

## 2020 Priority Health Medicare Prior Authorization Criteria

An alphabetical index by drug name appears after the drug criteria listings.

Last updated: December 2020

# ABILIFY MYCITE

## Products Affected

- ABILIFY MYCITE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Must be age 18 or older
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For diagnoses of bipolar disorder and schizophrenia, patient must have tried and failed (defined as taking the medication as prescribed without an adequate response or with intolerance) with one of the following generic atypical antipsychotics: ziprasidone, olanzapine, risperidone, quetiapine, paliperidone ER. For diagnosis of major depressive disorder, patient must be taking an antidepressant concurrently with Abilify Mycite. For all diagnoses, patient must have tried and failed (defined as taking the medication as prescribed without an adequate response or with intolerance) aripiprazole oral tablets.
Indications	All FDA-approved Indications.
Off Label Uses	

# abiraterone acetate

## Products Affected

- *abiraterone acetate*

PA Criteria	Criteria Details
Exclusion Criteria	Patient must not have a history of adrenal or pituitary gland disorders.
Required Medical Information	Patient must have evidence of disease progression. Patient must have Eastern Cooperative Oncology Group (ECOG) performance standard of 0 to 2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorized for 8 months
Other Criteria	Patient must not have Eastern Cooperative Oncology Group (ECOG) performance status greater than or equal to 3. Patient must not have severe hepatic impairment. Patient must not have NYHA Class III or IV heart failure.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ABSTRAL

## Products Affected

- ABSTRAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patient must be age 18 or over.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For diagnosis of management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Prescriber must be enrolled in the TIRF REMS Access Program. Patient must have signed the Patient-Prescriber Agreement form for the TIRF REMS program.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ACTEMRA ACTPEN

## Products Affected

- ACTEMRA ACTPEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient must not be receiving Actemra in combination with another biologic drug.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of rheumatoid arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. methotrexate, leflunomide, hydroxychloroquine, sulfasalazine).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ACTEMRA SYRINGE

## Products Affected

- ACTEMRA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient must not be receiving Actemra in combination with another biologic drug.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of rheumatoid arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. methotrexate, leflunomide, hydroxychloroquine, sulfasalazine).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ACTIMMUNE

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## Products Affected

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient's body surface area (BSA)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# ADASUVE

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## Products Affected

- ADASUVE

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS approval
Required Medical Information	Pending CMS approval
Age Restrictions	Pending CMS approval
Prescriber Restrictions	Pending CMS approval
Coverage Duration	Pending CMS approval
Other Criteria	Pending CMS approval
Indications	Pending CMS approval
Off Label Uses	Pending CMS approval



# ADCIRCA

## Products Affected

- ADCIRCA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must have a pulmonary arterial hypertension (PAH) classification that meets World Health Organization (WHO) Group 1 criteria.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ADEMPAS

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## Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For chronic thromboembolic pulmonary hypertension, must be in World Health Organization Group 4. For pulmonary arterial hypertension, must be in World Health Organization Group 1, and patients not previously treated for pulmonary arterial hypertension must first try sildenafil (generic Revatio).
Indications	All Medically-accepted Indications.
Off Label Uses	

# AFINITOR

## Products Affected

- AFINITOR DISPERZ
- AFINITOR ORAL TABLET 10 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer in postmenopausal women, patient must have Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorized for one year.
<b>Other Criteria</b>	For diagnosis of advanced renal cell carcinoma (RCC), patient must try and fail sunitinib or sorafenib. For diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer in postmenopausal women, all of the following must be met: patient must have prior treatment with letrozole (Femara) or anastrozole (Arimidex), patient must not have had prior treatment with exemastane (Aromasin), Afinitor must be used in combination with exemastane (Aromasin).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# AIMOVIG

## Products Affected

- AIMOVIG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with Botox (botulinum toxin) or other CGRP antagonist therapy.
<b>Required Medical Information</b>	Documentation supporting diagnosis, other therapies tried, and outcome. Medication overuse headache has been ruled out.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a neurologist or pain specialist.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For migraine prevention, patient must have an inadequate response, contraindication, or intolerance to two of the following oral chronic migraine prevention drugs: one each from a different class and tried for a minimum of 28 days each each: anticonvulsants (topiramate or valproate), beta blockers (propranolol or metoprolol), antidepressants (amitriptyline or venlafaxine). For continuation of previously authorized therapy, must provide evidence of significant clinical improvement.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# AJOVY

## Products Affected

- AJOVY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with Botox (botulinum toxin) or other CGRP antagonist therapy.
<b>Required Medical Information</b>	Documentation supporting diagnosis, other therapies tried, and outcome. Medication overuse headache has been ruled out.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a neurologist or pain specialist.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For migraine prevention, patient must have an inadequate response, contraindication, or intolerance to two of the following oral chronic migraine prevention drugs: one each from a different class and tried for a minimum of 28 days each: anticonvulsants (topiramate or valproate), beta blockers (propranolol or metoprolol), antidepressants (amitriptyline or venlafaxine). For continuation of previously authorized therapy, must provide evidence of significant clinical improvement. For coverage of Ajovy dosed as 675 mg every 3 months, patient must first have used Ajovy at 225mg monthly for 3 months.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# ALECENSA

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## Products Affected

- ALECENSA

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

# ALUNBRIG

## Products Affected

- ALUNBRIG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must have progressed on or be intolerant to Xalkori (crizotinib).
Indications	All Medically-accepted Indications.
Off Label Uses	

# ARALAST

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## Products Affected

- ARALAST NP INTRAVENOUS SOLUTION  
RECONSTITUTED 1000 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have a predicted FEV1 value between 30 and 65% and have serum AAT level less than 11 micromoles per liter (80 milligrams per deciliter if measured by radial immunodiffusion or 50 milligrams per deciliter if measure by nephelometry)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	



# ARIKAYCE

## Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For initial review, sputum culture supporting the diagnosis of Mycobacterium avium complex (MAC) lung disease must be submitted. For continuation, documentation of negative sputum culture obtained within the last 30 days must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with an infectious disease specialist.
<b>Coverage Duration</b>	Initial approval for 6 months. Continuation for 12 months.
<b>Other Criteria</b>	For initial review, documentation of failure to obtain a negative sputum cultures after a minimum of 6 months of a multidrug background regimen therapy for MAC lung disease must be provided. Criteria will be applied consistent with current ATS/IDSA guidelines.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# ARIPIRAZOLE

## Products Affected

- *aripiprazole oral solution*
- *aripiprazole oral tablet*
- *aripiprazole oral tablet dispersible*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For diagnosis of bipolar disorder or schizophrenia, patient must have a therapeutic trial and clinical failure with one generic atypical antipsychotic. For diagnosis of major depressive disorder, patient must be taking an antidepressant concurrently with aripiprazole.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# armodafinil

## Products Affected

- *armodafinil oral tablet 150 mg, 250 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For diagnosis of narcolepsy and obstructive sleep apnea, confirmation of diagnosis by polysomnography
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Auryxia

## Products Affected

- AURYXIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For a diagnosis of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis, must first try and fail calcium acetate. For a diagnosis of iron-deficiency anemia in CKD in patients not on dialysis, must first try and fail iron supplementation.
Indications	All FDA-approved Indications.
Off Label Uses	

# AUSTEDO

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with tetrabenazine, Ingrezza, a monoamine oxidase inhibitor (MAOI), or reserpine.
<b>Required Medical Information</b>	Baseline documentation of Abnormal Involuntary Movement Scale (AIMS) score must be provided.
<b>Age Restrictions</b>	Must be age 18 or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval for 6 months, continuation for one year.
<b>Other Criteria</b>	For diagnosis of tardive dyskinesia (TD), must have moderate or severe TD, indicated by minimum AIMS score of 3 on item 8 (severity of abnormal movements). For continuation, documentation of improvement in chorea symptoms for Huntingtons disease or improvement in AIMS score compared to baseline for TD.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# AVEED

## Products Affected

- AVEED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Subnormal serum total testosterone concentration must be less than 300 ng/dL, on more than one occasion in the past year.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must be male. Patient must have prior use of generic testosterone, either topical or injectable, for a minimum of two months. Patient must have clinical symptoms and signs consistent with androgen deficiency. Men over age 50 years (or over 40 years who have a family history or are African-American) must be screened for prostate cancer before starting therapy and routinely while on therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# AYVAKIT

## Products Affected

- AYVAKIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation showing the presence of a PDGFRA exon 18 mutation must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# BALVERSA

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## Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	



# BANZEL

## Products Affected

- BANZEL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Must be one year of age or older.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must be used in conjunction with other anti-epileptic medications.
Indications	All FDA-approved Indications.
Off Label Uses	

# BENLYSTA

## Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not have severe nephritis, central nervous system manifestations, or chronic infection. Must not use any other biologic drug or intravenous cyclophosphamide.
<b>Required Medical Information</b>	Must have a SELENA-SLEDAI score of 6 or more before starting Benlysta. Must have an anti-dsDNA antibody greater than 30 IU/ml or ANA greater than 1:80.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber must be a specialist in treating SLE (e.g. rheumatologist) or consulted with a specialist.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Must currently be taking two of: corticosteroids, immunosuppressants, and hydroxychloroquine for at least 12 weeks each. For continuation, must provide evidence of significant clinical improvement.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# BERINERT

## Products Affected

- BERINERT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient is on an angiotensin-converting enzyme (ACE) inhibitor.
<b>Required Medical Information</b>	For HAE Type I or II, documentation of C4, C1-INH protein, and C1-INH function lab results. Patient's weight.
<b>Age Restrictions</b>	Must be age 5 or older.
<b>Prescriber Restrictions</b>	Prescriber is an allergist, immunologist, hematologist, or other specialist experienced in treating HAE.
<b>Coverage Duration</b>	Limited to one fill of 20 units/kg (supplied in 500 unit vials).
<b>Other Criteria</b>	Patient has attacks either affecting upper airways, involving the face, neck, or abdomen, or resulting in debilitation or dysfunction. Patient has received training for self-administration. Each additional fill requires documentation of the patients use of the previous supply of Berinert, as well as documentation of symptom relief with use.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# BOSULIF

## Products Affected

- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year.
Other Criteria	Patient must try imatinib except for newly diagnosed CP Ph+ CML. BCR-ALB1 Gene Arrangement, Quantitative PCR must be completed at baseline, then every 3 months to assess response to therapy until complete cytogenic response, then every 3 months for 3 years, then every 3-6 months thereafter. If loss of response to Bosulif occurs, BCR-ABL kinase domain mutation analysis must be done before changing therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# BRAFTOVI

## Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have documentation of BRAF V600 mutation status as detected by an FDA-approved test. Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# BRUKINSA

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## Products Affected

- BRUKINSA

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

# BUPRENORPHINE HCL/NALOXONE HCL

## Products Affected

- *buprenorphine hcl-naloxone hcl sublingual film 12-3 mg, 2-0.5 mg, 4-1 mg, 8-2 mg*
- *buprenorphine hcl-naloxone hcl sublingual tablet sublingual*

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

# CABOMETYX

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## Products Affected

- CABOMETYX

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



# CALQUENCE

## Products Affected

- CALQUENCE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For mantle cell lymphoma, must be used as monotherapy. Must not have been previously treated with a Bruton tyrosine kinase (BTK) inhibitor (e.g., ibrutinib) or BCL-2 inhibitor (e.g., venetoclax)
Indications	All Medically-accepted Indications.
Off Label Uses	

# CAPLYTA

## Products Affected

- CAPLYTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Must be age 18 or older.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must have tried and failed (defined as taking the medication as prescribed without an adequate response or with intolerance) two of the following generic atypical antipsychotics: aripiprazole, ziprasidone, olanzapine, risperidone, quetiapine.
Indications	All FDA-approved Indications.
Off Label Uses	

# CAPRELSA

## Products Affected

- CAPRELSA

PA Criteria	Criteria Details
Exclusion Criteria	Patient must not have uncorrected hypocalcemia, hypokalemia, hypomagnesemia, or long QT syndrome.
Required Medical Information	A baseline ECG must be obtained to monitor the QT at baseline, 2-4 weeks, and 8-12 weeks after starting treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# CARBAGLU

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## Products Affected

- CARBAGLU

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

# CAYSTON

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## Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# CHOLBAM

## Products Affected

- CHOLBAM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval for 3 months, continuation approval for one year
<b>Other Criteria</b>	For continuation, must provide documentation showing the patient has met 2 of the following laboratory criteria or 1 laboratory criterion plus a body weight increase by 10% (or stability at greater than the 50th percentile): (1) AST or ALT less than 50 U/L (or baseline levels reduced by 80%) (2) total bilirubin less than 1 mg/dL, and (3) no evidence of cholestasis on liver biopsy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# CIMZIA

## Products Affected

- CIMZIA PREFILLED
- CIMZIA SUBCUTANEOUS KIT 2 X 200 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Cimzia must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	For diagnosis of ankylosing spondylitis, must have BASDAI score of 4.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of ankylosing spondylitis, must first have presence of disease for at least 4 weeks and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) and Humira or Enbrel. For a diagnosis of psoriasis, must first have 5% or more of body surface area affected (unless hands, feet, head, neck, or genitalia are affected) and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one topical drug, one non-biologic immunomodulator (e.g. methotrexate, cyclosporine, acitretin), and either Humira or Enbrel. For a diagnosis of psoriatic arthritis, rheumatoid arthritis, or Crohn's disease, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. methotrexate, leflunomide, sulfasalazine, azathioprine) and either Humira or Enbrel.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# clobazam

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## Products Affected

- *clobazam oral suspension*
- *clobazam oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must first try one generic anticonvulsant. Clobazam suspension may only be used in patients where tablets are contraindicated (e.g., dysphagia).
Indications	All FDA-approved Indications.
Off Label Uses	



# clomiphene citrate

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## Products Affected

- *clomiphene citrate oral*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS approval
Required Medical Information	Pending CMS approval
Age Restrictions	Pending CMS approval
Prescriber Restrictions	Pending CMS approval
Coverage Duration	Pending CMS approval
Other Criteria	Pending CMS approval
Indications	Pending CMS approval
Off Label Uses	Pending CMS approval

# COMETRIQ

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## Products Affected

- COMETRIQ (100 MG DAILY DOSE)
- COMETRIQ (140 MG DAILY DOSE)
- COMETRIQ (60 MG DAILY DOSE)

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

# COPIKTRA

## Products Affected

- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Patient must not have prior use of a P13K inhibitor, such as Zydelig or Aliqopa, nor a BTK inhibitor, such as Imbruvica or Calquence. For diagnosis of follicular lymphoma, patient must not have grade 3b disease, large cell transformations, or prior allogenic transplant.
Indications	All Medically-accepted Indications.
Off Label Uses	

# COSENTYX

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Cosentyx must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	For a diagnosis of ankylosing spondylitis, must have a BASDAI score of at least 4.
<b>Age Restrictions</b>	Must be age 18 or older
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of ankylosing spondylitis and non-radiographic axial spondyloarthritis (NRAS), must first have presence of disease for at least 4 weeks and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one nonsteroidal anti-inflammatory drug (NSAID). For a diagnosis of psoriasis, must first have 5% or more of body surface area affected (unless hands, feet, head, neck, or genitalia are affected) and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one topical drug or one non-biologic immunomodulator (e.g. methotrexate, cyclosporine, acitretin). For a diagnosis of psoriatic arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. methotrexate, leflunomide, sulfasalazine).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# COTELLIC

## Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For diagnosis of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, must be used in combination with Zelboraf.
Indications	All Medically-accepted Indications.
Off Label Uses	

# CRINONE

## Products Affected

- CRINONE VAGINAL GEL 8 %

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

# DAKLINZA

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## Products Affected

- DAKLINZA ORAL TABLET 30 MG, 60 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS approval
Required Medical Information	Pending CMS approval
Age Restrictions	Pending CMS approval
Prescriber Restrictions	Pending CMS approval
Coverage Duration	Pending CMS approval
Other Criteria	Pending CMS approval
Indications	Pending CMS approval
Off Label Uses	Pending CMS approval

# DALFAMPRIDINE ER

## Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient must not have history of seizure and creatinine clearance must be greater than 50 ml per min.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval for 12 weeks, recertification required every 12 months thereafter
<b>Other Criteria</b>	Baseline timed 25-foot walk (T25FW) completed within 8-45 seconds, patient must be currently ambulatory with minimal walking impairment or use of cane, crutch or brace. Continuation approval based on results of T25FW and (or) significant clinical improvement.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# DALIRESP

## Products Affected

- DALIRESP

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient must have an FEV1 less than 50%. Patient must have had more than one COPD exacerbation in the past year.
<b>Age Restrictions</b>	Must be age 18 or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must have tried and failed triple therapy with an inhaled corticosteroid (ICS), long-acting beta agonist (LABA), and a long-acting antimuscarinic (LAMA) in the past 6 months (failure is defined as no improvement, a worsening of the condition, or an intolerance after trying triple therapy at the maximum dosages for at least 4 weeks consistently). For continuation, documentation must be provided showing a reduction in COPD exacerbations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# DAURISMO

## Products Affected

- DAURISMO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must be used in combination with cytarabine.
Indications	All Medically-accepted Indications.
Off Label Uses	

# **diclofenac epolamine patch**

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## **Products Affected**

- *diclofenac epolamine*

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

# DOJOLVI

## Products Affected

- DOJOLVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must provide documentation supporting the diagnosis (e.g., medical records).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Patient must not have pancreatic insufficiency. For continuation, patient must have clinically significant benefit compared to baseline (e.g., reduced hospitalizations, myopathy, cardiac symptoms, muscle weakness, etc.).
Indications	All FDA-approved Indications.
Off Label Uses	

# DUPIXENT

## Products Affected

- DUPIXENT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorized for 1 year. Limited to 4 syringes the first month, 2 syringes per month thereafter.
<b>Other Criteria</b>	For diagnosis of diagnosis of moderate to severe atopic dermatitis, patient must have had a trial and inadequate response to one medium potency or higher topical steroid, such as clobetasol, betamethasone dipropionate, halobetasol, or fluocinonide, and one topical calcineurin inhibitor, such as pimecrolimus or tacrolimus. For diagnosis of moderate to severe asthma, patient must either have eosinophilic phenotype or be dependent on oral corticosteroid. Dupixent must be used as an add-on to current maintenance treatment with an ICS/LABA inhaler, or if contraindicated or not tolerated, another maintenance medication for the condition. Dupixent must not be used in combination with other monoclonal antibodies, such as Xolair or Nucala. For continuation, all initial requirements must be met, and patient must have documented clinical benefit from therapy (e.g. decrease in exacerbation frequency, improvement in asthma symptoms, or decrease in oral corticosteroid use). For a diagnosis of chronic rhinosinusitis with nasal polyp (CRSwNP), must have disease persistence for a minimum of 12 weeks with symptoms of nasal obstruction, rhinorrhea, and diminished or loss of smell. Must have recurrent CRSwNP despite prior sino-nasal surgery or at least one prior treatment course with a systemic corticosteroid, and a documented trial and failure (failure defined as a minimum 3 months of treatment) with an intranasal glucocorticoid. Must be used in combination with an intranasal steroid.

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

# EMGALITY

## Products Affected

- EMGALITY
- EMGALITY (300 MG DOSE)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with Botox (botulinum toxin) or other CGRP antagonist therapy.
<b>Required Medical Information</b>	Documentation supporting diagnosis, other therapies tried, and outcome. Medication overuse headache has been ruled out.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a neurologist, pain specialist, or headache specialist.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For migraine prevention, patient must have an inadequate response, contraindication, or intolerance to two of the following oral chronic migraine prevention drugs: one each from a different class and tried for a minimum of 28 days each: anticonvulsants (topiramate or valproate), beta blockers (propranolol or metoprolol), antidepressants (amitriptyline or venlafaxine). For episodic cluster headache, patient must have an inadequate response, contraindication, or intolerance to verapamil, corticosteroids, or lithium. For continuation of previously authorized therapy, must provide evidence of significant clinical improvement. For migraine prophylaxis, Emgality is limited to one initial dose of two 120mg/mL injections/30 days, then one 120mg/mL injection/30 days thereafter.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# ENBREL

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Enbrel must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	For diagnosis of ankylosing spondylitis, must have presence of active disease for at least 4 weeks, BASDAI score of at least 4. For diagnosis of moderate to severe plaque psoriasis, must have involvement of greater than 5% of body surface area (unless hands, feet, head, neck, or genitalia are involved).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of ankylosing spondylitis, must first have presence of disease for at least 4 weeks and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one nonsteroidal anti-inflammatory drug (NSAID). For a diagnosis of psoriasis, must first have 5% or more of body surface area affected (unless hands, feet, head, neck, or genitalia are affected) and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one topical drug or one non-biologic immunomodulator (e.g. methotrexate, cyclosporine, acitretin). For a diagnosis of psoriatic arthritis or rheumatoid arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. methotrexate, leflunomide, sulfasalazine). For a diagnosis of hidradenitis suppurativa, must first have a documented trial and failure (defined as an inability to improve symptoms) with systemic or topical antibiotic therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# ENBREL MINI

## Products Affected

- *enbrel mini*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Enbrel must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	For diagnosis of ankylosing spondylitis, must have presence of active disease for at least 4 weeks, BASDAI score of at least 4. For diagnosis of moderate to severe plaque psoriasis, must have involvement of greater than 5% of body surface area (unless hands, feet, head, neck, or genitalia are involved).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of ankylosing spondylitis, must first have presence of disease for at least 4 weeks and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one nonsteroidal anti-inflammatory drug (NSAID). For a diagnosis of psoriasis, must first have 5% or more of body surface area affected (unless hands, feet, head, neck, or genitalia are affected) and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one topical drug or one non-biologic immunomodulator (e.g. methotrexate, cyclosporine, acitretin). For a diagnosis of psoriatic arthritis or rheumatoid arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. methotrexate, leflunomide, sulfasalazine). For a diagnosis of hidradenitis suppurativa, must first have a documented trial and failure (defined as an inability to improve symptoms) with systemic or topical antibiotic therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# EPCLUSA

## Products Affected

- EPCLUSA ORAL TABLET 400-100 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Must be age 18 or older.
Prescriber Restrictions	Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist.
Coverage Duration	12 weeks
Other Criteria	Criteria will be applied consistent with current AASLD-IDSA guidance. For GT1 and 4, must first try Harvoni.
Indications	All Medically-accepted Indications.
Off Label Uses	

# EPIDIOLEX

## Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# ERIVEDGE

## Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorized for one year.
Other Criteria	For diagnosis of locally advanced basal cell carcinoma (BCC), patient must not be a candidate for radiation and documentation of an appropriate surgical consultation indicating patient is not a candidate for surgery must be provided.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ERLEADA

## Products Affected

- ERLEADA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concurrently or have had a bilateral orchiectomy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# erlotinib

## Products Affected

- *erlotinib hcl*

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

# ESBRIET

## Products Affected

- ESBRIET ORAL CAPSULE
- *esbriet oral tablet 267 mg*
- ESBRIET ORAL TABLET 801 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have presence of a UIP pattern on HRCT in patients not subjected to surgical lung biopsy
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Prescriber must rule out other known causes of interstitial lung disease.
Indications	All Medically-accepted Indications.
Off Label Uses	

# EVENITY

## Products Affected

- EVENITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient's T-score must be provided
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months total therapy
Other Criteria	For diagnosis of postmenopausal osteoporosis, the following criteria must be met: documented therapeutic trial with failure, contraindication, or intolerance (defined as creatinine clearance less than 35 mL/min, inability to remain upright for 30 minutes after dose, esophageal stricture (known stricture or dysphagia), significant decrease in BMD after at least one year of therapy, or new fracture while on therapy) to alendronate, risedronate, or ibandronate AND documented therapeutic trial with failure, contraindication, or intolerance (defined as significant decrease in BMD after at least one year of therapy, or new fracture while on therapy) to zoledronic acid (generic Reclast) or Prolia.
Indications	All Medically-accepted Indications.
Off Label Uses	



# everolimus

## Products Affected

- *everolimus oral tablet 2.5 mg, 5 mg, 7.5 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer in postmenopausal women, patient must have Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorized for one year.
<b>Other Criteria</b>	For diagnosis of advanced renal cell carcinoma (RCC), patient must try and fail sunitinib or sorafenib. For diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer in postmenopausal women, all of the following must be met: patient must have prior treatment with letrozole (Femara) or anastrozole (Arimidex), patient must not have had prior treatment with exemastane (Aromasin), everolimus must be used in combination with exemastane (Aromasin).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# FARYDAK

## Products Affected

- FARYDAK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	48 weeks
Other Criteria	Must first try two prior regimens, including bortezomib and an immunomodulatory agent. Limited to 6 capsules for every 21-day cycle. Covered for 16 cycles when approved.
Indications	All Medically-accepted Indications.
Off Label Uses	

# FASENRA

## Products Affected

- FASENRA
- FASENRA PEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial approval for 12 months, continuation for 12 months
Other Criteria	For initial approval, Fasenra must be used as an add-on to current maintenance treatment with an ICS/LABA inhaler or, if contraindicated or not tolerated, another maintenance medication for the condition. Must not be used in combination with other monoclonal antibodies (e.g., Xolair, Nucala). For continuation, all initial requirements must be met and patient must have documented clinical benefit from therapy (e.g., decrease in exacerbation frequency, improvement in asthma symptoms, or decrease in oral corticosteroid use). First year is limited to 1 syringe every 4 weeks for 3 months, then 1 syringe every 8 weeks thereafter. Subsequent years are limited to 1 syringe every 8 weeks.
Indications	All Medically-accepted Indications.
Off Label Uses	

# fentanyl citrate transmucosal

## Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patient must be age 16 or over
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For diagnoses of management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Prescriber must be enrolled in the TIRF REMS Access Program. Patient must have signed the Patient-Prescriber Agreement form for the TIRF REMS program.
Indications	All Medically-accepted Indications.
Off Label Uses	

# FINTEPLA

## Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# Firdapse

## Products Affected

- FIRDAPSE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient must have clinical symptoms of LEMS (i.e., proximal extremity weakness) that interfere with daily activities. Must provide a baseline disease severity score using the Quantitative Myasthenia Gravis (QMG) or the Triple-Timed Up-And-Go (3TUG) test.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval for 4 weeks. Subsequent approvals will be for 12 months.
<b>Other Criteria</b>	For initial approval, patient must have tried and failed pyridostigmine (fail is defined as taking the medication as prescribed and at an appropriate dose for the condition). If the patient has a cancer diagnosis associated with LEMS, the cancer must have been appropriately treated. Patient must not have history of seizures nor have conditions (e.g., no active brain metastases) or be taking medications (e.g., bupropion, clozapine, fluoroquinolones) that increase the risk of seizures. Patient must be ambulatory. For continuation, patient must show improvement or stabilization in condition from baseline using the QMG or 3TUG test and/or other measures per providers attestation.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# FORTEO

## Products Affected

- FORTEO SUBCUTANEOUS SOLUTION  
600 MCG/2.4ML
- FORTEO SUBCUTANEOUS SOLUTION  
PEN-INJECTOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient's T-score must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Two years total therapy
<b>Other Criteria</b>	For diagnosis of postmenopausal osteoporosis, the following criteria must be met: documented therapeutic trial with failure, contraindication, or intolerance to one antiresorptive therapy (defined as creatinine clearance less than 35 mL/min, inability to remain upright for 30 minutes after dose, esophageal stricture [known stricture or dysphagia], significant decrease in BMD after at least one year of therapy, or new fracture while on therapy to alendronate, risedronate, ibandronate OR significant decrease in BMD after at least one year of therapy or new fracture while on therapy to Prolia or zoledronic acid) AND documented therapeutic trial with failure, contraindication, or intolerance (defined as significant decrease in BMD after at least one year of therapy or new fracture while on therapy) to Tymlos. For diagnosis of osteoporosis (primary or hypogonadal, or due to corticosteroids) the following criteria must be met: documented therapeutic trial with failure, contraindication, or intolerance (defined as creatinine clearance less than 35 mL/min, inability to remain upright for 30 minutes after dose, esophageal stricture (known stricture or dysphagia), significant decrease in BMD after at least one year of therapy, or new fracture while on therapy) to alendronate, risedronate, or ibandronate AND documented therapeutic trial with failure, contraindication, or intolerance (defined as significant decrease in BMD after at least one year of therapy, or new fracture while on therapy) to zoledronic acid (generic Reclast) or Prolia.

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



# GALAFOLD

## Products Affected

- GALAFOLD

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have a confirmed diagnosis of Fabry disease and documentation of an amenable galactosidase alpha gene variant based on in vitro assay data.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Patient must not be taking Galafold in combination with enzyme replacement therapy (ERT), such as Fabrazyme.
Indications	All Medically-accepted Indications.
Off Label Uses	

# GATTEX

## Products Affected

- GATTEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial approval is for 24 weeks. Each continuation approval is for 6 months
Other Criteria	Patient must have received appropriate laboratory assessments (bilirubin, alkaline phosphatase, lipase, and amylase within 6 months before starting Gattex. Patient with an intact large intestine must have documentation of a colonoscopy within 6 months before starting Gattex. Patient must not have a history of colorectal or other GI malignancy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# GAVRETO

## Products Affected

- GAVRETO

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

# GILOTRIF

## Products Affected

- GILOTRIF

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

# GLASSIA

## Products Affected

- GLASSIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have a predicted FEV1 value between 30 and 65% and have serum AAT level less than 11 micromoles per liter (80 milligrams per deciliter if measured by radial immunodiffusion or 50 milligrams per deciliter if measure by nephelometry)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# GROWTH HORMONE

## Products Affected

- GENOTROPIN
- GENOTROPIN MINIQUICK
- HUMATROPE
- NORDITROPIN FLEXPRO
- NUTROPIN AQ NUSPIN 10
- NUTROPIN AQ NUSPIN 20
- NUTROPIN AQ NUSPIN 5
- ZOMACTON

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	FOR CHILDREN: must submit an untreated growth velocity curve with a minimum of 1 year of growth data showing a growth velocity of less than 10th % for bone age and gender, growth plates must be open, bone age must be a minimum of 1 year behind chronological age (unless GHD is related to pituitary surgery, radiation therapy, or with precocious puberty), must have a documented GH deficiency via 2 growth hormone stimulation tests below 10ng/ml or GH stimulation test level less than 15 ng/ml + IGF-1 and IGF-PB3 levels below normal for bone age and sex, decreased muscle tone by exam. FOR ADULTS: documented growth hormone deficiency by suboptimal response (less than 3 mcg/l) to a hypoglycemic challenge (unless contraindicated, then can use other accepted method) or at least 2 other pituitary-related hormonal deficiencies and an abnormally low IGF and one of the following: hypothalamic pituitary disease resulting from tumor or infarct, hx of cranial irradiation during childhood or adulthood resulting in GH deficiency, pituitary surgery resulting in GH deficiency, or continuing treatment of childhood onset GH deficiency.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by an endocrinologist, gastroenterologist, or nephrologist.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	FOR CHILDREN: Diagnosis of Growth Hormone Deficiency-height must be less than the 5th% for age/sex. Dx Turner's syndrome-height must be less than 10th%. Dx Pre-transplant chronic renal insufficiency-height must be less than 5th% for age/sex and patient must be receiving weekly dialysis or SCR less than 2 mg/dL. FOR CHILDREN: must not have constitutional growth delay, or acute or chronic catabolic illness. FOR ADULTS: patients must not have been treated during childhood without documented evidence of persistent GH deficiency, physiologic reductions in GH related to aging, treatment of Turner's syndrome or cystinosis.

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# HARVONI

## Products Affected

- HARVONI ORAL PACKET 33.75-150 MG
- HARVONI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All Medically-accepted Indications.
Off Label Uses	



# HETLIOZ

## Products Affected

- HETLIOZ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Must be prescribed by a sleep specialist or a neurologist.
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# HUMIRA

## Products Affected

- HUMIRA PEDIATRIC CROHNS START
- HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT
- HUMIRA PEN-CD/UC/HS STARTER
- HUMIRA PEN-PS/UV/ADOL HS START
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Humira must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	For diagnosis of ankylosing spondylitis, must have presence of active disease for at least 4 weeks, BASDAI score of at least 4. For diagnosis of moderate to severe plaque psoriasis, must have involvement of greater than 5% of body surface area (unless hands, feet, head, neck, or genitalia are involved).
<b>Age Restrictions</b>	Must be 2 years of age or older
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of ankylosing spondylitis, must first have presence of disease for at least 4 weeks and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one nonsteroidal anti-inflammatory drug (NSAID). For a diagnosis of psoriasis, must first have 5% or more of body surface area affected (unless hands, feet, head, neck, or genitalia are affected) and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one topical drug or one non-biologic immunomodulator (e.g. methotrexate, cyclosporine, acitretin). For a diagnosis of Crohns disease, psoriatic arthritis, rheumatoid arthritis, or ulcerative colitis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. azathioprine, 6-mercaptopurine, methotrexate). For a diagnosis of hidradenitis suppurativa, must first have a documented trial and failure (defined as an inability to improve symptoms) with systemic or topical antibiotic therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# hydrocodone er (generic Zohydro ER)

## Products Affected

- *hydrocodone bitartrate er*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Must be age 18 or over.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must first try one of the following: morphine sulfate extended-release, fentanyl patch, or methadone. Patient must also try one non-opioid or immediate-release opioid options (unless contraindicated). Patient must sign a pain management agreement. Hydrocodone ER (generic Zohydro ER) is not covered for as needed use, acute pain, post-operative pain.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# HYSINGLA ER

## Products Affected

- HYSINGLA ER

PA Criteria	Criteria Details
Exclusion Criteria	Not covered in combination with buprenorphine/naloxone.
Required Medical Information	
Age Restrictions	Patient must be age 18 or over
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Must first try two of the following: morphine sulfate extended-release, fentanyl patch, methadone, tramadol, morphine sulfate, hydromorphone, or hydromorphone extended-release. Patient must sign a pain management agreement. Hysingla ER is not covered for as needed use, acute pain, or post-operative pain.
Indications	All Medically-accepted Indications.
Off Label Uses	

# IBRANCE

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## Products Affected

- IBRANCE

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

# icatibant acetate

## Products Affected

- *icatibant acetate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient is on an angiotensin-converting enzyme (ACE) inhibitor
<b>Required Medical Information</b>	For HAE Type I or II, documentation of C4, C1-INH protein, and C1-INH function lab results.
<b>Age Restrictions</b>	Must be age 18 or older
<b>Prescriber Restrictions</b>	Prescriber is an allergist, immunologist, hematologist, or other specialist experienced in treating HAE.
<b>Coverage Duration</b>	Approved for three syringes (9ml) every 15 days
<b>Other Criteria</b>	Patient has attacks either affecting upper airways, involving the face, neck, or abdomen, or resulting in debilitation or dysfunction. Patient has received training for self-administration. Each additional fill requires documentation of the patients use of the previous supply of icatibant acetate, as well as documentation of symptom relief with use.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ICLUSIG

## Products Affected

- ICLUSIG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorized for one year
<b>Other Criteria</b>	For diagnosis of chronic myeloid leukemia, patient must have a trial of one of Sprycel or Tasigna. BCR-ALB1 Gene Arrangement, Quantitative PCR must be completed at baseline, then every 3 months to assess response to therapy until complete cytogenic response, then every 3 months for 3 years, then every 3-6 months thereafter. If loss of response to Iclusig occurs, BCR-ABL kinase domain mutation analysis must be done before changing therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# IDHIFA

## Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2. Results of FDA approved companion test detecting an IDH2 (isocitrate dehydrogenase-2) mutation must be submitted.
Age Restrictions	Must be age 18 or older.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	



# imatinib mesylate

## Products Affected

- *imatinib mesylate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorized for one year.
Other Criteria	BCR-ALB1 Gene Arrangement, Quantitative PCR must be completed at baseline, then every 3 months to assess response to therapy until complete cytogenic response, then every 3 months for 3 years, then every 3-6 months thereafter. If loss of response to imatinib mesylate occurs, BCR-ABL kinase domain mutation analysis must be done before changing therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# IMBRUVICA

## Products Affected

- IMBRUVICA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	GVHD, initial approval 12 weeks. Subsequent approvals 12 months. All other indications 12 months.
<b>Other Criteria</b>	For mantle cell lymphoma, must have prior use of one other treatment (cyclophosphamide, vincristine, doxorubicin, cytarabine, rituximab, etoposide, ifosfamide, carboplatin, cladribine). For GVHD, must fail one systemic corticosteroid and one immunosuppressant (tacrolimus, cyclosporine). Failure is defined as disease progression, inability to taper steroid dose, or failure to improve after 1 month of therapy and/or treatment-related toxicity. For GVHD, continuation requires no disease progression of chronic GVHD, recurrence of malignancy, or unacceptable toxicity.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# IMIPRAMINE

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## Products Affected

- *imipramine hcl oral*
- *imipramine pamoate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# IMPAVIDO

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## Products Affected

- IMPAVIDO

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS approval
Required Medical Information	Pending CMS approval
Age Restrictions	Pending CMS approval
Prescriber Restrictions	Pending CMS approval
Coverage Duration	Pending CMS approval
Other Criteria	Pending CMS approval
Indications	Pending CMS approval
Off Label Uses	Pending CMS approval

# INGREZZA

## Products Affected

- INGREZZA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with tetrabenazine or Austedo.
<b>Required Medical Information</b>	Baseline documentation of Abnormal Involuntary Movement Scale (AIMS) score must be provided.
<b>Age Restrictions</b>	Must be age 18 or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval is 6 months, continuation for one year.
<b>Other Criteria</b>	For diagnosis of tardive dyskinesia (TD), must have moderate or severe TD, indicated by minimum AIMS score of 3 on item 8 (severity of abnormal movements). For continuation, documentation of improvement compared to baseline AIMS score.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# INLYTA

## Products Affected

- INLYTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorized for one year.
Other Criteria	For diagnosis of renal cell carcinoma, patient must have a trial with one of Sutent, Nexavar or Votrient.
Indications	All Medically-accepted Indications.
Off Label Uses	

# INQOVI

## Products Affected

- INQOVI

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

# INREBIC

## Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Baseline platelet count of 50 X 10 <sup>9</sup> cells/L or greater and liver function tests (ALT, AST, bilirubin) before starting therapy with monitoring every 2 to 4 weeks until dosing is stable, then as clinically necessary.
Age Restrictions	Must be age 18 or older.
Prescriber Restrictions	
Coverage Duration	Initial approval 6 months with continuation approval for 12 months
Other Criteria	Patient must have intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis. Patient must be resistant, intolerant, or have a contraindication to Jakafi. Patient must not currently have thiamine deficiency. Physician must be familiar with the FDA labeling and dose modification information for Inrebic. For continuation, patient must have experienced a 35% reduction in spleen volume (approximately a 50% reduction in spleen size on palpation).
Indications	All FDA-approved Indications.
Off Label Uses	



# IRESSA

## Products Affected

- IRESSA

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

# ISTURISA

## Products Affected

- ISTURISA ORAL TABLET 1 MG, 10 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have failed pituitary surgery or have a contraindication to pituitary surgery.
Age Restrictions	Must be 18 years of age or older.
Prescriber Restrictions	Must be prescribed by an endocrinologist
Coverage Duration	One year
Other Criteria	Patient must have tried and failed two of the following: ketoconazole, Lysodren, cabergoline, and/or Signifor/LAR.
Indications	All FDA-approved Indications.
Off Label Uses	

# IVIG

## Products Affected

- BIVIGAM INTRAVENOUS SOLUTION 5 GM/50ML
- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA
- GAMUNEX-C INJECTION SOLUTION 1 GM/10ML
- PANZYGA

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

# JAKAFI

## Products Affected

- JAKAFI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For myelofibrosis and polycythemia vera: Complete blood count (CBC) prior to initiating therapy (platelet count greater than $50 \times 10^9/L$ ) with monitoring every 2 to 4 weeks until dose is stabilized, then as clinically necessary.
<b>Age Restrictions</b>	Must be age 12 or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Myelofibrosis/PV-Initial: 12 weeks, cont: 12 mos. GVHD-Initial: 12 weeks, cont: 6 mos.
<b>Other Criteria</b>	If treating primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, patient must be at intermediate or high risk. Physician must be familiar with the FDA labeling and dose modification information for Jakafi. For continuation, patient must have experienced a 35% reduction in spleen volume (approximately a 50% reduction in spleen size on palpation). For steroid-refractory, acute, graft-versus-host disease: must have disease progression after at least 3-5 days steroid treatment or no response after 7 days therapy. Must have a trial, or medical contraindication to therapy, with mycophenolate mofetil or have tried one other therapy. For continuation of therapy, must have a documented response to therapy. After 6 months of treatment in responders who have discontinued therapeutic doses of corticosteroids, taper Jakafi dose unless medically contraindicated.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# KALYDECO

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## Products Affected

- KALYDECO ORAL PACKET
- KALYDECO ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Must be age 4 months or older.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# KEVEYIS

## Products Affected

- KEVEYIS

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

# KEVZARA

## Products Affected

- *kevzara subcutaneous solution auto-injector*
- KEVZARA SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Kevzara must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of rheumatoid arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one (1) non-biologic immunomodulator (e.g. methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) and either Enbrel or Humira.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# KINERET

## Products Affected

- KINERET SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Kineret must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of rheumatoid arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one (1) non-biologic immunomodulator (e.g. methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) and either Enbrel or Humira.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# KISQALI

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For advanced or metastatic breast cancer, patient must be HR-positive, HER2-negative.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	If treating advanced or metastatic breast cancer, patient must be using Kisqali in combination with an aromatase inhibitor.
Indications	All Medically-accepted Indications.
Off Label Uses	

# KISQALI FEMARA

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For advanced or metastatic breast cancer, patient must be HR-positive, HER2-negative.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# KOSELUGO

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## Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# lapatinib

## Products Affected

- *lapatinib ditosylate*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS approval
Required Medical Information	Pending CMS approval
Age Restrictions	Pending CMS approval
Prescriber Restrictions	Pending CMS approval
Coverage Duration	Pending CMS approval
Other Criteria	Pending CMS approval
Indications	Pending CMS approval
Off Label Uses	Pending CMS approval

# LENVIMA

## Products Affected

- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)
- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)

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

# LIDOCAINE PATCH

## Products Affected

- *lidocaine external patch 5 %*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Six months for diagnosis of post-herpetic neuralgia. One year for diagnosis of diabetic neuropathy.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# LINEZOLID

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Linezolid will not be authorized in patients taking any of the following interacting/contraindicated medications: dopamine, SSRIs, SNRIs, tricyclic antidepressants, MAOIs, bupropion, sympathomimetic agents, triptans, meperidine, buspirone.
<b>Required Medical Information</b>	Fax copy of culture, determination of antibiotic susceptibility (fax copy must be provided).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber must be an infectious disease specialist or have consulted with an infectious disease specialist
<b>Coverage Duration</b>	14 days, including days administered inpatient. Max of 28 days for vancomycin-resistant Enterococcus
<b>Other Criteria</b>	For all medically-accepted indications, the patient's infection must not be susceptible to alternative oral antibiotics or the patient has an allergy or intolerance to all other susceptible oral antibiotics. For all medically-accepted indications, the patient must try IV vancomycin for susceptible infections (unless patient has a contraindication) and have an inadequate response or intolerance. Trial with IV vancomycin only applies to Medicare Advantage-Prescription Drug (MA-PD) contract members.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# LONSURF

## Products Affected

- LONSURF

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation of KRAS mutation status. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For metastatic colorectal cancer, must first try fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy. For metastatic gastric cancer, must first try two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either ataxane or irinotecan, and if appropriate, HER2/NEU-targeted therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# LORBRENA

## Products Affected

- LORBRENA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of ALK-positive mutation must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must have tried and experienced disease progression on Xalkori and at least one other ALK inhibitor, or patient must have experienced disease progression on Alecensa or Zykadia as first-line therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# LYNPARZA

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## Products Affected

- LYNPARZA ORAL TABLET 100 MG, 150 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must provide germline BRCA test results (must use FDA-approved test)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# MATULANE

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## Products Affected

- MATULANE

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

# MAVENCLAD

## Products Affected

- MAVENCLAD (10 TABS)
- MAVENCLAD (4 TABS)
- MAVENCLAD (5 TABS)
- MAVENCLAD (6 TABS)
- MAVENCLAD (7 TABS)
- MAVENCLAD (8 TABS)
- MAVENCLAD (9 TABS)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Must be age 18 or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Two years total therapy
<b>Other Criteria</b>	Patient must first try glatiramer. Patient must not have concurrent use with other MS disease modifying drugs. Patient must not have clinically isolated syndrome (CIS).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# MAVYRET

## Products Affected

- MAVYRET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have chronic hepatitis C infection. Must be age 12 or older or weigh 45kg or more.
Age Restrictions	Must be age 12 or older.
Prescriber Restrictions	Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist.
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	For GT1, must first try Harvoni
Indications	All Medically-accepted Indications.
Off Label Uses	

# MEKINIST

## Products Affected

- MEKINIST ORAL TABLET 0.5 MG, 2 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorized for one year.
Other Criteria	For melanoma and non-small cell lung cancer, must not have prior use of a BRAF or MEK inhibitor.
Indications	All Medically-accepted Indications.
Off Label Uses	

# MEKTOVI

## Products Affected

- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have documentation of BRAF V600 mutation status as detected by an FDA-approved test. Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# METHYLTESTOSTERONE

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## Products Affected

- *methyldtestosterone oral*

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



# MIRVASO

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## Products Affected

- MIRVASO

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

# MYALEPT

## Products Affected

- MYALEPT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Laboratory confirmed leptin deficiency. Must have one of the following: triglyceride level more than 200mg/dL or diabetes mellitus.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must not have HIV, infectious liver disease, or acquired lipodystrophy with hematologic abnormalities
Indications	All Medically-accepted Indications.
Off Label Uses	

# NATPARA

## Products Affected

- NATPARA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have two consecutive calcium levels less than 8.9
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# NERLYNX

## Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
Age Restrictions	Must be age 18 or older.
Prescriber Restrictions	
Coverage Duration	12 months total therapy
Other Criteria	Must be used as extended adjuvant treatment following treatment with adjuvant Herceptin (trastuzumab)-based therapy within the past 24 months.
Indications	All Medically-accepted Indications.
Off Label Uses	

# NEXAVAR

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## Products Affected

- NEXAVAR

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

# NEXLETOL

## Products Affected

- NEXLETOL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must submit most recent LDL cholesterol (LDL-C) laboratory report. For HeFH, must confirm diagnosis by genetic testing, WHO Dutch Lipid Network or Simon-Broome criteria.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Must first try ezetimibe and one high intensity statin medication (e.g., atorvastatin 40 mg daily or higher dose and rosuvastatin 20 mg daily or higher) or, if a high-intensity statin is not tolerated, one statin at the maximally tolerated dose and be unable to reach LDL-C goal. Statin trial is not required for patients who have tried, but are unable to tolerate a statin at any dose and have provider attestation certifying statin intolerance. Must not be used in combination with PCSK9s.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# NEXLIZET

## Products Affected

- NEXLIZET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must submit most recent LDL cholesterol (LDL-C) laboratory report. For HeFH, must confirm diagnosis by genetic testing, WHO Dutch Lipid Network or Simon-Broome criteria.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Must first try ezetimibe and one high intensity statin medication (e.g., atorvastatin 40 mg daily or higher dose and rosuvastatin 20 mg daily or higher) or, if a high-intensity statin is not tolerated, one statin at the maximally tolerated dose and be unable to reach LDL-C goal. Statin trial is not required for patients who have tried, but are unable to tolerate a statin at any dose and have provider attestation certifying statin intolerance. Must not be used in combination with PCSK9s.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# NIVESTYM

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## Products Affected

- NIVESTYM INJECTION SOLUTION  
PREFILLED SYRINGE

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



# NORTHERA

## Products Affected

- NORTHERA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two weeks
Other Criteria	Patient must first try midodrine.
Indications	All Medically-accepted Indications.
Off Label Uses	

# NUBEQA

## Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concurrently or have had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off Label Uses	

# NUCALA

## Products Affected

- NUCALA SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- NUCALA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For severe eosinophilic asthma, peripheral blood eosinophil count must be provided. For Hypereosinophilic Syndrome (HES), must have blood eosinophil count at least 1,000 cells/mcL.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval for 12 months, continuation for 12 months
<b>Other Criteria</b>	For initial approval for severe eosinophilic asthma, Nucala must be used as add-on to current maintenance treatment with an ICS/LABA inhaler or, if contraindicated or not tolerated, another maintenance medication for the condition. For a diagnosis of severe eosinophilic asthma, Nucala is limited to one syringe every 28 days. For a diagnosis of eosinophilic granulomatosis with polyangiitis, must have first tried one systemic non-biologic disease modifying drug (e.g., azathioprine, cyclophosphamide). For a diagnosis of eosinophilic granulomatosis with polyangiitis up to three syringes every 28 days will be authorized. Nucala must not be used in combination with other monoclonal antibodies (e.g., Xolair, Fasenra). For continuation, all initial requirements must be met and patient must have documented clinical benefit from therapy. For initial approval for Hypereosinophilic Syndrome (HES), must have been diagnosed with HES for at least 6 months with at least 2 flares in the past year (e.g., signs or symptoms or increased eosinophils requiring an increase in steroid dose or addition of another therapy) and must have tried and failed one generic, steroid-sparing therapy (e.g., methotrexate, hydroxyurea). For continuation, must have clinical improvement in condition on Nucala (e.g., reduction in flares, reduced steroid dosing, etc.) compared to previous steroid-sparing therapy.
<b>Indications</b>	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	

# NUEDEXTA

## Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# NUPLAZID

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## Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# OCALIVA

## Products Affected

- OCALIVA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have one of the following: alkaline phosphatase level greater than or equal to 1.67 times the upper limit of normal, or total bilirubin greater than or equal to 1 times the upper limit of normal but less than 2 times the upper limit of normal.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must have received 12 months of ursodiol therapy and have had an inadequate response or be intolerant to ursodiol.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ODOMZO

## Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Carcinoma must have recurred following surgery or radiation therapy or in patients who are not candidates for surgery or radiation therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	



# OFEV

## Products Affected

- OFEV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For idiopathic pulmonary fibrosis (IPF), must have presence of a UIP pattern on HRCT in patients not subjected to surgical lung biopsy. For systemic sclerosis related Interstitial Lung Disease (SSc-ILD), diagnosis must be confirmed by HRCT.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For IPF, prescriber must rule out other known causes of interstitial lung disease. For SSc-ILD, fibrotic disease in the lung must be at least 10%, Forced Vital Capacity (FVC) must be at least 40% of predicted normal, and SSc disease onset (defined by first non-Raynaud symptom) must be within 7 past years. Must have disease progression (e.g., greater than or equal to 10 percent decline in FVC or DLCO) on trials of mycophenolate mofetil and cyclophosphamide at maximally tolerated doses, or medical contraindication to treatment. Provider must attest that the patient is being adequately treated for any complications of SSc (e.g., pulmonary hypertension) and comorbid disease (e.g., chronic obstructive pulmonary disease - COPD).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# OLUMIANT

## Products Affected

- OLUMIANT ORAL TABLET 1 MG, 2 MG

PA Criteria	Criteria Details
Exclusion Criteria	Olumiant must not be used in combination with other biological drugs.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	One year
Other Criteria	For a diagnosis of rheumatoid arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one (1) non-biologic immunomodulator (e.g. methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) and either Enbrel or Humira.
Indications	All Medically-accepted Indications.
Off Label Uses	

# OPSUMIT

## Products Affected

- OPSUMIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For diagnosis of pulmonary arterial hypertension, must be in World Health Organization Group category 1.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ORENCIA

## Products Affected

- ORENCIA SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Orencia must not be used in combination with other biological products.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Must be age 6 years or older for intravenous formulation and age 2 years or older for subcutaneous formulation.
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of psoriatic arthritis or rheumatoid arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one (1) non-biologic immunomodulator (e.g. methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) and either Enbrel or Humira.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ORENCIA CLICKJECT

## Products Affected

- ORENCIA CLICKJECT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Orencia Clickject must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Must be age 6 years or older for intravenous formulation and age 2 years or older for subcutaneous formulation.
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of psoriatic arthritis or rheumatoid arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one (1) non-biologic immunomodulator (e.g. methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) and either Enbrel or Humira.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ORENITRAM

## Products Affected

- ORENITRAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must first try generic Revatio (sildenafil).
Indications	All Medically-accepted Indications.
Off Label Uses	

# ORKAMBI

## Products Affected

- ORKAMBI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have laboratory confirmation of homozygous F508del mutation in the cystic fibrosis transmembrane regulator (CFTR) gene
Age Restrictions	Must be age 2 or older
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# OTEZLA

## Products Affected

- OTEZLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For moderate to severe plaque psoriasis, patient must try one systemic non-biologic treatment (cyclosporine, cyclosporine modified, methotrexate, methylprednisolone, prednisone, or Soriatane). For psoriatic arthritis, patient must try one non-biologic DMARD (methotrexate, sulfasalazine, hydroxychloroquine, leflunomide, azathioprine, cyclosporine). For oral ulcers associated with Behcet's disease, must have tried one other systemic therapy (colchicine, systemic corticosteroids, azathioprine, thalidomide, interferon alpha, tumor necrosis factor inhibitors).
Indications	All Medically-accepted Indications.
Off Label Uses	



# OXERVATE

## Products Affected

- OXERVATE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation confirming diagnosis must be submitted.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	8 weeks total treatment
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# PEMAZYRE

## Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year - dose and frequency must align with FDA label
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# penicillamine

## Products Affected

- *penicillamine oral capsule*

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

# pentamidine

## Products Affected

- *pentamidine isethionate inhalation*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	CD4 lymphocyte count. For patients 30 days to 1 year of age, was the patient born to a mother known to be HIV-infected? Is HIV seropositive or infected? For patients 2 years of age and older, has the patient experienced at least one episode of PCP?
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must have therapeutic trial of Co-trimoxazole (trimethoprim/sulfamethoxazole).
Indications	All Medically-accepted Indications.
Off Label Uses	

# PERSERIS

## Products Affected

- PERSERIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must be stable on or be able to tolerate an oral risperidone dose of 3 to 4 mg/day. For Perseris 120 mg, the patient must try and fail Rispderal Consta (fail means the drug was tried at an equivalent dose to currently requested Perseris, but the condition did not improve or patient had an intolerance).
Indications	All Medically-accepted Indications.
Off Label Uses	

# PHENOBARBITAL

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## Products Affected

- *phenobarbital oral elixir*
- *phenobarbital oral tablet*

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

# PIQRAY

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer, documentation of evidence confirming mutations must be submitted. Patient must have an ECOG score of 0 or 1.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must have previously tried and progressed on or after an endocrine-based regimen. Piqray must be given in combination with fulvestrant.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# POMALYST

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## Products Affected

- POMALYST

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



# PRETOMANID

## Products Affected

- PRETOMANID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	26 weeks
Other Criteria	Must be used in combination with linezolid and Sirturo.
Indications	All FDA-approved Indications.
Off Label Uses	

# PREVYMIS

## Products Affected

- PREVYMIS ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	100 days
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# PROLASTIN-C

## Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have a predicted FEV1 value between 30 and 65% and have serum AAT level less than 11 micromoles per liter (80 milligrams per deciliter if measured by radial immunodiffusion or 50 milligrams per deciliter if measure by nephelometry).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# PROLIA

## Products Affected

- PROLIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For diagnosis of post-menopausal osteoporosis and for males with diagnosis of osteoporosis, must have a therapeutic trial with one oral bisphosphonate (e.g., alendronate, risedronate, ibandronate) and zoledronic acid. For diagnosis of prophylaxis of post-menopausal osteoporosis, must have a therapeutic trial with one oral bisphosphonate (e.g., alendronate, risedronate, ibandronate) and zoledronic acid. Applies only to beneficiaries enrolled in an MA-PD plan.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# PROMACTA

## Products Affected

- PROMACTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Current platelet count
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	For chronic ITP, must first try IVIG or immunoglobulin. For thrombocytopenia from hepatitis C infection, must also use interferon-based therapy. For aplastic anemia, must be used with standard immunosuppressive therapy (antithymocyte globulin and cyclosporine) for first-line treatment or must have had an insufficient response to cyclosporine or cyclosporine modified for second-line or subsequent treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# QINLOCK

## Products Affected

- QINLOCK

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

# QUETIAPINE FUMARATE ER

## Products Affected

- *quetiapine fumarate er oral tablet extended release 24 hour 150 mg, 200 mg, 300 mg, 400 mg, 50 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must first try immediate-release quetiapine.
Indications	All Medically-accepted Indications.
Off Label Uses	

# RAVICTI

## Products Affected

- RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patient must be age 2 months or older.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	



# RAYALDEE

## Products Affected

- RAYALDEE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Serum total 25-hydroxyvitamin D level must be less than 30 ng/mL (must be submitted to Priority Health).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must have chronic kidney disease (CKD) stage 3 or 4.
Indications	All Medically-accepted Indications.
Off Label Uses	

# RELISTOR

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## Products Affected

- RELISTOR ORAL
- RELISTOR SUBCUTANEOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Patient must not have mechanical gastrointestinal obstruction.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	4 months
Other Criteria	Patient must be unresponsive with a minimum of 2 other laxative therapies or is unable to tolerate oral laxatives.
Indications	All Medically-accepted Indications.
Off Label Uses	

# REPATHA

## Products Affected

- REPATHA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must submit most recent LDL cholesterol (LDL-C) laboratory report. For HeFH or HoFH, must confirm diagnosis by genetic testing, WHO Dutch Lipid Network or Simon-Broome criteria.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Must first try two high intensity statin medications (e.g., atorvastatin 40 mg daily or higher dose and rosuvastatin 20 mg daily or higher) or, if a high-intensity statin is not tolerated, two statins at the maximally tolerated dose and be unable to reach LDL-C less than 100 mg/dL. Statins trials are not required for patients who have tried, but are unable to tolerate a statin at any dose and have provider attestation certifying statin intolerance.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# REPATHA PUSHTRONEX SYSTEM

## Products Affected

- REPATHA PUSHTRONEX SYSTEM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must submit most recent LDL cholesterol (LDL-C) laboratory report. For HeFH or HoFH, must confirm diagnosis by genetic testing, WHO Dutch Lipid Network or Simon-Broome criteria.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Must first try two high intensity statin medications (e.g., atorvastatin 40 mg daily or higher dose and rosuvastatin 20 mg daily or higher) or, if a high-intensity statin is not tolerated, two statins at the maximally tolerated dose and be unable to reach LDL-C less than 100 mg/dL. Statins trials are not required for patients who have tried, but are unable to tolerate a statin at any dose and have provider attestation certifying statin intolerance.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# REPATHA SURECLICK

## Products Affected

- REPATHA SURECLICK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must submit most recent LDL cholesterol (LDL-C) laboratory report. For HeFH or HoFH, must confirm diagnosis by genetic testing, WHO Dutch Lipid Network or Simon-Broome criteria.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Must first try two high intensity statin medications (e.g., atorvastatin 40 mg daily or higher dose and rosuvastatin 20 mg daily or higher) or, if a high-intensity statin is not tolerated, two statins at the maximally tolerated dose and be unable to reach LDL-C less than 100 mg/dL. Statins trials are not required for patients who have tried, but are unable to tolerate a statin at any dose and have provider attestation certifying statin intolerance.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# RETEVMO

## Products Affected

- RETEVMO

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

# REVLIMID

## Products Affected

- REVLIMID

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

# REXULTI

## Products Affected

- REXULTI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For diagnosis of schizophrenia, patient must first try one generic atypical antipsychotic. For diagnosis of major depressive disorder, Rexulti must be taken concurrently with an antidepressant.
Indications	All Medically-accepted Indications.
Off Label Uses	



# RHOFADE

## Products Affected

- RHOFADE

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

# RINVOQ

## Products Affected

- RINVOQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must have tried and failed one oral DMARD (e.g. methotrexate) or one injectable DMARD (e.g. Humira).
Indications	All Medically-accepted Indications.
Off Label Uses	

# ROZLYTREK

## Products Affected

- ROZLYTREK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of NTRK gene fusion must be submitted for NTRK gene fusion positive solid tumors. Documentation of ROS 1 mutation testing must be submitted for ROS1 positive non-small cell lung cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# RUBRACA

## Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must have tried at least two other chemotherapies.
Indications	All Medically-accepted Indications.
Off Label Uses	

# RUZURGI

## Products Affected

- RUZURGI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient must have clinical symptoms of LEMS(i.e., proximal lower extremity weakness) that interfere with daily activities. If the patient has a cancer diagnosis associated with LEMS, the cancer must have been appropriately treated. Must provide a baseline disease severity score using the Triple-Timed Up-And-Go (3TUG) test.
<b>Age Restrictions</b>	Patient must be between the ages of 6 and 16 years.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval for 3 months. Subsequent approvals for 12 months.
<b>Other Criteria</b>	Patient must not have history of seizures nor have conditions (e.g., no active brain metastases) or be taking medications (e.g., bupropion, clozapine, fluoroquinolones) that increase the risk of seizures. Patient must be ambulatory. For continuation, patient must show improvement or stabilization in condition from baseline using the 3TUG test and/or other measures per provider's attestation.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# RYDAPT

## Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For diagnosis of acute myeloid leukemia (AML), patient must have FLT3 mutation-positive disease as detected by an FDA-approved test.
Age Restrictions	Must be age 18 or older
Prescriber Restrictions	
Coverage Duration	One year. For AML, limited to 6 cycles.
Other Criteria	For diagnosis of AML, patient must be using Rydapt in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# SAMSCA

## Products Affected

- SAMSCA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Treatment must be initiated in an inpatient setting.
Indications	All Medically-accepted Indications.
Off Label Uses	

# SEROSTIM

## Products Affected

- SEROSTIM SUBCUTANEOUS SOLUTION  
RECONSTITUTED 4 MG, 5 MG, 6 MG

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



# SIGNIFOR

## Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must be too ill for pituitary surgery or patient must have had surgery that failed to completely removed the tumor. Patient must have a documented trial with ketoconazole to reduce cortisol secretion.
Indications	All Medically-accepted Indications.
Off Label Uses	

# SIKLOS

## Products Affected

- SIKLOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patient must be between age 2 and 17 years.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# SILDENAFIL CITRATE

## Products Affected

- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must have a pulmonary arterial hypertension (PAH) classification that meets World Health Organization (WHO) Group 1 criteria.
Indications	All Medically-accepted Indications.
Off Label Uses	

# SILIQ

## Products Affected

- SILIQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Siliq must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Must be age 18 or older.
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of psoriasis, must first have 5% or more of body surface area affected (unless hands, feet, head, neck, or genitalia are affected) and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one (1) topical drug, one (1) non-biologic immunomodulator (e.g. methotrexate, cyclosporine, acitretin) and either Enbrel or Humira.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# SIMPONI

## Products Affected

- SIMPONI SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- SIMPONI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Simponi must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	For diagnosis of ankylosing spondylitis, must have presence of active disease for at least 4 weeks, BASDAI score of at least 4.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year.
<b>Other Criteria</b>	For a diagnosis of ankylosing spondylitis, must first have presence of disease for at least 4 weeks and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) and any two of the following: Humira, Rinvoq, Skyrizi, Actemra, Cosentyx, Otezla, Xeljanz/XeljanzXR, Enbrel, Stelara. For a diagnosis of psoriatic arthritis, rheumatoid arthritis, or ulcerative colitis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. azathioprine, 6-mercaptopurine, methotrexate, leflunomide) and any two of the following: Humira, Rinvoq, Skyrizi, Actemra, Cosentyx, Otezla, Xeljanz/XeljanzXR, Enbrel, Stelara.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# SIVEXTRO

## Products Affected

- SIVEXTRO ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Culture and sensitivity results showing the patient's infection is not susceptible to alternative antibiotic treatments.
Age Restrictions	
Prescriber Restrictions	Prescriber must be an infectious disease specialist or have consulted with an infectious disease specialist.
Coverage Duration	6 days
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# SKYRIZI

## Products Affected

- SKYRIZI (150 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Must be age 18 or older
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For diagnosis of plaque psoriasis, 5% or more of the patient's body surface area must be affected (unless hands, feet, head, neck, or genitalia are affected), patient must first try one non-biologic systemic drug. When authorized, up to 150mg (two 75mg syringes) will be covered at weeks 0 and 4, followed by 150mg (two 75mg syringes) every 12 weeks for maintenance dosing.
Indications	All Medically-accepted Indications.
Off Label Uses	

# SOVALDI

## Products Affected

- SOVALDI ORAL PACKET 150 MG
- SOVALDI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patient must be age 3 or over.
Prescriber Restrictions	Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist.
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All Medically-accepted Indications.
Off Label Uses	



# SPRYCEL

## Products Affected

- SPRYCEL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	BCR-ALB1 Gene Arrangement, Quantitative PCR must be completed at baseline, then every 3 months to assess response to therapy until complete cytogenetic response, then every 3 months for 3 years, then every 3-6 months thereafter. If loss of response to Sprycel occurs, BCR-ABL kinase domain mutation analysis must be done before changing therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# STELARA

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Stelara must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Patient must be age 12 or over.
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of psoriasis, must first have 5% or more of body surface area affected (unless hands, feet, head, neck, or genitalia are affected) and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one topical drug or one non-biologic immunomodulator (e.g. methotrexate, cyclosporine, acitretin). For a diagnosis of Crohns disease, psoriatic arthritis, or ulcerative colitis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. azathioprine, 6-mercaptopurine, methotrexate, leflunomide).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# STIVARGA

## Products Affected

- STIVARGA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation of KRAS mutation status. Eastern Cooperative Oncology Group (ECOG) performance status of 0-1. ECOG not required for diagnosis of Gastrointestinal Stromal Tumors.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For diagnosis of metastatic colorectal cancer, patient must have a documented trial with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy and an anti-vascular endothelial growth factor (VEGF) therapy. Patients with KRAS wild-type, patient must have a documented trial with an anti-epidermal growth factor receptor (EGFR) therapy. For diagnosis of gastrointestinal stromal tumor, patient must have had prior treatment with both Gleevec and Sutent.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# STRIANT

## Products Affected

- STRIANT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Subnormal serum total testosterone concentration must be less than 300 ng/dL, on more than one occasion in the past year.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must be male. Patient must have prior use of generic testosterone, either topical or injectable, for a minimum of two months. Patient must have clinical symptoms and signs consistent with androgen deficiency. Men over age 50 years (or over 40 years who have a family history or are African-American) must be screened for prostate cancer before starting therapy and routinely while on therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# SUTENT

## Products Affected

- SUTENT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For diagnosis of gastrointestinal stromal tumor, patient must have a trial with Gleevec.
Indications	All Medically-accepted Indications.
Off Label Uses	

# SYLATRON

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Patient must not have autoimmune hepatitis, hepatic decompensation, or sever neuropsychiatric disorders.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Sylatron administration must begin within 84 days after cutaneous lesion is removed with documentation of adequate surgical margins and complete regional lymphadenectomy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# SYMDEKO

## Products Affected

- SYMDEKO ORAL TABLET THERAPY  
PACK 100-150 & 150 MG, 50-75 & 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Must be age 6 or older.
Prescriber Restrictions	
Coverage Duration	One year.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# SYMPAZAN

## Products Affected

- SYMPAZAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Must be age 2 years or older.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must first try and fail generic clobazam.
Indications	All FDA-approved Indications.
Off Label Uses	



# SYNRIBO

## Products Affected

- SYNRIBO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorized for one year.
Other Criteria	For diagnosis of chronic myeloid leukemia, patient must have a trial with one of Gleevec, Sprycel or Tasigna.
Indications	All Medically-accepted Indications.
Off Label Uses	

# TABRECTA

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## Products Affected

- TABRECTA

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

## tadalafil 2.5mg and 5mg (Cialis)

### Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must have tried and failed either 6 months of finasteride or 3 months of dutasteride and must have tried and failed 28 days of alfuzosin, doxazosin, tamsulosin, or terazosin.
Indications	All Medically-accepted Indications.
Off Label Uses	

## tadalafil 20mg (Adcirca)

### Products Affected

- *tadalafil (pah)*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must have a pulmonary arterial hypertension (PAH) classification that meets World Health Organization (WHO) Group 1 criteria.
Indications	All FDA-approved Indications.
Off Label Uses	

# TAFINLAR

## Products Affected

- TAFINLAR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must not have prior use of Zelboraf or Mekinist.
Indications	All Medically-accepted Indications.
Off Label Uses	

# TAGRISSO

## Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have laboratory confirmation of epidermal growth factor receptor T790M mutation, as detected by an FDA approved test or exon 19 deletion or exon 21 (L858R) substitution mutations.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For EGFR T790M mutation positive non-small cell lung cancer, must have had disease progression on or after EGFR TKI therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# TAKHZYRO

## Products Affected

- TAKHZYRO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient is on an angiotensin-converting enzyme (ACE) inhibitor.
<b>Required Medical Information</b>	Patient has attacks either affecting upper airways, involving the face, neck, or abdomen, or resulting in debilitation or dysfunction. Requires submission of C4, C1-INH protein, and C1-INH function lab results confirming diagnosis.
<b>Age Restrictions</b>	Must be age 12 or older.
<b>Prescriber Restrictions</b>	Prescriber is an allergist, immunologist, hematologist, or other specialist experienced in treating HAE.
<b>Coverage Duration</b>	Limited to 300mg (one vial) every 2 weeks. Duration of each authorization is limited to 6 months.
<b>Other Criteria</b>	Documentation that on-demand/acute therapy (e.g. Firazyr, Berinert, Kalibtor) AND one previously optimized prophylactic treatment with an attenuated androgen or antifibrinolytic did not provide adequate symptom control.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# TALTZ

## Products Affected

- TALTZ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Taltz must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	For a diagnosis of ankylosing spondylitis, must have a BASDAI score of at least 4.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of psoriasis, must first have 5% or more of body surface area affected (unless hands, feet, head, neck, or genitalia are affected) and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one (1) topical drug, one (1) non-biologic immunomodulator (e.g. methotrexate, cyclosporine, acitretin) and either Enbrel or Humira. For a diagnosis of psoriatic arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one (1) non-biologic immunomodulator (e.g. methotrexate, leflunomide, sulfasalazine, azathioprine) and either Enbrel or Humira. For a diagnosis of ankylosing spondylitis, must first have presence of disease for at least 4 weeks and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one (1) nonsteroidal anti-inflammatory drug (NSAID) and either Enbrel or Humira. For a diagnosis of non-radiographic axial spondyloarthritis (NRAS), must first have presence of disease for at least 4 weeks and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) and Humira.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# TALZENNA

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## Products Affected

- TALZENNA

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

# TARGRETIN

## Products Affected

- TARGRETIN

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

# TASIGNA

## Products Affected

- TASIGNA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	BCR-ALB1 Gene Arrangement, Quantitative PCR must be completed at baseline, then every 3 months to assess response to therapy until complete cytogenetic response, then every 3 months for 3 years, then every 3-6 months thereafter. If loss of response to Tasigna occurs, BCR-ABL kinase domain mutation analysis must be done before changing therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# TAZVERIK

## Products Affected

- TAZVERIK

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

# TEGSEDI

## Products Affected

- TEGSEDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy, diagnosis confirmed by the following: documented transthyretin (TTR) mutation (e.g., V30M) by genetic testing AND documented amyloid deposits in biopsy tissue. Must provide documentation of one of the following: Baseline polyneuropathy disability (PND) score less than or equal to IIIb or baseline FAP Stage 1 or 2. Patient must have a platelet count of greater than or equal to 100 x 10 <sup>9</sup> /L. Patient must have a urine protein to creatinine ratio (UPCR) less than 1,000 mg/g.
<b>Age Restrictions</b>	Must be age 18 or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months on initial and continuation requests
<b>Other Criteria</b>	Patient must present with clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.). Patient must not be receiving Tegsedi in combination with tafamidis (Vyndaqel, Vyndamax) or Onpattro. For continuation, patient must show clinical benefit from Tegsedi (e.g., improved neuropathy symptoms, slowing of disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# TERIPARATIDE

## Products Affected

- TERIPARATIDE (RECOMBINANT)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patients T-score must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Two years total therapy
<b>Other Criteria</b>	For diagnosis of postmenopausal osteoporosis, the following criteria must be met: documented therapeutic trial with failure, contraindication, or intolerance to one antiresorptive therapy (defined as creatinine clearance less than 35 mL/min, inability to remain upright for 30 minutes after dose, esophageal stricture [known stricture or dysphagia], significant decrease in BMD after at least one year of therapy, or new fracture while on therapy to alendronate, risedronate, ibandronate OR significant decrease in BMD after at least one year of therapy or new fracture while on therapy to Prolia or zoledronic acid) AND documented therapeutic trial with failure, contraindication, or intolerance (defined as significant decrease in BMD after at least one year of therapy or new fracture while on therapy) to Tymlos. For diagnosis of osteoporosis (primary or hypogonadal, or due to corticosteroids) the following criteria must be met: documented therapeutic trial with failure, contraindication, or intolerance (defined as creatinine clearance less than 35 mL/min, inability to remain upright for 30 minutes after dose, esophageal stricture (known stricture or dysphagia), significant decrease in BMD after at least one year of therapy, or new fracture while on therapy) to alendronate, risedronate, or ibandronate AND documented therapeutic trial with failure, contraindication, or intolerance (defined as significant decrease in BMD after at least one year of therapy, or new fracture while on therapy) to zoledronic acid (generic Reclast) or Prolia.

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

# testosterone gel

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Subnormal serum total testosterone concentration must be less than 300 ng/dL, on more than one occasion in the past year.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must be male. Patient must have clinical symptoms and signs consistent with androgen deficiency. Men over age 50 years (or over 40 years who have a family history or are African-American) must be screened for prostate cancer before starting therapy and routinely while on therapy. Patient must have a documented trial and failure (defined as an intolerance or an inability to improve symptoms or testosterone levels after 2 months of therapy) to a generic injectable testosterone product. Trial with injectable testosterone applies only to members who are enrolled in a MAPD plan.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# testosterone solution

## Products Affected

- *testosterone transdermal solution*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Subnormal serum total testosterone concentration must be less than 300 ng/dL, on more than one occasion in the past year.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must be male. Patient must have clinical symptoms and signs consistent with androgen deficiency. Men over age 50 years (or over 40 years who have a family history or are African-American) must be screened for prostate cancer before starting therapy and routinely while on therapy. Patient must have a documented trial and failure (defined as an intolerance or an inability to improve symptoms or testosterone levels after 2 months of therapy) to a generic injectable testosterone product. Trial with injectable testosterone applies only to members who are enrolled in a MAPD plan.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# tetrabenazine

## Products Affected

- *tetrabenazine*

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with Austedo.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year.
Other Criteria	CYP2D6 genotype must be provided for doses greater than 50mg/day.
Indications	All FDA-approved Indications.
Off Label Uses	

# THALOMID

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## Products Affected

- THALOMID

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

# TIBSOVO

## Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have documentation of IDH1 mutation status as detected by an FDA-approved test. Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# TREMFYA

## Products Affected

- TREMFYA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Tremfya must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Must be age 18 or older.
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	Up to 100mg (1 syringe) at weeks 0 and 4, 100mg (1 syringe) every 8 weeks for maintenance
<b>Other Criteria</b>	For a diagnosis of psoriasis, must first have 5% or more of body surface area affected (unless hands, feet, head, neck, or genitalia are affected) and a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one (1) topical drug, one (1) non-biologic immunomodulator (e.g. methotrexate, cyclosporine, acitretin), and either Enbrel or Humira. For a diagnosis of psoriatic arthritis, must have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to (1) non-biologic immunomodulator (e.g. methotrexate, leflunomide, sulfasalazine), and either Enbrel or Humira.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# TRETINOIN CAPSULES

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## Products Affected

- *tretinoin oral*

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

# TRIKAFTA

## Products Affected

- TRIKAFTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For diagnosis of cystic fibrosis, must provide documentation of the presence of at least one F508del mutation in CFTR gene.
Age Restrictions	Must be age 12 years or older.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# trimipramine

## Products Affected

- *trimipramine maleate oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	



# TUKYSA

## Products Affected

- TUKYSA

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

# TURALIO

## Products Affected

- TURALIO

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

# TYKERB

## Products Affected

- TYKERB

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

# TYMLOS

## Products Affected

- TYMLOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient's T-score must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years total therapy (inclusive of all parathyroid hormone analogs)
Other Criteria	For diagnosis of postmenopausal osteoporosis, the following criteria must be met: documented therapeutic trial with failure, contraindication, or intolerance (defined as creatinine clearance less than 35 mL/min, inability to remain upright for 30 minutes after dose, esophageal stricture (known stricture or dysphagia), significant decrease in BMD after at least one year of therapy, or new fracture while on therapy) to alendronate, risedronate, or ibandronate AND documented therapeutic trial with failure, contraindication, or intolerance (defined as significant decrease in BMD after at least one year of therapy, or new fracture while on therapy) to zoledronic acid (generic Reclast) or Prolia.
Indications	All Medically-accepted Indications.
Off Label Uses	

# UPTRAVI

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## Products Affected

- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have World Health Organization (WHO) group 1 classification of pulmonary arterial hypertension.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# VALCHLOR

## Products Affected

- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must have tried one of the following: topical corticosteroids, topical chemotherapy such as BiCNU an mechlorethamine), topical retinoids, or topical imiquimod.
Indications	All Medically-accepted Indications.
Off Label Uses	

# VASCEPA

## Products Affected

- VASCEPA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For severe hypertriglyceridemia, laboratory confirmation of a baseline triglyceride level of at least 500 mg/dL prior to starting Vascepa. For reducing the risk of myocardial infarction (MI), stroke, coronary revascularization, and unstable angina requiring hospitalization, laboratory confirmation of a baseline triglyceride level of at least 150mg/dL prior to starting Vascepa.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For reducing the risk of myocardial infarction (MI), stroke, coronary revascularization, and unstable angina requiring hospitalization: must have either established cardiovascular disease (defined as a documented history of coronary artery disease, cerebrovascular or carotid disease, or peripheral artery disease) OR diabetes mellitus with 2 or more additional risk factors for cardiovascular disease (e.g., current or recent cigarette smoker, hypertension, elevated CRP, etc.), must be used with maximally tolerated statin therapy. Must have had a minimum 12-week trial on omega-3-acid ethyl esters (generic Lovaza) with inability to lower triglycerides below 150mg/dL.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# VENCLEXTA

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## Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

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



# VERZENIO

## Products Affected

- VERZENIO

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

# VITRAKVI

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of NTRK gene fusion must be submitted.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# VIZIMPRO

## Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of laboratory report confirming EGFR exon 19 deletion or exon 21 L858R mutation must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# VOTRIENT

## Products Affected

- VOTRIENT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For diagnosis of soft tissue sarcoma, patient must have a trial with anthracycline-containing chemotherapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# VYNDAMAX

## Products Affected

- VYNDAMAX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of ATTR-CM must be confirmed by presence of amyloid deposits in biopsy tissue AND one of the following: For wild-type disease, must identify TTR as the precursor protein by immunohistochemistry, scintigraphy, or mass spectrometry, and for hereditary disease, must have a TTR mutation (e.g., V122I, Val122Ile) on genetic testing. Patient must have medical history of heart failure (e.g., prior hospitalization for heart failure, clinical evidence of heart failure such as volume overload). Patient must have evidence of cardiac involvement on ECHO with increased wall thickness.
<b>Age Restrictions</b>	Must be age 18 or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months on initial and continuation requests
<b>Other Criteria</b>	Vyndamax will not be approved if any of the following apply: Patient has primary (light-chain) amyloidosis, patient has had a prior liver or heart transplant or an implanted cardiac device, use of Vyndamax with Onpattro or Tegsedi, or NYHA Class 3 and 4 heart failure. For continuation, patient must continue to meet initial criteria and have had a positive clinical response to Vyndamax compared to baseline evidenced by objective (e.g., reduced cardiovascular-related hospitalizations, cardiac function) and subjective measures (e.g., function, quality of life).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# VYNDAQEL

## Products Affected

- VYNDAQEL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of ATTR-CM must be confirmed by presence of amyloid deposits in biopsy tissue AND one of the following: For wild-type disease, must identify TTR as the precursor protein by immunohistochemistry, scintigraphy, or mass spectrometry, and for hereditary disease, must have a TTR mutation (e.g., V122I, Val122Ile) on genetic testing. Patient must have medical history of heart failure (e.g., prior hospitalization for heart failure, clinical evidence of heart failure such as volume overload). Patient must have evidence of cardiac involvement on ECHO with increased wall thickness.
<b>Age Restrictions</b>	Must be age 18 or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months on initial and continuation requests
<b>Other Criteria</b>	Vyndaqel will not be approved if any of the following apply: Patient has primary (light-chain) amyloidosis, patient has had a prior liver or heart transplant or an implanted cardiac device, use of Vyndaqel with Onpattro or Tegsedi, or NYHA Class 3 and 4 heart failure. For continuation, patient must continue to meet initial criteria and have had a positive clinical response to Vyndaqel compared to baseline evidenced by objective (e.g., reduced cardiovascular-related hospitalizations, cardiac function) and subjective measures (e.g., function, quality of life).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# XALKORI

## Products Affected

- XALKORI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have an Eastern Cooperative Oncology Group (ECOG) performance score between 0 and 3.
Age Restrictions	Must be 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# XATMEP

## Products Affected

- XATMEP

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	



# XELJANZ

## Products Affected

- XELJANZ ORAL TABLET 10 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Xeljanz must not be used in combination with other biological drugs.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For a diagnosis of psoriatic arthritis, rheumatoid arthritis, or ulcerative colitis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. azathioprine, 6-mercaptopurine, methotrexate, leflunomide). For a diagnosis of ulcerative colitis, induction dosing is limited to 16 weeks. Induction and maintenance dosing must be applied consistent with the FDA-approved label. For a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA), must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. methotrexate, leflunomide, sulfasalazine).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# XELJANZ XR

## Products Affected

- XELJANZ XR

PA Criteria	Criteria Details
Exclusion Criteria	Xeljanz XR must not be used in combination with other biological drugs.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	One year
Other Criteria	For a diagnosis of psoriatic arthritis, rheumatoid arthritis, or ulcerative colitis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. azathioprine, 6-mercaptopurine, methotrexate, leflunomide). For a diagnosis of ulcerative colitis, induction dosing is limited to 16 weeks. Induction and maintenance dosing must be applied consistent with the FDA-approved label.
Indications	All Medically-accepted Indications.
Off Label Uses	

# XERMELO

## Products Affected

- XERMELO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must be experiencing 4 or more bowel movements per day.
Age Restrictions	Must be 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must have been receiving stable dose SSA therapy (either long-acting release (LAR), depot, or infusion pump) for at least 3 months.
Indications	All Medically-accepted Indications.
Off Label Uses	

# XIFAXAN

## Products Affected

- XIFAXAN ORAL TABLET 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year. Limited to 42 tablets for 14 days for IBS-D. 60 tablets per 30 days for other indications.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# XOLAIR

## Products Affected

- XOLAIR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For diagnosis of asthma, patient must have had a positive skin test or in-vitro reactivity to a perennial aeroallergen.
<b>Age Restrictions</b>	For diagnosis of chronic urticaria patient must be age 12 or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For diagnosis of asthma, patient's symptoms must be inadequately controlled with inhaled corticosteroids. For diagnosis of chronic urticaria, patient must first try two or more H1 antihistamines, or patient must first try one H1 antihistamine and one or more of the following: H2 antihistamines, oral corticosteroids, or leukotriene modifiers.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# XOSPATA

## Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of laboratory report confirming FLT3 mutation must be submitted.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# XPOVIO

## Products Affected

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

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

# XTANDI

## Products Affected

- XTANDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For CRPC, patient must have Eastern Cooperative Oncology Group (ECOG) performance status of 0-2, two sequential rising PSA levels obtained 2 to 3 weeks apart or other evidence of disease progression, and serum testosterone must be less than 50ng/dL or patient is currently receiving gonadotropin-releasing hormone (GnRH) analog therapy or has had a bilateral orchiectomy. For metastatic CSPC, patient must have had a bilateral orchiectomy or receive a gonadotropin-releasing hormone (GnRH) analog concurrently.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# XYOSTED

## Products Affected

- XYOSTED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Subnormal serum total testosterone concentration must be less than 300 ng/dL, on more than one occasion in the past year.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must be male. Patient must have prior use of generic testosterone, either topical or injectable, for a minimum of two months. Patient must have clinical symptoms and signs consistent with androgen deficiency. Men over age 50 years (or over 40 years who have a family history or are African-American) must be screened for prostate cancer before starting therapy and routinely while on therapy.
Indications	All FDA-approved Indications.
Off Label Uses	

# XYREM ORAL

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## Products Affected

- XYREM

PA Criteria	Criteria Details
Exclusion Criteria	Patient must not be receiving sedative hypnotics with Xyrem. Patient must not suffer from succinic semialdehyde dehydrogenase deficiency.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescriber must be a sleep specialist, neurologist, or pulmonologist.
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# Yonsa

## Products Affected

- YONSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient must not have a history of adrenal or pituitary gland disorders.
<b>Required Medical Information</b>	Patient must have evidence of disease progression. Patient must have Eastern Cooperative Oncology Group (ECOG) performance standard of 0 to 2. Patient must have a PSA level greater than 5ng/ml.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	8 months
<b>Other Criteria</b>	Patient must not have Eastern Cooperative Oncology Group (ECOG) performance status greater than or equal to 3. Patient must not have severe hepatic impairment. Patient must not have NYHA Class III or IV heart failure.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ZEJULA

## Products Affected

- ZEJULA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For annual continuation, patient must have no evidence of disease progression or treatment-limiting adverse reactions.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ZELBORAF

## Products Affected

- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 (excluding patients with Erdheim-Chester disease). Baseline ECG, electrolytes (including potassium, magnesium, and calcium), liver enzymes (transaminase and alkaline phosphatase), and bilirubin baseline values must be within clinically acceptable limits and will continued to be monitored throughout treatment.
Age Restrictions	Must be 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# ZEMAIRA

## Products Affected

- ZEMAIRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have a predicted FEV1 value between 30 and 65% and have serum AAT level less than 11 micromoles per liter (80 milligrams per deciliter if measured by radial immunodiffusion or 50 milligrams per deciliter if measure by nephelometry).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# ZEPATIER

## Products Affected

- ZEPATIER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	For GT1 and 4, must first try Harvoni. Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ZOLINZA

## Products Affected

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For diagnosis of primary cutaneous T-cell lymphoma, patient must have prior use of two of the following systemic therapies: a retinoid (bexarotene, all-trans retinoic acid, isotretinoin, acitretin), an interferon (IFN-alpha, IFN-gamma), methotrexate, or extracorporeal photopheresis.
Indications	All Medically-accepted Indications.
Off Label Uses	



# ZORBTIVE

## Products Affected

- ZORBTIVE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Four weeks only
Other Criteria	Patient must be receiving TPN in conjunction with Zorbtive.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ZUBSOLV

## Products Affected

- ZUBSOLV SUBLINGUAL TABLET  
SUBLINGUAL 1.4-0.36 MG, 11.4-2.9 MG,  
2.9-0.71 MG, 5.7-1.4 MG, 8.6-2.1 MG

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

# ZYDELIG

## Products Affected

- ZYDELIG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For chronic lymphocytic leukemia (CLL), must be used in combination with Rituximab. For relapsed Follicular lymphoma (FL) and relapsed Small lymphocytic lymphoma (SLL), must have had 2 previous treatments such as Rituxan, bendamustine, chlorambucil, fludarabine, or cyclophosphamide.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ZYKADIA

## Products Affected

- ZYKADIA

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

# ZYTIGA

## Products Affected

- ZYTIGA ORAL TABLET 500 MG

PA Criteria	Criteria Details
Exclusion Criteria	Patient must not have a history of adrenal or pituitary gland disorders.
Required Medical Information	Patient must have evidence of disease progression. Patient must have Eastern Cooperative Oncology Group (ECOG) performance standard of 0 to 2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	8 months
Other Criteria	Patient must not have Eastern Cooperative Oncology Group (ECOG) performance status greater than or equal to 3. Patient must not have severe hepatic impairment. Patient must not have NYHA Class III or IV heart failure.
Indications	All Medically-accepted Indications.
Off Label Uses	

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