



# **MCS Classicare 2026 Formulary 1 Prior Authorization Criteria**

**MCS Classicare MA-PD Group (HMO), MCS Classicare RxMax (HMO)**

MCS Classicare requires you (or your physician) to get prior authorization for certain drugs. This means that you will need to get approval from MCS Classicare before you fill your prescriptions. If you don't get approval, MCS Classicare may not cover the drug.

MCS Classicare is an HMO plan offered by MCS Advantage, Inc.

Last Updated: 12/09/2025

## Prior Authorization Requirements

# ABIRATERONE

### Products Affected

- *abiraterone acetate oral tablet 250 mg, 500 mg*
- YONSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Castration-resistant metastatic prostate cancer (CRPC), or B.) High risk, castration-sensitive metastatic prostate cancer (CSPC). For treatment of CRPC and CSPC, abiraterone will be used in combination with prednisone AND one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog (e.g. leuprolide, triptorelin), OR 2) Patient has received bilateral orchiectomy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ABIRTEGA

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## Products Affected

- *abirtega*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Castration-resistant metastatic prostate cancer (CRPC), or B.) High risk, castration-sensitive metastatic prostate cancer (CSPC). For treatment of CRPC and CSPC, abiraterone will be used in combination with prednisone AND one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog (e.g. leuprolide, triptorelin), OR 2) Patient has received bilateral orchiectomy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ACITRETIN

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## Products Affected

- *acitretin*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Severely impaired liver or kidney function, B.) Chronic abnormally elevated blood lipid values, C.) Concomitant use of methotrexate or tetracyclines or D.) hypersensitivity (e.g., angioedema, urticaria) to the preparation (acitretin or excipients) or to other retinoids.
<b>Required Medical Information</b>	Diagnosis of severe, recalcitrant psoriasis (including plaque, guttate, erythrodermic palmar- plantar and pustular) AND patient must have tried and failed, contraindication or intolerance to one formulary first line agent (e.g., Topical Corticosteroids (betamethasone, fluocinonide, desoximetasone),Topical Calcipotriene/Calcitriol, Topical Calcipotriene, OR Topical Tazarotene)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# ADALIMUMAB-ADBM

## Products Affected

- *adalimumab-adbm (2 pen)* *mg/0.2ml, 20 mg/0.4ml, 40 mg/0.4ml, 40 mg/0.8ml*
- *adalimumab-adbm (2 syringe)*  
*subcutaneous prefilled syringe kit 10*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate, F.) Moderate to severe Crohns disease G.) Moderate to severe ulcerative colitis, H.) Non-infectious uveitis (including intermediate, posterior, and panuveitis), or I.) Moderate to severe hidradenitis suppurativa. For moderately to severely active rheumatoid arthritis: 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX), or corticosteroids. For active ankylosing spondylitis: patient has experienced an inadequate treatment response, intolerance, or contraindication to a non-steroidal anti-inflammatory drug(NSAID).For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas, scalp) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected)
<b>Age Restrictions</b>	For Juvenile Idiopathic Arthritis: 2 years of age or older. For Pediatric Crohns disease: 6 years of age or older. For Hidradenitis Suppurativa: 12 years of age or older. For Uveitis: 2 years of age or older. For Ulcerative

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<b>PA Criteria</b>	<b>Criteria Details</b>
	Colitis: 5 years of age or older. All other indications 18 years of age or older.
<b>Prescriber Restrictions</b>	1) For PsO and HS: Dermatologist, 2) For CD and UC: Gastroenterologist, 3) For Uveitis: Ophthalmologist, 4) For RA, PJIA, and AS: Rheumatologist, 5) For PsA: Dermatologist or Rheumatologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physicians certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray. For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# ADEMPAS

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## Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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# AFINITOR

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## Products Affected

- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Hypersensitivity to everolimus , or B.) Hypersensitivity to rapamycin derivatives (e.g. sirolimus)
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery, B.) Advanced hormone receptor-positive, HER2 negative breast cancer in postmenopausal women and taken in combination with exemestane, after failure with letrozole or anastrozole, C.) Progressive, well-differentiated, nonfunctional neuroendocrine tumors of gastrointestinal or lung origin and disease is unresectable, locally advanced, or metastatic, D.) Pancreatic progressive neuroendocrine tumors and disease is unresectable, locally advanced, or metastatic, E.) Advanced renal cell carcinoma (RCC) after failure with sunitinib or sorafenib, F.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# AKEEGA

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## Products Affected

- AKEEGA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) as detected on an FDA-approved test AND used in combination with prednisone
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ALECENSA

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## Products Affected

- ALECENSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: A)metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer as detected by an FDA-approved test, or B)adjuvant treatment in adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ALOSETRON

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## Products Affected

- *alosetron hcl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Constipation, B.) History of Chronic or severe constipation or sequelae from constipation, C.) History of ischemic colitis, intestinal obstruction, stricture, toxic megacolon, GI perforation, adhesions, diverticulitis, Crohns disease, ulcerative colitis, D.) History of severe hepatic impairment, E.) History of impaired intestinal circulation, thrombophlebitis, or hypercoagulable state, or F.) Coadministration with fluvoxamine
<b>Required Medical Information</b>	Diagnosis of irritable bowel syndrome, severe diarrhea-predominant in women who have not responded adequately to conventional therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ALUNBRIG

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of anaplastic lymphoma kinase-positive (ALK) metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# AMBRISENTAN

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## Products Affected

- *ambrisentan*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Idiopathic pulmonary fibrosis (IPF), including those with pulmonary hypertension
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension classified as WHO Group I, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Continuation of therapy: patient is tolerating and responding to medication and has improved exercise capacity or a delay in clinical worsening.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ARIKAYCE

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## Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Known sensitivity to any aminoglycoside
<b>Required Medical Information</b>	Diagnosis of pulmonary <i>Mycobacterium avium</i> complex (MAC) infection and used as part of a combination antibacterial regimen in treatment refractory patients (greater than 6 months of a multidrug background regimen)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist or pulmonologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ATYPICALS

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## Products Affected

- CAPLYTA
- FANAPT
- FANAPT TITRATION PACK A
- FANAPT TITRATION PACK B
- FANAPT TITRATION PACK C
- LYBALVI
- REXULTI
- SECUADO
- VERSACLOZ
- VRAYLAR ORAL CAPSULE 1.5 MG, 3 MG, 4.5 MG, 6 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Select atypical antipsychotics will be covered when one of the following is met A.) Patient is using the requested drug for an FDA-Approved or compendia supported indication and the patient unable to take at least two generic oral atypical antipsychotics (risperidone, clozapine tab, olanzapine, quetiapine fumarate IR, ziprasidone, asenapine, paliperidone) due to inadequate treatment response, intolerance, or contraindication, B.) Patient is using the requested drug for an FDA-Approved or compendia supported indication and patient has a clinical condition for which there is no generic alternative or the generic alternatives are not recommended based on published guidelines or clinical literature, or C.) Patient is using the requested drug for an FDA-Approved or compendia supported indication and patient medically requires use of a specific dosage form that is not available in the generic alternatives (examples: suspension, solution, injection).
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist
Coverage Duration	12 Months
Other Criteria	None
Indications	All Medically-accepted Indications.

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# AUGTYRO

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## Products Affected

- AUGTYRO ORAL CAPSULE 160 MG,  
40 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Locally advanced or metastatic ROS1-positive non-small cell lung cancer, or B.) solid tumors that have an NTRK gene fusion are locally advanced, metastatic, or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy
<b>Age Restrictions</b>	12 years or older for the indication solid tumors that have an NTRK gene fusion are locally advanced, metastatic, or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# AUSTEDO

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## Products Affected

- AUSTEDO
- AUSTEDO XR ORAL TABLET  
EXTENDED RELEASE 24 HOUR 12  
MG, 18 MG, 24 MG, 30 MG, 36 MG, 42  
MG, 48 MG, 6 MG
- AUSTEDO XR PATIENT TITRATION  
ORAL TABLET EXTENDED RELEASE  
THERAPY PACK 12 & 18 & 24 & 30  
MG, 6 & 12 & 24 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Suicidal ideation and/or untreated or inadequately treated depression in a patient with Huntington's Disease, B.) Hepatic impairment, C.) Concomitant use of MAOIs, reserpine, tetrabenazine, or valbenazine
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chorea associated with Huntington's disease (Huntington's chorea), or B.) Tardive dyskinesia
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or psychiatrist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# AUVELITY

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## Products Affected

- AUVELITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A) Seizure disorder. B) Current or prior diagnosis of bulimia or anorexia nervosa, C) Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs, or D) Use with an MAOI or within 14 days of stopping treatment with AUVELITY. Do not use AUVELITY within 14 days of discontinuing an MAOI.
<b>Required Medical Information</b>	Diagnosis of major depressive disorder AND Failure, contraindication or intolerance to at least 2 generic alternatives such as SSRIs, SNRIs or Tricyclic antidepressants or the generic alternatives are not recommended based on published guidelines or clinical literature
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a psychiatrist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# AVMAPKI FAKZYNJA

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## Products Affected

- AVMAPKI FAKZYNJA CO-PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of recurrent low-grade serous ovarian cancer (LGSOC) with KRAS mutation in adult patients who have received prior systemic therapy.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# AYVAKIT

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## Products Affected

- AYVAKIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Unresectable or metastatic gastrointestinal stromal tumor, with a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations, B.) Advanced Systemic Mastocytosis (AdvSM), including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), or mast cell leukemia (MCL), and platelet count of at least 50,000/mcL, or C.) Indolent systemic mastocytosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist, allergist, or immunologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# BALVERSA

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of locally advanced or metastatic urothelial carcinoma and both of the following 1.) Susceptible fibroblast growth factor receptor (FGFR)3 genetic alterations confirmed by an FDA-approved diagnostic test, and 2.) Patient has progressed during or following at least one line of prior systemic therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# BENLYSTA

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## Products Affected

- BENLYSTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Active, autoantibody-positive, system lupus erythematosus (SLE), or B.) Active lupus nephritis and patient is receiving standard therapy (corticosteroids, antimalarials, NSAIDs, immunosuppressives)
<b>Age Restrictions</b>	5 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist or rheumatologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# BESREMI

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## Products Affected

- BESREMI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Existence of, or history of severe psychiatric disorders (severe depression, suicidal ideation, or suicide attempt), B.) Hypersensitivity to interferons including interferon alfa-2b or excipients, C.) Hepatic impairment (Child-Pugh B or C), D.) History or presence of active serious or untreated autoimmune disease, or E.) Immunosuppressed transplant recipients
<b>Required Medical Information</b>	Diagnosis of polycythemia vera
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# BEXAROTENE GEL

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## Products Affected

- *bexarotene*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of primary cutaneous T-cell lymphoma (CTCL Stage 1A/1B) and patient had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) indicated for cutaneous manifestations of CTCL
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# BEXAROTENE ORAL

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## Products Affected

- *bexarotene*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cutaneous T-cell lymphoma (CTCL) and patient is not a candidate for or had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) for cutaneous manifestations of CTCL
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# BOSENTAN

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## Products Affected

- *bosentan oral tablet*
- *bosentan oral tablet soluble*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant cyclosporine A or glyburide therapy
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension (WHO Group I) and patient has New York Heart Association (NYHA) Functional Class II-IV, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.). In pediatric patients with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR).
<b>Age Restrictions</b>	For Idiopathic or congenital PAH: 3 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	Initial: 6 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# BOSULIF

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## Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or inadequate response to prior therapy, or B.) Newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) CML
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# BRAFTOVI

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## Products Affected

- BRAFTOVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) unresectable or metastatic melanoma with documented BRAF V600E or V600K mutation as detected by a FDA-approved test and used in combination with binimetinib, B.) metastatic colorectal cancer with documented BRAF V600E mutation as detected by a FDA-approved test AND used in combination with cetuximab OR used in combination with cetuximab and mFOLFOX6 (fluorouracil, leucovorin, and oxaliplatin). C.) Metastatic non-small cell lung cancer with a BRAF V600E mutation as detected by an FDA-approved test and used in combination with binimetinib
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# BRIVIACT

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## Products Affected

- BRIVIACT ORAL SOLUTION
- BRIVIACT ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of partial-onset seizures, member must have history of inadequate response, contraindication, or intolerance to levetiracetam prior to approval.
<b>Age Restrictions</b>	1 month of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# BRONCHITOL

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## Products Affected

- BRONCHITOL TOLERANCE TEST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Cystic fibrosis of the lung
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by Pneumologist or pulmonologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# BRUKINSA

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## Products Affected

- BRUKINSA ORAL CAPSULE
- BRUKINSA ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) mantle cell lymphoma (MCL) and patient has received at least one prior therapy, B.) Treatment of adult patients with Waldenstrom macroglobulinemia, C.) Treatment of adult patients with relapsed or refractory marginal zone lymphoma who have received at least one anti-CD20-based regimen (e.g., rituximab, obinutuzumab, ofatumumab), D.) Chronic lymphocytic leukemia, E.) Small lymphocytic lymphoma, or F.) Relapsed or refractory follicular lymphoma, in combination with obinutuzumab, after 2 or more lines of systemic therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# CABOMETYX

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## Products Affected

- CABOMETYX ORAL TABLET 20 MG,  
40 MG, 60 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Advanced hepatocellular carcinoma (HCC) and patient has been previously treated with sorafenib, C.) Advanced renal cell carcinoma and used as first line treatment in combination with nivolumab or D.) treatment of adults and pediatric patients 12 years and older with locally advanced or metastatic differentiated thyroid cancer that has progressed following VEGFR-targeted therapy (e.g., Axitinib, Lenvatinib, Pazopanib, Sorafenib, Sunitinib, vandetanib) and who are radioactive iodine-refractory or ineligible E.)Pancreatic neuroendocrine well-differentiated tumors (pNET) previously treated, unresectable, locally advanced or metastatic F.) Extra-pancreatic neuroendocrine well-differentiated tumors (epNET) previously treated, unresectable, locally advanced or metastatic.
<b>Age Restrictions</b>	Advanced renal cell carcinoma, Advanced hepatocellular carcinoma: 18 years of age and older. All other indication 12 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# CALQUENCE

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## Products Affected

- CALQUENCE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Mantle cell lymphoma (MCL) and patient has received at least 1 prior therapy, B.) Chronic lymphocytic leukemia (CLL), C.) Small lymphocytic lymphoma (SLL) or D.) In combination with bendamustine and rituximab for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are ineligible for autologous hematopoietic stem cell transplantation (HSCT).
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# CAMZYOS

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## Products Affected

- CAMZYOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use of strong CYP2C19 inhibitors, moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers
<b>Required Medical Information</b>	Diagnosis of symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) in adult patients
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# CAPRELSA

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## Products Affected

- CAPRELSA ORAL TABLET 100 MG,  
300 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Congenital long QT syndrome
<b>Required Medical Information</b>	Diagnosis of metastatic or unresectable locally advanced medullary thyroid cancer (MTC) AND disease is symptomatic or progressive
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# CARGLUMIC ACID

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## Products Affected

- *carglumic acid*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) N-acetyl glutamate synthase (NAGS) deficiency (confirmed by appropriate genetic testing) with acute or chronic hyperammonemia, or B.) Propionic or methylmalonic acidemia with acute hyperammonemia
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# CAYSTON

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## Products Affected

- CAYSTON

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (confirmed by appropriate diagnostic or genetic testing) and patient has <i>Pseudomonas aeruginosa</i> lung infection confirmed by positive culture
<b>Age Restrictions</b>	7 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by Pneumologist, pulmonologist or infectious diseases specialist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# CLOBAZAM

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of seizures associated with Lennox-Gastaut syndrome
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# CNS STIMULANTS

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## Products Affected

- *armodafinil*
- *modafinil*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Obstructive sleep apnea (OSA) confirmed by sleep lab evaluation, B.) Narcolepsy confirmed by sleep lab evaluation, or C.) Shift work disorder (SWD)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# COBENFY

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## Products Affected

- COBENFY
- COBENFY STARTER PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Urinary retention, B.) Moderate or severe hepatic impairment, C.) Gastric retention, D.) History of hypersensitivity to COBENFY or trospium chloride, E.) Untreated narrow-angle glaucoma
<b>Required Medical Information</b>	Diagnosis of Schizophrenia and the patient has a trial/failure or intolerance to at least two generic oral atypical antipsychotic (risperidone, clozapine tab, olanzapine, quetiapine fumarate IR, ziprasidone, asenapine, paliperidone)
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a psychiatrist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# 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
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of progressive, metastatic medullary thyroid cancer
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# COPIKTRA

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## Products Affected

- COPIKTRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsed or refractory chronic lymphocytic leukemia (CLL), or B.) Relapsed or refractory small lymphocytic lymphoma (SLL). For CLL or SLL, the patient must have history of at least 2 prior therapies
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# CORLANOR

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## Products Affected

- CORLANOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Decompensated acute heart failure, B.) hypotension (i.e. blood pressure less than 90/50 mmHg), C.) sick sinus syndrome or sinoatrial block or 3rd degree AV block (unless a functioning demand pacemaker is present), D.) bradycardia (i.e., resting heart rate less than 60 bpm prior to treatment), E.) Severe hepatic impairment (Child-Pugh C), F.) Pacemaker dependent (heart rate maintained exclusively by the pacemaker), G.) Concomitant use of strong CYP3A4 inhibitors
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Adult patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction 35% or less, who are in sinus rhythm with resting heart rate 70 beats per minute or more and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use, or B.) Pediatric patients with stable, symptomatic heart failure due to dilated cardiomyopathy and are in sinus rhythm with an elevated heart rate
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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## COSENTYX\_2

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### Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Ankylosing spondylitis, B.) Moderate to severe plaque psoriasis in adults, C.) Moderate to severe plaque psoriasis in patients 6 years to less than 18 years of age, D.) Active psoriatic arthritis in adult patients, E.) Active psoriatic arthritis in patients 2 years to less than 18 years of age, F.) Non-radiographic axial spondyloarthritis G.) Active enthesitis-related arthritis, or H.) Moderate to severe hidradenitis suppurativa in adults. For ankylosis spondylitis and non-radiographic axial spondyloarthritis: patient has experienced an inadequate treatment response, intolerance, or contraindication to a non-steroidal anti-inflammatory drug (NSAID). For moderate to severe plaque psoriasis: 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected)
<b>Age Restrictions</b>	4 years of age for JIA. 2 years of age PsA, and 6 years of age for PsO
<b>Prescriber Restrictions</b>	For PsO and HS: Dermatologist 1) PsA Dermatologist or Rheumatologist 2)RA, nr-axSpA and AS: rheumatologist
<b>Coverage Duration</b>	12 Months

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PA Criteria	Criteria Details
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physicians certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray. For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# COTELLIC

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## Products Affected

- COTELLIC

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.)unresectable or metastatic malignant melanoma with BRAF V600E OR V600K mutation, and documentation of combination therapy with vemurafenib (Zelboraf), or B.) Histiocytic neoplasms
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# CRESEMBA

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## Products Affected

- CRESEMBA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following: 1.) Coadministration with strong CYP3A4 inhibitors, such as ketoconazole or high-dose ritonavir, 2.) Coadministration with strong CYP3A4 inducers, such as rifampin, carbamazepine, St. Johns wort, or long acting barbiturates, 3.) Use in patients with familial short QT syndrome
<b>Required Medical Information</b>	Diagnosis of invasive mucormycosis or invasive aspergillosis (IA) and patient had a trial or failure of voriconazole, fluconazole or echinocandin.
<b>Age Restrictions</b>	6 years of age or older and weighs at least 16 kg (35.2 lbs)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# CYSTAGON

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## Products Affected

- CYSTAGON

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Known serious hypersensitivity to penicillamine or cysteamine
<b>Required Medical Information</b>	Diagnosis of nephropathic cystinosis confirmed by the presence of increased cystine concentration in leukocytes or by genetic testing
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# DALFAMPRIDINE

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## Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) History of seizure. B.) Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute)
<b>Required Medical Information</b>	Diagnosis of multiple sclerosis and patient must demonstrate sustained walking impairment, but with the ability to walk 25 feet (with or without assistance) prior to starting dalfampridine
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# DANZITEN

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## Products Affected

- DANZITEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Hypokalemia, B.) Hypomagnesemia or C.) Long QT syndrome
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase or accelerated phase AND all of the following 1) patient is resistant or intolerant to prior therapy that included imatinib, 2) patient had a mutational analysis prior to initiation, and 3) therapy is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile, or B) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# DASATINIB

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## Products Affected

- *dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, B.) Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy, C.) Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy, or D.) Newly diagnosed Ph+ ALL in combination with chemotherapy
<b>Age Restrictions</b>	1 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# DAURISMO

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## Products Affected

- DAURISMO ORAL TABLET 100 MG,  
25 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of newly diagnosed acute myeloid leukemia (AML) and used in combination with cytarabine in patients 75 years of age or older OR in patients that have comorbidities that preclude use of intensive induction chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an Oncologist or Hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# DAYBUE

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## Products Affected

- DAYBUE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Rett syndrome
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or pediatric neurologist
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# DEFERASIROX

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## Products Affected

- *deferasirox*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Creatinine clearance less than 40 mL/min, B.) Poor performance status, C.) Platelet count less than 50 x 10(9)/L, D.) Advanced malignancy, E.) High-risk myelodysplastic syndrome (MDS)
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes who have liver iron concentrations of at least 5 mg Fe/g dry weight AND serum ferritin level greater than 300 mcg/L, or B.) Chronic iron overload due to blood transfusions (transfusion hemosiderosis) as evidenced by transfusion of at least 100 mL/kg packed red blood cells AND serum ferritin level greater than 1000 mcg/L
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# DEFERIPRONE

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## Products Affected

- *deferiprone*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) Diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease, or other anemias 2.) failure to current chelation therapy (e.g., deferoxamine)
<b>Age Restrictions</b>	8 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# DIACOMIT

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## Products Affected

- DIACOMIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of severe myoclonic epilepsy in infancy (Dravet syndrome) in patients taking clobazam
<b>Age Restrictions</b>	6 months of age or older and weighing 7 kg or more
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# DICLOFENAC PATCH

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## Products Affected

- *diclofenac epolamine*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of acute mild to moderate pain due to minor strains, sprains and contusions
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# DIMETHYL FUMARATE

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# DROXIDOPA

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## Products Affected

- *droxidopa*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure (e.g., Parkinson disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 1 month, Renewal: 3 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# DUPIXENT

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## Products Affected

- DUPIXENT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	For atopic dermatitis (AD), initial therapy: 1) Patient has moderate-to-severe disease, AND 2) Patient has had an inadequate treatment response to either a topical corticosteroid or a topical calcineurin inhibitor, OR topical corticosteroids and topical calcineurin inhibitors are not advisable for the patient. For oral corticosteroid dependent asthma, initial therapy: Patient has inadequate asthma control despite current treatment with medium to High-dose inhaled corticosteroid unless patient has an intolerance or contraindication to such therapies. For moderate-to-severe asthma, initial therapy: Patient has a baseline blood eosinophil count of at least 150 cells per microliter and their asthma remains inadequately controlled despite current treatment with : inhaled corticosteroids unless patient has an intolerance or contraindication to such therapies. C.) Nasal polyps in patients with inadequate response to nasal corticosteroid. For chronic rhinosinusitis with nasal polyposis (CRSwNP): 1) The requested drug is used as add-on maintenance treatment, AND 2) Patient has experienced an inadequate treatment response to intranasal corticosteroid . For Eosinophilic esophagitis failure, intolerance or contraindication to PPIs. For adult patients with inadequately controlled chronic obstructive pulmonary disease and an eosinophilic phenotype as an add-on maintenance treatment. For treatment of Purigo Nodularis. For the treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment.
<b>Age Restrictions</b>	For Atopic Dermatitis: 6 months of age or older, 2) For Asthma: 6 years of age or older, 3) For CRSwNP: 12 years and older, 4) For PN and COPD: 18 years of age or older, 5) For EoE: 1 year and older, weighing at least 15 kg., or 5) For chronic spontaneous urticaria (CSU): 12 years of age or older

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, dermatologist, gastroenterologist, immunologist, otolaryngologist, pulmonologist, or rheumatologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# EMGALITY

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## Products Affected

- EMGALITY
- EMGALITY (300 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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# EMSAM

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## Products Affected

- EMSAM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant use with any of the following: SSRIs, SNRIs, clomipramine, imipramine, meperidine, tramadol, methadone, pentazocine, propoxyphene, dextromethorphan, carbamazepine, or B.) Pheochromocytoma
<b>Required Medical Information</b>	Diagnosis of major depressive disorder and patient had trial of at least 2 generic oral antidepressants from differing classes (at least one should be from the following list: selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, mirtazapine, or bupropion unless contraindicated), unless unable to take any oral medication AND Patient had an adequate washout period (for patients previously on agents requiring a washout period)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a psychiatrist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# ENBREL

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## Products Affected

- ENBREL
- ENBREL MINI
- ENBREL SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, or E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy. For moderately to severely active rheumatoid arthritis: 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX), or corticosteroids. For active ankylosing spondylitis: patient has experienced an inadequate treatment response, intolerance, or contraindication to a non-steroidal anti-inflammatory drug(NSAID). For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).
Age Restrictions	2 years of age for JIA and PsA, and 4 years of age for PsO
Prescriber Restrictions	1) For RA, PJIA, AS: Rheumatologist, 2) For PsA: Dermatologist or Rheumatologist, 3) For PsO: Dermatologist.
Coverage Duration	12 months

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physicians certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray. For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# ENSPRYNG

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## Products Affected

- ENSPRYNG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Active Hepatitis B infection, or B.) Active or untreated latent tuberculosis
<b>Required Medical Information</b>	Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist, immunologist, or ophthalmologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# EPIDIOLEX

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## Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Lennox-Gastaut syndrome, B.) Severe myoclonic epilepsy in infancy (Dravet syndrome), or C.) Seizures associated with tuberous sclerosis complex (TSC)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# EPOETIN THERAPY

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## Products Affected

- RETACRIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Uncontrolled hypertension, B.) Pure red cell aplasia (PRCA) that begins after treatment with erythropoietin protein drugs.
<b>Required Medical Information</b>	Must meet all of the following criteria. 1) Diagnosis of one of the following: A.) Non-myeloid neoplastic disease and utilized for the treatment of chemotherapy induced anemia, B.) HIV infection and utilized for the treatment of zidovudine induced anemia, C.) Chronic kidney disease resulting in anemia, or D.) High risk surgical candidate status at risk for perioperative blood loss and undergoing elective, noncardiac, or nonvascular surgery, 2) Pretreatment hemoglobin levels of less than 10g/dL, 3) Dose reduction or interruption if hemoglobin exceeds 10 g/dL (CKD not on dialysis-adult, cancer), 11 g/dL (CKD on dialysis), 12 g/dL (pediatric CKD), and 4) Patients with perioperative hemoglobin greater than 10 g/dL and less than or equal to 13 g/dL scheduled to undergo elective, noncardiac, nonvascular surgery
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	6 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

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# ERIVEDGE

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## Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic basal cell carcinoma, or B.) Locally advanced basal cell carcinoma that has recurred following surgery or the patient is not a candidate for surgery or radiation
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ERLEADA

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## Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Nonmetastatic, castration-resistant prostate cancer (nmCRPC), or B.) Metastatic, castration-sensitive prostate cancer (mCSPC). For treatment of nmCRPC and mCSPC, one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog, OR 2) Patient has received bilateral orchectomy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ERLOTINIB

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Locally advanced, unresectable, or metastatic pancreatic cancer and erlotinib will be used in combination with gemcitabine, B.) Locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility AND one of the following 1.) Erlotinib will be used as first-line treatment, 2.) Failure with at least one prior chemotherapy regimen, OR 3.) No evidence of disease progression after four cycles of first-line platinum-based chemotherapy and erlotinib will be used as maintenance treatment
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# ERZOFRI

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## Products Affected

- ERZOFRI INTRAMUSCULAR SUSPENSION PREFILLED SYRINGE  
117 MG/0.75ML, 156 MG/ML, 234 MG/1.5ML, 351 MG/2.25ML, 39 MG/0.25ML, 78 MG/0.5ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following 1)Schizophrenia 2) Schizoaffective disorder
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an psychiatrist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ESLICARBAZEPINE

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## Products Affected

- *eslicarbazepine acetate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of partial-onset seizures
<b>Age Restrictions</b>	4 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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Effective date: 01/01/2026 Last Updated: 12/09/2025

# EUCRISA

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## Products Affected

- EUCRISA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of mild to moderate atopic dermatitis and patient had a trial or failure of 1 generic topical corticosteroid (e.g., fluocinolone acetonide 0.025% ointment, fluticasone propionate 0.05% cream) or generic topical calcineurin inhibitor (e.g., tacrolimus ointment, pimecrolimus cream)
<b>Age Restrictions</b>	3 months of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# EULEXIN

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## Products Affected

- EULEXIN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe hepatic impairment
<b>Required Medical Information</b>	Used in combination with a leuteinizing hormone-release hormone (LHRH) agonist and a diagnosis of one of the following A.) Locally confined stage B2 to C starting eight weeks prior to initiating radiation therapy and continue during radiation therapy, or B.) stage D2 metastatic prostate cancer.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# EVEROLIMUS SUSPENSION

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## Products Affected

- *everolimus oral tablet soluble 2 mg, 3 mg, 5 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Hypersensitivity to everolimus , or B.) Hypersensitivity to rapamycin derivatives (e.g. sirolimus)
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Tuberous sclerosis complex (TSC) subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected, B.) TSC associated partial-onset seizures as adjunctive treatment.
<b>Age Restrictions</b>	TSC with SEGA: 1 year and older. TSC associated partial-onset seizures: 2 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# FASENRA

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## Products Affected

- FASENRA
- FASENRA PEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: 1) Severe asthma with an eosinophilic phenotype, AND blood eosinophilic count greater than 150 cells/ $\mu$ l or patient is dependent on systemic corticosteroids, AND/OR symptoms are inadequately controlled with inhaled corticosteroids. 2) Eosinophilic granulomatosis with polyangiitis (EGPA)
<b>Age Restrictions</b>	For Asthma: 6 years of age or older. For EGPA: 18 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, dermatologist, immunologist, otolaryngologist, pulmonologist or rheumatologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# FEBUXOSTAT

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## Products Affected

- *febuxostat*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use of azathioprine or mercaptopurine
<b>Required Medical Information</b>	Diagnosis of Gout and all of the following 1.) documented inadequate treatment response, adverse event, or contraindication to maximally titrated dose of Allopurinol, and 2.) patients with established cardiovascular disease, prescriber attests that benefit of treatment outweighs the risk of treatment
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# FINTEPLA

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## Products Affected

- FINTEPLA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.)Use within 14 days of the administration of monoamine oxidase inhibitors B.) Valvular heart disease C.) Pulmonary arterial hypertension
<b>Required Medical Information</b>	Diagnosis of one or both of the following: Dravet Syndrome, Lennox-Gastaut Syndrome
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# FIRMAGON

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## Products Affected

- FIRMAGON
- FIRMAGON (240 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced prostate cancer
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 Months
Other Criteria	B vs D determination required per CMS guidance
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

Prior Authorization Criteria

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# FOTIVDA

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## Products Affected

- FOTIVDA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of relapsed or refractory advanced renal cell cancer (RCC) following 2 or more prior systemic therapies
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# FRUZAQLA

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## Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic colorectal cancer (mCRC) and all of the following: A.) patient has been previously treated with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapy, B.) an anti-VEGF therapy, and C.) if RAS wild-type and medically appropriate, patient has also been previously treated with anti-EGFR therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# FULPHILA

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## Products Affected

- FULPHILA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of a non-myeloid malignancy and drug is being used as prophylaxis for chemotherapy-induced neutropenia
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# FYCOMPA

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## Products Affected

- FYCOMPA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Partial-onset seizures with or without secondary generalization, or B.) Primary generalized tonic-clonic seizure disorder as adjunctive therapy. Member must have history of inadequate response, contraindication, or intolerance to levetiracetam prior to approval.
<b>Age Restrictions</b>	4 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# GAVRETO

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## Products Affected

- GAVRETO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test, B.) Advanced or metastatic RET-mutant medullary thyroid cancer and patient requires systemic therapy, or C.) Advanced or metastatic RET fusion-positive thyroid and patient requires systemic therapy and is radioactive iodine-refractory, when radioactive iodine is appropriate
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# GEFITINIB

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## Products Affected

- *gefitinib*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic non-small cell lung cancer (NSCLC) and must meet all of the following 1.) Tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility and 2.) Used as first-line treatment
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# GILOTrif

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## Products Affected

- GILOTrif

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test, or B.) Metastatic squamous NSCLC with progression after platinum-based chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# GLATIRAMER

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## Products Affected

- *glatiramer acetate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease,), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# GLP1

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## Products Affected

- MOUNJARO
- OZEMPIC (0.25 OR 0.5 MG/DOSE)
- OZEMPIC (1 MG/DOSE)
- OZEMPIC (2 MG/DOSE)
- RYBELSUS
- RYBELSUS (FORMULATION R2)
- TRULICITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Used for weight loss. Ozempic only: patient has a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
<b>Required Medical Information</b>	The drug is prescribed for an FDA-approved indication
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# GOMEKLI

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## Products Affected

- GOMEKLI ORAL CAPSULE 1 MG, 2 MG
- GOMEKLI ORAL TABLET SOLUBLE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Treatment of neurofibromatosis type 1 in adult and pediatric patients 2 years of age or older who have symptomatic plexiform neurofibromas not amenable to complete resection
<b>Age Restrictions</b>	2 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# GROWTH HORMONE

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## Products Affected

- OMNITROPE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Use for growth promotion in pediatric patients with closed epiphyses, B.) Acute critical illness caused by complications following open-heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure, C.) Active malignancy, D.) Active proliferative or severe nonproliferative diabetic retinopathy, E.) Prader-Willi Syndrome in patients who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment
<b>Required Medical Information</b>	Supporting statement of diagnosis from the physician
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or nephrologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# HADLIMA

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## Products Affected

- HADLIMA
- HADLIMA PUSHTOUCH

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, E.) Moderate to severe Crohns disease, F.) Moderate to severe ulcerative colitis, G.) Non-infectious uveitis (including intermediate, posterior, and panuveitis), H.) Moderate to severe hidradenitis suppurativa, or I.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. For moderately to severely active rheumatoid arthritis: 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX), or corticosteroids. For active ankylosis spondylitis: patient has experienced an inadequate treatment response, intolerance, or contraindication to a non-steroidal anti-inflammatory drug(NSAID). For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas, scalp) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected)
<b>Age Restrictions</b>	For Juvenile Idiopathic Arthritis: 2 years of age or older. For Pediatric Crohns disease: 6 years of age or older. All other indications 18 years of age or older.

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	1)For PsO and HS: Dermatologist, 2) For CD and UC: Gastroenterologist, 3) For Uveitis: Ophthalmologist, 4) For RA, PJIA, and AS: Rheumatologist, 5) For PsA: Dermatologist or Rheumatologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physicians certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray. For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# HEPATITIS B

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## Products Affected

- *adefovir dipivoxil*
- BARACLUDE
- VEMLIDY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of chronic hepatitis B and all of the following 1.) Patient has or had evidence of viral replication prior to initiation, 2.) Patient has evidence of persistent elevations in serum aminotransferase (ALT or AST) or histologically active disease, and 3.) Patient is receiving anti-retroviral therapy if the patient has HIV co-infection
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# HEPATITIS C

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## Products Affected

- *ledipasvir-sofosbuvir*
- MAVYRET ORAL PACKET
- MAVYRET ORAL TABLET
- *sofosbuvir-velpatasvir*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must submit documentation of chronic hepatitis C genotype (confirmed by HCV RNA level within the last 6 months). Must submit laboratory results within 12 weeks prior to initiating therapy including: 1) CBC w Platelets, 2) AST/ALT, 3) Total Bilirubin, 4) Serum Albumin, and 5) PT/INR. Genotype and subtype are not required for: (1) initial treatment of patients without cirrhosis if using Sofosbuvir-Velpatasvir or Mavyret, (2) treatment of patients with compensated cirrhosis if using Mavyret OR (3) Acute Hepatitis C patients using Mavyret.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
<b>Coverage Duration</b>	Duration of approval per AASLD Guidelines
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

## Prior Authorization Criteria

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# HERNEXEOS

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## Products Affected

- HERNEXEOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# HRM - ADHD CARDIOVASCULAR

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## Products Affected

- *guanfacine hcl er*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	Formulary Non HRM alternatives: atomoxetine, dexamethylphenidate, methylphenidate
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# HRM - ANALGESICS

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## Products Affected

- *butalbital-acetaminophen*
- *butalbital-apap-caffeine*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# HRM - ANTI-ARRHYTHMICS

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## Products Affected

- DIGOXIN ORAL SOLUTION
- *digoxin oral tablet 250 mcg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	Formulary Non HRM alternatives: propranolol, sotalol, dofetilide, amiodarone, propafenone, mexiletine
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# HRM - ANTICHOLINERGIC

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## Products Affected

- *chlordiazepoxide-clidinium*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# HRM - ANTIDEPRESSANTS

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## Products Affected

- *chlordiazepoxide-amitriptyline*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	Formulary non-HRM alternatives: mirtazapine, trazodone, fluoxetine, escitalopram, fluvoxamine, desvenlafaxine, duloxetine, sertraline, venlafaxine, bupropion
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# HRM - ANTIHISTAMINES

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## Products Affected

- *hydroxyzine hcl*
- *hydroxyzine pamoate*
- *promethazine hcl*
- *promethegan*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	Formulary non-HRM alternatives FOR MANAGEMENT OF ALLERGIC CONDITIONS: desloratadine, cetirizine syrup, levocetirizine. FOR MANAGEMENT OF ANXIETY/SEDATION: buspirone, trazodone. FOR MANAGEMENT OF NAUSEA/VOMITING: granisetron, ondansetron
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

## Prior Authorization Criteria

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# HRM - BENZODIAZEPINES

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## Products Affected

- *alprazolam oral tablet 0.25 mg, 0.5 mg, 1 mg, 2 mg*
- *estazolam*
- *temazepam*
- *chlordiazepoxide hcl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication. For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs)
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# HRM - MEGESTROL

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## Products Affected

- *megestrol acetate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	Formulary Non HRM alternatives: dronabinol
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# HRM - PCD - BENZODIAZEPINES

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## Products Affected

- *clonazepam oral tablet 0.5 mg, 1 mg, 2 mg*
- *clonazepam oral tablet dispersible 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, 2 mg*
- *clorazepate dipotassium*
- *diazepam intensol*
- *diazepam oral solution*
- *diazepam oral tablet*
- *lorazepam intensol*
- *lorazepam oral concentrate*
- *lorazepam oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of seizure disorder or must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication. For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs).
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older
Prescriber Restrictions	None
Coverage Duration	12 months

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# HRM - SEDATIVE HYPNOTICS

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## Products Affected

- *eszopiclone*
- *zaleplon*
- *zolpidem tartrate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg)3.)The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	Formulary non-HRM alternatives: doxepin 3mg and 6mg tablets, mirtazipine, trazodone
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# HRM - SKELETAL MUSCLE RELAXANTS

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## Products Affected

- *cyclobenzaprine hcl*
- *orphenadrine citrate er*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# HYFTOR

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## Products Affected

- HYFTOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Facial angiofibroma associated with tuberous sclerosis
<b>Age Restrictions</b>	6 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# IBRANCE

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## Products Affected

- IBRANCE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer used in combination with fulvestrant and disease has progressed following endocrine therapy, or B.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and used in combination with an aromatase inhibitor in a male or female patient as initial endocrine-based therapy or C.) Endocrine-resistant, PIK3CA-mutated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer, in combination with inavolisib and fulvestrant, following recurrence on or after completing adjuvant endocrine therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# IBTROZI

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## Products Affected

- IBTROZI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ICATIBANT

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## Products Affected

- *icatibant acetate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of hereditary angioedema AND medication will be used for the treatment of acute attacks
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, hematologist, or immunologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ICLUSIG

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) in adult patients who are T315I-positive or for whom no other tyrosine kinase inhibitor therapy is indicated, B.) Chronic phase, chronic myeloid leukemia (CML) in adult patients with resistance or intolerance to at least two prior kinase inhibitors, C.) Newly diagnosed Ph+ ALL, in combination with chemotherapy, or D)Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in adult patients who are T315I-positive or for whom no other tyrosine kinase inhibitor therapy is indicated
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# IDHIFA

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## Products Affected

- IDHIFA ORAL TABLET 100 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase 2 (IDH2) mutation as detected by an FDA approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

## Prior Authorization Criteria

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# IMATINIB

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## Products Affected

- *imatinib mesylate oral tablet 100 mg, 400 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), B.) Ph+ acute lymphoblastic leukemia (ALL), C.) Gastrointestinal stromal tumor (GIST) where patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST or patient had resection of c-KIT positive GIST and imatinib will be used as an adjuvant therapy, D.) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic, E.) Hypereosinophilic syndrome or chronic eosinophilic leukemia, F.) Myelodysplastic syndrome or myeloproliferative disease associated with platelet-derived growth factor receptor gene re-arrangements, or G.) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with allergist, dermatologist, hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

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# IMBRUVICA

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## Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL), B.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion, C.) Waldenstroms macroglobulinemia (WM), or D.) Chronic graft vs host disease (cGVHD) after failure of at least one first-line corticosteroid therapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

## Prior Authorization Criteria

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# IMKELDI

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## Products Affected

- IMKELDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), B.) Ph+ acute lymphoblastic leukemia (ALL), C.) Gastrointestinal stromal tumor (GIST) where patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST or patient had resection of c-KIT positive GIST and imatinib will be used as an adjuvant therapy, D.) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic, E.) Hypereosinophilic syndrome or chronic eosinophilic leukemia, F.) Myelodysplastic syndrome or myeloproliferative disease associated with platelet-derived growth factor receptor gene re-arrangements, or G.) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with allergist, dermatologist, hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

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# IMPAVIDO

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## Products Affected

- IMPAVIDO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Sjogren-Larsson-Syndrome
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) Visceral leishmaniasis caused by Leishmania donovani, B.) Cutaneous leishmaniasis caused by Leishmania braziliensis, Leishmania guyanensis, and Leishmania panamensis, or C.) Mucosal leishmaniasis caused by Leishmania braziliensis
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# INCRELEX

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## Products Affected

- INCRELEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Active or suspected malignancy, B.) Use for growth promotion in patients with closed epiphyses, or C.) Intravenous administration
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Severe primary insulin-like growth factor-1 (IGF-1) deficiency and utilized for pediatric treatment of growth failure, or B.) Growth hormone (GH) gene deletion and patient has developed neutralizing antibodies to GH and utilized for pediatric treatment of growth failure
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# INJECTABLE TESTOSTERONE

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## Products Affected

- *testosterone cypionate*
- *testosterone enanthate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Carcinoma of the breast (males only), or B.) Known or suspected carcinoma of the prostate
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Hypogonadotropic hypogonadism, B.) Inoperable metastatic breast cancer in women who are postmenopausal (testosterone enanthate), C.) Primary hypogonadism, or D.) Delayed puberty (testosterone enanthate). Diagnosis of hypogonadism must be confirmed by a low-for-age serum testosterone (total or free) level defined by the normal laboratory reference value
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# INLYTA

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## Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced renal cell carcinoma and patient failed one or more systemic therapies for renal cell carcinoma (e.g., sunitinib-, bevacizumab-, temsirolimus-, or cytokine-containing regimens), or B.) Advanced renal cell carcinoma and used as first-line therapy in combination with avelumab or pembrolizumab
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# INQOVI

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## Products Affected

- INQOVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# INREBIC

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## Products Affected

- INREBIC

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# INVEGA HAFYERA

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## Products Affected

- INVEGA HAFYERA  
INTRAMUSCULAR SUSPENSION

PREFILLED SYRINGE 1092 MG/3.5ML,  
1560 MG/5ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following A.) Diagnosis of schizophrenia, and B.) Adequate treatment has been established with Invega Sustenna for at least 4 months or Invega Trinza for at least one three-month injection cycle
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an psychiatrist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# INVEGA SUSTENNA

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## Products Affected

- INVEGA SUSTENNA  
INTRAMUSCULAR SUSPENSION  
PREFILLED SYRINGE 117 MG/0.75ML, 156 MG/ML, 234 MG/1.5ML, 39 MG/0.25ML, 78 MG/0.5ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Part B Prerequisite</b>	Pending CMS Review
<b>Prerequisite Therapy Required</b>	Pending CMS Review

Prior Authorization Criteria

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# INVEGA TRINZA

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## Products Affected

- INVEGA TRINZA INTRAMUSCULAR SUSPENSION PREFILLED SYRINGE 273 MG/0.88ML, 410 MG/1.32ML, 546 MG/1.75ML, 819 MG/2.63ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following A.) Diagnosis of schizophrenia, and B.) Adequate treatment has been established with Invega Sustenna for at least 4 months
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an psychiatrist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

## Prior Authorization Criteria

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# ITOVEBI

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## Products Affected

- ITOVEBI ORAL TABLET 3 MG, 9 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of locally advanced or metastatic endocrine resistant, hormone receptor positive, HER2 negative, PIK3CA mutated breast cancer and being used in combination with palbociclib and fulvestrant
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# ITRACONAZOLE

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## Products Affected

- *itraconazole*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Ventricular dysfunction (e.g., congestive heart failure (CHF) or history of CHF), B.) Concurrent therapy with a CYP3A4 substrate (e.g., methadone, lovastatin, simvastatin, etc.), C.) Concurrent use of CYP2D6 inhibitors (e.g., bupropion, fluoxetine, paroxetine, quinidine, terbinafine), or D.) Renal or hepatic impairment and concomitant use of colchicine, fesoterodine, or solifenacin
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), or B.) Onychomycosis confirmed by one of the following: positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# IVABRADINE

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## Products Affected

- *ivabradine hcl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Decompensated acute heart failure, B.) hypotension (i.e. blood pressure less than 90/50 mmHg), C.) sick sinus syndrome or sinoatrial block or 3rd degree AV block (unless a functioning demand pacemaker is present), D.) bradycardia (i.e., resting heart rate less than 60 bpm prior to treatment), E.) Severe hepatic impairment (Child-Pugh C), F.) Pacemaker dependent (heart rate maintained exclusively by the pacemaker), G.) Concomitant use of strong CYP3A4 inhibitors
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Adult patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction 35% or less, who are in sinus rhythm with resting heart rate 70 beats per minute or more and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use, or B.) Pediatric patients with stable, symptomatic heart failure due to dilated cardiomyopathy and are in sinus rhythm with an elevated heart rate
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# IVERMECTIN

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## Products Affected

- *ivermectin*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Prevention or treatment of COVID-19
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) Strongyloidiasis of the intestinal tract or B.) Onchocerciasis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# IWILFIN

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## Products Affected

- IWILFIN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of high-risk neuroblastoma to be used to reduce the risk of relapse in adult and pediatric patients who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# JAKAFI

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## Products Affected

- JAKAFI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis, B.) Polycythemia vera AND patient has had an inadequate response to or is intolerant of hydroxyurea, C.) Acute graft versus host disease AND disease is refractory to steroid therapy, or D.) Chronic graft-versus-host disease (cGVHD) after failure of corticosteroid therapy (alone or in combination with a calcineurin inhibitor) and up to one additional line of systemic therapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist, hematologist or transplant physician.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# JAYPIRCA

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## Products Affected

- JAYPIRCA ORAL TABLET 100 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) relapsed or refractory mantle cell lymphoma (MCL) and is being used after at least two lines of systemic therapy, including a BTK inhibitor or B.) chronic lymphocytic leukemia or small lymphocytic lymphoma who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase inhibitor and a B-cell lymphoma 2 inhibitor.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# JOENJA

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## Products Affected

- JOENJA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist or immunologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# KALYDECO

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## Products Affected

- KALYDECO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (CF) and the patient has 1 mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# KERENDIA

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## Products Affected

- KERENDIA

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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# KESIMPTA

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## Products Affected

- KESIMPTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Active HBV infection
<b>Required Medical Information</b>	Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# KINERET

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## Products Affected

- KINERET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coronavirus disease 2019 (COVID-19) in hospitalized adults
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Moderately to severely active rheumatoid arthritis (RA) on patients who have failed 1 or more disease modifying antirheumatic drugs (DMARDs) and two preferred products ( i.e adalimumab-adbm, Hadlima, Orencia, Rinvoq, Simlandi) B.) Cryopyrin-Associated Periodic Syndromes (i.e., neonatal-onset multisystem inflammatory disease) C.) Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	For RA: prescribed by or in consultation with a rheumatologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physicians certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# KISQALI

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: 1.) Advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and one of the following A.) The patient is a pre-or perimenopausal woman or man and the requested drug will be used in combination with an aromatase inhibitor as initial endocrine-based therapy, B.) The patient is a postmenopausal woman or man, the requested drug will be used in combination with an aromatase inhibitor as initial endocrine-based therapy, and the patient has experienced disease progression, an intolerable adverse event, or contraindication to Ibrance (palbociclib) or Verzenio (abemaciclib), C.) The requested drug is being used with fulvestrant as initial endocrine-based therapy, or D.) The requested drug is being used in combination with Fulvestrant in adults with disease progression following endocrine therapy, and the patient has experienced disease progression, an intolerable adverse event, or contraindication to Ibrance (palbociclib) or Verzenio (abemaciclib), or 2.) Adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence in combination with an aromatase inhibitor.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# KISQALI FEMARA

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and one of the following AND The patient is pre-or perimenopausal woman or male and the requested drug will be used as initial endocrine-based therapy, OR the patient is postmenopausal, the requested drug will be used as initial endocrine-based therapy, and the patient has experienced disease progression, an intolerable adverse event, or contraindication to Ibrance (palbociclib) or Verzenio (abemaciclib) B.) For the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# KORLYM

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## Products Affected

- KORLYM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Coadministration with simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges, B.) Concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses, C.) History of unexplained vaginal bleeding, D.) Endometrial hyperplasia with atypia or endometrial carcinoma
<b>Required Medical Information</b>	Diagnosis of endogenous Cushing syndrome in patients with type 2 diabetes mellitus or glucose intolerance and must meet all of the following 1.) Used to control hyperglycemia secondary to hypercortisolism, AND 2.) Patient has failed or is not a candidate for surgery
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# KOSELUGO

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## Products Affected

- KOSELUGO ORAL CAPSULE 10 MG,  
25 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of neurofibromatosis type 1 (NF1) in a patient who has symptomatic, inoperable plexiform neurofibromas (PN)
<b>Age Restrictions</b>	2 years of age to 17 years of age
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# KRAZATI

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## Products Affected

- KRAZATI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) as determined by an FDA-approved test and patient has received at least one prior systemic therapy, or B.) KRAS G12C-mutated locally advanced or metastatic colorectal cancer in combination with cetuximab, as determined by an FDA-approved test, who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# LAPATINIB

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## Products Affected

- *lapatinib ditosylate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced or metastatic breast cancer with tumors that overexpress human epidermal growth factor receptor 2 (HER2) AND meets one of the following A.) Used in combination with capecitabine in a patient who has received prior therapy including an anthracycline, a taxane, and trastuzumab, OR B.) Used in combination with letrozole in a postmenopausal female for whom hormonal therapy is indicated
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# LAZCLUZE

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## Products Affected

- LAZCLUZE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations as detected by an approved test in adults and Lazcluze is used as first-line treatment in combination with amivantamab
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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Effective date: 01/01/2026 Last Updated: 12/09/2025

# LENALIDOMIDE

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## Products Affected

- *lenalidomide*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Multiple myeloma and medication will be used in combination with dexamethasone, B.) Autologous hematopoietic stem-cell transplantation (HSCT) in multiple myeloma patients, C.) Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality or without additional cytogenetic abnormalities, D.) Mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib, E.) Follicular lymphoma and used in combination with rituximab, or F.) Marginal zone lymphoma and used in combination with rituximab
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# LENVIMA

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## 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
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer, B.) Advanced renal cell carcinoma, in combination with everolimus, following one prior anti-angiogenic therapy, C.) Unresectable hepatocellular carcinoma, first-line therapy, D.) Advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient, in combination with pembrolizumab, when disease has progressed following prior systemic therapy and patient is not a candidate for curative surgery or radiation, or E.) Advanced renal cell carcinoma, in combination with pembrolizumab and used as first-line therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria  
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# LEUKERAN

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## Products Affected

- LEUKERAN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic lymphocytic leukemia, B.) Hodgkin lymphoma, C.) Mycosis fungoides, or D.) Non-Hodgkin lymphomas
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# LEUKINE

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## Products Affected

- LEUKINE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Patient has undergone allogeneic or autologous bone marrow transplant (BMT) and engraftment is delayed or failed, B.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, C.) Medication will be used for myeloid reconstitution after an autologous or allogeneic BMT, D.) Patient has acute myeloid leukemia and administration will be after completion of induction chemotherapy, E.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS) or F.) Autologous peripheral blood stem cell transplant, Following myeloablative chemotherapy.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# LEUPROLIDE

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## Products Affected

- ELIGARD SUBCUTANEOUS KIT 22.5 MG, 30 MG, 45 MG, 7.5 MG
- *leuprolide acetate*
- LEUPROLIDE ACETATE (3 MONTH)
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)
- LUPRON DEPOT-PED (1-MONTH)
- LUPRON DEPOT-PED (3-MONTH)
- LUPRON DEPOT-PED (6-MONTH)
- LUTRATE DEPOT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet one of the following: 1.) Eligard only: Advanced or metastatic prostate cancer, or 2.) For Lupron depot and leuprolide products only: A.) Advanced or metastatic prostate cancer and patient has failed or is intolerant to Eligard or Trelstar (7.5 mg 1-month, 22.5 mg 3-month, 30 mg 4-month, and 45 mg 6-month depots only), B.) Endometriosis (3.75 mg 1-month and 11.25 mg 3-month depots only), C.) Anemia due to uterine leiomyomata (Fibroids) (3.75 mg 1-month and 11.25 mg 3-month depots only) and patient is preoperative, or D.) Central precocious puberty (idiopathic or neurogenic) in children
Age Restrictions	None
Prescriber Restrictions	For cancer: urologist or oncologist, For endometriosis: OBGYN, For central precocious puberty: endocrinologist.
Coverage Duration	12 months
Other Criteria	None
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria  
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# L-GLUTAMINE

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## Products Affected

- *l-glutamine*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of sickle cell disease AND one of the following 1.) Patient has acute complications and is being treated with Hydroxyurea, or 2.) Patient has acute complications and is unable to tolerate Hydroxyurea
<b>Age Restrictions</b>	5 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# LIDOCAINE EXT

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## Products Affected

- APRIZIO PAK II
- EMPRICAINE-II
- *lidocaine external ointment*
- *lidocaine hcl*
- *lidocaine-prilocaine*
- NUVAKAAN-II
- PRIZOPAK II

PA Criteria	Criteria Details
Exclusion Criteria	Amide hypersensitivity
Required Medical Information	The requested drug will be used for or topical anesthesia of skin or mucous membranes
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

Prior Authorization Criteria

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# LINEZOLID

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## Products Affected

- *linezolid oral suspension reconstituted*
- *linezolid oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Community acquired pneumonia, B.) Hospital-acquired pneumonia, C.) Vancomycin-resistant Enterococcus faecium infection, D.) Complicated skin and skin structure infections, or E.) Uncomplicated skin and skin structure infections
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# LIVTENCITY

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## Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# LONSURF

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic colorectal cancer, previously treated with fluoropyrimidine, oxaliplatin, and irinotecan-based regimens, an anti-VEGF therapy, and if RAS wild-type, an anti-EGFR therapy, or B.) Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan and if appropriate, HER2/neu-targeted therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# LORBRENA

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## Products Affected

- LORBRENA ORAL TABLET 100 MG,  
25 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with strong CYP3A4 inducers
<b>Required Medical Information</b>	Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# LUMAKRAS

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## Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 240 MG, 320 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: 1)KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) as determined by an FDA-approved test, and patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy) 2)KRAS G12C-mutated metastatic colorectal cancer (mCRC), as determined by an FDA-approved test, in combination with Vectibix in patients who have received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

## Prior Authorization Criteria

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# LYNPARZA

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## Products Affected

- LYNPARZA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) HER2-negative, deleterious or suspected deleterious germline BRCA mutated high-risk early or metastatic breast cancer AND patient has been previously treated with chemotherapy in neoadjuvant, adjuvant, or metastatic setting, B.) Recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer AND used for maintenance treatment in patients who are in complete or partial response to platinum-based chemotherapy (e.g. cisplatin, carboplatin), C.) Deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients with complete or partial response to first-line platinum-based chemotherapy, D.) Deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma and disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen, E.) Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA-mutation and/or genomic instability AND are using in combination with bevacizumab for maintenance treatment, F.) Deleterious or suspected deleterious germline or somatic homologous recombination repair gene mutated metastatic castration-resistant prostate cancer in patients who have progressed following prior treatment with enzalutamide or abiraterone, or G.) Deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer in combination with abiraterone and prednisone or prednisolone
Age Restrictions	18 years of age and older

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# LYTGOBI

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## Products Affected

- LYTGOBI (12 MG DAILY DOSE)
- LYTGOBI (16 MG DAILY DOSE)
- LYTGOBI (20 MG DAILY DOSE)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements and previously treated
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# MATULANE

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## Products Affected

- MATULANE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Inadequate marrow reserve
<b>Required Medical Information</b>	Diagnosis of Hodgkins Disease, Stages III and IV and used in combination with other anticancer drugs
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# MEKINIST

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## Products Affected

- MEKINIST ORAL SOLUTION RECONSTITUTED
- MEKINIST ORAL TABLET 0.5 MG, 2 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and used in combination with dabrafenib and no locoregional treatment options, B.) Malignant melanoma with lymph node involvement and following complete resection with BRAF V600E or V600K mutations and used in combination with dabrafenib, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutations and used in combination with dabrafenib or as monotherapy, D.) Metastatic non-small cell lung cancer, with BRAF V600E mutation, in combination with dabrafenib, E.) Unresectable or metastatic solid tumors with BRAF V600E mutation, in combination with dabrafenib, and have progressed following prior treatment and have no satisfactory alternative treatment options, F.) Low-grade glioma with a BRAF V600E mutation and require systemic therapy, in combination with dabrafenib
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# MEKTOVI

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## Products Affected

- MEKTOVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Unresectable or metastatic malignant melanoma with documented BRAF V600E or V600K mutation as detected by an FDA approved test AND used in combination with encorafenib or B.) Metastatic non-small cell lung cancer with a BRAF V600E mutation as detected by an FDA-approved test AND used in combination with encorafenib
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# MERCAPTOPURINE

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## Products Affected

- mercaptopurine oral suspension*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) Diagnosis of acute lymphocytic leukemia, 2.) Patient unable to swallow or intolerance to mercaptopurine tablets.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# MIFEPRISTONE

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## Products Affected

- *mifepristone*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Coadministration with simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges, B.) Concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses, C.) History of unexplained vaginal bleeding, D.) Endometrial hyperplasia with atypia or endometrial carcinoma
<b>Required Medical Information</b>	Diagnosis of endogenous Cushing syndrome in patients with type 2 diabetes mellitus or glucose intolerance and must meet all of the following 1.) Used to control hyperglycemia secondary to hypercortisolism, and 2.) Patient has failed or is not a candidate for surgery
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# MIGLUSTAT

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## Products Affected

- *miglustat*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of mild to moderate type 1 Gaucher disease and patient is not a candidate for enzyme replacement therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# MODEYSO

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## Products Affected

- MODEYSO

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

Prior Authorization Criteria

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# NAYZILAM

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## Products Affected

- NAYZILAM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute narrow angle glaucoma
<b>Required Medical Information</b>	Diagnosis of epilepsy and documentation of acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures), that are distinct from a patient's usual seizure pattern
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	This criteria applies to new starts only
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# NERLYNX

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## Products Affected

- NERLYNX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Early stage HER2-positive breast cancer and used following adjuvant trastuzumab therapy, or B.) Advanced or metastatic HER2-positive breast cancer, used in combination with capecitabine, AND patient has received 2 or more prior anti-HER2-based regimens in the metastatic setting
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# NEXLETOL

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## Products Affected

- NEXLETOL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) established cardiovascular disease (CVD) or at high risk for a CVD event but without established CVD, to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin). B.) In combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	For all indications: Document: i)Baseline LDL-C Level greater than 70 mg/dL (lipid panel results), and ii) One of the following: a) Patient has completed a trial of 3 consecutive months of one high or moderate intensity statin at the patients maximally tolerated dose, or b) Therapeutic failure, adverse effects, or intolerance to at least 2 high intensity statins (e.g. atorvastatin equal to or greater than 40 mg, rosuvastatin equal to or greater than 20 mg) or 2 moderate intensity statin (e.g. simvastatin 20 or 40 mg) in combination with ezetimibe. For renewals: Prescribing physician must attest the patient is tolerating and responding to medication, and provide LDL-C levels
<b>Indications</b>	All FDA-approved Indications.

Prior Authorization Criteria

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria  
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# NEXLIZET

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## Products Affected

- NEXLIZET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) established cardiovascular disease (CVD) or at high risk for a CVD event but without established CVD, to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin). B.) In combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	For all indications: Document: i)Baseline LDL-C Level greater than 70 mg/dL (lipid panel results), and ii) One of the following: a) Patient has completed a trial of 3 consecutive months of one high or moderate intensity statin at the patients maximally tolerated dose, or b) Therapeutic failure, adverse effects, or intolerance to at least 2 high intensity statins (e.g. atorvastatin equal to or greater than 40 mg, rosuvastatin equal to or greater than 20 mg) or 2 moderate intensity statin (e.g. simvastatin 20 or 40 mg) in combination with ezetimibe. For renewals: Prescribing physician must attest the patient is tolerating and responding to medication, and provide LDL-C levels
<b>Indications</b>	All FDA-approved Indications.

Prior Authorization Criteria

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# NINLARO

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## Products Affected

- NINLARO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of multiple myeloma, used in combination with lenalidomide and dexamethasone, AND patient has history of at least 1 prior therapy . Examples include bortezomib, cyclophosphamide, Kyprolis (carfilzomib intravenous infusion), lenalidomide, Darzalex (daratumumab intravenous infusion).
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# NUBEQA

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## Products Affected

- NUBEQA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Non-metastatic, castration-resistant prostate cancer (nmCRPC), B.) Metastatic castration-sensitive prostate cancer (mCSPC), or C.) Metastatic hormone-sensitive prostate cancer in combination with docetaxel. For treatment of nmCRPC, one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient has received bilateral orchectomy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# NUEDEXTA

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## Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) History of prolonged QT interval, congenital long QT syndrome or Torsades de pointes, B.) Heart failure, C.) Complete AV block without an implanted pacemaker or high risk of complete AV block, D.) Concomitant use with quinidine, quinine, mefloquine, or drugs that prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), E.) Concomitant use with MAOIs or within 14 days of MAOI therapy, F.) History of quinine-, mefloquine-, or quinidine-induced thrombocytopenia, bone marrow depression, or lupus-like syndrome
<b>Required Medical Information</b>	Diagnosis of pseudobulbar affect
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# NUPLAZID

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## Products Affected

- NUPLAZID

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Parkinsons disease and both of the following apply A.) Used for treatment of hallucinations and/or delusions associated with Parkinsons disease psychosis, and B.) Diagnosis of Parkinsons disease was made prior to the onset of psychotic symptoms
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or psychiatrist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# ODOMZO

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## Products Affected

- ODOMZO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of locally advanced basal cell carcinoma of the skin and one of the following A.) Cancer has recurred following surgery or radiation therapy, B.) Patient is not a candidate for surgery or radiation therapy.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# OFEV

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## Products Affected

- OFEV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Idiopathic pulmonary fibrosis (IPF), B.) Systemic sclerosis-associated interstitial lung disease (ILD), or C.) Chronic fibrosing interstitial lung disease with a progressive phenotype
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or rheumatologist.
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# OGSIVEO

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## Products Affected

- OGSIVEO ORAL TABLET 100 MG, 150 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of progressing desmoid tumors who require systemic treatment
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# OJEMDA

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## Products Affected

- OJEMDA ORAL SUSPENSION  
RECONSTITUTED
- OJEMDA ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# OJJAARA

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## Products Affected

- OJJAARA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [postpolycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# ONUREG

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## Products Affected

- ONUREG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of acute myeloid leukemia (AML) used in maintenance treatment for adult patients who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# OPIPZA

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## Products Affected

- OPIPZA ORAL FILM 10 MG, 2 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following A.) Diagnosis of one of the following 1)Schizophrenia 2) Adjunctive treatment of major depressive disorder(MDD) 3) Irritability associated with autistic disorders, OR 4)Tourettes disorder, AND B.) Unable to swallow or intolerance to aripiprazole tablets
<b>Age Restrictions</b>	For schizophrenia: 13 years or older, For MDD: 18 years or older, All others: 6 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an psychiatrist or neurologist.
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

## Prior Authorization Criteria

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# OPSUMIT

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## Products Affected

- OPSUMIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	Initial: 6 months, Renewal: 12 months
<b>Other Criteria</b>	Continuation of therapy: patient is tolerating and responding to medication and has improved exercise capacity or a delay in clinical worsening.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# ORENCIA

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## Products Affected

- ORENCEA CLICKJECT
- ORENCEA SUBCUTANEOUS  
SOLUTION PREFILLED SYRINGE 125  
MG/ML, 50 MG/0.4ML, 87.5 MG/0.7ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, or D.) Prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in patients undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.
<b>Age Restrictions</b>	For RA: 18 years of age or older. All other indications 2 years of age or older.
<b>Prescriber Restrictions</b>	For RA and PJIA: Rheumatologist, For PsA: Dermatologist or Rheumatologist, For aGVHD: Hematologist or Transplant Specialist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physicians certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray. For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

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# ORGOVYX

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## Products Affected

- ORGOVYX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced prostate cancer
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# ORKAMBI

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## Products Affected

- ORKAMBI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (CF) with documented homozygous F508del mutation confirmed by FDA-approved CF mutation test
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# ORSERDU

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## Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced or metastatic, ER-positive, HER2-negative, ESR1-mutated, breast cancer in postmenopausal women or adult man after at least 1 line of endocrine therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# OTEZLA

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## Products Affected

- OTEZLA ORAL TABLET
- OTEZLA ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) Active psoriatic arthritis, B.) Moderate to severe plaque psoriasis and patient is a candidate for phototherapy or systemic therapy, C.) Mild plaque psoriasis and patient is a candidate for phototherapy or systemic therapy, or D.) Behcets Disease and patient has active oral ulcers. For plaque psoriasis: the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy
<b>Age Restrictions</b>	6 years of age and older
<b>Prescriber Restrictions</b>	PsA: Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis: Prescribed by or in consultation with a dermatologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# PANRETIN

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## Products Affected

- PANRETIN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of AIDS-related Kaposi's sarcoma and both of the following 1.) Used to treat cutaneous lesions, and 2.) Systemic anti-Kaposi's Sarcoma therapy is not indicated (e.g., patient does not have more than 10 new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS, or symptomatic visceral involvement)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist, oncologist or HIV specialist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# PAZOPANIB

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## Products Affected

- *pazopanib hcl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced renal cell carcinoma (RCC), or B.) Advanced soft tissue sarcoma (STS), has received prior chemotherapy and does not have adipocytic soft tissue sarcoma (STS) or gastrointestinal stromal tumors (GIST)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# PEGYLATED INTERFERON

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## Products Affected

- PEGASYS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Autoimmune hepatitis, B.) Hepatic decompensation (Child-Pugh score greater than 6 (Class B and C) in cirrhotic patients before treatment, OR hepatic decompensation (Child-Pugh score greater than or equal to 6) in cirrhotic patients co-infected with hepatitis C and HIV before treatment, or C.) Hypersensitivity reactions, including urticaria, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome to alfa interferons or any component of the product
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic hepatitis B infection, or B.) Chronic hepatitis C
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# PEMAZYRE

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## Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with confirmed fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or B.) Relapsed or refractory myeloid/lymphoid neoplasms with fibroblast growth factor receptor 1 rearrangement
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist, gastroenterologist, or hepatologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# PENICILLAMINE

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## Products Affected

- *penicillamine*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Breastfeeding, B.) Hypersensitivity to penicillamine products, C.) Penicillamine-related aplastic anemia/agranulocytosis, or D.) Rheumatoid arthritis patients with history or evidence of renal insufficiency
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Cystinuria, B.) Severe, active rheumatoid arthritis, or C.) Wilsons disease
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

MCS Classicare Formulary 1 - Formulary ID: 26262

Effective date: 01/01/2026 Last Updated: 12/09/2025

# PIQRAY

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## 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>	None
<b>Required Medical Information</b>	Diagnosis of hormone receptor (HR) positive, HER2-negative, PIK3CA-mutated, advanced or metastatic breast cancer and must meet all of the following 1.) Used in combination with fulvestrant, and 2.) Disease has progressed on or after an endocrine-based regimen
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# PIRFENIDONE

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## Products Affected

- *pirfenidone*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of idiopathic pulmonary fibrosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# POMALYST

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## Products Affected

- POMALYST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) AIDS-related Kaposi sarcoma and patient has failure on highly active antiretroviral therapy (HAART), B.) Kaposi sarcoma in HIV-negative adults, or C.) Multiple myeloma and in combination with dexamethasone in adults who have received at least 2 prior therapies (including lenalidomide and a proteasome inhibitor) and have demonstrated disease progression on or within 60 days of completion of the last therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# POSACONAZOLE

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## Products Affected

- *posaconazole*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Part B Prerequisite</b>	Pending CMS Review
<b>Prerequisite Therapy Required</b>	Pending CMS Review

Prior Authorization Criteria

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# PREVYMIS

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## Products Affected

- PREVYMIS ORAL PACKET
- PREVYMIS ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant use with pimozide or ergot alkaloids (ergotamine, dihydroergotamine), B.) Concomitant use with pitavastatin or simvastatin when coadministered with cyclosporine
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Prophylaxis of cytomegalovirus (CMV) infection and disease in CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant, or B.) Prophylaxis of CMV disease in kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# PROLIA

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## Products Affected

- PROLIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Hypocalcemia (calcium less than 8.0 mg/dL)
<b>Required Medical Information</b>	Must meet all of the following A.) Diagnosis of one of the following 1.) Treatment of osteoporosis in postmenopausal females at high risk of fracture, 2.) Treatment of osteoporosis in males at high risk of fracture 3.) Treatment of bone loss in males receiving androgen-deprivation therapy for nonmetastatic prostate cancer, 4.) Treatment of bone loss in females receiving aromatase inhibitor therapy for breast cancer, or 5.) Treatment of glucocorticoid-induced osteoporosis in patients at high risk of fracture who are initiating or continuing systemic glucocorticoids at a daily dose greater than or equal to 7.5 mg of prednisone for an anticipated duration of at least 6 months B.) Bone density scan (DEXA) documenting a T-score less than -1.0 at lumbar spine, total hip, femoral neck, or 33% radius and member has high risk factors (high risk defined as osteoporotic fracture history, multiple risk factors for fracture, or failure of or intolerance to other available osteoporosis therapy) or T-score less than or equal to -2.5 in the lumbar spine, total hip, femoral neck, or 33% radius
<b>Age Restrictions</b>	none
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# PROMACTA

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Persistent or chronic idiopathic thrombocytopenic purpura (ITP), B.) Chronic hepatitis C infection associated thrombocytopenia, or C.) Severe aplastic anemia with insufficient response to immunosuppressive therapy or in combination with standard immunosuppressive therapy
<b>Age Restrictions</b>	For thrombocytopenia or chronic immune thrombocytopenia (ITP): 1 year of age and older. For Severe Aplastic Anemia: 2 years of age and older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with hematologist, hepatologist, gastroenterologist or infectious disease specialist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For continuation of therapy: Prescribing physician attests patient platelet count is greater than $50 \times 10^9/L$
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# PYRIMETHAMINE

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## Products Affected

- *pyrimethamine*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Documented megaloblastic anemia due to folate deficiency
<b>Required Medical Information</b>	Diagnosis of Toxoplasmosis and treatment in combination with a sulfonamide
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist
<b>Coverage Duration</b>	10 weeks
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# QINLOCK

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## Products Affected

- QINLOCK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced gastrointestinal stromal tumor (GIST) and patient has received prior treatment with 3 or more kinase inhibitors, including imatinib
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# QUININE SULFATE

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## Products Affected

- *quinine sulfate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Prolongation of QT interval, B.) Myasthenia gravis, C.) Known hypersensitivity to mefloquine or quinidine, D.) Optic neuritis, E.) Diagnosis of Blackwater fever, F.) Use solely for treatment or prevention of nocturnal leg cramps, G.) Thrombocytopenia (including ITP, TTP), H.) Hemolytic uremic syndrome (HUS)
<b>Required Medical Information</b>	Diagnosis of one of the following A.) uncomplicated Plasmodium falciparum malaria, B.) uncomplicated Plasmodium vivax malaria, or C.) babesiosis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	None
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# RALDESY

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## Products Affected

- RALDESY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Major Depressive Disorder and patient has a contraindication or is unable to swallow trazodone tablets
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# RAVICTI

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## Products Affected

- RAVICTI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of urea cycle disorders
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# REPATHA

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## Products Affected

- REPATHA
- REPATHA SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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# RETEVMO

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## Products Affected

- RETEVMO ORAL TABLET 120 MG,  
160 MG, 40 MG, 80 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced or metastatic RET-mutant medullary thyroid cancer (MTC) in patients who require systemic therapy, B.) Metastatic RET fusion-positive non-small cell lung cancer (NSCLC), C.) Advanced or metastatic RET fusion-positive thyroid cancer in patients who require systemic therapy and are refractory to radioactive iodine, if appropriate, or D.) Locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

## Prior Authorization Criteria

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# REVCORI

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## Products Affected

- REVCORI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) confirmed by one of the following criteria (i or ii): i. At baseline (i.e., prior to initiating enzyme replacement therapy), the patient has had absent or very low (less than 1% of normal) adenosine deaminase (ADA) catalytic activity, OR ii. Patient has had molecular genetic testing confirming bi-allelic mutations in the ADA gene, AND B. Patient has elevated deoxyadenosine triphosphate (dATP) or total deoxyadenosine nucleotides (dAXP) in red blood cells, AND i. ii. Patient is not a candidate for or has failed definitive therapy with bone marrow transplantation (BMT), OR Patient is a candidate for definitive therapy with BMT and elapegadimase will be used as bridge therapy.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist or immunologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	For continuation of therapy: Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in ONE or more of the following: 1. Increase in plasma ADA activity (target trough level greater than or equal to 15 mmol/hr/L) 2. Decrease in red blood cell dATP level (target less than or equal to 0.005 to 0.015 mmol/L) 3. Improvement in immune function with diminished frequency/complications of infection as evidenced in improvement in the ability to produce antibodies 4. Decrease in red blood cell dAXP level (target trough level less than or equal to 0.02 mmol/L) 5. Increase in total lymphocyte counts

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# REVUFORJ

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## Products Affected

- REVUFORJ ORAL TABLET 110 MG, 160 MG, 25 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of relapsed or refractory acute leukemia and patient has a lysine methyltransferase 2A gene (KMT2A) translocation
<b>Age Restrictions</b>	1 year of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# REZDIFFRA

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## Products Affected

- REZDIFFRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Disease is fibrosis stage F2 or F3 as confirmed by one of the following: (1) Liver stiffness measurement (LSM) by vibration-controlled transient elastography (VCTE) (e.g., FibroScan) (2) LSM by magnetic resonance elastography (MRE) (3) Liver biopsy within the past 12 months.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist or hepatologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	For continuation of therapy: Documentation of positive clinical response to Rezdiffra therapy (e.g., improvement in or stabilization of fibrosis) - AND- Patient has not progressed to cirrhosis.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# REZLIDHIA

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## Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# REZUROCK

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## Products Affected

- REZUROCK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of chronic graft-vs-host disease and patient has failed at least 2 prior lines of systemic therapy (e.g., prednisone, methotrexate, cyclosporine, tacrolimus, mycophenolate, Imbruvica (ibrutinib), Jakafi (ruxolitinib), etc.)
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# RILUZOLE

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## Products Affected

- *riluzole*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of amyotrophic lateral sclerosis (ALS)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# RINVOQ

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## Products Affected

- RINVOQ

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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# RINVOQ LQ

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## Products Affected

- RINVOQ LQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Active psoriatic arthritis with inadequate response or intolerance to 1 or more TNF blockers, or B.) Active polyarticular juvenile idiopathic arthritis with inadequate response or intolerance to 1 or more TNF blockers
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	For PsA: Dermatologist or Rheumatologist, For PJIA: Rheumatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Screening for latent tuberculosis infection is required prior to initiation of treatment. For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# RIVFLOZA

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## Products Affected

- RIVFLOZA SUBCUTANEOUS SOLUTION
- RIVFLOZA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 128 MG/0.8ML, 160 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Primary hyperoxaluria type 1 and the patient has relatively preserved kidney function (eGFR is greater than or equal to 30mL/min/1.73m <sup>2</sup> )
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a NEPHROLOGIST
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ROMVIMZA

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## Products Affected

- ROMVIMZA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) and patients tumor cannot be surgically resected, as that may cause worsening functional limitation or severe morbidity
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ROZLYTREK

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## Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG
- ROZLYTREK ORAL PACKET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) ROS1-positive metastatic non-small cell lung cancer (NSCLC), or B.) Solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have either progressed following treatment or have no satisfactory alternative therapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	Verify the pregnancy status of females of reproductive potential prior to initiating ROZLYTREK
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

## Prior Authorization Criteria

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# RUBRACA

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## Products Affected

- RUBRACA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, used as maintenance treatment, and patient is in complete or partial response to platinum-based chemotherapy, or B.) Deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer and patient has been treated with androgen receptor-directed therapy and a taxane-based chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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Effective date: 01/01/2026 Last Updated: 12/09/2025

# RUFINAMIDE

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## Products Affected

- *rufinamide oral suspension*
- *rufinamide oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Familial Short QT Syndrome
<b>Required Medical Information</b>	Diagnosis of seizures associated with Lennox-Gastaut syndrome and used as adjunctive treatment
<b>Age Restrictions</b>	1 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# RYDAPT

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## Products Affected

- RYDAPT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) treatment naive FLT3 mutation-positive acute myelogenous leukemia (AML) and must be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation therapy, or B.) systemic mastocytosis or mast cell leukemia
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# SAPROPTERIN

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## Products Affected

- *sapropterin dihydrochloride*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of hyperphenylalaninemia (HPA) caused by tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 2 months, Renewal: 12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# SCEMBLIX

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## Products Affected

- SCEMBLIX ORAL TABLET 100 MG,  
20 MG, 40 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), B.) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) with the T315I mutation, or C.) Newly diagnosed adults with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

## Prior Authorization Criteria

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# SELARSDI

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## Products Affected

- SELARSDI SUBCUTANEOUS  
SOLUTION PREFILLED SYRINGE 45  
MG/0.5ML, 90 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy, B.) Active psoriatic arthritis, C.) Moderately to severely active Crohns disease, D.) Moderately to severely active ulcerative colitis.
<b>Age Restrictions</b>	For PsO or PsA: 6 years of age or older, For all other indications: 18 years of age or older
<b>Prescriber Restrictions</b>	For PsO: Dermatologist, For PsA: Dermatologist or Rheumatologist, For CD and UC: Gastroenterologist.
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	Only for biologic therapy-naïve patients: Physicians certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray. For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria  
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# SIGNIFOR

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## Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Cushing disease and patient has had inadequate response to or is not a candidate for surgery. For renewal: Documentation of a clinically meaningful reduction in 24-hour urinary free cortisol (UFC) levels or improvement in signs or symptoms of the disease
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# SILDENAFIL

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## Products Affected

- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Nitrate therapy, including intermittent use, B.) Concomitant use with riociguat or other guanylate cyclase stimulators, C.) Concomitant use with HIV protease inhibitors or elvitegravir/cobicistat/tenofovir/emtricitabine
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Continuation of therapy: patient is tolerating and responding to medication and has improved exercise capacity or a delay in clinical worsening.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# SIMLANDI

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## Products Affected

- SIMLANDI (1 PEN)
- SIMLANDI (1 SYRINGE)
- SIMLANDI (2 PEN)
- SIMLANDI (2 SYRINGE)  
SUBCUTANEOUS PREFILLED  
SYRINGE KIT 20 MG/0.2ML, 40  
MG/0.4ML

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

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# SIRTURO

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## Products Affected

- SIRTURO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) Diagnosis of pulmonary multidrug resistant tuberculosis (MDR-TB) and 2.) Used in combination with at least 2 other antibiotics for the treatment of pulmonary multi-drug resistant tuberculosis
<b>Age Restrictions</b>	2 years and older and weighing at least 8 kg
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist
<b>Coverage Duration</b>	24 weeks
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# SKYRIZI

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## Products Affected

- SKYRIZI PEN
- SKYRIZI SUBCUTANEOUS SOLUTION CARTRIDGE 180 MG/1.2ML, 360 MG/2.4ML
- SKYRIZI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Moderate to severe plaque psoriasis and patient is a candidate for systemic therapy or phototherapy, B.) Active psoriatic arthritis, C.) Moderately to severely active Crohns disease, or D.) Moderately to severely active ulcerative colitis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	For PsO: Dermatologist. For PsA: Dermatologist or Rheumatologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physicians certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray. For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# SODIUM OXYBATE

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## Products Affected

- *sodium oxybate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant treatment with sedative hypnotic agents, B.) Succinic semialdehyde dehydrogenase deficiency
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Narcolepsy with excessive daytime drowsiness and has trial of/or contraindication to a central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate) or a CNS wakefulness promoting drug (e.g., armodafinil, modafinil), or B.) Cataplexy and narcolepsy
<b>Age Restrictions</b>	7 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# SOLTAMOX

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## Products Affected

- SOLTAMOX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant coumarin-type anticoagulant therapy, B.) history of thromboembolic disease such as DVT or PE
<b>Required Medical Information</b>	Diagnosis of breast cancer and documentation of inability to swallow tablet formulation
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# SOMAVERT

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## Products Affected

- SOMAVERT SUBCUTANEOUS  
SOLUTION RECONSTITUTED 10 MG,  
15 MG, 20 MG, 25 MG, 30 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of acromegaly confirmed by high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range and patient has had an inadequate response to or is ineligible for surgery or radiation therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# SORAFENIB

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## Products Affected

- *sorafenib tosylate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Squamous cell lung cancer being treated with carboplatin and paclitaxel
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioactive iodine treatment, or C.) Unresectable hepatocellular carcinoma
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# STELARA

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## Products Affected

- STELARA SUBCUTANEOUS SOLUTION
- STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 45 MG/0.5ML, 90 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following (A.) Moderate to severely active Crohns disease, B.) Moderate to severe plaque psoriasis, C.) Active psoriatic arthritis, or D.) Moderate to severe active ulcerative colitis. For moderate to severe plaque psoriasis: 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., scalp, feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected)
<b>Age Restrictions</b>	For PsO or PsA: 6 years of age or older, For all other indications: 18 years of age or older
<b>Prescriber Restrictions</b>	For PsO: Dermatologist, For PsA: Dermatologist or Rheumatologist, For CD and UC: Gastroenterologist.
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	Only for biologic therapy-naïve patients: Physicians certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest

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<b>PA Criteria</b>	<b>Criteria Details</b>
	x ray. For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# STIVARGA

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## Products Affected

- STIVARGA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic colorectal cancer in patients previously treated with fluoropyrimidine, oxaliplatin, and irinotecan containing chemotherapy, anti-VEGF therapy, and if RAS wild type, anti-EGFR therapy, B.) Liver carcinoma in patients previously treated with sorafenib, or C.) Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) after treatment with imatinib and sunitinib
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# SUNITINIB

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## Products Affected

- *sunitinib malate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Gastrointestinal stromal tumor after disease progression on or intolerance to imatinib, B.) Pancreatic neuroendocrine tumors in a patient with unresectable locally advanced or metastatic disease, C.) Advanced renal cell carcinoma, or D.) Renal cell carcinoma and used as adjuvant therapy following nephrectomy in patients who are at high risk for recurrence
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# SYNAREL

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## Products Affected

- SYNAREL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Breastfeeding, or B.) undiagnosed abnormal vaginal bleeding
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Central precocious puberty, or B.) Endometriosis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# TABLOID

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## Products Affected

- TABLOID

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of induction or consolidation therapy for acute myeloid (nonlymphocytic) leukemia (AML)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# TABRECTA

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## Products Affected

- TABRECTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# TADALAFIL

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## Products Affected

- *tadalafil*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) concurrent use of nitrates, including intermittent use, B.) diagnosis of erectile dysfunction without signs and symptoms of BPH, or C.) concomitant use of guanylate cyclase (GC) stimulators, such as riociguat.
<b>Required Medical Information</b>	Diagnosis of benign prostatic hyperplasia (BPH) and patient has experienced intolerance to or treatment failure to ONE alpha-blocker (e.g., doxazosin, prazosin, tamsulosin) AND to ONE 5-alpha reductase inhibitor (e.g., dutasteride, finasteride).
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# TAFINLAR

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## Products Affected

- TAFINLAR ORAL CAPSULE
- TAFINLAR ORAL TABLET SOLUBLE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid carcinoma with BRAF V600E mutation, in combination with trametinib and no satisfactory locoregional treatment options, B.) Metastatic non-small cell lung cancer with BRAF V600E mutation, in combination with trametinib OR in patients previously treated as monotherapy, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutation, D.) Unresectable or metastatic solid tumors with BRAF V600E mutation, in combination with trametinib, and have progressed following prior treatment and have no satisfactory alternative treatment options, or E.) Low-grade glioma with a BRAF V600E mutation and require systemic therapy, in combination with trametinib
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# TAGRISSO

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## Products Affected

- TAGRISSO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R mutation and used as first line therapy, B.) Metastatic non-small cell lung cancer with T790M EGFR mutation (as confirmed by an FDA-approved test) AND whose disease has progressed on or after EGFR tyrosine kinase inhibitor therapy, C.) Non-small cell lung cancer (NSCLC) with tumor epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations (as confirmed by an FDA-approved test) AND patient requires adjuvant therapy after tumor resection, or D.) First-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test, in combination with pemetrexed and platinum-based chemotherapy. E.) Adult patients with locally advanced, unresectable (stage III) NSCLC whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# TAKHZYRO

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## Products Affected

- TAKHZYRO SUBCUTANEOUS SOLUTION
- TAKHZYRO SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 150 MG/ML, 300 MG/2ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following and used as routine prophylaxis A.) Hereditary angioedema (HAE) with C1 inhibitor deficiency (Type 1) confirmed by laboratory testing, B.) HAE with C1 inhibitor dysfunction (Type 2) confirmed by laboratory testing, or C.) HAE with normal C1 inhibitor (Type 3) confirmed by laboratory testing and one of the following 1.) Positive test for an F12, angiopoietin-1, or plasminogen gene mutation, or 2.) Family history of angioedema and the angioedema was refractory to a trial of an antihistamine for at least one month
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist, immunologist, or allergist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# TALZENNA

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## Products Affected

- TALZENNA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer, or B.) Homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer in combination with enzulatamide
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# TASIGNA

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## Products Affected

- TASIGNA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML), B.) Chronic phase or accelerated phase Philadelphia chromosome-positive CML in a patient with resistance or intolerance to prior therapy that included imatinib, or C.) Chronic phase Philadelphia chromosome-positive CML in a patient with resistance or intolerance to prior tyrosine-kinase inhibitor therapy
<b>Age Restrictions</b>	1 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# TAVNEOS

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## Products Affected

- TAVNEOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) and both of the following apply 1.) Used as adjunctive treatment, and 2.) Used in combination with standard therapy including glucocorticoids
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# TAZAROTENE

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## Products Affected

- *tazarotene external cream*
- *tazarotene external gel*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Acne vulgaris and patient has trial with at least one generic topical acne product, or B.) Stable moderate to severe plaque psoriasis with 20% or less body surface area involvement and patient has trial with at least one other topical psoriasis product (e.g., medium to high potency corticosteroid and/or vitamin D analogs)
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# TAZVERIK

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## Products Affected

- TAZVERIK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic or locally advanced epithelioid sarcoma in patients not eligible for complete resection, B.) Relapsed or refractory follicular lymphoma in patients whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, or C.) Relapsed or refractory follicular lymphoma in patients who have no satisfactory alternative treatment options
<b>Age Restrictions</b>	16 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# TEPMETKO

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## Products Affected

- TPMETKO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic non-small cell lung cancer (NSCLC) with mesenchymal-epithelial transition (MET) exon 14 skipping alterations
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# TETRABENAZINE

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## Products Affected

- *tetrabenazine oral tablet 12.5 mg, 25 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Actively suicidal, B.) Untreated or inadequately treated depression, C.) Impaired hepatic function, D.) Concomitant use of monoamine oxidase inhibitors, E.) Concomitant use of reserpine or within 20 days of discontinuing reserpine, F.) Concomitant use of deutetabenazine or valbenazine
<b>Required Medical Information</b>	Diagnosis of chorea associated with Huntington's disease
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# THALOMID

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## Products Affected

- THALOMID ORAL CAPSULE 100 MG,  
150 MG, 200 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Multiple myeloma that is newly diagnosed, or B.) Erythema nodosum leprosum (ENL)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist, infectious disease specialist, or dermatologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# TIBSOVO

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## Products Affected

- TIBSOVO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test), B.) Previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test.), C.) Acute myeloid leukemia (newly-diagnosed) with susceptible isocitrate dehydrogenase-1 mutation and meets one of the following: 1.) Patient is 75 years of age or older, or 2.) Patient has comorbidities that preclude intensive induction chemotherapy, or D.) Relapsed or refractory myelodysplastic syndromes with a susceptible isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hematologist, hepatologist, or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# TOBI

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## Products Affected

- TOBI PODHALER

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Known sensitivity to any aminoglycoside
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (confirmed by appropriate diagnostic or genetic testing) and patient has suspected or confirmed <i>Pseudomonas aeruginosa</i> infection in the lungs
<b>Age Restrictions</b>	6 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# TOLVAPTAN

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## Products Affected

- *tolvaptan oral tablet 15 mg, 30 mg*
- *tolvaptan oral tablet therapy pack*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) History of signs or symptoms of significant liver impairment or injury, does not include uncomplicated polycystic liver disease B.) Concomitant use of strong CYP3A inhibitors C.) Uncorrected abnormal blood sodium concentrations D.) Unable to sense or respond to thirst E.) Hypovolemia F.) Hypersensitivity to tolvaptan or any of its components G.) Uncorrected urinary outflow obstruction H.) Anuria
<b>Required Medical Information</b>	Diagnosis of autosomal dominant polycystic kidney disease (ADPKD) on patients considered at risk of rapid progression of the disease, confirmed by ultrasonography, magnetic resonance imaging [MRI] or , computed tomography [CT]
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

## Prior Authorization Criteria

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# TOPICAL RETINOID

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## Products Affected

- *adapalene*
- *tretinoin external*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of mild to moderate acne vulgaris
Age Restrictions	PA applies to patients older than 26 years of age
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

Prior Authorization Criteria

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# TOPICAL TESTOSTERONE

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Carcinoma of the breast (males only), or B.) Known or suspected carcinoma of the prostate
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Hypogonadotropic hypogonadism, or B.) Primary hypogonadism. Diagnosis of hypogonadism must be confirmed by a low-for-age serum testosterone (total or free) level defined by the normal laboratory reference value
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# TOREMIFENE

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## Products Affected

- *toremifene citrate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Acquired or congenital long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia
<b>Required Medical Information</b>	Diagnosis of metastatic breast cancer and patient must have previous inadequate response or intolerance to tamoxifen
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# TRELSTAR

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## Products Affected

- TRELSTAR MIXJECT  
INTRAMUSCULAR SUSPENSION

RECONSTITUTED 11.25 MG, 22.5 MG,  
3.75 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced prostate cancer
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an urologist or oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# TRIENTINE

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## Products Affected

- *trientine hcl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Wilsons disease in patients that are intolerant to penicillamine
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# TRIKAFTA

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## Products Affected

- TRIKAFTA ORAL TABLET THERAPY PACK
- TRIKAFTA ORAL THERAPY PACK 100-50-75 & 75 MG, 80-40-60 & 59.5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (CF) AND patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene OR a mutation in the CFTR gene that is responsive to elexacaftor/tezacaftor/ivacaftor, AND presence of at least one indicated mutation was confirmed by an FDA-cleared CF mutation test.
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# TRUQAP

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## Products Affected

- TRUQAP

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with 1 or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test and, A.) patient has had disease progression following 1 or more endocrine-based regimen(s) in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy, and B.) will be used in combination with fulvestrant injection.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# TUKYSA

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## Products Affected

- TUKYSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) advanced unresectable or metastatic HER2-positive breast cancer (including brain metastases) in patients who have received one or more prior anti-HER2-based regimens in the metastatic setting and drug is being used in combination with trastuzumab and capecitabine, or B.) unresectable or metastatic RAS wild-type, HER2-positive colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy and drug is being used in combination with trastuzumab
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# TURALIO

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## Products Affected

- TURALIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery. Liver function tests prior to initiation.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# TYENNE

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## Products Affected

- TYENNE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Moderately to severely active rheumatoid arthritis (RA) and patient has trial and failure or intolerance or contraindication to two preferred products (i.e. adalimumab-adbm, Hadlima, Orencia, Rinvoq, Simlandi), B.) Giant Cell Arteritis (GCA) and patient has a trial and failure, intolerance or contraindication to Rinvoq, C.) Polyarticular Juvenile Idiopathic Arthritis (PJIA) and patient has trial and failure or intolerance or contraindication to two preferred products (i.e. adalimumab-adbm, Hadlima, Orencia, Rinvoq, Simlandi), or D.) Systemic Juvenile Idiopathic Arthritis (SJIA)
<b>Age Restrictions</b>	For PJIA and SJIA: 2 years or older. Other conditions: 18 years of age and older
<b>Prescriber Restrictions</b>	For PJIA , RA and SJIA: Rheumatologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physicians certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray. For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# TYMLOS

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## Products Affected

- TYMLOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of osteoporosis in men or postmenopausal women and one of the following A.) osteoporotic fracture or multiple risk factors for fracture, or B.) previous trial of/or contraindication to bisphosphonate
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 24 months, continuity to complete 2 yrs, Renewal:12 months, if treatment beyond 2 yrs
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# UBRELVY

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## Products Affected

- UBRELVY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin)
<b>Required Medical Information</b>	Diagnosis of migraine disorder with or without aura and patient has documented trial, inadequate response, or contraindication to at least 1 generic formulary triptan
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication, demonstrated by a reduction in headache frequency and/or intensity.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# UPTRAVI

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## Products Affected

- UPTRAVI ORAL TABLET 1000 MCG, 1200 MCG, 1400 MCG, 1600 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG
- UPTRAVI TITRATION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with strong inhibitors of CYP2C8 (e.g., gemfibrozil)
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension (PAH, WHO Group 1), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.) and patient has a trial and failure, contraindication or intolerance to generic alternative including bosentan or ambrisentan, and tadalafil or sildenafil.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or cardiologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	Continuation of therapy: patient is tolerating and responding to medication
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# USTEKINUMAB

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## Products Affected

- *ustekinumab subcutaneous solution prefilled syringe 45 mg/0.5ml, 90 mg/ml*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

Prior Authorization Criteria

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# VALCHLOR

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## Products Affected

- VALCHLOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cutaneous T-cell lymphoma (stage IA and IB mycosis fungoides-type) and patient has received prior skin-directed therapy (e.g. Topical corticosteroids, phototherapy, or topical nitrogen mustard)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# VALTOCO

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## Products Affected

- VALTOCO 10 MG DOSE
- VALTOCO 15 MG DOSE
- VALTOCO 20 MG DOSE
- VALTOCO 5 MG DOSE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute narrow angle glaucoma
<b>Required Medical Information</b>	Diagnosis of epilepsy and documentation of use for acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patients usual seizure pattern.
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# VANFLYTA

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## Products Affected

- VANFLYTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia
<b>Required Medical Information</b>	Patient must have all of the following A.) Newly diagnosed acute myeloid leukemia with FLT3-ITD mutation, B.) Used in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, and C.) Must be enrolled in the VANFLYTA REMS program
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# VENCLEXTA

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## Products Affected

- VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with strong CYP3A inhibitor during the initial and titration phase in patients with CLL or SLL
<b>Required Medical Information</b>	Diagnosis of one of the following A.) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), or B.) Newly-diagnosed acute myeloid leukemia (AML) and used in combination with azacitidine, decitabine or low-dose cytarabine in patients 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# VEOZAH

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## Products Affected

- VEOZAH

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Cirrhosis, B.) Severe renal impairment or end-stage renal disease, C.) Concomitant use with CYP1A2 inhibitors
<b>Required Medical Information</b>	Diagnosis of moderate to severe menopausal vasomotor symptoms (VMS) and A.) Initial treatment: The patient is experiencing 7 or more hot flashes per day and has a trial, failure or contraindication to hormonal therapy such as estradiol patch or oral conjugated estrogens, or B.) Continuing therapy: The patient has continued need for VMS treatment and experienced a reduction in VMS frequency or severity due to Veozah treatment
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# VERQUVO

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## Products Affected

- VERQUVO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use of other soluble guanylate cyclase (sGC) stimulators
<b>Required Medical Information</b>	Diagnosis of chronic heart failure (HF), NYHA Class II to IV and all of the following 1.) Left ventricular ejection fraction less than 45%, 2.) Previous hospitalization for HF within 6 months or outpatient IV diuretic treatment for HF within 3 months
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# VERZENIO

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## Products Affected

- VERZENIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer and ALL of the following: 1.) Patient is at high risk of recurrence, and 2.) Requested drug will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for adjuvant treatment, OR B.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and one of the following 1.) Used in combination with fulvestrant in a patient with disease progression following endocrine therapy, 2.) Used as monotherapy in a patient with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting, or 3.) For postmenopausal women, and men, used as initial endocrine-based treatment in combination with an aromatase inhibitor
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# VIGABATRIN

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## Products Affected

- *vigabatrin*
- *vigadron*
- *vigpoder*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Infantile spasms, or B.) Refractory complex partial seizures and the drug is being used as adjunctive therapy in patients who have responded inadequately to two alternative treatments
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# VIJOICE

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## Products Affected

- VIJOICE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) in patients who require systemic therapy
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# VITRAKVI

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic or surgically unresectable neurotrophic receptor tyrosine kinase (NTRK) gene fusion positive solid tumors without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have no satisfactory alternative treatments or that have progressed following treatment.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# VIZIMPRO

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## Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic non-small cell lung cancer with confirmed epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# VONJO

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## Products Affected

- VONJO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use of strong CYP3A4 inhibitors or inducers
<b>Required Medical Information</b>	Diagnosis of intermediate or high-risk primary or secondary myelofibrosis in adults AND a platelet count less than 50 X 10(9)/L
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# VOQUEZNA

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## Products Affected

- VOQUEZNA ORAL TABLET 10 MG,  
20 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with rilpivirine-containing products
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Erosive Esophagitis and the diagnosis is confirmed by endoscopy (E.g. Los Angeles classification of reflux esophagitis grade A-D) B.) Heartburn associated with Non-Erosive Gastroesophageal Reflux Disease (NERD) and diagnosis confirmed by endoscopy and does not have presence of visible erosion (E.g. Does not have Los Angeles classification of reflux esophagitis grade A-D) C.) H. pylori infection.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist
<b>Coverage Duration</b>	INITIAL: H PYLORI: 14 DAYS. EE: 8 WEEKS. NERD: 4 WEEKS. RENEWAL: EE: 24 WEEKS.
<b>Other Criteria</b>	Initial: EE: Trial of or contraindication of two proton pump inhibitors at maximum dose for 8 weeks each. NERD: 1. No previous treatment failure with Voquezna in the last 12 months 2. Trial of or contraindication to two proton pump inhibitors at a max dose for 8 weeks each. Renewal EE: maintained a clinical response to Voquezna
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# VORANIGO

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## Products Affected

- VORANIGO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of grade 2 astrocytoma or oligodendrogloma in adult and pediatric patients 12 years of age and older with a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation following surgery, including biopsy, subtotal resection, or gross total resection
<b>Age Restrictions</b>	12 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# VORICONAZOLE

## Products Affected

- *voriconazole intravenous*
- *voriconazole oral suspension reconstituted*
- *voriconazole oral tablet 200 mg, 50 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant use of carbamazepine, CYP3A4 substrates (e.g., terfenadine, astemizole, cisapride, pimozide, or quinidine), B.) Concomitant use with high-dose ritonavir (400mg every 12 hours), C.) Concomitant use with ergot alkaloids, D.) Concomitant use with long-acting barbiturates, E.) Concomitant use with rifabutin or rifampin, F.) Concomitant use with sirolimus, G.) Concomitant use with efavirenz at standard doses of 400mg/day or higher, or H.) Concomitant use of naloxegol, tolvaptan, venetoclax or lurasidone.
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Invasive aspergillosis, B.) Candidemia, C.) Esophageal Candidiasis, D.) Invasive candidiasis of the skin and abdomen, kidney, bladder wall, and wounds, or E.) Serious fungal infection due to <i>Scedosporium apiospermum</i> or <i>Fusarium</i> species
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# VOTRIENT

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## Products Affected

- VOTRIENT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced renal cell carcinoma, or B.) Advanced soft tissue sarcoma and patient received at least one prior chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# VOWST

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## Products Affected

- VOWST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of prevention of recurrent Clostridioides difficile infection (CDI) and one of the following 1.) Patient has completed antibiotic treatment for at least 3 CDI episodes, or 2.) Previously received Vowst and both of the following A.) Treatment failure (defined as the presence of CDI diarrhea within 8 weeks of first dose of Vowst and a positive stool test for C. difficile, and B.) Patient has not received more than one treatment course of Vowst which was at least 12 days and not more than 8 weeks prior
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	30 days
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# VUMERITY

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## Products Affected

- VUMERITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use of dimethyl fumarate
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# WELIREG

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## Products Affected

- WELIREG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Von Hippel-Lindau (VHL) disease and therapy is required for any of the following disease associated tumors that do not require immediate surgery 1.) Renal cell carcinoma (RCC), 2.) Central nervous system (CNS) hemangioblastoma, or 3.) Pancreatic neuroendocrine tumor (pNET), or B.) Advanced renal cell carcinoma following a programmed death receptor-1 or programmed death-ligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor or C.) Treatment of Adults and Pediatric Patients 12 Years and Older With Locally Advanced, Unresectable, or Metastatic Pheochromocytoma or Paraganglioma (PPGL)
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# WINREVAIR

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## Products Affected

- WINREVAIR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension (PAH, WHO Group 1) , to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events. Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.) Failure, contraindication or intolerance to generic alternative including bosentan or ambrisentan, and tadalafil or sildenafil , to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or cardiologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# XALKORI

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## Products Affected

- XALKORI ORAL CAPSULE
- XALKORI ORAL CAPSULE SPRINKLE  
150 MG, 20 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive or ROS1-positive as detected by an FDA-approved test, B.) Relapsed or refractory systemic anaplastic large cell lymphoma that is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved test, or C.) Unresectable, recurrent, or refractory inflammatory myofibroblastic tumors that are anaplastic lymphoma kinase (ALK)-positive
<b>Age Restrictions</b>	NSCLC: 18 years of age and older, Relapsed or refractory systemic anaplastic large cell lymphoma, or myofibroblastic tumors that are anaplastic lymphoma kinase (ALK)-positive: 1 year of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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Effective date: 01/01/2026 Last Updated: 12/09/2025

# XCOPRI

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## Products Affected

- XCOPRI (250 MG DAILY DOSE)
- XCOPRI (350 MG DAILY DOSE)
- XCOPRI ORAL TABLET 100 MG, 150 MG, 200 MG, 25 MG, 50 MG
- XCOPRI ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	Familial short QT syndrome
Required Medical Information	Diagnosis of partial-onset seizures. Member must have history of inadequate response, contraindication, or intolerance to levetiracetam prior to approval
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 Months
Other Criteria	None
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Prior Authorization Criteria

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# XDEMVY

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## Products Affected

- XDEMVY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Demodex blepharitis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# XERMELO

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## Products Affected

- XERMELO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of carcinoid syndrome diarrhea and both of the following 1.) Diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide, lanreotide) for at least 3 months, and 2.) Used in combination with SSA therapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# XGEVA

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## Products Affected

- XGEVA

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

Prior Authorization Criteria

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# XOLAIR

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## Products Affected

- XOLAIR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic idiopathic urticaria in patients who remain symptomatic despite H1 antihistamine therapy for patients 12 years of age and older, B.) Moderate to severe persistent asthma in patients 6 years of age or older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms are inadequately controlled with inhaled corticosteroids or Dupixent, C.) Nasal polyps in patients 18 years of age or older with inadequate response to nasal corticosteroids, or D.) Reduction of allergic reactions (type I), including anaphylaxis, that may occur with accidental exposure to 1 or more foods in with IgE-mediated food allergy and is being used in conjunction with food allergen avoidance in patient 1 year of age or older
<b>Age Restrictions</b>	Chronic idiopathic urticaria: 12 years of age or older, Moderate to severe persistent asthma: 6 years of age, Nasal polyps: 18 years of age or older , Reduction of allergic reactions (type I): 1 year of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, dermatologist, immunologist, otolaryngologist, or pulmonologist
<b>Coverage Duration</b>	Initial: 6 months, Renewal: 12 months
<b>Other Criteria</b>	For continuation of therapy: Prescribing physician attests patient is tolerating and responding positively to medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria  
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# XOSPATA

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## Products Affected

- XOSPATA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an Oncologist or Hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# XPOVIO

## Products Affected

- XPOVIO (100 MG ONCE WEEKLY)
- XPOVIO (40 MG ONCE WEEKLY)  
ORAL TABLET THERAPY PACK 10  
MG, 40 MG
- 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
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsed or refractory multiple myeloma being used in combination with dexamethasone in a patient who has received at least 4 prior therapies and is refractory to at least 2 proteasome inhibitors, at least 2 immunomodulatory agents, and an anti-CD38 monoclonal antibody, B.) Multiple myeloma being used in combination with bortezomib and dexamethasone in a patient who has received at least 1 prior therapy, C.) Relapsed or refractory diffuse large B-cell lymphoma not otherwise specified, or D.) Relapsed or refractory DLBCL arising from follicular lymphoma and patient has received at least 2 lines of systemic therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

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# XTANDI

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## Products Affected

- XTANDI ORAL CAPSULE
- XTANDI ORAL TABLET 40 MG, 80 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Castration-resistant prostate cancer (CRPC), B.) Metastatic, castration-sensitive prostate cancer (mCSPC). For treatment of CRPC and mCSPC, one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient has received bilateral orchiectomy, or C.) Nonmetastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ZARXIO

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## Products Affected

- ZARXIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chemotherapy induced febrile neutropenia (prophylaxis), B.) Severe chronic neutropenia, C.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, or D.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ZEJULA

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## Products Affected

- ZEJULA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Advanced or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and used as maintenance therapy in a patient who is in a complete or partial response to platinum-based chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# ZELBORAF

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## Products Affected

- ZELBORAF

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Unresectable or metastatic melanoma and patient has positive BRAF-V600E mutation documented by an FDA-approved test, or B.) Erdheim-Chester disease and patient has documented BRAF V600 mutation
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ZIEXTENZO

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## Products Affected

- ZIEXTENZO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of a non-myeloid malignancy and drug is being used as prophylaxis for chemotherapy-induced neutropenia
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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# ZOLINZA

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## Products Affected

- ZOLINZA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of primary cutaneous T-cell lymphoma (CTCL) in patients who have progressive, persistent or recurrent disease on or following two systemic therapies (e.g., bexarotene, romidepsin, etc)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

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# ZTALMY

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## Products Affected

- ZTALMY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# ZURZUVAE

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## Products Affected

- ZURZUVAE ORAL CAPSULE 20 MG,  
25 MG, 30 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following A) Diagnosis of postpartum depression B) Patient is less than or equal to 12 months post-partum
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a psychiatrist or obstetrician.
<b>Coverage Duration</b>	14 days
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Prior Authorization Criteria

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# ZYDELIG

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## Products Affected

- ZYDELIG ORAL TABLET 100 MG, 150 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	History of toxic epidermal necrosis with any drug
<b>Required Medical Information</b>	Diagnosis of Chronic lymphocytic leukemia, used in combination with rituximab and patient has relapsed on at least one prior therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 Months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Prior Authorization Criteria

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# ZYKADIA

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## Products Affected

- ZYKADIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

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## PART B VERSUS PART D

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### Products Affected

- ABILIFY ASIMTUFII INTRAMUSCULAR PREFILLED SYRINGE 720 MG/2.4ML, 960 MG/3.2ML
- ABILIFY MAINTENA INTRAMUSCULAR PREFILLED SYRINGE 300 MG, 400 MG
- ABILIFY MAINTENA INTRAMUSCULAR SUSPENSION RECONSTITUTED ER 300 MG, 400 MG
- *acetylcysteine inhalation solution 10 %, 20 %*
- ACTIMMUNE SUBCUTANEOUS SOLUTION 100 MCG/0.5ML
- *acyclovir sodium intravenous solution 50 mg/ml*
- *albuterol sulfate inhalation nebulization solution (2.5 mg/3ml) 0.083%, 0.63 mg/3ml, 1.25 mg/3ml, 2.5 mg/0.5ml*
- *amphotericin b intravenous solution reconstituted 50 mg*
- *amphotericin b liposome intravenous suspension reconstituted 50 mg*
- *ampicillin sodium injection solution reconstituted 1 gm*
- *aprepitant oral capsule 125 mg, 40 mg, 80 & 125 mg, 80 mg*
- ARCALYST SUBCUTANEOUS SOLUTION RECONSTITUTED 220 MG
- *azathioprine oral tablet 50 mg*
- *azithromycin intravenous solution reconstituted 500 mg*
- *budesonide inhalation suspension 0.25 mg/2ml, 0.5 mg/2ml, 1 mg/2ml*
- *calcitonin (salmon) nasal solution 200 unit/act*
- *cefoxitin sodium intravenous solution reconstituted 1 gm, 10 gm, 2 gm*
- *cefuroxime sodium injection solution reconstituted 750 mg*
- *cefuroxime sodium intravenous solution reconstituted 1.5 gm*
- *cinacalcet hcl oral tablet 30 mg, 60 mg, 90 mg*
- *ciprofloxacin in d5w intravenous solution 200 mg/100ml*
- *clindamycin phosphate injection solution 300 mg/2ml, 600 mg/4ml, 900 mg/6ml*
- CLINIMIX/DEXTROSE (4.25/5) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 %
- CLINIMIX/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 %
- *colistimethate sodium (cba) injection solution reconstituted 150 mg*
- *cromolyn sodium inhalation nebulization solution 20 mg/2ml*
- CYCLOPHOSPHAMIDE ORAL CAPSULE 25 MG
- *cyclophosphamide oral capsule 50 mg*
- *cyclophosphamide oral tablet 25 mg*
- CYCLOPHOSPHAMIDE ORAL TABLET 50 MG
- *cyclosporine modified oral capsule 100 mg, 25 mg, 50 mg*
- *cyclosporine modified oral solution 100 mg/ml*
- *cyclosporine oral capsule 100 mg, 25 mg*
- *dextrose intravenous solution 10 %*
- DEXTROSE-SODIUM CHLORIDE INTRAVENOUS SOLUTION 10-0.2 %, 10-0.45 %
- *doxy 100 intravenous solution reconstituted 100 mg*

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- *doxycycline hyclate intravenous solution reconstituted 100 mg*
- *dronabinol oral capsule 10 mg, 2.5 mg, 5 mg*
- **ENGERIX-B INJECTION SUSPENSION 20 MCG/ML**
- **ENGERIX-B INJECTION SUSPENSION PREFILLED SYRINGE 10 MCG/0.5ML, 20 MCG/ML**
- **ENVARSUS XR ORAL TABLET EXTENDED RELEASE 24 HOUR 0.75 MG, 1 MG, 4 MG**
- *everolimus oral tablet 0.25 mg, 0.5 mg, 0.75 mg, 1 mg*
- *fluconazole in sodium chloride intravenous solution 200-0.9 mg/100ml-%, 400-0.9 mg/200ml-%*
- **GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML**
- **GAMMAGARD S/D LESS IGA INTRAVENOUS SOLUTION RECONSTITUTED 10 GM, 5 GM**
- **GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 5 GM/50ML**
- **GAMUNEX-C INJECTION SOLUTION 1 GM/10ML**
- *gransetron hcl oral tablet 1 mg*
- *heparin sodium (porcine) injection solution 10000 unit/ml, 20000 unit/ml, 5000 unit/ml*
- **HEPLISAV-B INTRAMUSCULAR SOLUTION PREFILLED SYRINGE 20 MCG/0.5ML**
- **IMOVAX RABIES INTRAMUSCULAR SUSPENSION RECONSTITUTED 2.5 UNIT/ML**
- *ipratropium bromide inhalation solution 0.02 %*
- *ipratropium-albuterol inhalation solution 0.5-2.5 (3) mg/3ml*
- **ISOLYTE-S INTRAVENOUS SOLUTION**
- **ISOLYTE-S PH 7.4 INTRAVENOUS SOLUTION**
- **JYLAMVO ORAL SOLUTION 2 MG/ML**
- *levalbuterol hcl inhalation nebulization solution 0.31 mg/3ml, 0.63 mg/3ml, 1.25 mg/0.5ml, 1.25 mg/3ml*
- *linezolid intravenous solution 600 mg/300ml*
- *methotrexate sodium (pf) injection solution 50 mg/2ml*
- **METHOTREXATE SODIUM INJECTION SOLUTION 50 MG/2ML**
- *metronidazole intravenous solution 500 mg/100ml*
- *micafungin sodium intravenous solution reconstituted 100 mg, 50 mg*
- *mycophenolate mofetil oral capsule 250 mg*
- *mycophenolate mofetil oral suspension reconstituted 200 mg/ml*
- *mycophenolate mofetil oral tablet 500 mg*
- *mycophenolate sodium oral tablet delayed release 180 mg, 360 mg*
- **NUTRILIPID INTRAVENOUS EMULSION 20 %**
- *octreotide acetate injection solution 100 mcg/ml, 1000 mcg/ml, 200 mcg/ml, 50 mcg/ml, 500 mcg/ml*
- *ondansetron hcl oral solution 4 mg/5ml*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet dispersible 4 mg, 8 mg*
- *penicillin g potassium injection solution reconstituted 20000000 unit*
- *penicillin g sodium injection solution reconstituted 5000000 unit*
- *pentamidine isethionate inhalation solution reconstituted 300 mg*

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- *pentamidine isethionate injection solution reconstituted 300 mg*
- PERSERIS SUBCUTANEOUS PREFILLED SYRINGE 120 MG, 90 MG
- PLASMA-LYTE A INTRAVENOUS SOLUTION
- POTASSIUM CL IN DEXTROSE 5% INTRAVENOUS SOLUTION 20 MEQ/L
- PROGRAF ORAL PACKET 0.2 MG, 1 MG
- PROLASTIN-C INTRAVENOUS SOLUTION 1000 MG/20ML
- PULMOZYME INHALATION SOLUTION 2.5 MG/2.5ML
- RABAVERT INTRAMUSCULAR SUSPENSION RECONSTITUTED
- RECOMBIVAX HB INJECTION SUSPENSION 10 MCG/ML, 40 MCG/ML, 5 MCG/0.5ML
- RECOMBIVAX HB INJECTION SUSPENSION PREFILLED SYRINGE 10 MCG/ML, 5 MCG/0.5ML
- RISPERDAL CONSTA INTRAMUSCULAR SUSPENSION RECONSTITUTED ER 12.5 MG, 25 MG, 37.5 MG, 50 MG
- *risperidone microspheres er intramuscular suspension reconstituted er 12.5 mg, 25 mg, 37.5 mg, 50 mg*
- *sirolimus oral solution 1 mg/ml*
- *sirolimus oral tablet 0.5 mg, 1 mg, 2 mg*
- *tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg*
- TEFLARO INTRAVENOUS SOLUTION RECONSTITUTED 400 MG, 600 MG
- TIGECYCLINE INTRAVENOUS SOLUTION RECONSTITUTED 50 MG
- *tobramycin inhalation nebulization solution 300 mg/5ml*
- *tobramycin sulfate injection solution 10 mg/ml, 80 mg/2ml*
- TPN ELECTROLYTES INTRAVENOUS CONCENTRATE
- TRAVASOL INTRAVENOUS SOLUTION 10 %
- TROPHAMINE INTRAVENOUS SOLUTION 10 %
- XATMEP ORAL SOLUTION 2.5 MG/ML
- *ziprasidone mesylate intramuscular solution reconstituted 20 mg*

## Details

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

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### A

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