

- Orkambi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with Kalydeco
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	CF - homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation)
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## OTEZLA

### Products Affected

- Otezla
- Otezla Starter oral tablets, dose pack 10 mg (4)-20 mg (4)-30 mg (47)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies tried.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	For Psoriatic Arthritis (PsA), must be prescribed by, or in consultation with, a dermatologist or rheumatologist. For Plaque psoriasis (PP), must be prescribed by, or in consultation with, a dermatologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For PP, approve if the patient has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant. Patients who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first. For PsA, patient has tried at least one conventional systemic DMARD (eg, MTX, leflunomide, sulfasalazine) for at least 3 months, unless intolerant. Patients who have already tried a biologic are not required to step back and try a conventional DMARD first.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# OXERVATE

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## Products Affected

- Oxervate

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies tried, the request specifies the affected eye(s) intended for treatment
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an ophthalmologist.
<b>Coverage Duration</b>	8 weeks
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# PENICILLAMINE

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## Products Affected

- Depen Titratabs
- penicillamine

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# PHENOXYBENZAMINE

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## Products Affected

- phenoxybenzamine

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## PIQRAY

### Products Affected

- Piqray oral tablet 200 mg/day (200 mg x 1), 250 mg/day (200 mg x1-50 mg x1), 300 mg/day (150 mg x 2)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of HER2-negative, hormone receptor-positive, advanced or metastatic breast cancer. Documentation of PIK3CA-mutation as detected by an FDA-approved test. Previous therapies tried. Current therapy regimen.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For the treatment of postmenopausal women, or in men, patient has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen AND Piqray is being used in combination with fulvestrant.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## POMALYST

### Products Affected

- Pomalyst

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	Diagnosis, prior therapies, for female patients of childbearing potential, pregnancy is excluded by 2 negative serum or urine pregnancy tests. For all patients, complete blood counts are monitored for hematologic toxicity while receiving Pomalyst.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist or Hematologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For multiple myeloma must be used in combination with dexamethasone and patient has received at least two prior therapies including lenalidomide and a proteasome inhibitor and has demonstrated disease progression on or within 60 days of completion of the last therapy. Male and female patients of child-bearing potential should be instructed on the importance of proper utilization of appropriate contraceptive methods for Pomalyst use. Patients should be monitored for signs and symptoms of thromboembolism.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## PRALUENT

### Products Affected

- Praluent Pen subcutaneous pen injector  
150 mg/mL, 75 mg/mL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use of Praluent with Repatha, Juxtapid or Kynamro.
<b>Required Medical Information</b>	Current LDL-C (within the past 90 days), prior therapies tried, medication adverse event history
<b>Age Restrictions</b>	18 years of age and older.
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Hyperlipidemia in pts w/ (ASCVD) apprv if the pt has a curr LDL-C lvl of grtr or eq to 70 mg/dL w/in the past 90 ds (after tx with antihyperlipidemic agnts but prior to PCSK9 inh tx such as Praluent or Repatha) AND the pt has had one of the following conds or dxs: prev MI,OR has a hx of an acute coronary syndrome, OR The pt has a dx of angina (stable or unstable) ,OR The pt has a past hx of stroke or TIA, OR The pt has PAD, The pt has undergone a coronary or other arterial revascularization procedure AND The pt has tried 1 high-intensity statin tx (i.e., atorvastatin 80 mg daily or Crestor 40 mg daily) for equal or more than 12 cont wks AND the LDL-C lvl remains equal or more than 70 mg/dL unless pt experienced statin-related rhabdomyolysis, OR the pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c. AND If pt able to tolerate statins cont to rec. the max tolerated dose of a statin while rec. Praluent tx. Heterozygous Familial Hypercholesterolemia apprve if the pt has a curnt LDL-C lvl eq or more than 100 mg/dL w/in the past 30 days, AND the pts dx of HeFH is def as probable or definite by WHO/Dutch Lipid grp criteria OR definite by Simon-Broome Criteria OR genetic testing, AND The pt has tried 1 high-intensity statin txs (i.e., atorvastatin 80 mg daily or Crestor 40 mg daily) for equal or more than 12

PA Criteria	Criteria Details
	cont wks, AND the LDL-C lvl remains eq or more than 100 mg/dL, unless pt experienced statin-related rhabdomyolysis, OR the pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c. AND If pt able to tolerate statins cont to rec. the max tolerated dose of a statin while rec. Praluent tx.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## PREVYMIS

### Products Affected

- Prevymis oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with pimozide, ergot alkaloids (e.g. ergotamine, dihydroergotamine), concurrent use with either pitavastatin or simvastatin when letermovir is being used in combination with cyclosporine, initiation of therapy after day 28 following transplant, treatment beyond day 100 following transplant
<b>Required Medical Information</b>	Diagnosis, patient has received allogeneic hematopoietic stem cell transplant (HSCT), the HSCT procedure date, confirmation that patient is CMV-seropositive
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a physician who specializes in infectious disease, hematology, oncology or transplant specialist.
<b>Coverage Duration</b>	100 days
<b>Other Criteria</b>	For the prophylaxis of CMV infection and disease, patient is CMV seropositive, patient has received an HSCT, and therapy is being initiated between day 0 and day 28 following transplant.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## PROCRT/RETACRIT

### Products Affected

- Procrit injection solution 10,000 unit/mL, 2,000 unit/mL, 20,000 unit/mL, 3,000 unit/mL, 4,000 unit/mL, 40,000 unit/mL
- Retacrit injection solution 10,000 unit/mL, 2,000 unit/mL, 3,000 unit/mL, 4,000 unit/mL, 40,000 unit/mL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	CRF anemia in patients on and not on dialysis. Hemoglobin (Hb) of less than 10.0 g/dL to start. Hb less than or equal to 10 g/dL for adults (CKD, not on dialysis), 11 g/dL (CKD on dialysis) or 12 g/dL or less for pediatric CKD. Anemia w/myelosuppressive chemotx.pt must be currently receiving myelosuppressive chemo and Hb less than or equal to 10.0 g/dL. MDS, approve if Hb is 10 g/dL or less. Surgical pts to reduce RBC transfusions - pt is unwilling or unable to donate autologous blood prior to surgery
<b>Age Restrictions</b>	MDS anemia/HepC anemia = 18 years of age and older
<b>Prescriber Restrictions</b>	MDS anemia, prescribed by or in consultation with, a hematologist or oncologist. Hep C anemia, prescribed by or in consultation with hepatologist, gastroenterologist, hematologist or infectious disease physician who specializes in the management of hepatitis C.
<b>Coverage Duration</b>	Anemia w/myelosuppress = 4 mos. Transfus=1 mo. Other= 6mo. HIV + zidovudine = 4 mo
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

## PROLIA

### Products Affected

- Prolia

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, raloxifene, calcitonin nasal spray [Miacalcin, Fortical]), except calcium and Vitamin D.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Treatment of postmenopausal osteoporosis/Treatment of osteoporosis in men (to increase bone mass), approve if the patient meets one of the following: 1. has had inadequate response after 12 months of therapy with an oral bisphosphonate, had osteoporotic fracture while receiving an oral bisphosphonate, or intolerability to an oral bisphosphonate, OR 2. the patient cannot take an oral bisphosphonate because they cannot swallow or have difficulty swallowing, they cannot remain in an upright position, or they have a pre-existing GI medical condition, OR 3. pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR 4. the patient has severe renal impairment (eg, creatinine clearance less than 35 mL/min) or chronic kidney disease, or if the patient has multiple osteoporotic fractures. Treatment of bone loss in men at high risk for fracture receiving ADT for nonmetastatic prostate cancer, approve if the patient has prostate cancer that is not metastatic to the bone and the patient is receiving ADT (eg, leuprolide, triptorelin, goserelin) or the patient has undergone a bilateral orchiectomy. Treatment of bone loss (to increase bone mass) in patients at high risk for fracture receiving adjuvant AI therapy for breast cancer, approve if the patient has breast cancer that is not metastatic to the bone and is receiving concurrent AI therapy (eg, anastrozole, letrozole, exemestane). Treatment of glucocorticoid induced osteoporosis (GIO), approve if: pt is initiating or continuing therapy with systemic

PA Criteria	Criteria Details
	<p>glucocorticoids, AND has had an inadequate response after a trial duration of 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or patient had an osteoporotic fracture while receiving therapy or patient experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]).</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## PROMACTA

### Products Affected

- Promacta oral tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Use in the management of thrombocytopenia in myelodysplastic syndrome (MDS). Use in combination with Nplate for treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura.
<b>Required Medical Information</b>	Cause of thrombocytopenia.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Treatment of thrombocytopenia due to chronic immune (idiopathic) thrombocytopenic purpura (ITP), approve if prescribed by, or after consultation with, a hematologist. Treatment of thrombocytopenia due to HCV-related cirrhosis, approve if prescribed by, or after consultation with, either a hematologist, gastroenterologist, a hepatologist, or a physician who specializes in infectious disease.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura, approve if the patient has tried corticosteroids or IVIG or has undergone a splenectomy. Treatment of thrombocytopenia due to HCV-related cirrhosis, approve to allow for initiation of antiviral therapy if the patient has low platelet counts (eg, less than 75,000 mm <sup>3</sup> ) and the patient has chronic HCV infection and is a candidate for hepatitis C therapy .
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# QUININE

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## Products Affected

- quinine sulfate

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# RAVICTI

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## Products Affected

- Ravicti

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## REGRANEX

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### Products Affected

- Regranex

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with known neoplasm(s) at the site(s) of application. The treatment of pressure ulcers, venous stasis ulcers, diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue [Stage I or II, International Association of Enterostomal Therapy (IAET) staging classification] or ischemic diabetic ulcers.
<b>Required Medical Information</b>	Diagnosis, Wound type, Wound location, Current treatment regimen
<b>Age Restrictions</b>	16 years of age or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	20 weeks
<b>Other Criteria</b>	For lower extremity diabetic neuropathic ulcers, wounds must extend into the subcutaneous tissue or beyond and have an adequate blood supply. Treatment with Regranex must be used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## REPATHA

### Products Affected

- Repatha
- Repatha Pushtronex
- Repatha SureClick

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use of Repatha with Praluent, Juxtapid or Kynamro
<b>Required Medical Information</b>	Current LDL-C (within the past 90 days), prior therapies tried, medication adverse event history
<b>Age Restrictions</b>	ASCVD/HeFH/Primary Hyperlipidemia - 18 yo and older, HoFH 13 yo and older.
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Hyperlipidemia in pts w/ (ASCVD) apprv if the pt has a curr LDL-C lvl of grtr or eq to 70 mg/dL w/in the past 90 ds (after tx with antihyperlipidemic agnts but prior to PCSK9 inh tx such as Praluent or Repatha) AND the pt has had one of the following conds or dxs: prev MI,OR has a hx of an acute coronary syndrome, OR The pt has a dx of angina (stable or unstable) ,OR The pt has a past hx of stroke or TIA, OR The pt has PAD, The pt has undergone a coronary or other arterial revascularization procedure AND The pt has tried 1 high-intensity statin tx (i.e., atorvastatin 80 mg daily or Crestor 40 mg daily) for equal or more than 12 cont wks AND the LDL-C lvl remains equal or more than 70 mg/dL unless pt experienced statin-related rhabdomyolysis, OR the pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c. AND If pt able to tolerate statins cont to rec. the max tolerated dose of a statin while rec. Repatha tx. Heterozygous Familial Hypercholesterolemia apprve if the pt has a curnt LDL-C lvl eq or more than 100 mg/dL w/in the past 30 days, AND the pts dx of HeFH is def as probable or definite by WHO/Dutch Lipid grp criteria OR definite by Simon-Broome Criteria OR genetic testing, AND The pt has tried 1 high-intensity statin txs (i.e., atorvastatin 80 mg daily or Crestor 40 mg daily) for equal or more than 12

PA Criteria	Criteria Details
	<p>cont wks, AND the LDL-C lvl remains eq or more than 100 mg/dL, unless pt experienced statin-related rhabdomyolysis, OR the pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c. AND If pt able to tolerate statins cont to rec. the max tolerated dose of a statin while rec. Repatha tx. Primary hyperlipidemia apprve if the pt has a curnt LDL-C lvl eq or more than 100 mg/dL w/in the past 90 days, AND The pt has tried 1 high-intensity statin txs (i.e., atorvastatin 80 mg daily or Crestor 40 mg daily) for equal or more than 12 cont wks, AND the LDL-C lvl remains eq or more than 100 mg/dL, unless pt experienced statin-related rhabdomyolysis, OR the pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c. AND If pt able to tolerate statins cont to rec. the max tolerated dose of a statin while rec. Repatha tx.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## REVLIMID

### Products Affected

- Revlimid

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	For active myeloma patient meets one of the following: 1) Revlimid is used in combination with dexamethasone. 2) Revlimid is used as maintenance monotherapy following response to either stem cell transplant or primary induction therapy. For mantle cell lymphoma (MCL): Revlimid is used after 2 prior therapies, 1 of which is bortezomib. For Low or Intermediate-1 Risk myelodysplastic syndrome (MDS): for those with 5q deletion, patients should have transfusion-dependent anemia or symptomatic anemia with clinically significant cytopenias. For those with non-5q deletion MDS and symptomatic anemia, patients should have failed to respond to epoetin alfa or darbepoetin or have a pretreatment serum erythropoietin levels greater than 500 mU/mL and a low probability of response to immunosuppressive therapy. For female patients of childbearing potential, pregnancy is excluded by 2 negative serum or urine pregnancy tests. For all patients, complete blood counts are monitored for hematologic toxicity while receiving Revlimid.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Male and female patients of child-bearing potential should be instructed on the importance of proper utilization of appropriate contraceptive methods for Revlimid use. Patients should be monitored for signs and symptoms of thromboembolism.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## RUBRACA

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### Products Affected

- Rubraca

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, Prior therapies, documentation of the presence of a deleterious BRCA mutation (germline and/or somatic)
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Patient selection must be based on an FDA-approved companion diagnostic. Patient must have been treated with two or more chemotherapies prior to Rubraca. Rubraca must be used as monotherapy. For maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, patient has had a complete or partial response to platinum-based chemotherapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## RYDAPT

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### Products Affected

- Rydapt

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	For AML, use as monotherapy for the treatment of patients with AML and patients with FLT3-mutation negative disease, Pediatric patients
<b>Required Medical Information</b>	Diagnosis, for AML, patients must have the FLT3-mutation, as detected by an FDA approved test
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For AML, patient is newly diagnosed, AND Rydapt will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation therapy AND the patient has FLT3-mutation positive AML as detected by an FDA approved test AND patient is receiving Rydapt on days 8-21 of each cycle of induction with cytarabine and daunorubicin and on days 8-21 of each cycle of consolidation with high-dose cytarabine
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## SAMSCA

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### Products Affected

- Samsca oral tablet 15 mg, 30 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	30 days
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## SIGNIFOR

### Products Affected

- Signifor

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Signifor is being used.
<b>Age Restrictions</b>	Cushing's, 18 years of age and older.
<b>Prescriber Restrictions</b>	Initial course, prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	Initial therapy, approve for 3 months. Continuation therapy, approve for 12 months
<b>Other Criteria</b>	Cushing's disease, approve if according to the prescribing physician the patient is not a candidate for surgery or surgery has not been curative. Patients who have already been started on Signifor for Cushing's disease will be approved if the patient has had a response, as determined by the prescribing physician and the patient is continuing therapy to maintain response.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## SILDENAFIL - PAH

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### Products Affected

- sildenafil (Pulmonary Arterial Hypertension) oral tablet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Nitrate therapy
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension (PAH), (WHO Group 1). PAH been confirmed by right heart catheterization.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# SKYRIZI

## Products Affected

- Skyrizi subcutaneous syringe kit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies tried
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	For Plaque psoriasis (PP), must be prescribed by, or in consultation with, a dermatologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For PP, approve if the patient has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant. Patients who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first. Clinical criteria incorporated into the Skyrizi quantity limit edit, approve additional quantity (to allow for loading doses at week 0 and week 4 then every 12 weeks thereafter).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## SPRYCEL

### Products Affected

- Sprycel oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Acute lymphoblastic leukemia (ALL) and newly diagnosed chronic myeloid leukemia (CML) must be positive for the Philadelphia chromosome or BCR-ABL gene. For CML, patient meets one of the following: 1) newly diagnosed in chronic phase, 2) resistance or intolerance to imatinib, or 3) relapse after stem cell transplant. For ALL, resistance or intolerance to prior therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## STELARA

### Products Affected

- Stelara subcutaneous solution
- Stelara subcutaneous syringe 45 mg/0.5 mL, 90 mg/mL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried.
<b>Age Restrictions</b>	Plaque psoriasis (PP)- 12 years and older. Crohn's disease (CD) and Psoriatic arthritis (PsA)- 18 years and older.
<b>Prescriber Restrictions</b>	For PP, must be prescribed by, or in consultation with, a dermatologist. For PsA, must be prescribed by, or in consultation with, a rheumatologist or dermatologist. For CD, must be prescribed by, or in consultation with, a gastroenterologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For PP, approve if the patient has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant. Patients who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first. or CD, approve if patient has tried corticosteroids (CS) or if patient is currently on CS or if patient has tried one other agent for CD (eg, azathioprine, 6-mercaptopurine, MTX, infliximab, or adalimumab) or patient had ileocolonic resection or enterocutaneous (perianal or abdominal) or rectovaginal fistulas AND patient has received a single IV loading dose. Clinical criteria incorporated into the Stelara 90 mg quantity limit edit, approve additional quantity (to allow for 90 mg every 8 weeks) if the patient has a diagnosis of CD. For PsA, patient has tried at least one conventional systemic DMARD (eg, MTX, leflunomide, sulfasalazine) for at least 3 months, unless intolerant. Patients who have already tried a biologic are not required to step back and try a conventional DMARD first.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## STIVARGA

### Products Affected

- Stivarga

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Stivarga is being used. For metastatic colorectal cancer (CRC) and gastrointestinal stromal tumors (GIST), prior therapies tried. For metastatic CRC, KRAS mutation status.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For metastatic CRC with KRAS mutation, patient must have been treated with ALL of the following for approval: a fluoropyrimidine (eg, Xeloda, 5-FU), oxaliplatin, irinotecan, anti-VEGF therapy (eg, Avastin, Zaltrap). For metastatic CRC with no detected KRAS mutation (KRAS wild-type), patient must ALSO have been treated with an anti-EGFR therapy (eg, Eribitux, Vectibix). For GIST, patient must have previously been treated with imatinib and sunitinib (Sutent). For Liver carcinoma, patient must have been previously treated with sorafenib (Nexavar).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SUTENT

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## Products Affected

- Sutent

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Clinical manifestations of congestive heart failure.
<b>Required Medical Information</b>	Diagnosis, prior therapies, For gastrointestinal stromal tumor (GIST), disease progression while on an at least 30-day regimen of imatinib or intolerance to imatinib is required.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Therapy will be interrupted for serious hepatic adverse events and discontinued if serious hepatic adverse events do not resolve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## SYMDEKO

### Products Affected

- Symdeko

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination therapy with Orkambi or Kalydeco.
<b>Required Medical Information</b>	Diagnosis, Cystic Fibrosis Transmembrane Regulator (CFTR) gene mutation, Current medication regimen
<b>Age Restrictions</b>	6 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a pulmonologist or a physician who specializes in the treatment of cystic fibrosis (CF).
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For Cystic Fibrosis, patient must have at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3A G, S945L, S977F, F1052V, E831X, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G A, 3272-26A G, or 3849 + 10kbC T OR the patient has two copies of the F508del mutation.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## SYMPAZAN

### Products Affected

- Sympazan

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, current treatment regimen, previous therapies tried
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Patient has a diagnosis of Lennox-Gastaut syndrome (LGS) AND the patient is concomitantly receiving ONE other antiepileptic drug specifically for the treatment of LGS (e.g., lamotrigine, topiramate, felbamate) AND the patient has had a trial of clobazam unless contraindicated (e.g., oral or motor difficulties, dysphagia).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## TADALAFIL - BPH

### Products Affected

- tadalafil oral tablet 2.5 mg, 5 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Indication for which tadalafil is being prescribed.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed to treat the signs and symptoms of BPH and not for the treatment of erectile dysfunction (ED) and after a trial of an alpha-1 blocker (eg, doxazosin [Cardura XL], terazosin, tamsulosin [Flomax], alfuzosin extended-release [UroXatral]) or 5 alpha reductase inhibitor (eg, finasteride, dutasteride [Avodart]).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## TADALAFIL - PAH

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### Products Affected

- Alyq
- tadalafil (pulm. hypertension)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Nitrate therapy
<b>Required Medical Information</b>	PAH has been confirmed by right heart catheterization.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## TAFINLAR

### Products Affected

- Tafinlar

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, Documentation of the detected BRAF V600E or V600K mutations
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For unresectable or metastatic melanoma with BRAF V600K mutation, must be used in combination with Mekinist. For metastatic NSCLC with BRAF V600E mutation, must be used in combination with Mekinist. For locally advanced or metastatic anaplastic thyroid carcinoma with BRAF V600E mutation and no satisfactory locoregional treatment options, must be used in combination with Mekinist.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TAGRISSO

## Products Affected

- Tagrisso

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	For EGFR T790M mutation-positive NSCLC, tyrosine kinase inhibitor treatment naive patients.
<b>Required Medical Information</b>	Confirmed T790M mutation-positive OR EGFR exon 19 deletions or exon 21 (L858R) substitution mutation positive NSCLC as detected by an FDA approved test. For T790M mutation-positive NSCLC, prior therapies tried.
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	The patient has metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC as detected by an FDA approved test AND The patient has progressed on or after one of Tarceva (erlotinib tablets), Iressa (gefitinib tablets), or Gilotrif (afatinib tablets) therapy. Approve if the patient has metastatic NSCLC, whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TALZENNA

## Products Affected

- Talzenna oral capsule 0.25 mg, 1 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, documentation of the presence of germline BRCA mutation, Human epidermal growth factor receptor 2 (HER2) status.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For locally advanced or metastatic breast cancer, patient has germline BRCA mutation-positive breast cancer AND patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TARCEVA

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For 1st line therapy of locally advanced or metastatic NSCLC, patient should have a known active EGFR exon 19 deletions or exon 21 substitution mutation or amplification of the EGFR gene.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For first line treatment of locally advanced, unresectable, or metastatic pancreatic cancer, erlotinib must be used in combination with gemcitabine.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## TASIGNA

### Products Affected

- Tasigna oral capsule 150 mg, 200 mg, 50 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Long QT syndrome, uncorrected electrolyte disorders (hypokalemia, hypomagnesemia). Concomitant use with drugs known to prolong the QT interval and strong CYP3A4 inhibitors.
<b>Required Medical Information</b>	Diagnosis, prior therapies tried, Philadelphia chromosome or BCR-ABL gene status, stage of disease (accelerated, chronic).
<b>Age Restrictions</b>	1 year of age and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For adult and pediatric patients with newly diagnosed CML, approve if the patient has Philadelphia chromosome-positive CML in chronic phase. For adult patients with resistant or intolerant CML, approve if the patient has Philadelphia chromosome positive CML in chronic or accelerated phase AND patient has resistance or intolerance to prior therapy that included imatinib. For pediatric patients with resistant or intolerant CML, approve if the patient has Philadelphia chromosome positive CML in chronic phase AND patient has resistance or intolerance to prior tyrosine-kinase inhibitor therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## TEGSEDI

### Products Affected

- Tegsedi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with a platelet count below 100 x 10 <sup>9</sup> /L. Patients with a history of acute glomerulonephritis caused by Tegsedi.
<b>Required Medical Information</b>	Diagnosis. Documented transthyretin (TTR) mutation verified by genetic testing. Medical history.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	The patient has a documented diagnosis of Polyneuropathy of Hereditary Transthyretin Mediated Amyloidosis (hATTR) AND the patient has a documented transthyretin (TTR) mutation (e.g., V30M) verified by genetic testing AND the patient has symptomatic peripheral neuropathy (e.g., reduced motor strength/ coordination, impaired sensation [e.g., pain, temperature, vibration, touch]).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# TETRABENAZINE

## Products Affected

- tetrabenazine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

## THALOMID

### Products Affected

- Thalomid oral capsule 100 mg, 150 mg, 200 mg, 50 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	For active myeloma, patient meets one of the following: 1) Thalomid is used as salvage or palliative therapy. 2) Thalomid is used for newly diagnosed disease or as primary induction therapy in combination with dexamethasone or in combination with melphalan and prednisone in nontransplant candidates. 3) Thalomid is used as maintenance monotherapy following response to either stem cell transplant or primary induction therapy. For female patients of childbearing potential, pregnancy is excluded by a negative pregnancy test.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Patients are monitored for signs and symptoms of thromboembolism. Male and female patients of child-bearing potential are instructed on the importance of proper utilization of appropriate contraceptive methods.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## TIBSOVO

### Products Affected

- Tibsovo

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute myeloid leukemia without the presence of the isocitrate dehydrogenase-1 (IDH1) mutation
<b>Required Medical Information</b>	Diagnosis. For relapsed or refractory AML, previous therapies tried. Documentation of the presence of the isocitrate dehydrogenase-1 (IDH1) mutation in the blood or bone marrow as detected by an FDA-approved test.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For relapsed or refractory acute myeloid leukemia, patient has the isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test. For newly-diagnosed acute myeloid leukemia, patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test AND the patient is at least 75 years old OR according to the prescribing physician, the patient has comorbidities that preclude the use of intensive induction chemotherapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## TIRF MEDICATIONS

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### Products Affected

- fentanyl citrate buccal lozenge on a handle  
1,200 mcg, 1,600 mcg, 200 mcg, 400 mcg,  
600 mcg, 800 mcg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate). Clinical criteria incorporated into the quantity limit edits for all transmucosal fentanyl drugs require confirmation that the indication is breakthrough cancer pain (ie, FDA labeled use) prior to reviewing for quantity exception.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## TOLSURA

### Products Affected

- Tolsura

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Diagnosis of onychomycosis, patients with known hypersensitivity to itraconazole.
<b>Required Medical Information</b>	Diagnosis, previous therapies tried
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For approval of Tolsura, patient has a documented diagnosis of histoplasmosis, pulmonary or extrapulmonary blastomycosis OR pulmonary or extrapulmonary aspergillosis AND patient has had a trial and documented therapeutic failure with generic itraconazole 100 mg tablets AND if the diagnosis is aspergillosis, patient must also have had an intolerance to or treatment failure with amphotericin B.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## TRACLEER

### Products Affected

- bosentan
- Tracleer oral tablet for suspension

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	PAH WHO group, right heart catheterization
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For pulmonary arterial hypertension (PAH) WHO Group 1, patients not currently on bosentan or another agent indicated for WHO Group 1 PAH are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment. PAH WHO Group 1 patients currently on bosentan or another agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization. For CTEPH, patient must have tried Adempas, has a contraindication to Adempas, or is currently receiving bosentan for CTEPH.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chronic thromboembolic pulmonary hypertension (CTEPH)

## TRANSDERMAL FENTANYL

### Products Affected

- fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute (i.e., non-chronic) pain.
<b>Required Medical Information</b>	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For pain severe enough to require daily, around-the-clock, long-term opioid treatment (with no cancer diagnosis, not in long term care facility and not in hospice), approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), unless unavailable in the state, AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescribing physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids (including transdermal fentanyl products) require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TRETINOIN

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## Products Affected

- adapalene topical cream
- adapalene topical gel
- adapalene topical solution
- tretinoin microspheres topical gel
- tretinoin topical cream
- tretinoin topical gel 0.01 %, 0.025 %

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for cosmetic use.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A



## TRIENTINE

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### Products Affected

- trientine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous drugs tried.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For Wilson's disease, patient must have history of intolerance, failure or contraindication to penicillamine (i.e., Cuprimine or Depen).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## TYKERB

### Products Affected

- Tykerb

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Liver function tests must be monitored at baseline and every four to six weeks during therapy and as clinically indicated. In patients with severe hepatic impairment, Tykerb is used at a reduced dose.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For advanced or metastatic breast cancer with HER2 overexpression, Tykerb must be used in combination with capecitabine after previous treatment with an anthracycline, a taxane, and trastuzumab. For breast cancer in postmenopausal women with HER2 overexpression, Tykerb must be used in combination with letrozole.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## UPTRA VI

### Products Affected

- Uptravi oral tablet
- Uptravi oral tablets,dose pack

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Breast feeding mother, severe hepatic impairment (Child-Pugh Class C)
<b>Required Medical Information</b>	prior treatments
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Right heart catheterization is NOT required in pts who are currently receiving Uptravi or another agent indicated for PAH (WHO group 1). Patient must have previously tried or is currently taking at least one other agent indicated for PAH treatment (eg, sildenafil, Adcirca, Revatio, Tracleer, Letairis Opsumit, Adempas, Orenitram, Tyvaso, Ventavis, Remodulin, or epoprostenol injection).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# VALCHLOR

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## Products Affected

- Valchlor

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, Past medical history
<b>Age Restrictions</b>	18 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>	For Stage 1A and 1B mycosis fungoides-type cutaneous T-cell lymphoma, patients must have received prior skin-directed therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# VENCLEXTA

## Products Affected

- Venclexta oral tablet 10 mg, 100 mg, 50 mg
- Venclexta Starting Pack

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapy, medical history, current medication regimen
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approve. For newly diagnosed AML, approve if the patient is using Venclexta in combination with azacitidine, decitabine, or low-dose cytarabine AND the patient is 75 years of age or older OR according to the prescribing physician, the patient has comorbidities that preclude the use of intensive induction chemotherapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## VERZENIO

### Products Affected

- Verzenio

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	For monotherapy, patients without prior endocrine therapy and prior chemotherapy, In combination with fulvestrant, patients without prior endocrine therapy.
<b>Required Medical Information</b>	Estrogen receptor (ER) status, Human epidermal growth factor receptor 2 (HER2) status, Previous therapies tried
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For advanced (metastatic) breast cancer, patient has estrogen receptor-positive (ER+), HER2 negative breast cancer and will be using Verzenio in combination with an aromatase inhibitor as initial endocrine-based therapy and is postmenopausal OR patient had disease progression following endocrine therapy (e.g. anastrozole, letrozole, exemastane, tamoxifen) and will be receiving Verzenio in combination with fulvestrant OR patient had disease progression following endocrine therapy (e.g. anastrozole, letrozole, exemastane, tamoxifen) AND prior chemotherapy and will be receiving Verzenio as monotherapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## VIGABATRIN

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### Products Affected

- vigabatrin

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with or at high risk of vision loss (except patients who have blindness). Patients using other medications associated with serious adverse ophthalmic effects such as retinopathy or glaucoma.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Infantile spasms: initial 4 wks, reauth 6 mths. CPS: initial 3 mths, reauth for 12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# VIMPAT

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## Products Affected

- Vimpat oral solution
- Vimpat oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	4 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A



## VITRAKVI

### Products Affected

- Vitrakvi oral capsule 100 mg, 25 mg
- Vitrakvi oral solution

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, Presence of a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, Previous therapies tried.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	The patient has a solid tumor that has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation AND the tumor is metastatic OR surgical resection of tumor will likely result in severe morbidity AND there are no satisfactory alternative treatments OR the patient has disease progression following treatment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## VIZIMPRO

### Products Affected

- Vizimpro

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, Confirmation of epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For metastatic non-small cell lung cancer (NSCLC), patient has the presence of EGFR exon 19 deletion or exon 21 (L858R) substitution mutation as detected by an FDA-approved test AND Vizimpro is being used as first-line treatment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## VOTRIENT

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### Products Affected

- Votrient

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Alanine transaminase (ALT) greater than 3 times the upper limit of normal (ULN) and bilirubin greater than 2 times the ULN.
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For advanced soft tissue sarcoma, patients must have received prior chemotherapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## VRAYLAR

### Products Affected

- Vraylar oral capsule 1.5 mg, 3 mg, 4.5 mg, 6 mg
- Vraylar oral capsule, dose pack

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies tried
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following: lurasidone, aripiprazole, olanzapine, paliperidone, quetiapine, risperidone, or ziprasidone.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## VYNDAQEL

### Products Affected

- Vyndaqel

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with Onpattro or Tegsedi. Concurrent use of Vyndaqel and Vyndamax.
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis-approve if the patient meets all of the following: patient has genetic testing to identify a transthyretin (TTR) mutation (e.g., Val122Ile mutation, Thr60Ala mutation) or wild-type amyloidosis AND diagnosis was confirmed by one of the following (i or ii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy) OR ii. Amyloid deposits are identified on cardiac biopsy AND Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# XALKORI

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## Products Affected

- Xalkori

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For the FDA-approved indication of NSCLC for patients new to therapy, ALK status required. ROS1 Status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	NSCLC, patient must have a tumor that is ALK-positive or ROS1-positive for approval.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## XATMEP

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### Products Affected

- Xatmep

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Adult patients. For ALL, use as monotherapy. For pJIA, first-line therapy. Pregnancy.
<b>Required Medical Information</b>	Diagnosis. For pJIA, prior therapies. For ALL, concurrent use of other chemotherapy
<b>Age Restrictions</b>	Pediatric patients under 18 years of age
<b>Prescriber Restrictions</b>	For ALL, prescribed by or in consultation with an oncologist. For pJIA, prescribed by or in consultation with a rheumatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For ALL, Xatmep is used as part of a combination chemotherapy maintenance regimen. For pJIA, patient had an insufficient response or intolerance to first-line therapy, including full-dose NSAIDs. Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is for a cancer diagnosis.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## XELJANZ

### Products Affected

- Xeljanz
- Xeljanz XR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a biologic for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, etanercept, adalimumab, infliximab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil].
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	For Rheumatoid arthritis (RA), must be prescribed by or in consultation with a rheumatologist. For Psoriatic Arthritis (PsA), must be prescribed by, or in consultation with, a dermatologist or rheumatologist. For Ulcerative Colitis (UC), must be prescribed by, or in consultation with, a gastroenterologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For RA, patient has tried one conventional synthetic DMARD for at least 3 months. Patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD. For UC, approve Xeljanz (not XR) if the patient has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab or a corticosteroid such as prednisone or methylprednisolone) or was intolerant to one of these agents, or the patient has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. For PsA, patient has tried at least one conventional systemic DMARD (eg, MTX, leflunomide, sulfasalazine) for at least 3 months, unless intolerant. Patients who have already tried a biologic are not required to step back and try a conventional DMARD first.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## XERMELO

### Products Affected

- Xermelo

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Treatment naive patients, use as a monotherapy
<b>Required Medical Information</b>	Diagnosis, previous therapies tried with dates of treatment, chart notes documenting number of bowel movements per day
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist or gastroenterologist
<b>Coverage Duration</b>	Initiation - 12 weeks, Continuation - 12 months
<b>Other Criteria</b>	For initiation for carcinoid syndrome diarrhea, the patient has been on a long-acting somatostatin analog (SSA) therapy (e.g. Somatuline Depot [lanreotide for injection], octreotide injection) for at least 3 months and while on long-acting somatostatin analog therapy (prior to starting Xermelo) the patient continues to have at least four bowel movements per day and iii. Xermelo will be used in combination with a long-acting somatostatin analog therapy. For continuation for carcinoid syndrome diarrhea, the patient has experienced a decrease in the number of bowel movements per day and the patient continues to take Xermelo in combination with a long-acting somatostatin analog therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## XOLAIR

### Products Affected

- Xolair subcutaneous recon soln
- Xolair subcutaneous syringe 150 mg/mL, 75 mg/0.5 mL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Body weight greater than 150 kg.
<b>Required Medical Information</b>	For IgE-mediated allergic asthma: for patients 12 years of age and older, pre-treatment serum IgE level greater than or equal to 30 IU/mL to less than or equal to 700 IU/mL and patient's body weight. For IgE-mediated allergic asthma: for patients 6 to less than 12 years of age, pre-treatment serum IgE level greater than or equal to 30 IU/mL to less than or equal to 1,300 IU/mL and patient's body weight. For CIU - must have urticaria for more than 6 weeks, with symptoms present more than 3 days per week despite daily non-sedating H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) AND must have tried therapy with a leukotriene modifier (e.g., montelukast) with a daily non-sedating H1 antihistamine.
<b>Age Restrictions</b>	6 years of age and older
<b>Prescriber Restrictions</b>	Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Moderate to severe persistent asthma must meet all criteria patient's asthma symptoms have not been adequately controlled by concomitant use of at least 3 months of inhaled corticosteroid and a long-acting beta-agonist (LABA) or LABA alternative, if LABA contraindicated or patient has intolerance then alternatives include sustained-release theophylline or a leukotriene modifier (eg, montelukast), AND inadequate control demonstrated by hospitalization for asthma, requirement for systemic corticosteroids to control asthma exacerbation(s), or increasing need (eg, more than 4 times a day) for short-acting inhaled beta2 agonists for symptoms (excluding preventative use for exercise-induced asthma).
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A

# XOSPATA

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## Products Affected

- Xospata

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Hypersensitivity to gilteritinib or any of the excipients.
<b>Required Medical Information</b>	Diagnosis, patients must have the FLT3-mutation, as detected by an FDA approved test
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an oncologist.
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Patient has a diagnosis of relapsed or refractory acute myeloid leukemia (AML) AND the patient has FLT3-mutation positive AML as detected by an FDA-approved test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## XPOVIO

### Products Affected

- Xpovio

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis. Previous therapies tried. Current therapy regimen.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For relapsed or refractory multiple myeloma (RRMM), patient has received at least four prior therapies AND the disease is refractory to at least two proteasome inhibitors (e.g. Ninlaro), at least two immunomodulatory agents (e.g. Pomalyst, Revlimid), AND an anti-CD38 monoclonal antibody AND Xpovio will be used in combination with dexamethasone.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## XYREM

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### Products Affected

- Xyrem

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients being treated with sedative hypnotic agents, the use of alcohol, patients with succinic semialdehyde dehydrogenase deficiency
<b>Required Medical Information</b>	Diagnosis, past medical history, current medication regimens
<b>Age Restrictions</b>	7 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist or sleep specialist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For excessive daytime sleepiness (EDS) in patients with narcolepsy, patient must have a trial and failure, contraindication, or intolerance to one CNS stimulant drug (e.g., methylphenidate, dexamethylphenidate, dextroamphetamine) OR one CNS wakefulness promoting drug (e.g. armodafinil).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ZARXIO

### Products Affected

- Zarxio

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with a history of serious allergic reactions to filgrastim or pegfilgrastim products. Administration within 24 hours preceding or following chemotherapy or radiotherapy.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	For cancer patients receiving chemotherapy, the patient must be receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen) OR the patient must be receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen AND the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (e.g., at least 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, HIV infection) OR the patient must have had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a CSF (e.g., filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment OR the patient has received chemotherapy, has febrile neutropenia, and has at least one risk factor for poor clinical outcomes or for developing infection-associated complications according to the prescribing physician (e.g., sepsis syndrome, older than 65 years, severe neutropenia - ANC less than 100 cells/mm <sup>3</sup> , neutropenia expected to be more than 10 days in duration,

<b>PA Criteria</b>	<b>Criteria Details</b>
	invasive fungal infection, other clinically documented infections, or prior episode of febrile neutropenia).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



## ZEJULA

### Products Affected

- Zejula

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, confirmed complete or partial response to platinum-based chemotherapy
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For ovarian cancer, patient has had a complete or partial response to platinum-based chemotherapy AND Zejula therapy is to begin within 8 weeks after the most recent platinum-containing regimen
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ZELBORAF

### Products Affected

- Zelboraf

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For the FDA-approved indication of melanoma, for patients new to therapy, BRAFV600E status required.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist or Hematologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Melanoma, patient new to therapy must have BRAFV600E mutation for approval. For Erdheim-Chester Disease (ECD), approve if BRAF V600 mutation has been detected by an FDA approved test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ZOLINZA

### Products Affected

- Zolinza

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies tried, current therapy regimen
<b>Age Restrictions</b>	18 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>	For the treatment of cutaneous manifestations of cutaneous T-cell lymphoma, patient has progressive, persistent, or recurrent disease on or following two systemic therapies.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ZYDELIG

### Products Affected

- Zydelig

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of AST/ALT less than 20 x ULN and Bilirubin less than 10 x ULN, history of previous therapies tried
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For relapsed chronic lymphoid leukemia, Zydelig must be used in combination with rituximab. For Follicular, B-cell, relapsed Non-Hodgkin's lymphoma, patient must have previous history of at least 2 prior therapies. For relapsed small lymphocytic lymphoma, patient must have previous history of at least 2 prior therapies.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ZYKADIA

### Products Affected

- Zykadia oral capsule
- Zykadia oral tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an Oncologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For metastatic non-small cell lung cancer that is anaplastic lymphoma kinase positive, patient must have progressed or be intolerant to crizotinib for approval.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## PART B VERSUS PART D

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### Products Affected

- Abelcet intravenous suspension
- acetylcysteine solution
- acyclovir sodium intravenous solution
- albuterol sulfate inhalation solution for nebulization 0.63 mg/3 mL, 1.25 mg/3 mL, 2.5 mg /3 mL (0.083 %), 2.5 mg/0.5 mL
- AmBisome intravenous suspension for reconstitution
- amikacin injection solution 500 mg/2 mL
- Aminosyn II 10 % intravenous parenteral solution
- Aminosyn II 15 % intravenous parenteral solution
- Aminosyn-PF 10 % intravenous parenteral solution
- Aminosyn-PF 7 % Sulfite Free intravenous parenteral solution
- amphotericin B injection recon soln
- ampicillin sodium injection recon soln 1 gram, 10 gram, 125 mg
- ampicillin-sulbactam injection recon soln
- aprepitant oral capsule
- aprepitant oral capsule,dose pack
- Aralast NP intravenous recon soln 1,000 mg
- Astagraf XL oral capsule,extended release 24hr
- Azasan oral tablet
- azathioprine oral tablet
- azithromycin intravenous recon soln
- BCG vaccine, live (PF) percutaneous suspension for reconstitution
- budesonide inhalation suspension for nebulization 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL
- calcitriol oral capsule
- calcitriol oral solution
- caspofungin intravenous recon soln
- cefazolin injection recon soln 10 gram
- cefepime injection recon soln
- ceftiofloxacin intravenous recon soln
- ceftriaxone injection recon soln 1 gram, 2 gram, 250 mg, 500 mg
- cefuroxime sodium injection recon soln 750 mg
- cefuroxime sodium intravenous recon soln
- cinacalcet oral tablet 30 mg, 60 mg, 90 mg
- clindamycin phosphate injection solution
- clindamycin phosphate intravenous solution 600 mg/4 mL
- CLINIMIX 5%/D15W SULFITE FREE INTRAVENOUS PARENTERAL SOLUTION
- Clinimix 4.25%/D10W Sulfite Free intravenous parenteral solution
- Clinimix 4.25%/D5W Sulfite Free intravenous parenteral solution
- Clinimix 5%-D20W Sulfite Free intravenous parenteral solution
- Clinimix E 2.75%/D5W Sulfite Free intravenous parenteral solution
- Clinimix E 4.25%/D10W Sulfite Free intravenous parenteral solution
- Clinimix E 4.25%/D5W Sulfite Free intravenous parenteral solution
- Clinimix E 5%/D15W Sulfite Free intravenous parenteral solution
- Clinimix E 5%/D20W Sulfite Free intravenous parenteral solution
- colistin (colistimethate Na) injection recon soln
- cromolyn inhalation solution for nebulization
- cyclophosphamide oral capsule
- cyclosporine modified oral capsule
- cyclosporine modified oral solution
- cyclosporine oral capsule
- D2.5 %-0.45 % sodium chloride intravenous parenteral solution
- D5 % and 0.9 % sodium chloride intravenous parenteral solution
- D5 %-0.45 % sodium chloride intravenous parenteral solution

- Depo-Provera intramuscular suspension 400 mg/mL
- dextrose 10 % and 0.2 % NaCl intravenous parenteral solution
- dextrose 10 % in water (D10W) intravenous parenteral solution
- dextrose 5 % in water (D5W) intravenous parenteral solution
- dextrose 5%-0.2 % sod chloride intravenous parenteral solution
- dextrose 5%-0.3 % sod.chloride intravenous parenteral solution
- Dextrose With Sodium Chloride intravenous parenteral solution
- dronabinol oral capsule
- Emend oral suspension for reconstitution
- Engerix-B (PF) intramuscular syringe
- Engerix-B Pediatric (PF) intramuscular syringe
- Envarsus XR oral tablet extended release 24 hr
- Erythrocin intravenous recon soln 500 mg
- fluconazole in NaCl (iso-osm) intravenous piggyback 200 mg/100 mL, 400 mg/200 mL
- furosemide injection syringe
- Gammagard S-D (IgA < 1 mcg/mL) intravenous recon soln
- Gengraf oral capsule 100 mg, 25 mg
- Gengraf oral solution
- gentamicin injection solution 40 mg/mL
- granisetron HCl oral tablet
- heparin (porcine) injection solution
- Hepatamine 8% intravenous parenteral solution
- hydromorphone (PF) injection solution 10 (mg/mL) (5 ml), 10 mg/mL
- imipenem-cilastatin intravenous recon soln
- Increlex subcutaneous solution
- Intralipid intravenous emulsion 20 %
- Intralipid intravenous emulsion 30 %
- Intron A injection recon soln
- Intron A injection solution
- ipratropium bromide inhalation solution
- ipratropium-albuterol inhalation solution for nebulization
- levalbuterol HCl inhalation solution for nebulization 0.31 mg/3 mL, 0.63 mg/3 mL, 1.25 mg/0.5 mL, 1.25 mg/3 mL
- levocarnitine (with sugar) oral solution
- levocarnitine oral tablet
- levofloxacin intravenous solution
- magnesium sulfate injection solution
- magnesium sulfate injection syringe
- meropenem intravenous recon soln
- methotrexate sodium (PF) injection solution
- methotrexate sodium injection solution
- methotrexate sodium oral tablet
- morphine injection syringe 10 mg/mL
- morphine intravenous syringe 8 mg/mL
- moxifloxacin-sod.chloride(iso) intravenous piggyback
- mycophenolate mofetil oral capsule
- mycophenolate mofetil oral suspension for reconstitution
- mycophenolate mofetil oral tablet
- mycophenolate sodium oral tablet,delayed release (DR/EC)
- nafcillin injection recon soln
- Nebupent inhalation recon soln
- Nephramine 5.4 % intravenous parenteral solution
- Normosol-M in 5 % dextrose intravenous parenteral solution
- Normosol-R in 5 % dextrose intravenous parenteral solution
- Normosol-R pH 7.4 intravenous parenteral solution
- ondansetron HCl oral solution
- ondansetron HCl oral tablet
- ondansetron oral tablet,disintegrating
- paricalcitol oral capsule
- penicillin G potassium injection recon soln 20 million unit
- penicillin G sodium injection recon soln
- Pentam injection recon soln
- Perforomist inhalation solution for nebulization

- piperacillin-tazobactam intravenous recon soln 2.25 gram, 3.375 gram, 4.5 gram, 40.5 gram
- Plasma-Lyte 148 intravenous parenteral solution
- Plasma-Lyte A intravenous parenteral solution
- Plenamaine intravenous parenteral solution
- potassium chlorid-D5-0.45%NaCl intravenous parenteral solution
- potassium chloride in 0.9%NaCl intravenous parenteral solution 20 mEq/L, 40 mEq/L
- potassium chloride in 5 % dex intravenous parenteral solution 20 mEq/L, 40 mEq/L
- potassium chloride in LR-D5 intravenous parenteral solution 20 mEq/L
- potassium chloride-D5-0.2%NaCl intravenous parenteral solution 20 mEq/L
- potassium chloride-D5-0.3%NaCl intravenous parenteral solution 20 mEq/L
- potassium chloride-D5-0.9%NaCl intravenous parenteral solution
- Premasol 10 % intravenous parenteral solution
- Premasol 6 % intravenous parenteral solution
- Procalamine 3% intravenous parenteral solution
- Prograf oral granules in packet
- Prosol 20 % intravenous parenteral solution
- Pulmozyme inhalation solution
- Recombivax HB (PF) intramuscular suspension 10 mcg/mL, 40 mcg/mL
- Recombivax HB (PF) intramuscular syringe
- rifampin intravenous recon soln
- Sandimmune oral solution
- sirolimus oral solution
- sirolimus oral tablet
- Somatuline Depot subcutaneous syringe
- Somavert subcutaneous recon soln
- Synribo subcutaneous recon soln
- tacrolimus oral capsule
- TDVAX intramuscular suspension
- Teflaro intravenous recon soln
- testosterone cypionate intramuscular oil 100 mg/mL, 200 mg/mL (1 ML)
- testosterone enanthate intramuscular oil
- tobramycin in 0.225 % NaCl inhalation solution for nebulization
- tobramycin sulfate injection solution
- Travasol 10 % intravenous parenteral solution
- Trelstar intramuscular suspension for reconstitution
- TrophAmine 10 % intravenous parenteral solution
- Trophamine 6% intravenous parenteral solution
- Twinrix (PF) intramuscular syringe
- vancomycin intravenous recon soln 1,000 mg, 10 gram, 500 mg, 750 mg
- Varubi oral tablet
- voriconazole intravenous recon soln
- Xgeva subcutaneous solution
- Zortress oral tablet

### Details

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



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