ABILIFY ASIMTUFII

Products Affected

• Abilify Asimtufii

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

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ABILIFY MYCITE

Products Affected

• Abilify Mycite Maintenance Kit

• Abilify Mycite Starter Kit

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ABIRATERONE

Products Affected

• Abiraterone Acetate

• Zytiga

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Node-positive (N1), non-metastatic (M0) prostate cancer, very-high-risk prostate cancer, non-metastatic high-risk prostate cancer, non-metastatic prostate cancer with prostate-specific antigen (PSA) persistence/recurrence after radical prostatectomy
Exclusion Criteria	N/A
Required Medical Information	The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ACITRETIN

Products Affected

• Acitretin

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Prevention of non-melanoma skin cancers in high risk individuals, Lichen planus, Keratosis follicularis (Darier Disease)
Exclusion Criteria	N/A
Required Medical Information	For psoriasis: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate or cyclosporine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ACTEMRA

Products Affected

• Actemra

• Actemra Actpen

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ACTHAR HP

Products Affected

• Acthar

• Acthar Gel

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ACTIMMUNE

Products Affected

• Actimmune INJ 100MCG/0.5ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Mycosis fungoides, Sezary syndrome
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ADAKVEO

Products Affected

• Adakveo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ADALIMUMAB AET

Products Affected

- Abrilada
- Abrilada 1-pen Kit
- Adalimumab-aaty 1-pen Kit
- Adalimumab-aaty 2-syringe Kit
- Adalimumab-adaz
- Adalimumab-adbm
- Adalimumab-adbm Crohns/uc/hs Starter
- Adalimumab-adbm Psoriasis/uveitis Starter
- Adalimumab-adbm Starter Package For Crohns Disease/uc/hs
- Adalimumab-adbm Starter Package For Psoriasis/uveitis
- Adalimumab-fkjp
- Adalimumab-ryvk
- Adalimumab-ryvk (2 Pen)
- Amjevita
- Cyltezo
- Cyltezo Starter Package For Crohns Disease/uc/hs

- Cyltezo Starter Package For Psoriasis
- Cyltezo Starter Package For Psoriasis/uveitis
- Hadlima
- Hadlima Pushtouch
- Hulio
- Hyrimoz
- Hyrimoz Crohn's Disease And Ulcerative Colitis Starter Pack
- Hyrimoz Pediatric Crohns Disease Starter Pack
- Hyrimoz Pediatric Crohn'sdisease Starter Pack
- Hyrimoz Plaque Psoriasis/uveitis Starter Pack
- Simlandi 1-pen Kit
- Simlandi 2-pen Kit
- Yuflyma 1-pen Kit
- Yuflyma 2-syringe Kit
- Yuflyma Cd/uc/hs Starter
- Yusimry

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ADAPALENE

Products Affected

- Adapalene CREA
- Adapalene GEL
- Adapalene PADS
- Adapalene SOLN
- Adapalene Pump
- Adapalene/benzoyl Peroxide

- Cabtreo
- Differin CREA
- Differin GEL 0.3%
- Differin LOTN
- Epiduo
- Epiduo Forte

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ADBRY

Products Affected

• Adbry

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ADEMPAS

Products Affected

• Adempas

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ADLARITY

Products Affected

• Adlarity

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ADZYNMA

Products Affected

• Adzynma

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

AGAMREE

Products Affected

• Agamree

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

AIMOVIG

Products Affected

• Aimovig

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the preventive treatment of migraine, initial: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants. For preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months, Continuation: Plan Year
Other Criteria	N/A

AJOVY AET

Products Affected

• Ajovy

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

AKEEGA

Products Affected

• Akeega

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested drug will be used in combination with a gonadotropin- releasing hormone (GnRH) analog or after bilateral orchiectomy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

AKLIEF

Products Affected

• Aklief

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ALDURAZYME

Products Affected

• Aldurazyme

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ALECENSA

Products Affected

• Alecensa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ALIQOPA

Products Affected

• Aliqopa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ALKINDI

Products Affected

• Alkindi Sprinkle

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ALOSETRON

Products Affected

• Lotronex

• Alosetron Hydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For severe diarrhea-predominant irritable bowel syndrome (IBS): 1) The requested drug is being prescribed for a biological female or a person that self-identifies as a female, 2) chronic IBS symptoms lasting at least 6 months, 3) gastrointestinal tract abnormalities have been ruled out, AND 4) inadequate treatment response to one conventional therapy (e.g., antispasmodics, antidepressants, antidiarrheals).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ALPHA1-PROTEINASE INHIBITOR

Products Affected

- Aralast Np INJ 1000MG, 500MG
- Glassia

- Prolastin-c
- Zemaira

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For alpha1-proteinase inhibitor deficiency: Patient must have 1) clinically evident emphysema, AND 2) pretreatment serum alpha1-proteinase inhibitor level less than 11 micromol/L (80 milligrams per deciliter [mg/dL] by radial immunodiffusion or 50 mg/dL by nephelometry).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ALUNBRIG

Products Affected

• Alunbrig

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), brain metastases from ALK-positive NSCLC, inflammatory myofibroblastic tumors (IMT) with ALK translocation, Erdheim-Chester disease (ECD) with ALK-fusion
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced, or metastatic, AND 2) the disease is anaplastic lymphoma kinase (ALK)-positive.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ALVAIZ

Products Affected

• Alvaiz

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For chronic or persistent immune thrombocytopenia (ITP) (new starts): 1) Patient (pt) has experienced an inadequate treatment response or is intolerant to a prior therapy such as corticosteroids or immunoglobulins, AND 2) Untransfused platelet (plt) count at any point prior to the initiation of the requested medication is less than 30,000/mcL OR 30,000-50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes pt to trauma). For ITP (continuation): plt count response to the requested drug: 1) Current plt count is less than or equal to 200,000/mcL, OR 2) Current plt count is greater than 200,000/mcL to less than or equal to 400,000/mcL and dosing will be adjusted to a plt count sufficient to avoid clinically important bleeding. For thrombocytopenia associated with chronic hepatitis C (new starts): the requested drug is used for initiation and maintenance of interferon-based therapy. For thrombocytopenia associated with chronic hepatitis C (continuation): pt is receiving interferon-based therapy. For severe aplastic anemia (AA) (new starts): Pt had an insufficient response to immunosuppressive therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HCV: 6mo, ITP/AA initial: 6mo, ITP reauth: Plan Year, AA reauth: APR-Plan Year, IPR-16 wks

Other Criteria

For severe AA (continuation): 1) Current plt count is 50,000-200,000/mcL, OR 2) Current plt count is less than 50,000/mcL and pt has not received appropriately titrated therapy for at least 16 weeks, OR 3) Current plt count is less than 50,000/mcL and pt is transfusion-independent, OR 4) Current plt count is greater than 200,000/mcL to less than or equal to 400,000/mcL and dosing will be adjusted to achieve and maintain an appropriate target plt count. APR: adequate platelet response (greater than 50,000/mcL), IPR: inadequate platelet response (less than 50,000/mcL).

ALYMSYS

Products Affected

• Alymsys

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

AMBRISENTAN

Products Affected

• Ambrisentan

• Letairis

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

AMITIZA AET

Products Affected

• Amitiza

• Lubiprostone

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

AMONDYS 45

Products Affected

• Amondys 45

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

AMVUTTRA

Products Affected

• Amvuttra

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

APOKYN

Products Affected

• Apokyn INJ 30MG/3ML

• Apomorphine Hydrochloride INJ

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ARANESP AET

Products Affected

 Aranesp Albumin Free INJ 100MCG/0.5ML, 100MCG/ML, 10MCG/0.4ML, 150MCG/0.3ML, 200MCG/0.4ML, 200MCG/ML, 25MCG/0.42ML, 25MCG/ML, 300MCG/0.6ML, 40MCG/0.4ML, 40MCG/ML, 500MCG/ML, 60MCG/0.3ML, 60MCG/ML

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ARCALYST

Products Affected

• Arcalyst

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Prevention of gout flares in patients initiating or continuing urate- lowering therapy
Exclusion Criteria	N/A
Required Medical Information	For prevention of gout flares in patients initiating or continuing urate-lowering therapy (e.g., allopurinol) (new starts): 1) two or more gout flares within the previous 12 months, AND 2) inadequate response, intolerance, or contraindication to maximum tolerated doses of a non-steroidal anti-inflammatory drug (NSAID) and colchicine, AND 3) concurrent use with urate-lowering therapy. For prevention of gout flares in patients initiating or continuing urate-lowering therapy (e.g., allopurinol) (continuation): 1) patient must have achieved or maintained a clinical benefit (i.e., a fewer number of gout attacks or fewer flare days) compared to baseline, AND 2) continued use of urate-lowering therapy concurrently with the requested drug. For recurrent pericarditis: patient must have had an inadequate response, intolerance, or contraindication to maximum tolerated doses of a NSAID and colchicine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ARESTIN AET

Products Affected

• Arestin

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ARIKAYCE

Products Affected

• Arikayce

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

ARMODAFINIL

Products Affected

• Armodafinil

• Nuvigil

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For excessive sleepiness associated with narcolepsy: The diagnosis has been confirmed by sleep lab evaluation. For excessive sleepiness associated with obstructive sleep apnea (OSA): The diagnosis has been confirmed by polysomnography.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ARZERRA

Products Affected

• Arzerra

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ASPARLAS

Products Affected

• Asparlas

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ASPRUZYO

Products Affected

• Aspruzyo Sprinkle

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

AUBAGIO

Products Affected

• Teriflunomide

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

AUGTYRO

Products Affected

• Augtyro

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

AUSTEDO

Products Affected

• Austedo

- Austedo Xr
- Austedo Xr Patient Titration Kit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Tourette's syndrome
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

AUVELITY

Products Affected

• Auvelity

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For Major Depressive Disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

AVASTIN

Products Affected

• Avastin

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

AVONEX AET

Products Affected

• Avonex INJ 30MCG/0.5ML

• Avonex Pen

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

AVSOLA

Products Affected

• Avsola

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

AVYCAZ

Products Affected

• Avycaz

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

AYVAKIT

Products Affected

• Ayvakit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Myeloid and lymphoid neoplasms with eosinophilia, gastrointestinal stromal tumor (GIST) for residual, unresectable, tumor rupture, or recurrent/metastatic disease without platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation.
Exclusion Criteria	N/A
Required Medical Information	For myeloid and lymphoid neoplasms with eosinophilia, the patient meets all of the following criteria: 1) The disease is FIP1L1- PDGFRA rearrangement-positive, AND 2) The disease harbors a PDGFRA D842V mutation, AND 3) The disease is resistant to imatinib. For GIST, the patient meets either of the following criteria: 1) The disease harbors PDGFRA exon 18 mutation, including a PDGFRA D842V mutation, OR 2) The requested drug will be used after failure on at least two Food and Drug Administration (FDA)-approved therapies in residual, unresectable, tumor rupture, or recurrent/metastatic disease without PDGFRA exon 18 mutation. For systemic mastocytosis: 1) The patient has a diagnosis of indolent systemic mastocytosis or advanced systemic mastocytosis (including aggressive systemic mastocytosis [ASM], systemic mastocytosis with associated hematological neoplasm [SM-AHN], and mast cell leukemia [MCL]) AND 2) The patient has a platelet count of greater than or equal to 50,000/microliter (mcL).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

BACLOFEN SOLN

Products Affected

• Baclofen ORAL SOLN 10MG/5ML, 5MG/5ML

• Ozobax Ds

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BAFIERTAM

Products Affected

• Bafiertam

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

BALVERSA

Products Affected

• Balversa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For urothelial carcinoma: 1) disease has susceptible fibroblast growth factor receptor 3 (FGFR3) genetic alterations, AND 2) the requested drug will be used as subsequent therapy for any of the following: a) locally advanced, recurrent, or metastatic urothelial carcinoma, OR b) stage II-IV, recurrent, or persistent urothelial carcinoma of the bladder.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

BANZEL

Products Affected

Banzel

• Rufinamide

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	1 year of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

BAVENCIO

Products Affected

• Bavencio

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BAXDELA

Products Affected

• Baxdela

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BELBUCA

Products Affected

• Belbuca

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BELEODAQ

Products Affected

• Beleodaq

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BENLYSTA

Products Affected

• Benlysta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	For patients new to therapy: severe active central nervous system lupus.
Required Medical Information	For systemic lupus erythematosus (SLE): 1) patient is currently receiving a stable standard therapy regimen for SLE (for example, corticosteroid, antimalarial, or NSAIDs), OR 2) patient has experienced an intolerance or has a contraindication to standard therapy regimen for SLE. For lupus nephritis: 1) patient is currently receiving a stable standard therapy regimen for lupus nephritis (for example, corticosteroid, cyclophosphamide, mycophenolate mofetil, or azathioprine) OR 2) patient has experienced an intolerance or has a contraindication to standard therapy regimen for lupus nephritis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

BENZNIDAZOLE

Products Affected

• Benznidazole

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BEOVU

Products Affected

• Beovu SOSY

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BERINERT

Products Affected

• Berinert

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For treatment of acute angioedema attacks due to hereditary angioedema (HAE): 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing, OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation, b) the patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	Plan Year
Other Criteria	N/A

BESPONSA

Products Affected

• Besponsa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BESREMI

Products Affected

• Besremi

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

BETASERON

Products Affected

• Betaseron

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

BEXAROTENE

Products Affected

• Bexarotene CAPS

• Targretin CAPS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Mycosis fungoides (MF)/Sezary syndrome (SS), CD30-positive primary cutaneous anaplastic large cell lymphoma (ALCL), CD30-positive lymphomatoid papulosis (LyP)
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

BIMZELX

Products Affected

• Bimzelx

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BLINCYTO

Products Affected

• Blincyto

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BOSENTAN

Products Affected

• Bosentan

• Tracleer

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) if the request is for an adult patient, the patient meets both of the following: a) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units, and b) the patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to ambrisentan (Letairis).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

BOSULIF

Products Affected

• Bosulif

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Philadelphia chromosome positive B-cell acute lymphoblastic leukemia (Ph+ B-ALL), myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase.
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML), including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I, G250E, V299L, and F317L, AND 3) Patient has experienced resistance or intolerance to imatinib, dasatinib, or nilotinib. For B-ALL including patients who have received hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I, G250E, V299L, and F317L.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

Вотох

Products Affected

• Botox

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BRAFTOVI

Products Affected

• Braftovi CAPS 75MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Adjuvant systemic therapy for cutaneous melanoma, appendiceal adenocarcinoma, recurrent NSCLC
Exclusion Criteria	N/A
Required Medical Information	For colorectal cancer (including appendiceal adenocarcinoma): 1) Tumor is positive for BRAF V600E mutation, AND 2) The requested drug will be used for either of the following: a) subsequent therapy for advanced or metastatic disease, b) primary treatment for unresectable metachronous metastases. For melanoma: 1) Tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used as a single agent or in combination with binimetinib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For non-small cell lung cancer (NSCLC): 1) Tumor is positive for BRAF V600E mutation, AND 2) Disease is advanced, recurrent, or metastatic, AND 3) The requested drug will be used in combination with binimetinib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

BRISDELLE

Products Affected

• Paroxetine

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BRIUMVI AET

Products Affected

• Briumvi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BRIVIACT

Products Affected

• Briviact ORAL SOLN

• Briviact TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom (if 4 years of age or older), Xcopri (if 18 years of age or older), Spritam (if 4 years of age or older).
Age Restrictions	1 month of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

BRIVIACT INJ

Products Affected

• Briviact INJ

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BRIXADI

Products Affected

• Brixadi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BROMSITE AET

Products Affected

• Bromfenac Sodium SOLN 0.075%

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BRONCHITOL

Products Affected

• Bronchitol

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

BROVANA AET

Products Affected

• Brovana

• Arformoterol Tartrate

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BRUKINSA

Products Affected

• Brukinsa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For mantle cell lymphoma and chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL): the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Calquence (acalabrutinib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

BUPRENORPHINE

Products Affected

• Buprenorphine Hcl SUBL

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested drug is being prescribed for the treatment of opioid use disorder AND patient meets one of the following: 1) The patient is pregnant or breastfeeding, and the requested drug is being prescribed for induction therapy and/or subsequent maintenance therapy for treatment of opioid use disorder OR 2) The requested drug is being prescribed for induction therapy for transition from opioid use to treatment of opioid use disorder OR 3) The requested drug is being prescribed for maintenance therapy for treatment of opioid use disorder in a patient who is intolerant to naloxone.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

BUPRENORPHINE PATCH

Products Affected

• Buprenorphine PTWK

• Butrans

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe and persistent enough to require an extended treatment period with a daily opioid analgesic in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

BUTALBITAL AET

Products Affected

- Allzital
- Ascomp/codeine
- Bupap TABS 300MG; 50MG
- Butalbital/acetaminophen CAPS
- Butalbital/acetaminophen TABS 300MG; 50MG, 325MG; 50MG
- Butalbital/acetaminophen/caffeine CAPS
- Butalbital/acetaminophen/caffeine TABS 325MG; 50MG; 40MG

- Butalbital/acetaminophen/caffeine/code ine
- Butalbital/aspirin/caffeine CAPS
- Butalbital/aspirin/caffeine/codeine
- Esgic
- Fioricet CAPS
- Fioricet/codeine CAPS 300MG; 50MG; 40MG; 30MG
- Tencon TABS 325MG; 50MG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BYDUREON

Products Affected

• Bydureon Beise

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BYETTA

Products Affected

• Byetta

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BYLVAY

Products Affected

• Bylvay

• Bylvay (pellets)

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

BYOOVIZ

Products Affected

• Byooviz

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CABLIVI

Products Affected

• Cablivi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CABOMETYX

Products Affected

• Cabometyx

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Non-small cell lung cancer, Ewing sarcoma, osteosarcoma, gastrointestinal stromal tumor, endometrial carcinoma
Exclusion Criteria	N/A
Required Medical Information	For renal cell carcinoma: The disease is advanced, relapsed, or stage IV (including brain metastases). For non-small cell lung cancer: 1) the disease is rearranged during transfection (RET) positive AND 2) the disease is recurrent, advanced, or metastatic. For hepatocellular carcinoma: the requested drug will be used as subsequent therapy. For gastrointestinal stromal tumor (GIST): 1) the disease is residual, unresectable, recurrent, or metastatic/tumor rupture, AND 2) the disease has progressed after at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib). For Ewing sarcoma and osteosarcoma: the requested drug will be used as subsequent therapy. For differentiated thyroid cancer (DTC) (follicular, papillary, oncocytic): 1) the disease is locally advanced or metastatic, AND 2) the disease has progressed after a vascular endothelial growth factor receptor (VEGFR)- targeted therapy, AND 3) the patient is refractory to radioactive iodine therapy (RAI) or ineligible for RAI. For endometrial carcinoma: 1) the disease is recurrent, AND 2) the requested drug will be used as subsequent therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

CALCIPOTRIENE

Products Affected

- Calcipotriene CREA
- Calcipotriene FOAM
- Calcipotriene OINT
- Calcipotriene SOLN
- Calcipotriene/betamethasone Dipropionate

- Calcitrene
- Calcitriol OINT
- Enstilar
- Sorilux
- Taclonex SUSP
- Vectical

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For psoriasis: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a topical steroid.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

CALQUENCE

Products Affected

• Calquence

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Waldenstrom macroglobulinemia (lymphoplasmacytic lymphoma), marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, splenic marginal zone lymphoma)
Exclusion Criteria	N/A
Required Medical Information	For marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, and splenic marginal zone lymphoma): the requested drug is being used for the treatment of relapsed, refractory, or progressive disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

CAMBIA

Products Affected

• Cambia

• Diclofenac Potassium PACK

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CAMZYOS

Products Affected

• Camzyos

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CAPRELSA

Products Affected

• Caprelsa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Thyroid carcinomas (follicular, oncocytic, papillary).
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

CARAC

Products Affected

• Carac

• Fluorouracil CREA 0.5%

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CARBAGLU

Products Affected

• Carbaglu

• Carglumic Acid

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For N-acetylglutamate synthase (NAGS) deficiency: Diagnosis of NAGS deficiency was confirmed by enzymatic, biochemical, or genetic testing.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

CAYSTON

Products Affected

• Cayston

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For treatment of respiratory symptoms in cystic fibrosis patients: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) The patient has a history of pseudomonas aeruginosa infection or colonization in the airways.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

CEQUA

Products Affected

• Cequa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CERDELGA

Products Affected

• Cerdelga

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For type 1 Gaucher disease (GD1): 1) Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing, and 2) Patient's CYP2D6 metabolizer status has been established using an FDA-cleared test, and 3) Patient is a CYP2D6 extensive metabolizer, an intermediate metabolizer, or a poor metabolizer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

CEREZYME

Products Affected

• Cerezyme

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CHANTIX AET

Products Affected

• Varenicline Tartrate

• Varenicline Starting Month Box

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	This Prior Authorization requirement applies after the patient has received a cumulative 24 weeks of therapy in a Plan Year.

CHENODAL AET

Products Affected

• Chenodal

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CHLORDIAZEPOXIDE - 65

Products Affected

- Chlordiazepoxide Hcl CAPS 10MG, 5MG
- Chlordiazepoxide Hydrochloride CAPS 25MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For all indications: the prescriber must acknowledge the benefit of therapy with the prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is 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), or b) serotonin-norepinephrine reuptake inhibitors (SNRIs).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Short-term relief anxiety-preop apprehens and anx-1 mo, Anxiety Disorder-4 mo, Alc Withdrawal-PlanYR
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older.

CHOLBAM

Products Affected

• Cholbam

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CIBINQO

Products Affected

• Cibinqo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CIMERLI

Products Affected

• Cimerli

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CIMZIA

Products Affected

• Cimzia

• Cimzia Starter Kit

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CINQAIR

Products Affected

• Cinqair

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CINRYZE

Products Affected

• Cinryze

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CINVANTI

Products Affected

• Cinvanti

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CITALOPRAM CAP AET

Products Affected

• Citalopram Hydrobromide CAPS

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CLOBAZAM

Products Affected

• Clobazam

- Onfi SUSP
- Onfi TABS 10MG, 20MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Seizures associated with Dravet syndrome
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Seizures associated with Lennox-Gastaut syndrome (LGS): 2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

CLOMIPRAMINE

Products Affected

• Anafranil

• Clomipramine Hydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Depression, panic disorder
Exclusion Criteria	N/A
Required Medical Information	For obsessive-compulsive disorder (OCD) and panic disorder: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to any of the following: a serotonin and norepinephrine reuptake inhibitor (SNRI), a selective serotonin reuptake inhibitor (SSRI). For depression: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to two of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

CLORAZEPATE

Products Affected

• Clorazepate Dipotassium TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Short-term relief anxiety-1 month, Anxiety Disorders-4 months, All other Diagnoses-Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older.

CLOZAPINE ODT

Products Affected

• Clozapine Odt

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

COLUMVI

Products Affected

• Columvi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

COLY-MYCIN

Products Affected

• Colistimethate Sodium INJ

• Coly-mycin M

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested drug is being used intravenously (IV) or intramuscularly (IM). Administration will not be via nebulizer (Note: CMS endorsed compendia do not support inhalation/nebulization of colistimethate.). The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	Initial approval: 3 months. Renewal: Plan Year
Other Criteria	N/A

COMETRIQ

Products Affected

• Cometriq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Non-small cell lung cancer (NSCLC), thyroid carcinomas (follicular, oncocytic, papillary).
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC): Disease is positive for rearranged during transfection (RET) rearrangements.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

COPIKTRA

Products Affected

• Copiktra

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Hepatosplenic T-Cell lymphoma, breast implant-associated anaplastic large cell lymphoma (ALCL), peripheral T-Cell lymphoma
Exclusion Criteria	N/A
Required Medical Information	For chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), breast implant-associated anaplastic large cell lymphoma (ALCL), and peripheral T-Cell lymphoma: the patient has relapsed or refractory disease. For hepatosplenic T-Cell lymphoma: the patient has refractory disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

CORTROPHIN

Products Affected

• Cortrophin

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

COSENTYX

Products Affected

• Cosentyx

- Cosentyx Sensoready Pen
- Cosentyx Unoready

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf), Skyrizi (risankizumab-rzaa), Sotyktu (deucravacitinib), Stelara (ustekinumab), Tremfya (guselkumab). For active ankylosing spondylitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active non-radiographic axial spondyloarthritis (new starts only): patient meets any of the following: 1) patient has experienced an inadequate treatment response to a non-steroidal anti-inflammatory drug (NSAID) OR 2) patient has experienced an intolerance or has a contraindication to NSAIDs. For an adult with active psoriatic arthritis (PsA) (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab), Tremfya (guselkumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For moderate to severe hidradenitis suppurativa (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf).
Age Restrictions	N/A

Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

COTELLIC

Products Affected

• Cotellic

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Central nervous system (CNS) cancer (i.e., glioma, glioblastoma), adjuvant systemic therapy for cutaneous melanoma.
Exclusion Criteria	N/A
Required Medical Information	For central nervous system (CNS) cancer (i.e., glioma, glioblastoma): 1) The tumor is positive for BRAF V600E activating mutation, AND 2) The requested drug will be used in combination with vemurafenib. For melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used in combination with vemurafenib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

CRINONE

Products Affected

• Crinone

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CRYSVITA

Products Affected

• Crysvita

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CUTAQUIG

Products Affected

• Cutaquig

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CUVITRU

Products Affected

• Cuvitru

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CUVRIOR

Products Affected

• Cuvrior

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CYCLOPHOSPHAMIDE ORAL

Products Affected

• Cyclophosphamide CAPS

• Cyclophosphamide TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.

CYCLOSET AET

Products Affected

• Cycloset

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CYRAMZA

Products Affected

• Cyramza

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

CYSTAGON

Products Affected

• Cystagon

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For nephropathic cystinosis: Diagnosis was confirmed by ANY of the following: 1) the presence of increased cystine concentration in leukocytes, OR 2) genetic testing, OR 3) demonstration of corneal cystine crystals by slit lamp examination.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

CYSTARAN

Products Affected

• Cystadrops

• Cystaran

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For cystinosis: 1) Diagnosis was confirmed by ANY of the following: a) the presence of increased cystine concentration in leukocytes, OR b) genetic testing, OR c) demonstration of corneal cystine crystals by slit lamp examination, AND 2) the patient has corneal cystine crystal accumulation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

DALFAMPRIDINE

Products Affected

• Ampyra

• Dalfampridine Er

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For multiple sclerosis, patient must meet the following (for new starts): prior to initiating therapy, patient demonstrates sustained walking impairment. For multiple sclerosis (continuation): patient must have experienced an improvement in walking speed OR other objective measure of walking ability since starting the requested drug.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

DAPAGLIFLOZIN AET

Products Affected

• Dapagliflozin Propanediol

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DAPAGLIFLOZIN-METFORMIN AET

Products Affected

• Dapagliflozin Propanediol/metformin Hydrochloride

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DARAPRIM

Products Affected

• Daraprim

• Pyrimethamine TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Toxoplasmosis prophylaxis, Pneumocystis jirovecii pneumonia prophylaxis, cystoisosporiasis treatment and secondary prophylaxis
Exclusion Criteria	N/A
Required Medical Information	For primary toxoplasmosis prophylaxis and Pneumocystis jirovecii pneumonia (PCP) prophylaxis: 1) The patient has experienced an intolerance or has a contraindication to trimethoprim-sulfamethoxazole (TMP-SMX) AND 2) The patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 3 months. For secondary toxoplasmosis prophylaxis: The patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 6 months. For cystoisosporiasis treatment: The patient has experienced an intolerance or has a contraindication to TMP-SMX. For secondary cystoisosporiasis prophylaxis: 1) The patient has experienced an intolerance or has a contraindication to TMP-SMX AND 2) The patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 6 months.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Congen toxo tx: Plan Yr. Acqu toxo tx, prim toxo ppx, PCP ppx: 3mo. Sec toxo ppx, cysto tx/ppx: 6mo
Other Criteria	N/A

DARZALEX

Products Affected

• Darzalex

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DARZALEX FASPRO

Products Affected

• Darzalex Faspro

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DAURISMO

Products Affected

• Daurismo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Post-induction therapy/consolidation following response to previous therapy with the same regimen for acute myeloid leukemia (AML), relapsed/refractory AML as a component of repeating the initial successful induction regimen
Exclusion Criteria	N/A
Required Medical Information	For acute myeloid leukemia (AML): 1) the requested drug must be used in combination with cytarabine, 2) the patient is 75 years of age or older OR has comorbidities that preclude intensive chemotherapy, AND 3) the requested drug will be used as treatment for induction therapy, post-induction/consolidation therapy, or relapsed or refractory disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

DAYBUE

Products Affected

• Daybue

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DEFERASIROX

Products Affected

- Deferasirox
- Exjade

- Jadenu
- Jadenu Sprinkle

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For chronic iron overload due to blood transfusions: pretreatment serum ferritin level is greater than 1000 mcg/L.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

DEMSER

Products Affected

• Demser

• Metyrosine

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to an alpha-adrenergic antagonist.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

DESVENLAFAXINE

Products Affected

• Desvenlafaxine Er TB24 100MG, 50MG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DHE NASAL

Products Affected

- Trudhesa
- Dihydroergotamine Mesylate NASAL SOLN
- Migranal

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Coverage will be denied when used in conjunction with potent CYP3A4 inhibitors (e.g., ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin).
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one triptan 5-HT1 receptor agonist.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

DIACOMIT

Products Affected

• Diacomit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	6 months of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

DIAZEPAM AET

Products Affected

- Diazepam CONC
- Diazepam INJ 5MG/MLDiazepam SOLN 5MG/5ML

- Diazepam TABS
- Diazepam Intensol
- Valium TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Short-term relief anx-1 mo, skeletal muscle spasm-3 mo, Anx Disorders-4 mo, Other Diagnoses-PlanYR
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older.

DICLOFENAC 2% SOL

Products Affected

• Diclofenac Sodium EXTERNAL SOLN 2%

• Pennsaid SOLN 2%

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DICLOFENAC 3% GEL

Products Affected

• Diclofenac Sodium GEL 3%

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DIMETHYL FUMARATE AET

Products Affected

- Dimethyl Fumarate CPDR
- Dimethyl Fumarate Starterpack CDPK 0
- Tecfidera
- Tecfidera Starter Pack

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DOJOLVI

Products Affected

• Dojolvi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DOPTELET AET

Products Affected

• Doptelet

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DRIZALMA

Products Affected

• Drizalma Sprinkle

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DRONABINOL

Products Affected

• Dronabinol

- Marinol
- Syndros

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For nausea and vomiting associated with cancer chemotherapy: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one oral 5-HT3 receptor antagonist.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.

DUEXIS

Products Affected

• Duexis

• Ibuprofen/famotidine

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DUOBRII

Products Affected

• Duobrii

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DUPIXENT

Products Affected

• Dupixent

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 AD, continuation of therapy: Patient achieved or maintained positive clinical response. For oral corticosteroid dependent asthma, initial therapy: Patient has inadequate asthma control despite current treatment with both of the following medications: 1) High-dose inhaled corticosteroid AND 2) Additional controller (i.e., long acting beta2-agonist, long-acting, muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) 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 both of the following medications: 1) Medium-to-high-dose inhaled corticosteroid, AND 2) Additional controller (i.e., long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. 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 Xhance (fluticasone).
Age Restrictions	Atopic Dermatitis: 6 months of age or older, Asthma: 6 years of age or older, Chronic Rhinosinusitis with Nasal Polyposis and Prurigo Nodularis: 18 years of age or older, Eosinophilic Esophagitis: 1 year of age or older

Prescriber Restrictions	N/A
Coverage Duration	AD, initial: 4 months, PN, initial: 6 months, All others: Plan Year
Other Criteria	For eosinophilic esophagitis (EoE), initial therapy: 1) Diagnosis has been confirmed by esophageal biopsy characterized by greater than or equal to 15 intraepithelial esophageal eosinophils per high power field, AND 2) Patient is exhibiting clinical manifestations of the disease (for example, dysphagia), AND 3) Patient weighs at least 15 kilograms, AND 4) Patient experienced an inadequate treatment response, intolerance, or patient has a contraindication to a topical corticosteroid. For EoE, continuation of therapy: Patient achieved or maintained a positive clinical response. For prurigo nodularis (PN), initial therapy: Patient has had an inadequate treatment response to a topical corticosteroid OR topical corticosteroids are not advisable for the patient. For PN, continuation of therapy: Patient achieved or maintained a positive clinical response.

DURYSTA

Products Affected

• Durysta

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DUVYZAT

Products Affected

• Duvyzat

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DYCLOPRO

Products Affected

• Dyclopro

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

DYSPORT

Products Affected

• Dysport

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EFUDEX

Products Affected

• Efudex CREA

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EGRIFTA

Products Affected

• Egrifta Sv

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ELAPRASE

Products Affected

• Elaprase

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ELELYSO

Products Affected

• Elelyso

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ELFABRIO

Products Affected

• Elfabrio

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ELIGARD

Products Affected

• Eligard

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent androgen receptor positive salivary gland tumors
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ELREXFIO

Products Affected

• Elrexfio

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ELYXYB

Products Affected

• Elyxyb

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EMFLAZA

Products Affected

• Deflazacort

• Emflaza

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EMGALITY

Products Affected

• Emgality

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the preventive treatment of migraine, initial: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants. For preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline. For episodic cluster headache, initial: The patient experienced an inadequate treatment response, intolerance, or contraindication to a triptan 5-HT1 receptor agonist. For episodic cluster headache, continuation: The patient received the requested drug for at least 3 weeks of treatment and had a reduction in weekly cluster headache attack frequency from baseline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months, Continuation: Plan Year
Other Criteria	N/A

EMPAVELI

Products Affected

• Empaveli

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EMPLICITI

Products Affected

• Empliciti

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EMSAM

Products Affected

• Emsam

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For Major Depressive Disorder (MDD): 1) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion OR 2) The patient is unable to swallow oral formulations.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ENDARI

Products Affected

• Endari

• L-glutamine PACK

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	5 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ENHERTU

Products Affected

• Enhertu

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ENJAYMO

Products Affected

• Enjaymo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ENSPRYNG

Products Affected

• Enspryng

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ENTADFI

Products Affected

• Entadfi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ENTYVIO

Products Affected

• Entyvio

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EOHILIA

Products Affected

• Eohilia

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EPCLUSA

Products Affected

• Epclusa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Criteria will be applied consistent with current AASLD-IDSA guidance
Other Criteria	N/A

EPIDIOLEX

Products Affected

• Epidiolex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	1 year of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

EPKINLY

Products Affected

• Epkinly

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ЕРО

Products Affected

• Procrit

• Retacrit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Anemia due to myelodysplastic syndromes (MDS), anemia in rheumatoid arthritis (RA), anemia due to hepatitis C treatment (ribavirin in combination with either interferon alfa or peginterferon alfa)
Exclusion Criteria	Patients receiving chemotherapy with curative intent. Patients with myeloid cancer.
Required Medical Information	Requirements regarding hemoglobin (Hgb) values exclude values due to a recent transfusion. For initial approval: 1) for all uses except anemia due to chemotherapy or myelodysplastic syndrome (MDS): patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%), AND 2) for all uses except surgery: pretreatment (no erythropoietin treatment in previous month) Hgb is less than 10 g/dL, AND 3) for MDS: pretreatment serum erythropoietin level is 500 international units/L or less. For reauthorizations (patient received erythropoietin treatment in previous month) in all uses except surgery: 1) patient has received at least 12 weeks of erythropoietin therapy, AND 2) patient responded to erythropoietin therapy, AND 3) current Hgb is less than 12 g/dL, AND 4) for all uses except anemia due to chemotherapy or MDS: patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	16 weeks
Other Criteria	Coverage includes use in anemia in patients whose religious beliefs forbid blood transfusions. Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual (e.g., used for treatment of anemia for a patient with chronic renal failure who is undergoing dialysis, or furnished from physician's supply incident to a physician service).

EPOGEN AET

Products Affected

• Epogen INJ 10000UNIT/ML, 20000UNIT/ML, 2000UNIT/ML, 4000UNIT/ML

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EPRONTIA

Products Affected

• Eprontia

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom (if 4 years of age or older), Xcopri (if 18 years of age or older), Spritam (if 4 years of age or older). For monotherapy treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response or intolerance to a generic topiramate immediate release product, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) If the patient is 6 years of age or older, the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Spritam. For the preventative treatment of migraines: 1) The patient has experienced an inadequate treatment response or intolerance to a generic topiramate immediate release product, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules).
Age Restrictions	Epilepsy: 2 years of age or older, Migraine: 12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

EPSOLAY

Products Affected

• Epsolay

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ERAXIS AET

Products Affected

• Eraxis

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ERBITUX

Products Affected

• Erbitux

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ERGOTAMINE

Products Affected

• Migergot

• Ergotamine Tartrate/caffeine

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Coverage will be denied when used in conjunction with potent CYP3A4 inhibitors (e.g., ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin).
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least ONE triptan 5-HT1 agonist.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ERIVEDGE

Products Affected

• Erivedge

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Adult medulloblastoma
Exclusion Criteria	N/A
Required Medical Information	For adult medulloblastoma: patient has received prior systemic therapy AND has tumor(s) with mutations in the sonic hedgehog pathway.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ERLEADA

Products Affected

• Erleada

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested drug will be used in combination with a gonadotropin- releasing hormone (GnRH) analog or after bilateral orchiectomy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ERLOTINIB

Products Affected

• Tarceva

• Erlotinib Hydrochloride TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent non-small cell lung cancer (NSCLC), recurrent chordoma, relapsed or stage IV renal cell carcinoma (RCC), brain metastases from non-small cell lung cancer (NSCLC), recurrent pancreatic cancer
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC) (including brain metastases from NSCLC): 1) the disease is recurrent, advanced, or metastatic, AND 2) the patient has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease. For pancreatic cancer: the disease is locally advanced, unresectable, recurrent, or metastatic.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ESBRIET

Products Affected

• Esbriet

• Pirfenidone

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For idiopathic pulmonary fibrosis (new starts only): 1) a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy reveals the usual interstitial pneumonia (UIP) pattern, OR 2) HRCT study of the chest reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported either by a lung biopsy or by a multidisciplinary discussion between at least a radiologist and pulmonologist who are experienced in idiopathic pulmonary fibrosis if a lung biopsy has not been conducted.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ETANERCEPT

Products Affected

- Enbrel INJ 25MG/0.5ML, 50MG/ML
- Enbrel Mini
- Enbrel Sureclick

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Hidradenitis suppurativa, non-radiographic axial spondyloarthritis
Exclusion Criteria	N/A
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX) OR 2) patient has experienced an inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication that would prohibit a trial of NSAIDs. 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) 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) 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). For hidradenitis suppurativa (new starts only): patient has severe, refractory disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year

Other Criteria	N/A

EVENITY AET

Products Affected

• Evenity

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EVEROLIMUS

Products Affected

- Afinitor
- Afinitor Disperz

- Everolimus TABS 10MG, 2.5MG, 5MG, 7.5MG
- Everolimus TBSO
- Torpenz

PA Criteria	Criteria Details
TH CHICH	
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EVKEEZA

Products Affected

• Evkeeza

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EVRYSDI

Products Affected

• Evrysdi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EXKIVITY

Products Affected

• Exkivity

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EXONDYS 51

Products Affected

• Exondys 51

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EXTAVIA AET

Products Affected

• Extavia

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EYLEA

Products Affected

• Eylea

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

EYLEA HD

Products Affected

• Eylea Hd

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FABHALTA

Products Affected

• Fabhalta

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FABRAZYME

Products Affected

• Fabrazyme

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FANAPT

Products Affected

• Fanapt

• Fanapt Titration Pack

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For treatment of schizophrenia: 1) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Rexulti, Secuado, Vraylar.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

FASENRA

Products Affected

• Fasenra

• Fasenra Pen

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For severe asthma, initial therapy: 1) Either a) Patient has baseline blood eosinophil count of at least 150 cells per microliter OR b) Patient is dependent on systemic corticosteroids, AND 2) Patient has a history of severe asthma despite current treatment with both of the following medications: a) medium-to-high-dose inhaled corticosteroid AND b) additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For severe asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose.
Age Restrictions	6 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

FENSOLVI

Products Affected

• Fensolvi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FENTANYL PATCH

Products Affected

• Fentanyl PT72

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe and persistent enough to require an extended treatment period with a daily opioid analgesic in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

FERRIPROX

Products Affected

• Deferiprone

- FerriproxFerriprox Twice-a-day

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FETZIMA

Products Affected

• Fetzima

• Fetzima Titration Pack

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For major depressive disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

FILGRASTIM

Products Affected

• Nivestym

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FILSPARI

Products Affected

• Filspari

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FILSUVEZ

Products Affected

• Filsuvez

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FINTEPLA

Products Affected

• Fintepla

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

FIRDAPSE

Products Affected

• Firdapse

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FIRMAGON

Products Affected

• Firmagon INJ 120MG/VIAL, 80MG

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

FLECTOR AET

Products Affected

• Diclofenac Epolamine

• Flector

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FLEQSUVY

Products Affected

• Baclofen SUSP

• Fleqsuvy

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FLUCYTOSINE

Products Affected

• Ancobon

• Flucytosine CAPS 250MG, 500MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 weeks
Other Criteria	N/A

FLUTICASONE FUROATE AND VILANTEROL AET

Products Affected

• Fluticasone Furoate/vilanterol Ellipta

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FLUTICASONE PROPIONATE HFA AET

Products Affected

• Fluticasone Propionate Diskus

• Fluticasone Propionate Hfa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FORM ALT PA ANALGESICS

Products Affected

- Diclofenac Potassium CAPS
- Diclofenac Potassium TABS 25MG
- Lofena
- Tramadol Hydrochloride TABS 25MG
- Zipsor

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FORM ALT PA METFORMIN

Products Affected

• Metformin Hydrochloride TABS 625MG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FORM ALT PA TOPICAL

Products Affected

• Bruselix GEL

- Lidotral GEL 3.88%
- Mycozyl Hc

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FORM ALT PA TOPICAL STEROIDS

Products Affected

• Hydroxym CREA

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FORM ALT PA VALSARTAN SOL

Products Affected

• Valsartan SOLN

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FORTEO

Products Affected

• Forteo INJ 600MCG/2.4ML

• Teriparatide

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For postmenopausal osteoporosis: patient has ONE of the following: 1) history of fragility fracture, OR 2) pre-treatment T-score of less than or equal to -2.5 or pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment Fracture Risk Assessment Tool (FRAX) fracture probability AND patient has ANY of the following: a) indicators for higher fracture risk (e.g., advanced age, frailty, glucocorticoid therapy, very low T-scores, or increased fall risk), OR b) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy OR c) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. For primary or hypogonadal osteoporosis in men: patient has ONE of the following: 1) history of osteoporotic vertebral or hip fracture, OR 2) pre-treatment T-score of less than or equal to -2.5, or pre-treatment FRAX fracture probability AND patient has ANY of the following: a) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy, OR b) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. For glucocorticoid-induced osteoporosis: patient has had an oral bisphosphonate trial of at least 1-year duration unless patient has a contraindication or intolerance to an oral bisphosphonate, AND patient meets ANY of the following: 1) patient has a history of fragility fracture, OR 2) pre-treatment T-score of less than or equal to -2.5, OR 3) pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment FRAX fracture probability.
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage Duration	Initial: 24 months, Continuation: Plan Year
Other Criteria	Continuation of therapy: If the patient has received greater than or equal to 24 months of therapy with any parathyroid hormone analog: 1) The patient remains at or has returned to having a high risk for fracture, AND 2) The benefit of therapy with this prescribed medication outweighs the potential risks for this patient. Patient has high FRAX fracture probability if the 10-year probability is either greater than or equal to 20 percent for any major osteoporotic fracture or greater than or equal to 3 percent for hip fracture. If glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day, the estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture.

FOSCAVIR

Products Affected

• Foscarnet Sodium INJ 6000MG/250ML

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FOTIVDA

Products Affected

• Fotivda

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For renal cell carcinoma: 1) The disease is advanced, relapsed, refractory or Stage IV, AND 2) The patient has received two or more prior systemic therapies.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

FRUZAQLA

Products Affected

• Fruzaqla

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

FYARRO

Products Affected

• Fyarro

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

FYCOMPA

Products Affected

• Fycompa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom, Xcopri, Spritam. For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Spritam.
Age Restrictions	Partial-onset seizures (i.e., focal-onset seizures): 4 years of age or older. Primary generalized tonic-clonic seizures: 12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

GALAFOLD

Products Affected

• Galafold

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

GATTEX

Products Affected

• Gattex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For short bowel syndrome (SBS) initial therapy: 1) for an adult patient, the patient has been dependent on parenteral support for at least 12 months OR 2) for a pediatric patient, the patient is dependent on parenteral support. For SBS continuation: requirement for parenteral support has decreased from baseline while on therapy with the requested drug.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, gastrointestinal surgeon, or nutritional support specialist.
Coverage Duration	Plan Year
Other Criteria	N/A

GAVRETO

Products Affected

• Gavreto

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent rearranged during transfection (RET) rearrangement-positive non-small cell lung cancer, RET mutation-positive medullary carcinoma
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer, patient must meet all of the following: 1) The disease is recurrent, advanced, or metastatic, AND 2) The tumor is rearranged during transfection (RET) fusion-positive or RET rearrangement-positive.
Age Restrictions	Non-small cell lung cancer: 18 years of age or older, Thyroid cancer: 12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

GAZYVA

Products Affected

• Gazyva

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

GILENYA

Products Affected

• Gilenya

• Fingolimod Hydrochloride

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

GILOTRIF

Products Affected

• Gilotrif

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC), patient meets either of the following: 1) has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease AND a) has experienced an intolerable adverse event or contraindication to erlotinib, gefitinib or osimertinib, OR 2) has metastatic squamous NSCLC that progressed after platinum-based chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

GIMOTI

Products Affected

• Gimoti

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

GIVLAARI

Products Affected

• Givlaari

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

GLATIRAMER

Products Affected

- Copaxone INJ 20MG/ML, 40MG/ML
- Glatiramer Acetate
- Glatopa

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

GLOPERBA AET

Products Affected

• Gloperba

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

GONADOTROPIN

Products Affected

• Chorionic Gonadotropin INJ

- Novarel INJ 5000UNIT
- Pregnyl W/diluent Benzyl Alcohol/nacl

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

GOPRELTO-NUMBRINO

Products Affected

• Goprelto

• Cocaine Hydrochloride

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

GRANIX

Products Affected

• Granix

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

GRASTEK

Products Affected

• Grastek

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

GROWTH HORMONE

Products Affected

• Genotropin

• Genotropin Miniquick

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Pediatric patients with closed epiphyses
Required Medical Information	Pediatric growth hormone deficiency (GHD): Patient (pt) is a neonate or was diagnosed with GHD as a neonate OR meets any of the following: 1) younger than 2.5 years old (yo) with pre-treatment (pre-tx) height (ht) more than 2 standard deviations (SD) below mean and slow growth velocity OR 2) 2.5 yo or older AND one of the following: a) pre-tx 1-year ht velocity more than 2 SD below mean OR b) pre-tx ht more than 2 SD below mean and 1-year ht velocity more than 1 SD below mean, AND patient meets any of the following: 1) failed 2 pre-tx growth hormone (GH) stimulation tests (peak below 10 ng/mL), OR 2) pituitary/central nervous system (CNS) disorder (e.g., genetic defects, acquired structural abnormalities, congenital structural abnormalities) and pre-tx insulin-like growth factor-1 (IGF-1) more than 2 SD below mean. Turner syndrome (TS): 1) Confirmed by karyotyping AND 2) pre-tx ht is less than the 5th percentile for age. Small for gestational age (SGA): 1) Birth weight (wt) less than 2500g at gestational age (GA) greater than 37 weeks, OR birth wt or length below 3rd percentile for GA or at least 2 SD below mean for GA, AND 2) did not manifest catch-up growth by age 2.
Age Restrictions	SGA: 2 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, nephrologist, infectious disease specialist, gastroenterologist/nutritional support specialist, or geneticist.
Coverage Duration	Plan Year

Other Criteria

Adult GHD: Pt meets any of the following: 1) failed 2 pre-tx GH stimulation tests, OR 2) pre-tx IGF-1 more than 2 SD below mean AND failed 1 pre-tx GH stimulation test, OR 3) organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with 3 or more pituitary hormone deficiencies AND pre-tx IGF-1 more than 2 SD below mean, OR 4) genetic or structural hypothalamic-pituitary defects, OR 5) childhood-onset GHD with congenital (genetic or structural) abnormality of the hypothalamus/pituitary/CNS. For pediatric GHD, TS, SGA, and adult GHD, continuation of therapy: Patient is experiencing improvement.

HAEGARDA

Products Affected

• Haegarda

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the prophylaxis of angioedema attacks due to hereditary angioedema (HAE): 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing, OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation, b) the patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month.
Age Restrictions	6 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	Plan Year
Other Criteria	N/A

HALAVEN

Products Affected

• Eribulin Mesylate

• Halaven

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

HALOG SOLUTION AET

Products Affected

• Halog SOLN

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

HARVONI

Products Affected

• Harvoni

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Criteria applied consistent w/ current AASLD-IDSA guidance. Reminder for 8wk option if appropriate.
Other Criteria	N/A

HERCEPTIN

- Herceptin INJ 150MG
- Herzuma

- KanjintiOgivri
- Ontruzant

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

HERCEPTIN HYLECTA

Products Affected

• Herceptin Hylecta

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

HETLIOZ

Products Affected

• Hetlioz

• Tasimelteon

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For Non-24-Hour Sleep-Wake Disorder: 1) For initial therapy and continuation of therapy the patient must meet both of the following: a) diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas) and b) unable to perceive light in either eye, AND 2) If currently on therapy with the requested drug, patient must meet at least one of the following: a) increased total nighttime sleep or b) decreased daytime nap duration. For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS): 1) For initial therapy and continuation therapy, the patient has a confirmed diagnosis of SMS, AND 2) If currently on therapy with the requested drug, the patient experienced improvement in the quality of sleep since starting therapy.
Age Restrictions	Non-24: 18 years of age or older, SMS: 16 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a sleep disorder specialist, neurologist, or psychiatrist
Coverage Duration	Initiation: 6 months, Renewal: Plan Year
Other Criteria	N/A

HETLIOZ LQ

Products Affected

• Hetlioz Lq

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

HIGH RISK MEDICATION - 65

- Atropine Sulfate INJ 0.25MG/5ML, 0.4MG/ML, 0.5MG/5ML, 1MG/10ML, 1MG/ML, 8MG/20ML
- Belladonna/opium SUPP 16.2MG; 60MG
- Chlordiazepoxide/amitriptyline
- Demerol INJ 100MG/ML, 25MG/ML, 50MG/ML, 75MG/ML
- Dicyclomine Hcl SOLN
- Dicyclomine Hydrochloride CAPS
- Dicyclomine Hydrochloride INJ
- Dicyclomine Hydrochloride TABS
- Dihydroergotamine Mesylate INJ
- Diphenhydramine Hcl ELIX
- Dipyridamole TABS
- Disopyramide Phosphate CAPS
- Ergoloid Mesylates TABS
- Guanfacine Hydrochloride
- Guanfacine Hydrochloride Er
- Hyoscyamine Sulfate ELIX
- Hyoscyamine Sulfate SOLN
- Hyoscyamine Sulfate SUBL
- Hyoscyamine Sulfate TABS
- Hyoscyamine Sulfate Odt
- Indocin SUPP
- Indocin SUSP
- Indomethacin CAPS 25MG, 50MG

- Indomethacin SUPP 50MG
- Indomethacin SUSP
- Indomethacin Er
- Intuniv
- Ketorolac Tromethamine TABS
- Levsin TABS
- Levsin/sl
- Meperidine Hcl INJ 100MG/ML, 25MG/ML, 50MG/ML
- Meperidine Hcl ORAL SOLN
- Meperidine Hcl TABS 50MG
- Meprobamate
- Methscopolamine Bromide TABS
- Nifedipine CAPS
- Norpace
- Nulev
- Oscimin SUBL
- Oscimin TABS
- Pentazocine/naloxone Hcl
- Perphenazine/amitriptyline
- Promethazine Vc
- Ryclora
- Thioridazine Hcl TABS 100MG, 10MG, 25MG, 50MG
- Tigan INJ
- Trimethobenzamide Hydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)

HIZENTRA

Products Affected

• Hizentra

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

HRM - ANTICONVULSANTS - 65

Products Affected

- Phenobarbital ELIX 20MG/5ML
- Phenobarbital TABS 100MG, 15MG, 16.2MG, 30MG, 32.4MG, 60MG, 64.8MG, 97.2MG

• Phenobarbital Sodium INJ 130MG/ML, 65MG/ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Epilepsy
Exclusion Criteria	N/A
Required Medical Information	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)

HRM - HYPNOTICS - 65

- Ambien
- Ambien Cr
- Edluar
- Eszopiclone

- Lunesta
- Zaleplon
- Zolpidem Tartrate SUBL
- Zolpidem Tartrate TABS
- Zolpidem Tartrate Er

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For insomnia: 1) The patient meets one of the following: a) the patient has a contraindication to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) OR b) The non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) has been tried AND the patient experienced an inadequate treatment response OR intolerance to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) AND 2) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient AND 3) If the patient is using two or more additional central nervous system (CNS) active medications (e.g., lorazepam, quetiapine, sertraline, clonazepam, escitalopram, alprazolam) with the requested drug, the prescriber has determined that taking multiple central nervous system (CNS) active medications is medically necessary for the patient [Note: Use of multiple central nervous system (CNS) active medications in older adults is associated with an increased risk of falls.].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year

Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older
	adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prior authorization applies to greater
	than cumulative 90 days of therapy per year.

HRM - SCOPOLAMINE - 65

Products Affected

• Transderm-scop PT72 1MG/3DAYS

• Scopolamine PT72 1MG/3DAYS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Excessive salivation
Exclusion Criteria	N/A
Required Medical Information	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.).

HRM-ANTIPARKINSON - 65

Products Affected

• Benztropine Mesylate TABS

- Trihexyphenidyl Hcl SOLNTrihexyphenidyl Hydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. EPS (extrapyramidal symptoms): 1) The patient has not tried the non-HRM alternative drug amantadine AND 2) The patient has a contraindication to the non-HRM alternative drug amantadine OR 3) The patient has tried the non-HRM alternative drug amantadine AND 4) The patient experienced an inadequate treatment response OR intolerance to the non-HRM alternative drug amantadine. Parkinson's: 1) The patient has tried two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole. AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)

HRM-CYPROHEPTADINE - 65

Products Affected

• Cyproheptadine Hcl SYRP

• Cyproheptadine Hydrochloride TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Pruritus, spasticity due to spinal cord injury
Exclusion Criteria	N/A
Required Medical Information	The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.). Prior Authorization applies to greater than cumulative 30 days of therapy per year.

HRM-DOXEPIN - 65

Products Affected

- Doxepin Hcl CAPS 75MG
- Doxepin Hcl CONC

• Doxepin Hydrochloride CAPS 100MG, 10MG, 150MG, 25MG, 50MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For depression: 1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone. For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)

HRM-HYDROXYZINE - 65

- Hydroxyzine Hcl TABS 50MG
- Hydroxyzine Hydrochloride SYRP
- Hydroxyzine Hydrochloride TABS 10MG, 25MG
- Hydroxyzine Pamoate CAPSVistaril CAPS 25MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release OR 3) The patient has not tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 4) The patient has acute anxiety. For all indications: 1) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. AND 2) If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, cyclobenzaprine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year

Other Criteria This Prior Authorization only applies to patients 65 years of age or (Note: The use of this medication is potentially inappropriate in old adults, meaning it is best avoided, prescribed at reduced dosage, or with caution or carefully monitored.).	er
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HRM-HYDROXYZINE INJ - 65

- Hydroxyzine Hcl INJ 25MG/ML
- Hydroxyzine Hydrochloride INJ

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

HRM-PROMETHAZINE - 65

- Phenergan INJ
- Promethazine Hcl INJ
- Promethazine Hcl SUPP 12.5MG, 25MG
- Promethazine Hcl TABS 12.5MG

- Promethazine Hydrochloride TABS 25MG, 50MG
- Promethazine Hydrochloride Plain
- Promethegan

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prior authorization applies to greater than cumulative 30 days of therapy per year.

HRMS - ANTIDEPRESSANTS

- Amitriptyline Hcl TABS 100MG, 150MG, 25MG, 75MG
- Amitriptyline Hydrochloride TABS 100MG, 10MG, 50MG
- Desipramine Hydrochloride

- Imipramine Hcl TABS 25MG, 50MG
- Imipramine Hydrochloride TABS 10MG
- Imipramine Pamoate
- Norpramin TABS 10MG, 25MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Neuropathic pain
Exclusion Criteria	N/A
Required Medical Information	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For depression: 1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)

HRMS - CARBINOXAMINE

- Carbinoxamine Maleate SOLN
- Carbinoxamine Maleate TABS
- Ryvent

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)

HRMS - CLEMASTINE- 65

Products Affected

• Clemastine Fumarate SYRP

• Clemastine Fumarate TABS 2.68MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)

HRMS - DIABETES AGENTS

Products Affected

- Glyburide TABS 1.25MG, 2.5MG, 5MG
- Glyburide Micronized

• Glyburide/metformin Hydrochloride

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

HRMS - TCAS

Products Affected

• Protriptyline Hcl

• Trimipramine Maleate CAPS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For depression: 1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 3) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)

HRM-SKELETAL MUSCLE RELAXANTS - 65

- Amrix
- Carisoprodol TABS
- Chlorzoxazone TABS
- Cyclobenzaprine Hydrochloride TABS
- Cyclobenzaprine Hydrochloride Er
- Fexmid
- Metaxalone
- Methocarbamol INJ 1000MG/10ML
- Methocarbamol TABS

- Norgesic
- Norgesic Forte
- Orphenadrine Citrate INJ
- Orphenadrine Citrate Er
- Orphenadrine/aspirin/caffeine
- Orphengesic Forte
- Robaxin INJ 1000MG/10ML
- Soma
- Tanlor

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient AND 2) If the patient is using one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, hydroxyzine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prior authorization applies to greater than cumulative 90 days of therapy per year.

HUMIRA

- Humira INJ 10MG/0.1ML, 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML
- Humira Pen

- Humira Pen-cd/uc/hs Starter INJ 80MG/0.8ML
- Humira Pen-pediatric Uc Starter Pack
- Humira Pen-ps/uv Starter INJ 0

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX) OR 2) patient has experienced an inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication that would prohibit a trial of NSAIDs. 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	N/A
Prescriber Restrictions	N/A

Coverage Duration	Plan Year
Other Criteria	For non-infectious intermediate, posterior and panuveitis (new starts only): 1) patient has experienced an inadequate treatment response or intolerance to a corticosteroid OR 2) the patient has a contraindication that would prohibit a trial of corticosteroids.

HYFTOR

Products Affected

• Hyftor

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

HYPNOTIC-BENZODIAZEPINES - 65

Products Affected

- Estazolam
- Halcion TABS 0.25MG
- Restoril CAPS 15MG, 22.5MG, 7.5MG
- Temazepam CAPS 15MG, 22.5MG, 7.5MG
- Triazolam

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For short-term treatment of insomnia: 1) Prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older. Prior authorization applies to greater than cumulative 90 days of therapy per year.

HYQVIA

Products Affected

• Hyqvia

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

IBRANCE

Products Affected

• Ibrance

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Unresectable well-differentiated/dedifferentiated liposarcoma of the retroperitoneum, recurrent hormone receptor-positive human epidermal growth factor receptor 2 (HER2)-negative breast cancer
Exclusion Criteria	N/A
Required Medical Information	For breast cancer: 1) the disease is advanced, recurrent, or metastatic, AND 2) the patient has hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative disease, AND 3) the requested drug will be used in combination with an aromatase inhibitor or fulvestrant, AND 4) the patient has experienced an intolerable adverse event to Kisqali (ribociclib) OR Verzenio (abemaciclib) or has a contraindication to Kisqali (ribociclib) AND Verzenio (abemaciclib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

IBSRELA AET

Products Affected

• Ibsrela

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ICATIBANT

Products Affected

• Firazyr

- Icatibant Acetate
- Sajazir

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the treatment of acute angioedema attacks due to hereditary angioedema (HAE): 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation, b) the patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	Plan Year
Other Criteria	N/A

ICLUSIG

Products Affected

• Iclusig

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Myeloid and/or lymphoid neoplasms with eosinophilia and FGFR1 or ABL1 rearrangement in the chronic phase or blast phase, Gastrointestinal Stromal Tumors
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML), including patients who have received a hematopoietic stem cell transplant: 1) Patient has accelerated or blast phase CML and no other kinase inhibitor is indicated, OR 2) Patient has chronic phase CML and has experienced resistance or intolerance to at least 2 prior kinase inhibitors AND at least one of those was imatinib, dasatinib, or nilotinib, OR 3) Patient is positive for the T315I mutation. For acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For gastrointestinal stromal tumors (GIST): 1) Disease meets any of the following: A) residual, B) unresectable, C) recurrent, D) metastatic/tumor rupture, AND 2) Disease has progressed after use of at least two Food and Drug Administration (FDA) approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

IDACIO

Products Affected

- Adalimumab-aacf (2 Pen)
- Adalimumab-aacf (2 Syringe)
- Idacio (2 Pen)
- Idacio (2 Syringe)

- Idacio Starter Package For Crohns Disease
- Idacio Starter Package For Plaque Psoriasis

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX) OR 2) patient has experienced an inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication that would prohibit a trial of NSAIDs. 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	N/A
Prescriber Restrictions	N/A

Coverage Duration	Plan Year
Other Criteria	For non-infectious intermediate, posterior and panuveitis (new starts only): 1) patient has experienced an inadequate treatment response or intolerance to a corticosteroid OR 2) the patient has a contraindication that would prohibit a trial of corticosteroids.

IDHIFA

Products Affected

• Idhifa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Newly-diagnosed acute myeloid leukemia
Exclusion Criteria	N/A
Required Medical Information	For acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation: 1) patient has newly-diagnosed AML and is not a candidate for intensive induction therapy, OR 2) the requested drug will be used as post-induction therapy following response to induction therapy with the requested drug, OR 3) patient has relapsed or refractory AML.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

IGALMI

Products Affected

• Igalmi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ILARIS

Products Affected

• Ilaris INJ 150MG/ML

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ILUMYA

Products Affected

• Ilumya

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

IMATINIB

Products Affected

• Gleevec TABS

• Imatinib Mesylate

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Desmoid tumors, pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT), recurrent chordoma, cutaneous melanoma, Kaposi sarcoma, chronic graft versus host disease (cGVHD), T-cell acute lymphoblastic leukemia with ABL-class translocation, aggressive systemic mastocytosis for well-differentiated systemic mastocytosis (WDSM) or when eosinophilia is present with FIP1L1-PDGFRA fusion gene, myeloid and/or lymphoid neoplasms with eosinophilia and ABL1, FIP1L1-PDGFRA, or PDGFRB rearrangement in the chronic phase or blast phase.
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), including patients who have received a hematopoietic stem cell transplant: Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For CML: Patient did not fail (excluding failure due to intolerance) prior therapy with a tyrosine kinase inhibitor. For cutaneous melanoma: 1) Disease is metastatic or unresectable AND 2) Disease is positive for c-KIT activating mutations AND 3) Requested medication will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

IMBRUVICA

Products Affected

- Imbruvica CAPS
- Imbruvica SUSP

• Imbruvica TABS 140MG, 280MG, 420MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Hairy cell leukemia, lymphoplasmacytic lymphoma, primary central nervous system (CNS) lymphoma, human immunodeficiency virus (HIV)-related B-cell lymphoma, diffuse large B-cell lymphoma, post-transplant lymphoproliferative disorders, high-grade B-cell lymphoma, mantle cell lymphoma, marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, splenic marginal zone lymphoma)
Exclusion Criteria	N/A

Required Medical Information	For mantle cell lymphoma: 1) the requested drug will be used as subsequent therapy AND the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Calquence (acalabrutinib), OR 2) the requested drug will be used in combination with rituximab as pretreatment to induction therapy with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen, OR 3) the requested drug will be used as aggressive induction therapy. For marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, and splenic marginal zone lymphoma): the requested drug will be used as second-line or subsequent therapy. For hairy cell leukemia: the requested drug will be used as a single agent for disease progression. For primary CNS lymphoma: 1) the disease is relapsed or refractory OR 2) the requested drug is used for induction therapy as a single agent. For diffuse large B-cell lymphoma, high-grade B-cell lymphoma, human immunodeficiency virus (HIV)-related B-cell lymphoma: The requested drug will be used as a single agent and as second-line or subsequent therapy for relapsed or refractory disease. For post-transplant lymphoproliferative disorders: the requested drug will be used in patients who have received prior chemoimmunotherapy. For chronic lymphocytic leukemia/small lymphocytic lymphoma: the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Calquence (acalabrutinib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year

N/A

Other Criteria

IMDELLTRA

Products Affected

• Imdelltra

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

IMFINZI

Products Affected

• Imfinzi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

IMJUDO

Products Affected

• Imjudo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

IMLYGIC

Products Affected

• Imlygic

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

IMPAVIDO

Products Affected

• Impavido

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Pregnancy. Sjogren-Larsson-Syndrome.
Required Medical Information	N/A
Age Restrictions	12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	28 days
Other Criteria	N/A

IMVEXXY

Products Affected

• Imvexxy Maintenance Pack

• Imvexxy Starter Pack

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

INBRIJA

Products Affected

• Inbrija

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For initial treatment of off episodes in Parkinson's disease: 1) The patient is currently being treated with oral carbidopa/levodopa, AND 2) The patient does not have any of the following: asthma, chronic obstructive pulmonary disease (COPD), or other chronic underlying lung disease. For continuation treatment of off episodes in Parkinson's disease: The patient is experiencing improvement on the requested drug.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

INCRELEX

Products Affected

• Increlex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Pediatric patients with closed epiphyses
Required Medical Information	For growth failure due to severe primary insulin-like growth factor-1 (IGF-1) deficiency or growth hormone (GH) gene deletion in patients who have developed neutralizing antibodies to GH, patient meets all of the following prior to beginning therapy with the requested drug (new starts only): 1) height 3 or more standard deviations (SD) below the mean for children of the same age and gender AND 2) basal IGF-1 level 3 or more SD below the mean for children of the same age and gender AND 3) provocative growth hormone test showing a normal or elevated growth hormone level. For growth failure due to severe primary IGF-1 deficiency or GH gene deletion in patients who have developed neutralizing antibodies to GH, continuation of therapy: patient is experiencing improvement.
Age Restrictions	2 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Plan Year
Other Criteria	N/A

INFLECTRA

Products Affected

• Inflectra

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

INGREZZA

Products Affected

• Ingrezza

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

INLYTA

Products Affected

• Inlyta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Thyroid carcinoma (papillary, oncocytic, or follicular), alveolar soft part sarcoma
Exclusion Criteria	N/A
Required Medical Information	For renal cell carcinoma: the disease is advanced, relapsed, or Stage IV.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

INPEFA

Products Affected

• Inpefa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

INQOVI

Products Affected

• Inqovi

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

INREBIC

Products Affected

• Inrebic

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and janus kinase 2 (JAK2) rearrangement, accelerated or blast phase myeloproliferative neoplasms
Exclusion Criteria	N/A
Required Medical Information	For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement: the disease is in chronic or blast phase.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

INSULIN SUPPLIES

Products Affected

- Alcohol Prep Pads PADS 70%
- Bd Insulin Syringe Safetyglide/1ml/29g X 1/2"
- B-d Insulin Syringe Ultrafine Ii/0.3ml/31g X 5/16"
- Bd Insulin Syringe Ultra-fine/0.5ml/30g X 12.7mm
- Bd Insulin Syringe Ultra-fine/1ml/31g X 8mm
- Bd Pen Needle/original/ultra-fine/29g X 12.7mm
- Bd Veo Insulin Syringe Ultrafine/0.3ml/31g X 6mm
- Curity Gauze Pads 2"x2" 12 Ply

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested product is being used with insulin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

INTRAROSA

Products Affected

• Intrarosa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

IQIRVO

Products Affected

• Iqirvo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

IR BEFORE ER

Products Affected

- Hydrocodone Bitartrate Er
- Hydromorphone Hcl Er TB24 12MG, 16MG, 8MG
- Hydromorphone Hydrochloride Er TB24 32MG
- Hysingla Er
- Methadone Hcl INJ
- Methadone Hcl ORAL SOLN
- Methadone Hcl TABS
- Methadone Hydrochloride CONC
- Methadose CONC 10MG/ML

- Methadose Sugar-free
- Morphine Sulfate Er TBCR 100MG, 200MG
- Ms Contin TBCR 100MG, 200MG
- Nucynta Er
- Oxymorphone Hydrochloride Er TB12 10MG, 15MG, 20MG, 30MG, 5MG, 7.5MG
- Oxymorphone Hydrochlorideer
- Xtampza Er

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe and persistent enough to require an extended treatment period with a daily opioid analgesic in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week.
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage Duration	Plan Year
Other Criteria	N/A

IRESSA

Products Affected

• Gefitinib

• Iressa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Sensitizing epidermal growth factor receptor (EGFR) mutation-positive recurrent non-small cell lung cancer (NSCLC)
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced, or metastatic, AND 2) the patient must have a sensitizing epidermal growth factor receptor (EGFR) mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ISOTRETINOIN

Products Affected

- Absorica
- Accutane
- Amnesteem

- Claravis
- Isotretinoin CAPS
- Zenatane

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Refractory acne vulgaris, severe refractory rosacea, neuroblastoma, cutaneous T-cell lymphoma (CTCL) (e.g., mycosis fungoides, Sezary syndrome), high risk for developing skin cancer (squamous cell cancers), transient acantholytic dermatosis (Grover's Disease), keratosis follicularis (Darier Disease), lamellar ichthyosis, pityriasis rubra pilaris.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ISTURISA

Products Affected

• Isturisa TABS 1MG, 5MG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ITRACONAZOLE

Products Affected

- Itraconazole CAPS
- Itraconazole SOLN

- Sporanox CAPS
- Sporanox SOLN

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Coccidioidomycosis, Coccidioidomycosis prophylaxis in HIV infection,, Cryptococcosis, Microsporidiosis, Talaromycosis (formerly Penicilliosis), Histoplasmosis prophylaxis in HIV infection, Invasive fungal infection prophylaxis in liver transplant, chronic granulomatous disease (CGD), and hematologic malignancy, Sporotrichosis, Pityriasis versicolor, Tinea versicolor, Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis, primary treatment for allergic bronchopulmonary aspergillosis, primary treatment for chronic cavitary or subacute invasive (necrotizing) pulmonary aspergillosis
Exclusion Criteria	N/A
Required Medical Information	The requested drug will be used orally. For the treatment of onychomycosis due to dermatophytes (Tinea unguium), the diagnosis has been confirmed by a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy). For primary treatment of allergic bronchopulmonary aspergillosis, the requested drug is initiated in combination with systemic corticosteroids.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Disseminated/CNS histo, histo/CM/CGD ppx, chronic cavitary/necrotizing PA: 12 mths. Others: 6 mths
Other Criteria	N/A

IVERMECTIN TAB

Products Affected

• Ivermectin TABS

• Stromectol TABS 3MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Ascariasis, Cutaneous larva migrans, Mansonelliasis, Scabies, Gnathostomiasis, Pediculosis
Exclusion Criteria	N/A
Required Medical Information	The requested drug is not being prescribed for the prevention or treatment of coronavirus disease 2019 (COVID-19).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A

IVIG

Products Affected

- Alyglo
- Asceniv
- Bivigam INJ 10%, 5GM/50ML
- Flebogamma Dif INJ 10GM/200ML, 20GM/400ML, 5GM/100ML
- Gammagard Liquid
- Gammagard S/d Iga Less Than 1mcg/ml
- Gammaked INJ 10GM/100ML, 1GM/10ML, 20GM/200ML, 5GM/50ML

- Gammaplex INJ 10GM/100ML, 10GM/200ML, 20GM/200ML, 20GM/400ML, 5GM/100ML, 5GM/50ML
- Gamunex-c
- Octagam INJ 10GM/100ML, 10GM/200ML, 1GM/20ML, 2.5GM/50ML, 20GM/200ML, 2GM/20ML, 30GM/300ML, 5GM/100ML, 5GM/50ML
- Panzyga
- Privigen

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For B-cell chronic lymphocytic leukemia (CLL): 1) serum IgG less than 500 mg/dL OR 2) a history of recurrent bacterial infections. For bone marrow transplant/hematopoietic stem cell transplant (BMT/HSCT): 1) IVIG is requested within the first 100 days post-transplant OR 2) serum IgG less than 400 mg/dL. For pediatric human immunodeficiency virus (HIV) infection: 1) serum IgG less than 400 mg/dL OR 2) history of recurrent bacterial infections. For dermatomyositis and polymyositis: 1) at least one standard first-line treatment (corticosteroid or immunosuppressant) has been tried but was unsuccessful or not tolerated OR 2) patient is unable to receive standard therapy because of a contraindication or other clinical reason. For pure red cell aplasia (PRCA): PRCA is secondary to parvovirus B19 infection.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year

Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
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IWILFIN

Products Affected

• Iwilfin

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

IXEMPRA

Products Affected

• Ixempra Kit

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

IZERVAY

Products Affected

• Izervay

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

JAKAFI

Products Affected

Jakafi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Lower-risk myelofibrosis, accelerated or blast phase myeloproliferative neoplasms, acute lymphoblastic leukemia (ALL), chronic myelomonocytic leukemia (CMML)-2, myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) with neutrophilia, essential thrombocythemia, myeloid, lymphoid or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement, T-cell prolymphocytic leukemia
Exclusion Criteria	N/A
Required Medical Information	For polycythemia vera: 1) patient had an inadequate response or intolerance to hydroxyurea and Besremi (ropeginterferon alfa-2b-njft), OR 2) patient has high risk disease. For acute lymphoblastic leukemia: patient has a cytokine receptor-like factor 2 (CRLF2) mutation or a mutation associated with activation of the Janus kinase/signal transducers and activators of transcription (JAK/STAT) pathway. For CMML-2: the requested drug is used in combination with a hypomethylating agent. For myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) with neutrophilia: the requested drug is used as a single agent or in combination with a hypomethylating agent. For essential thrombocythemia: patient had an inadequate response or loss of response to hydroxyurea, interferon therapy, or anagrelide. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement: the disease is in chronic or blast phase.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

JATENZO

Products Affected

• Jatenzo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

JAYPIRCA

Products Affected

• Jaypirca

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL): The patient meets both of the following: 1) The patient has received prior treatment with a Bruton Tyrosine Kinase (BTK) inhibitor, for example Calquence (acalabrutinib), AND 2) The patient has received prior treatment with a B-cell lymphoma 2 (BCL-2) inhibitor. For mantle cell lymphoma: the patient has received prior treatment for a BTK inhibitor, for example Calquence (acalabrutinib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

JEMPERLI

Products Affected

• Jemperli

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

JEVTANA

Products Affected

Jevtana

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

JOENJA

Products Affected

• Joenja

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

JUBLIA AET

Products Affected

• Jublia

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

JUXTAPID

Products Affected

• Juxtapid CAPS 10MG, 20MG, 30MG, 5MG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

JYNARQUE

Products Affected

• Jynarque

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

KALBITOR

Products Affected

• Kalbitor

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

KALYDECO

Products Affected

• Kalydeco

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For cystic fibrosis (CF): The requested medication will not be used in combination with other medications containing ivacaftor.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

KANUMA

Products Affected

• Kanuma

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

KERYDIN AET

Products Affected

• Kerydin

• Tavaborole

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

KESIMPTA

Products Affected

• Kesimpta

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

KETOCONAZOLE

Products Affected

• Ketoconazole TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Cushing's syndrome
Exclusion Criteria	Acute or chronic liver disease. Concurrent use with drugs that are contraindicated with ketoconazole tablets: dofetilide, quinidine, pimozide, cisapride, methadone, disopyramide, dronedarone, ranolazine, ergot alkaloids, irinotecan, lurasidone, oral midazolam, alprazolam, triazolam, felodipine, nisoldipine, tolvaptan, eplerenone, lovastatin, simvastatin, or colchicine.
Required Medical Information	The potential benefits outweigh the risks of treatment with oral ketoconazole. For systemic fungal infections, the patient has any of the following diagnoses: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis. For Cushing's syndrome: the requested drug is being prescribed for a patient who cannot tolerate surgery or where surgery has not been curative.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

KEVEYIS

Products Affected

• Dichlorphenamide

- KeveyisOrmalvi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

KEVZARA

Products Affected

• Kevzara

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

KEYTRUDA

Products Affected

• Keytruda INJ 100MG/4ML

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

KIMMTRAK

Products Affected

• Kimmtrak

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

KINERET

Products Affected

• Kineret

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

KISQALI

Products Affected

- Kisqali
- Kisqali Femara 200 Dose

- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer, in combination with an aromatase inhibitor, or fulvestrant. Endometrial cancer, in combination with letrozole, for estrogen receptor positive tumors.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

KLISYRI

Products Affected

• Klisyri

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

KONVOMEP

Products Affected

• Konvomep

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

KORLYM

Products Affected

• Korlym

• Mifepristone TABS 300MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Plan Year
Other Criteria	N/A

KOSELUGO

Products Affected

• Koselugo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	BRAF fusion or BRAF V600E activating mutation-positive recurrent or progressive circumscribed glioma, Langerhans cell histiocytosis.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	For neurofibromatosis type 1: 2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

KRAZATI

Products Affected

• Krazati

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent KRAS G12C-positive non-small cell lung cancer (NSCLC), Central nervous system (CNS) brain metastases from KRAS G12C- positive NSCLC, KRAS G12C-positive pancreatic adenocarcinoma
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

KRINTAFEL

Products Affected

• Krintafel

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

KRISTALOSE

Products Affected

• Kristalose

• Lactulose PACK

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For constipation: 1) The patient has experienced an inadequate treatment response to a one month trial of generic lactulose solution, OR 2) The patient has experienced an intolerance that would prohibit a one month trial of generic lactulose solution, OR 3) the patient has a contraindication to an inactive ingredient in generic lactulose solution which is not contained in the requested drug.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

KRYSTEXXA

Products Affected

• Krystexxa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

KYPROLIS

Products Affected

• Kyprolis

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LAGEVRIO AET

Products Affected

• Lagevrio

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LAMPIT

Products Affected

• Lampit

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LAMZEDE

Products Affected

• Lamzede

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LAPATINIB

Products Affected

• Lapatinib Ditosylate

• Tykerb

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Brain metastases from human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent HER2-positive breast cancer, recurrent epidermal growth factor receptor (EGFR)-positive chordoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma).
Exclusion Criteria	N/A
Required Medical Information	For breast cancer, the patient meets all the following: a) the disease is recurrent, advanced, or metastatic (including brain metastases), b) the disease is human epidermal growth factor receptor 2 (HER2)-positive, c) the requested drug will be used in combination with any of the following: 1) aromatase inhibitor, 2) capecitabine, OR 3) trastuzumab. For colorectal cancer: 1) requested drug will be used in combination with trastuzumab and 2) patient has not had previous treatment with a HER2 inhibitor.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

LEDIPASVIR-SOFOSBUVIR AET

Products Affected

• Ledipasvir/sofosbuvir

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LEMTRADA AET

Products Affected

• Lemtrada

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LENVIMA

Products Affected

- Lenvima 10 Mg Daily Dose
- Lenvima 12mg 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
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Medullary thyroid carcinoma, recurrent endometrial carcinoma, thymic carcinoma, unresectable or metastatic cutaneous melanoma.
Exclusion Criteria	N/A
Required Medical Information	For differentiated thyroid cancer (follicular, papillary, or oncocytic): disease is not amenable to radioactive iodine therapy and unresectable, locally recurrent, persistent, or metastatic. For hepatocellular carcinoma (HCC): disease is unresectable or inoperable, local, metastatic or with extensive liver tumor burden. For renal cell carcinoma (RCC): the disease is advanced, relapsed, or stage IV. For endometrial carcinoma (EC), the patient meets ALL of the following: 1) The disease is advanced, recurrent, or metastatic, 2) The requested drug will be used in combination with pembrolizumab, 3) The patient experienced disease progression following prior systemic therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

LEQVIO

Products Affected

• Leqvio

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LEUKINE

Products Affected

• Leukine INJ 250MCG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LEUPROLIDE

Products Affected

• Leuprolide Acetate INJ 1MG/0.2ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Use in combination with growth hormone for children with growth failure and advancing puberty, recurrent androgen receptor positive salivary gland tumors, central precocious puberty
Exclusion Criteria	N/A
Required Medical Information	For central precocious puberty (CPP): Patients not currently receiving therapy must meet all of the following criteria: 1) Diagnosis of CPP was confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test OR a pubertal level of a third generation luteinizing hormone (LH) assay, 2) Assessment of bone age versus chronological age supports the diagnosis of CPP, 3) The onset of secondary sexual characteristics occurred prior to 8 years of age for female patients OR prior to 9 years of age for male patients.
Age Restrictions	CPP: Patient must be less than 12 years old if female and less than 13 years old if male
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

LIBERVANT

Products Affected

• Libervant

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	2 to 5 years of age
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

LIBRAX

Products Affected

• Librax

• Chlordiazepoxide Hydrochloride/clidinium Bromide

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LIBTAYO

Products Affected

• Libtayo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LICART AET

Products Affected

• Licart

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LIDOCAINE PATCHES

Products Affected

- Lidocaine PTCH 5%
- Lidocan

- Lidoderm
- Tridacaine
- Tridacaine II

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Pain associated with diabetic neuropathy, pain associated with cancer- related neuropathy (including treatment-related neuropathy [e.g., neuropathy associated with radiation treatment or chemotherapy]).
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

LIDOTRAL HC

Products Affected

• Lidotral/hydrocortisone W/peptides & Arnica

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LINEZOLID

Products Affected

• Linezolid

• Zyvox

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns. The patient will be using the requested drug orally or intravenously.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed or directed by an Infectious Disease specialist when being converted from intravenous (IV) linezolid (Zyvox)
Coverage Duration	28 days
Other Criteria	N/A

Liqrev

Products Affected

• Liqrev

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LITFULO

Products Affected

• Litfulo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LIVMARLI

Products Affected

• Livmarli SOLN 9.5MG/ML

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LIVTENCITY

Products Affected

• Livtencity

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	12 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist, transplant specialist, hematologist, or oncologist.
Coverage Duration	3 months
Other Criteria	N/A

Lodoco

Products Affected

• Lodoco

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LONSURF

Products Affected

• Lonsurf

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Unresectable locally advanced, recurrent, or metastatic esophageal cancer. Unresectable locally advanced or recurrent gastric cancer and gastroesophageal junction cancers. Advanced or metastatic appendiceal adenocarcinoma.
Exclusion Criteria	N/A
Required Medical Information	For colorectal cancer (including appendiceal adenocarcinoma): The disease is advanced or metastatic. For gastric, esophageal, or gastroesophageal junction adenocarcinoma, ALL of the following criteria must be met: 1) The disease is unresectable locally advanced, recurrent, or metastatic, and 2) The patient has been previously treated with at least two prior lines of chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

LOQTORZI

Products Affected

• Loqtorzi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LORBRENA

Products Affected

• Lorbrena

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Anaplastic lymphoma kinase (ALK)-positive recurrent non-small cell lung cancer (NSCLC), proto-oncogene tyrosine-protein kinase ROS1 (ROS1) rearrangement-positive recurrent, advanced, or metastatic NSCLC, symptomatic or relapsed/refractory ALK-positive Erdheim-Chester Disease, inflammatory myofibroblastic tumor (IMT) with ALK translocation (including advanced, recurrent/metastatic, or inoperable uterine sarcoma for IMT with ALK translocation), central nervous system (CNS) brain metastases from ALK rearrangement-positive NSCLC, relapsed or refractory ALK-positive Diffuse Large B-Cell Lymphoma
Exclusion Criteria	N/A
Required Medical Information	For recurrent, advanced, or metastatic non-small cell lung cancer: 1) Disease is ALK-positive AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following products: Alecensa (alectinib) or Alunbrig (brigatinib) OR 3) Disease is positive for ROS1 rearrangement and the requested drug is being used following disease progression on crizotinib, entrectinib, or ceritinib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

LOREEV XR

Products Affected

• Loreev Xr

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LUCEMYRA

Products Affected

• Lofexidine Hydrochloride

• Lucemyra

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LUCENTIS

Products Affected

• Lucentis SOSY

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LUMAKRAS

Products Affected

• Lumakras

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent KRAS G12C-positive non-small cell lung cancer (NSCLC)
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

LUMIZYME

Products Affected

• Lumizyme

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LUMRYZ

Products Affected

• Lumryz

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LUNSUMIO

Products Affected

• Lunsumio

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LUPKYNIS

Products Affected

• Lupkynis

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LUPRON PED

Products Affected

• Lupron Depot-ped (1-month)

- Lupron Depot-ped (3-month)
- Lupron Depot-ped (6-month)

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For central precocious puberty (CPP): Patients not currently receiving therapy must meet all of the following criteria: 1) Diagnosis of CPP was confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test OR a pubertal level of a third generation luteinizing hormone (LH) assay, AND 2) Assessment of bone age versus chronological age supports the diagnosis of CPP, AND 3) The onset of secondary sexual characteristics occurred prior to 8 years of age for female patients OR prior to 9 years of age for male patients.
Age Restrictions	CPP: Patient must be less than 12 years old if female and less than 13 years old if male
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

LUPRON-ENDOMETRIOSIS

Products Affected

• Lupron Depot (3-month) INJ 11.25MG

• Lupron Depot (1-month) INJ 3.75MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Breast cancer, ovarian cancer/fallopian tube cancer/primary peritoneal cancer, androgen receptor positive recurrent salivary gland tumor
Exclusion Criteria	N/A
Required Medical Information	For retreatment of endometriosis, the requested drug is used in combination with norethindrone acetate. For uterine fibroids, patient must meet one of the following: 1) diagnosis of anemia (e.g., hematocrit less than or equal to 30 percent and/or hemoglobin less than or equal to 10g/dL), OR 2) the requested medication will be used prior to surgery for uterine fibroids. For breast cancer, the requested drug is used for hormone receptor (HR)-positive disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Fibroids: 3 months (mo), max 6 mo total. Endometriosis: 6 mo, max 12 mo total. Others: Plan Year
Other Criteria	N/A

LUPRON-PROSTATE CA

Products Affected

- Leuprolide Acetate INJ 22.5MG
- Lupron Depot (1-month) INJ 7.5MG
- Lupron Depot (3-month) INJ 22.5MG
- Lupron Depot (4-month)
- Lupron Depot (6-month)

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

Lybalvi

Products Affected

• Lybalvi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

LYNPARZA

Products Affected

• Lynparza TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent HER2-negative, BRCA 1/2-germline mutated breast cancer, recurrent or metastatic HER2-positive, BRCA 1/2-germline mutated breast cancer, uterine leiomyosarcoma.
Exclusion Criteria	N/A
Required Medical Information	For recurrent or metastatic breast cancer: the disease is BRCA 1/2-germline mutated. For prostate cancer: 1) The patient has a BRCA mutation and the requested drug will be used in combination with abiraterone and an oral corticosteroid OR 2) The patient has progressed on prior treatment with an androgen receptor-directed therapy. For ovarian, fallopian tube, or primary peritoneal cancer: The requested drug is used for maintenance therapy for stage II-IV or recurrent disease who are in complete or partial response to chemotherapy. For uterine leiomyosarcoma: 1) the patient has had at least one prior therapy AND 2) the patient has BRCA-altered disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

LYRICA CR

Products Affected

• Lyrica Cr

• Pregabalin Er

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN): The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

LYTGOBI

Products Affected

• Lytgobi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Extrahepatic cholangiocarcinoma
Exclusion Criteria	N/A
Required Medical Information	For cholangiocarcinoma: 1) patient has a diagnosis of unresectable, locally advanced or metastatic cholangiocarcinoma, 2) patient has received a previous treatment, AND 3) patient has a disease that has a fibroblast growth factor receptor 2 (FGFR2) gene fusion or other rearrangement.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

LYVISPAH

Products Affected

• Lyvispah

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MARGENZA

Products Affected

• Margenza

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MAVENCLAD AET

Products Affected

• Mavenclad

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MAVYRET

Products Affected

• Mavyret

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh [CTP] class B or C).
Required Medical Information	For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [CTP class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Criteria will be applied consistent with current AASLD-IDSA guidance
Other Criteria	N/A

MAYZENT AET

Products Affected

• Mayzent

• Mayzent Starter Pack

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MEKINIST

Products Affected

• Mekinist

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai-Dorfman disease.
Exclusion Criteria	N/A
Required Medical Information	For melanoma: 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used as a single agent or in combination with dabrafenib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For uveal melanoma: The requested drug will be used as a single agent. For ovarian cancer, fallopian tube cancer, and primary peritoneal cancer: The requested drug will be used to treat persistent or recurrent disease. For papillary, follicular, and oncocytic thyroid carcinoma: 1) The disease is positive for BRAF V600E mutation, AND 2) The disease is not amenable to radioactive iodine (RAI) therapy, AND 3) The requested drug will be used in combination with dabrafenib. For solid tumors: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used in combination with dabrafenib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

MEKTOVI

Products Affected

• Mektovi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Adjuvant systemic therapy for cutaneous melanoma, Langerhans Cell Histiocytosis, recurrent non-small cell lung cancer (NSCLC)
Exclusion Criteria	N/A
Required Medical Information	For melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used in combination with encorafenib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For non-small cell lung cancer: 1) The tumor is positive for BRAF V600E mutation, AND 2) The requested drug will be used in combination with encorafenib, AND 3) The disease is advanced, recurrent, or metastatic.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

MEMANTINE

Products Affected

- Memantine Hcl Titration Pak
- Memantine Hydrochloride SOLN 2MG/ML
- Memantine Hydrochloride TABS
- Memantine Hydrochloride Er

- Namenda TABS 5MG
- Namenda Titration Pak
- Namenda Xr CP24 14MG, 21MG, 28MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This prior authorization only applies to patients less than 30 years of age.

MEPRON AET

Products Affected

• Atovaquone SUSP

• Mepron SUSP

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Babesiosis, Toxoplasmosis, Pneumocystis jirovecii pneumonia prophylaxis in pediatric patients, mild-to-moderate Pneumocystis jirovecii pneumonia treatment in pediatric patients.
Exclusion Criteria	N/A
Required Medical Information	For the treatment of mild-to-moderate Pneumocystis jiroveci pneumonia (PCP): the patient had an intolerance or has a contraindication to sulfamethoxazole/trimethoprim (SMX-TMP). For the prevention of PCP and primary toxoplasmosis prophylaxis indications: 1) the patient had an intolerance or has a contraindication to SMX-TMP, AND 2) the patient is immunocompromised. For secondary toxoplasmosis prophylaxis: the patient is immunocompromised. For babesiosis treatment: the requested drug is used concurrently with azithromycin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Secondary toxoplasmosis prophylaxis: 6 months, All other indications: 3 months
Other Criteria	N/A

MEPSEVII

Products Affected

• Mepsevii

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

METFORMIN ER

Products Affected

• Glumetza

• Metformin Hydrochloride Er TB24 1000MG, 500MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The patient has experienced an intolerance that prohibited a 4-week trial of metformin immediate-release and generic Glucophage XR.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

METHYLTESTOSTERONE

Products Affected

• Methitest

• Methyltestosterone CAPS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to alternative testosterone products (e.g., topical testosterone, transdermal testosterone, injectable testosterone). For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

MIACALCIN AET

Products Affected

• Calcitonin Salmon INJ

• Miacalcin INJ

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MICO-ZN-PETR OINT

Products Affected

• Vusion

• Miconazole Nitrate/zinc Oxide/white Petrolatum

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MIGLUSTAT

Products Affected

• Miglustat

- YargesaZavesca

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MODAFINIL

Products Affected

• Modafinil TABS

• Provigil

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Idiopathic hypersomnia
Exclusion Criteria	N/A
Required Medical Information	For excessive sleepiness associated with narcolepsy: The diagnosis has been confirmed by sleep lab evaluation. For excessive sleepiness associated with obstructive sleep apnea (OSA): The diagnosis has been confirmed by polysomnography. For idiopathic hypersomnia, initial request, the diagnosis has been confirmed by ALL of the following: 1) Patient has experienced lapses into sleep or an irrepressible need to sleep during daytime, on a daily basis, for at least 3 months, AND 2) Insufficient sleep syndrome is confirmed absent, AND 3) Cataplexy is absent, AND 4) Fewer than 2 sleep onset rapid eye movement periods (SOREMPs) or no SOREMPs, if the rapid eye movement latency on an overnight sleep study was less than or equal to 15 minutes, AND 5) Average sleep latency of less than or equal to 8 minutes on Multiple Sleep Latency Test or total 24-hour sleep time is greater than or equal to 11 hours, AND 6) Another condition (sleep disorder, medical or psychiatric disorder, or drug/medication use) does not better explain the hypersomnolence and test results. For idiopathic hypersomnia, continuation of therapy: The patient has experienced a decrease in daytime sleepiness from baseline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

Monjuvi

Products Affected

• Monjuvi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MOTEGRITY AET

Products Affected

• Motegrity

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MOTPOLY XR

Products Affected

• Motpoly Xr

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

Mounjaro

Products Affected

• Mounjaro

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

Mozobil

Products Affected

• Mozobil

• Plerixafor

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MULPLETA

Products Affected

• Mulpleta

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MVASI

Products Affected

• Mvasi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MYALEPT

Products Affected

• Myalept

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MYCAPSSA

Products Affected

• Mycapssa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MYFEMBREE

Products Affected

• Myfembree

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MYLOTARG

Products Affected

• Mylotarg

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MYOBLOC

Products Affected

• Myobloc

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

MYTESI AET

Products Affected

• Mytesi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

NAGLAZYME

Products Affected

• Naglazyme

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

NAPROXEN SUSPENSION

Products Affected

• Naprosyn SUSP

• Naproxen SUSP

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ibuprofen oral suspension, AND 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

NAPROXEN-ESOMEPRAZOLE

Products Affected

• Vimovo

• Naproxen/esomeprazole Magnesium

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

NAYZILAM

Products Affected

• Nayzilam

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

NERLYNX

Products Affected

• Nerlynx

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer, brain metastases from HER2-positive breast cancer.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

NEULASTA

Products Affected

- Fulphila
- Fylnetra
- Neulasta
- Neulasta Onpro Kit

- Nyvepria
- Udenyca
- Udenyca Onbody
- Ziextenzo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

NEUPOGEN

Products Affected

• Neupogen

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

NEXAVAR

Products Affected

• Nexavar

• Sorafenib Tosylate TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Acute myeloid leukemia, soft tissue sarcoma (angiosarcoma, desmoid tumors/aggressive fibromatosis, and solitary fibrous tumor subtypes), gastrointestinal stromal tumor, medullary thyroid carcinoma, osteosarcoma, recurrent chordoma, epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, lymphoid and/or myeloid neoplasms with eosinophilia and FLT3 rearrangement in chronic or blast phase
Exclusion Criteria	N/A
Required Medical Information	For acute myeloid leukemia: the disease is FMS-like tyrosine kinase 3-internal tandem duplication (FLT3-ITD) mutation-positive and any of the following is met:1) the requested drug will be used as maintenance therapy after hematopoietic stem cell transplant, OR 2) the requested drug is being used for low-intensity treatment induction, post-induction therapy, or consolidation therapy, OR 3) the disease is relapsed/refractory. For thyroid carcinoma: histology is follicular, papillary, oncocytic, or medullary. For gastrointestinal stromal tumor (GIST): 1) the disease is residual, unresectable, recurrent, or metastatic/tumor rupture, AND 2) the disease has progressed after use of at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

NEXIUM IV

Products Affected

• Nexium I.v. INJ 40MG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

NEXVIAZYME

Products Affected

• Nexviazyme

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

NGENLA AET

Products Affected

• Ngenla

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

NINLARO

Products Affected

• Ninlaro

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Relapsed/refractory systemic light chain amyloidosis, Waldenstrom macroglobulinemia, lymphoplasmacytic lymphoma
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

NITISINONE

Products Affected

• Nitisinone

• Orfadin

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For hereditary tyrosinemia type 1 (HT-1): Diagnosis of HT-1 is confirmed by one of the following: 1) biochemical testing (e.g., detection of succinylacetone in urine) OR 2) DNA testing (mutation analysis).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

NITYR

Products Affected

• Nityr

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

NORTHERA

Products Affected

• Droxidopa

• Northera

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For neurogenic orthostatic hypotension (nOH): For initial therapy, patient has a persistent, consistent decrease in systolic blood pressure of at least 20 mmHg OR decrease in diastolic blood pressure of at least 10 mmHg within 3 minutes of standing or head-up tilt test. For continuation of therapy, patient has experienced a sustained reduction in symptoms of nOH (i.e., decrease in dizziness, lightheadedness, or feeling faint). For both initial and continuation of therapy, the requested drug will be used for patients with neurogenic orthostatic hypotension associated with one of the following diagnoses: 1) primary autonomic failure due to Parkinson's disease, multiple system atrophy, or pure autonomic failure, OR 2) dopamine beta-hydroxylase deficiency, OR 3) non-diabetic autonomic neuropathy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A

NOURIANZ AET

Products Affected

• Nourianz

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

NOXAFIL POWDER

Products Affected

• Noxafil PACK

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

NOXAFIL SUSP

Products Affected

• Noxafil SUSP

• Posaconazole SUSP

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested drug will be used orally. For treatment of oropharyngeal candidiasis: patient has experienced an inadequate treatment response, intolerance, or has a contraindication to fluconazole.
Age Restrictions	13 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Oropharyngeal candidiasis: 1 month. All other indications: 6 months
Other Criteria	N/A

NP GROWTH HORMONE

Products Affected

- Humatrope INJ 12MG, 24MG, 6MG
- Norditropin Flexpro
- Nutropin Aq Nuspin 10

- Nutropin Aq Nuspin 20
- Nutropin Aq Nuspin 5
- Omnitrope
- Zomacton

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

NPLATE

Products Affected

• Nplate

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

NUBEQA

Products Affected

• Nubeqa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested drug will be used in combination with a gonadotropin- releasing hormone (GnRH) analog or after bilateral orchiectomy. For metastatic hormone-sensitive prostate cancer (mHSPC) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to abiraterone, Xtandi, or Erleada.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

NUCALA

Products Affected

• Nucala

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For severe asthma, initial therapy: 1) Either a) Patient has baseline blood eosinophil count of at least 150 cells per microliter OR b) Patient is dependent on systemic corticosteroids, AND 2) Patient has a history of severe asthma despite current treatment with both of the following medications: a) medium-to-high-dose inhaled corticosteroid AND b) additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For severe asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. For eosinophilic granulomatosis with polyangiitis (EGPA), initial therapy: Patient has a history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10 percent. For EGPA, continuation of therapy: Patient has a beneficial response to treatment with the requested drug, as demonstrated by any of the following: 1) a reduction in the frequency of relapses, 2) a reduction in the daily oral corticosteroid dose, OR 3) no active vasculitis. For hypereosinophilic syndrome (HES), initial therapy: 1) Patient has had HES for greater than or equal to 6 months, 2) Patient has HES without an identifiable non-hematologic secondary cause, 3) Patient does not have FIP1L1-PDGFRA kinase-positive HES, 4) Patient has a history or presence of a blood eosinophil count of at least 1000 cells per microliter, AND 5) Patient has been on a stable dose of at least one HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy). For HES, continuation of therapy: Patient has a beneficial response to treatment as demonstrated by a reduction in HES flares.
Age Restrictions	Asthma: 6 years of age or older, EGPA and CRSwNP: 18 years of age or older, HES: 12 years of age or older

Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	For chronic rhinosinusitis with nasal polyps (CRSwNP): 1) The requested drug is used as add-on maintenance treatment, AND 2) The patient has experienced inadequate treatment response to Xhance (fluticasone).

NUEDEXTA

Products Affected

• Nuedexta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For pseudobulbar affect (PBA) (continuation): The patient has experienced a decrease in pseudobulbar affect (PBA) episodes since starting therapy with the requested drug.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 4 months, Continuation: Plan Year
Other Criteria	N/A

NULIBRY

Products Affected

• Nulibry

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

Nuplazid

Products Affected

• Nuplazid CAPS

• Nuplazid TABS 10MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For hallucinations and delusions associated with Parkinson's disease psychosis, the diagnosis of Parkinson's disease must be made prior to the onset of psychotic symptoms.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

NURTEC

Products Affected

• Nurtec

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute migraine treatment: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to one triptan 5-HT1 receptor agonist. Preventive treatment of migraine, initial: The patient meets either of the following: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants. Preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Preventive treatment of migraine, initial: 3 months, All other indications: Plan Year
Other Criteria	N/A

OCALIVA

Products Affected

• Ocaliva

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OCREVUS

Products Affected

• Ocrevus

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OCTREOTIDE

Products Affected

- Octreotide Acetate INJ 1000MCG/ML, 100MCG/ML, 200MCG/ML, 500MCG/ML, 50MCG/ML
- Sandostatin INJ 100MCG/ML, 500MCG/ML, 50MCG/ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Tumor control of thymomas and thymic carcinomas
Exclusion Criteria	N/A
Required Medical Information	For acromegaly, initial: 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range AND 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly, continuation of therapy: Patient's IGF-1 level has decreased or normalized since initiation of therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ODACTRA

Products Affected

• Odactra

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ODOMZO

Products Affected

• Odomzo

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

OFEV

Products Affected

• Ofev

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For idiopathic pulmonary fibrosis (new starts only): 1) a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy reveals the usual interstitial pneumonia (UIP) pattern, OR 2) HRCT study of the chest reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported either by a lung biopsy or by a multidisciplinary discussion between at least a radiologist and pulmonologist who are experienced in idiopathic pulmonary fibrosis if a lung biopsy has not been conducted.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

OGSIVEO

Products Affected

• Ogsiveo

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

OJEMDA

Products Affected

• Ojemda

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For relapsed or refractory pediatric low-grade glioma (LGG): the patient's tumor is positive for either a) BRAF fusion or rearrangement OR b) BRAF V600 mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

OJJAARA

Products Affected

• Ojjaara

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Accelerated or blast phase myeloproliferative neoplasms
Exclusion Criteria	N/A
Required Medical Information	For myelofibrosis, patient meets ALL of the following: 1) the patient has a diagnosis of intermediate or high-risk primary myelofibrosis or secondary myelofibrosis (i.e., post-polycythemia vera or post-essential thrombocythemia), AND 2) the patient has anemia defined as hemoglobin less than 10 grams per deciliter (g/dL) or having transfusion-dependent anemia, AND 3) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Jakafi (ruxolitinib) OR has hemoglobin less than 8 g/dL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

OLUMIANT

Products Affected

• Olumiant

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OMEGA-3

Products Affected

• Lovaza

• Omega-3-acid Ethyl Esters CAPS 375MG; 465MG; 1GM

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For hypertriglyceridemia: Prior to the start of treatment with a triglyceride lowering drug, the patient has/had a pretreatment triglyceride level greater than or equal to 500 milligram per deciliter (mg/dL).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

Омуон

Products Affected

• Omvoh

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ONCASPAR

Products Affected

• Oncaspar

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ONGENTYS AET

Products Affected

• Ongentys

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ONIVYDE

Products Affected

• Onivyde

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ONUREG

Products Affected

• Onureg

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Peripheral T-cell lymphoma
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

OPDIVO

Products Affected

• Opdivo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OPDUALAG

Products Affected

• Opdualag

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OPFOLDA

Products Affected

• Opfolda

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OPSUMIT

Products Affected

• Opsumit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

OPSYNVI

Products Affected

• Opsynvi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OPZELURA

Products Affected

• Opzelura

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ORACEA AET

Products Affected

Oracea

• Doxycycline CPDR

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a formulary generic topical metronidazole.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ORALAIR

Products Affected

• Oralair

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ORAL-INTRANASAL FENTANYL

Products Affected

- Fentanyl Citrate TABS 200MCG, 400MCG, 600MCG, 800MCG
- Fentanyl Citrate Oral Transmucosal

• Fentora TABS 100MCG, 200MCG, 400MCG, 600MCG, 800MCG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the management of breakthrough pain in cancer patients: 1) The requested drug is indicated for the treatment of breakthrough cancer-related pain only. The requested drug is being prescribed for the management of breakthrough pain in a cancer patient with underlying cancer pain AND 2) The International Classification of Diseases (ICD) diagnosis code provided supports the cancer-related diagnosis. [Note: For drug coverage approval, ICD diagnosis code provided MUST support the cancer-related diagnosis.] AND 3) The patient is currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying cancer pain AND 4) The requested drug is intended only for use in opioid tolerant patients. The patient can safely take the requested dose based on their current opioid use history. [Note: Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 60 mg of oral hydrocodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, or an equianalgesic dose of another opioid medication daily for one week or longer.].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ORENCIA

Products Affected

• Orencia

• Orencia Clickject

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ORENITRAM

Products Affected

- Orenitram
- Orenitram Titration Kit Month 1
- Orenitram Titration Kit Month 2
- Orenitram Titration Kit Month 3

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ORGOVYX

Products Affected

• Orgovyx

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

ORIAHNN

Products Affected

• Oriahnn

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ORILISSA

Products Affected

• Orilissa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ORKAMBI

Products Affected

• Orkambi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For cystic fibrosis (CF): The requested medication will not be used in combination with other medications containing ivacaftor.
Age Restrictions	1 year of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ORLADEYO

Products Affected

• Orladeyo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ORSERDU

Products Affected

• Orserdu

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: 1) the disease is estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER2)-negative, and ESR1 mutated AND 2) the patient meets either of the following: a) the disease is advanced, recurrent, or metastatic AND the patient has disease progression following at least one line of endocrine therapy OR b) the disease had no response to preoperative systemic therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

OSPHENA

Products Affected

• Osphena

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OTEZLA

Products Affected

• Otezla

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OXAZEPAM - 65

Products Affected

• Oxazepam

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is 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, anxiety associated with depression, and the management of anxiety, tension, agitation and irritability in older patients: 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Short-term relief anxiety-1 month, Anxiety Disorders-4 months, Alcohol Withdrawal-Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older.

OXBRYTA

Products Affected

• Oxbryta

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OXERVATE

Products Affected

• Oxervate

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OXLUMO

Products Affected

• Oxlumo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OXTELLAR XR

Products Affected

• Oxtellar Xr

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OXYCONTIN AET

Products Affected

- Oxycodone Hcl Er T12A 10MG, 20MG, 40MG, 80MG
- Oxycodone Hydrochloride Er T12A 10MG, 20MG
- Oxycontin T12A

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

OZEMPIC

Products Affected

• Ozempic INJ 2MG/3ML, 4MG/3ML, 8MG/3ML

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

PADCEV

Products Affected

• Padcev

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PALFORZIA

Products Affected

- Palforzia Initial Dose Escalation
- Palforzia Level 1
- Palforzia Level 10
- Palforzia Level 11 (maintenance)
- Palforzia Level 11 (titration)
- Palforzia Level 2

- Palforzia Level 3
- Palforzia Level 4
- Palforzia Level 5
- Palforzia Level 6
- Palforzia Level 7
- Palforzia Level 8
- Palforzia Level 9

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PALYNZIQ AET

Products Affected

• Palynziq

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PANRETIN

Products Affected

• Panretin

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Topical treatment of cutaneous lesions in patients with non-AIDS-related Kaposi sarcoma
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

PEGASYS

Products Affected

• Pegasys

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PEMAZYRE

Products Affected

• Pemazyre

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

PERFOROMIST AET

Products Affected

• Formoterol Fumarate NEBU

• Perforomist

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PERJETA

Products Affected

• Perjeta

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PHENYLBUTYRATE

Products Affected

- Buphenyl
- OlpruvaPheburane

- Sodium Phenylbutyrate POWD 3GM/TSP
- Sodium Phenylbutyrate TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For urea cycle disorders (UCD): Diagnosis of UCD was confirmed by enzymatic, biochemical, or genetic testing.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

PHESGO

Products Affected

• Phesgo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PIASKY

Products Affected

• Piasky

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PIQRAY

Products Affected

• Piqray 200mg Daily Dose

- Piqray 250mg Daily DosePiqray 300mg Daily Dose

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated breast cancer in combination with fulvestrant.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

PLEGRIDY AET

Products Affected

• Plegridy

• Plegridy Starter Pack

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

POLIVY

Products Affected

• Polivy

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

POMALYST

Products Affected

• Pomalyst

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Relapsed/refractory systemic light chain amyloidosis, primary central nervous system (CNS) lymphoma, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome
Exclusion Criteria	N/A
Required Medical Information	For multiple myeloma, patient has previously received at least two prior therapies, including an immunomodulatory agent AND a proteasome inhibitor.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

POMBILITI

Products Affected

• Pombiliti

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PONVORY AET

Products Affected

• Ponvory

• Ponvory 14-day Starter Pack

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PORTRAZZA

Products Affected

• Portrazza

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

POSACONAZOLE

Products Affected

• Noxafil TBEC

• Posaconazole Dr

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested drug will be used orally. For prophylaxis of invasive Aspergillus and Candida infections: patient weighs greater than 40 kilograms.
Age Restrictions	Treatment of Invasive Aspergillosis: 13 years of age or older, Prophylaxis of Invasive Aspergillus and Candida Infections: 2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

POTELIGEO

Products Affected

• Poteligeo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PRALUENT

Products Affected

• Praluent

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PREGABALIN

Products Affected

• Lyrica

- Pregabalin CAPSPregabalin SOLN

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Cancer-related neuropathic pain, cancer treatment-related neuropathic pain
Exclusion Criteria	N/A
Required Medical Information	For the management of postherpetic neuralgia, the management of neuropathic pain associated with diabetic peripheral neuropathy: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

PRETOMANID AET

Products Affected

• Pretomanid

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For tuberculosis (TB), patient meets ALL of the following: 1) the requested drug is being used for treatment of pulmonary extensively drug resistant (XDR), treatment intolerant or nonresponsive multidrug resistant (MDR) tuberculosis, AND 2) the requested drug is used in combination with bedaquiline and linezolid.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

PREVYMIS

Products Affected

• Prevymis TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For prophylaxis of cytomegalovirus (CMV) infection or disease in hematopoietic stem cell transplant (HSCT): 1) the patient is CMV-seropositive, AND 2) the patient is a recipient of an allogeneic HSCT. For prophylaxis of CMV disease in kidney transplant: 1) the patient is CMV-seronegative, AND 2) the patient is a high risk recipient of kidney transplant.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	7 months
Other Criteria	N/A

PROAIR DIGIHALER

Products Affected

• Proair Digihaler

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PROCYSBI

Products Affected

• Procysbi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PROLATE AET

Products Affected

- Oxycodone And Acetaminophen
- Oxycodone Hydrochloride/acetaminophen SOLN 300MG/5ML; 10MG/5ML
- Oxycodone/acetaminophen TABS 300MG; 10MG, 300MG; 5MG
- Prolate

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PROLENSA AET

Products Affected

• Bromfenac Sodium SOLN 0.07%

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PROMACTA AET

Products Affected

• Promacta

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

PULMOZYME

Products Affected

• Pulmozyme SOLN 2.5MG/2.5ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.

PYRUKYND

Products Affected

• Pyrukynd

• Pyrukynd Taper Pack

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

QBREXZA

Products Affected

• Qbrexza

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

QELBREE

Products Affected

• Qelbree

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

QINLOCK

Products Affected

• Qinlock

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Gastrointestinal stromal tumor (GIST) for residual, unresectable, tumor rupture, recurrent, or progressive disease. Metastatic or unresectable cutaneous melanoma.
Exclusion Criteria	N/A
Required Medical Information	For residual, unresectable, tumor rupture, advanced, recurrent/metastatic, or progressive gastrointestinal stromal tumor (GIST): 1) Patient has received prior treatment with 3 or more kinase inhibitors, including imatinib OR 2) Patient has experienced disease progression following treatment with avapritinib and dasatinib OR 3) Patient has received prior treatment with imatinib and is intolerant of second-line sunitinib. For cutaneous melanoma: 1) Disease is metastatic or unresectable AND 2) Disease is positive for KIT activating mutations AND 3) Requested drug will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

QUETIAPINE XR

Products Affected

• Quetiapine Fumarate Er

• Seroquel Xr

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Maintenance monotherapy treatment in bipolar I disorder, monotherapy treatment of generalized anxiety disorder, monotherapy treatment of major depressive disorder
Exclusion Criteria	N/A
Required Medical Information	For all indications: If the patient is 65 years of age or older AND is using two or more additional central nervous system (CNS) active medications (e.g., lorazepam, sertraline, clonazepam, escitalopram, alprazolam, zolpidem) with the requested drug, the prescriber determined that taking multiple central nervous system (CNS) active medications is medically necessary. [Note: Use of multiple central nervous system (CNS) active medications in older adults is associated with an increased risk of falls]. For treatment of schizophrenia: The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine immediate-release, risperidone, ziprasidone. For acute treatment of manic or mixed episodes associated with bipolar I disorder or maintenance treatment of bipolar I disorder: The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine immediate-release, risperidone, ziprasidone. For acute treatment of depressive episodes associated with bipolar I disorder: The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: lurasidone, olanzapine, quetiapine immediate-release. For acute treatment of depressive episodes associated with bipolar II disorder: The patient experienced an inadequate treatment response or intolerance to generic quetiapine immediate-release. For adjunctive treatment of major depressive disorder (MDD): The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, olanzapine, quetiapine immediate-release.
Age Restrictions	N/A

Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

QUININE SULFATE

Products Affected

• Qualaquin

• Quinine Sulfate CAPS 324MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Babesiosis, uncomplicated Plasmodium vivax malaria.
Exclusion Criteria	N/A
Required Medical Information	For babesiosis: the requested drug is used in combination with clindamycin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A

QULIPTA

Products Affected

• Qulipta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Preventive treatment of migraine, initial: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants. Preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months, Continuation: Plan Year
Other Criteria	N/A

QUTENZA

Products Affected

• Qutenza

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

QUZYTTIR

Products Affected

• Quzyttir

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RADICAVA

Products Affected

- Edaravone
- Radicava

- Radicava Ors
- Radicava Ors Starter Kit

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RAGWITEK

Products Affected

• Ragwitek

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RAVICTI AET

Products Affected

• Ravicti

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

REBIF OPEN

Products Affected

- Rebif
- Rebif Rebidose

- Rebif Rebidose Titration Pack
- Rebif Titration Pack

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

REBLOZYL

Products Affected

• Reblozyl

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

REBYOTA

Products Affected

• Rebyota

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RECARBRIO

Products Affected

• Recarbrio

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RECORLEV

Products Affected

• Recorlev

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

REGRANEX

Products Affected

• Regranex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	20 weeks
Other Criteria	N/A

RELEUKO

Products Affected

• Releuko INJ 300MCG/0.5ML, 480MCG/0.8ML

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RELISTOR INJ

Products Affected

• Relistor INJ

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the treatment of opioid-induced constipation in a patient with chronic non-cancer pain, including chronic pain related to prior cancer or its treatment who does not require frequent (e.g., weekly) opioid dosage escalation: 1) the patient is unable to tolerate oral medications, OR 2) the patient meets one of the following criteria: A) experienced an inadequate treatment response or intolerance to an oral drug indicated for opioid-induced constipation in a patient with chronic non-cancer pain (e.g., Movantik), OR B) the patient has a contraindication that would prohibit a trial of an oral drug indicated for opioid-induced constipation in a patient with chronic non-cancer pain (e.g., Movantik).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	4 months
Other Criteria	N/A

RELISTOR TAB

Products Affected

• Relistor TABS

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RELTONE

Products Affected

• Reltone

• Ursodiol CAPS 200MG, 400MG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RELYVRIO

Products Affected

• Relyvrio

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

REMICADE

Products Affected

• Infliximab

• Remicade

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RENFLEXIS

Products Affected

• Renflexis

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

REPATHA

Products Affected

• Repatha

- Repatha Pushtronex SystemRepatha Sureclick

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

RETEVMO

Products Affected

• Retevmo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent rearranged during transfection (RET)-rearrangement positive non-small cell lung cancer (NSCLC), brain metastases from RET fusion-positive NSCLC, Langerhans Cell Histiocytosis with a RET gene fusion, symptomatic or relapsed/refractory Erdheim-Chester Disease with a RET gene fusion, symptomatic or relapsed/refractory Rosai-Dorfman Disease with a RET gene fusion, occult primary cancer with RET gene fusion, solid tumors with RET-gene fusion for recurrent disease
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC), patient must meet all of the following: 1) The disease is recurrent, advanced or metastatic, AND 2) The tumor is rearranged during transfection (RET) fusion-positive or RET rearrangement positive. For solid tumors, patient must meet all of the following: 1) The disease is recurrent, persistent, progressive, unresectable, locally advanced, or metastatic, 2) The patient has progressed on or following prior systemic treatment or has no satisfactory alternative treatment options, AND 3) The tumor is RET fusion-positive.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

REVCOVI

Products Affected

• Revcovi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

REVLIMID

Products Affected

• Lenalidomide

• Revlimid

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Systemic light chain amyloidosis, classical Hodgkin lymphoma, myelodysplastic syndrome without the 5q deletion cytogenetic abnormality, myelofibrosis-associated anemia, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome, myeloproliferative neoplasms, Kaposi Sarcoma, Langerhans cell histiocytosis, Rosai-Dorfman disease, peripheral T-Cell lymphomas not otherwise specified, angioimmunoblastic T-cell lymphoma (AITL), enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma, adult T-cell leukemia/lymphoma, hepatosplenic T-cell lymphoma, primary central nervous system (CNS) lymphoma, chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), human immunodeficiency virus (HIV)-related B-cell lymphomas, monomorphic post-transplant lymphoproliferative disorder, diffuse large B-cell lymphoma, multicentric Castlemans disease, high-grade B-cell lymphomas, histologic transformation of indolent lymphoma to diffuse large B-cell lymphoma
Exclusion Criteria	N/A
Required Medical Information	For myelodysplastic syndrome (MDS): patient has lower risk MDS with symptomatic anemia per the Revised International Prognostic Scoring System (IPSS-R), International Prognostic Scoring System (IPSS), or World Health organization (WHO) classification-based Prognostic Scoring System (WPSS).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

REYVOW

Products Affected

• Reyvow

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

REZDIFFRA

Products Affected

• Rezdiffra

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

REZLIDHIA

Products Affected

• Rezlidhia

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

REZUROCK

Products Affected

• Rezurock

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

REZZAYO

Products Affected

• Rezzayo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RIABNI

Products Affected

• Riabni

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RINVOQ

Products Affected

• Rinvoq

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RINVOQ LQ

Products Affected

• Rinvoq Lq

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RITUXAN

Products Affected

• Rituxan

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RITUXAN HYCELA

Products Affected

• Rituxan Hycela

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RIVFLOZA

Products Affected

• Rivfloza

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ROLVEDON

Products Affected

• Rolvedon

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ROZLYTREK

Products Affected

• Rozlytrek

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent ROS1-positive non-small cell lung cancer (NSCLC), Non-metastatic neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, first-line treatment of NTRK gene fusion-positive solid tumors, ROS1-gene fusion-positive cutaneous melanoma
Exclusion Criteria	N/A
Required Medical Information	For all neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors: the disease is without a known acquired resistance mutation. For ROS1-positive non-small cell lung cancer: the patient has recurrent, advanced, or metastatic disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

RUBRACA

Products Affected

• Rubraca

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Uterine leiomyosarcoma, pancreatic adenocarcinoma, advanced (stage II-IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer
Exclusion Criteria	N/A
Required Medical Information	For metastatic castration-resistant prostate cancer with a deleterious breast cancer susceptibility gene (BRCA) mutation (germline and/or somatic): 1) patient has been treated with androgen receptor-directed therapy, AND 2) patient has been treated with a taxane-based chemotherapy or the patient is not fit for chemotherapy, AND 3) the requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. For maintenance treatment of BRCA mutated ovarian, fallopian tube, primary peritoneal cancer: 1) the patient has advanced (stage II-IV) disease and is in complete or partial response to primary therapy, OR 2) the patient has recurrent disease and is in complete or partial response to platinum-based chemotherapy. For uterine leiomyosarcoma: 1) the requested drug is used as second-line therapy, AND 2) the patient has BRCA-altered disease. For pancreatic adenocarcinoma: 1) the patient has metastatic disease, AND 2) the patient has somatic or germline BRCA or PALB-2 mutations.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

RUCONEST

Products Affected

• Ruconest

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RUXIENCE

Products Affected

• Ruxience

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RYBELSUS

Products Affected

• Rybelsus

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

RYBREVANT

Products Affected

• Rybrevant

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RYDAPT

Products Affected

• Rydapt

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Relapsed or refractory acute myeloid leukemia (AML), myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FGFR1 or FLT3 rearrangements, post-induction therapy for AML, re-induction in residual disease for AML
Exclusion Criteria	N/A
Required Medical Information	For acute myeloid leukemia (AML): AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and Fibroblast growth factor receptor type 1 (FGFR1) or FLT3 rearrangements: the disease is in chronic or blast phase.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

RYLAZE

Products Affected

• Rylaze

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RYPLAZIM

Products Affected

• Ryplazim

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RYSTIGGO

Products Affected

• Rystiggo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

RYTELO

Products Affected

• Rytelo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SAMSCA

Products Affected

• Samsca

• Tolvaptan

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SANDOSTATIN LAR

Products Affected

• Sandostatin Lar Depot

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SAPHNELO

Products Affected

• Saphnelo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SAPROPTERIN

Products Affected

• Javygtor

- Kuvan
- Sapropterin Dihydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For phenylketonuria (PKU): For patients who have not yet received a therapeutic trial of the requested drug, the patient's pretreatment (including before dietary management) phenylalanine level is greater than 6 mg/dL (360 micromol/L). For patients who completed a therapeutic trial of the requested drug, the patient must have experienced improvement (e.g., reduction in blood phenylalanine levels, improvement in neuropsychiatric symptoms).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 2 months, All others: Plan Year
Other Criteria	N/A

SARCLISA

Products Affected

• Sarclisa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SAVELLA

Products Affected

• Savella

• Savella Titration Pack

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SCEMBLIX

Products Affected

• Scemblix

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic phase or blast phase.
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML) in the chronic phase: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) Patient meets either of the following: A) Patient has previously been treated with 2 or more tyrosine kinase inhibitors (TKIs) AND at least one of those was imatinib, dasatinib, or nilotinib OR B) Patient is positive for the T315I mutation, AND 3) Patient is negative for the following mutations: A337T, P465S.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

SEGLENTIS

Products Affected

• Seglentis

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SEROSTIM

Products Affected

• Serostim INJ 4MG, 5MG, 6MG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SEYSARA

Products Affected

• Seysara

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SIGNIFOR

Products Affected

• Signifor

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Plan Year
Other Criteria	N/A

SIGNIFOR LAR

Products Affected

• Signifor Lar

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SIKLOS

Products Affected

• Siklos

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SILDENAFIL

Products Affected

• Revatio TABS

- Sildenafil Citrate SUSR
- Sildenafil Citrate TABS 20MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) If the request is for an adult, pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

SILDENAFIL INJ

Products Affected

• Revatio INJ

• Sildenafil INJ

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SILIQ

Products Affected

• Siliq

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SIMPONI

Products Affected

• Simponi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SIMPONI ARIA

Products Affected

• Simponi Aria

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SIRTURO

Products Affected

• Sirturo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	Plan Year
Other Criteria	N/A

SKYCLARYS

Products Affected

• Skyclarys

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SKYRIZI

Products Affected

- Skyrizi INJ 150MG/ML, 180MG/1.2ML, 360MG/2.4ML, 600MG/10ML
- Skyrizi Pen

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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) patient meets any of the following: a) 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) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

SKYTROFA AET

Products Affected

• Skytrofa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SOFOSBUVIR AND VELPATASVIR AET

Products Affected

• Sofosbuvir/velpatasvir

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SOGROYA AET

Products Affected

• Sogroya

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SOHONOS

Products Affected

• Sohonos

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SOLIRIS

Products Affected

• Soliris

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SOMATULINE DEPOT

Products Affected

• Lanreotide Acetate

• Somatuline Depot

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SOMAVERT

Products Affected

• Somavert

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For acromegaly, initial: 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, AND 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly, continuation of therapy: Patient's IGF-1 level has decreased or normalized since initiation of therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

SOTYKTU

Products Affected

• Sotyktu

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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) patient meets any of the following: a) 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) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

SOVALDI AET

Products Affected

• Sovaldi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SPEVIGO

Products Affected

• Spevigo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SPRIX

Products Affected

• Sprix

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SPRYCEL

Products Affected

• Sprycel

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Gastrointestinal stromal tumor (GIST), metastatic and/or widespread chondrosarcoma, recurrent chordoma, T-cell acute lymphoblastic leukemia (ALL), and Philadelphia (Ph)-like B-ALL, myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase, cutaneous melanoma
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia (Ph) chromosome or BCR-ABL gene AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I/A, F317L/V/I/C, and V299L. For acute lymphoblastic leukemia (ALL), the patient has a diagnosis of one of the following: 1) Philadelphia chromosome positive ALL, including patients who have received a hematopoietic stem cell transplant: Diagnosis that has been confirmed by detection of the Ph chromosome or BCR-ABL gene AND if patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I/A, F317L/V/I/C, and V299L OR 2) Ph-like B-ALL with ABL-class kinase fusion OR 3) Relapsed or refractory T-cell ALL with ABL-class translocation. For gastrointestinal stromal tumor (GIST): 1) Patient meets all of the following: A) Disease is residual, unresectable, recurrent/progressive, or metastatic/tumor rupture, B) Patient has received prior therapy with avapritinib AND C) Patient is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutations. For cutaneous melanoma: 1) Disease is metastatic or unresectable, 2) Disease is positive for c-KIT activating mutations AND 3) Requested drug will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage Duration	Plan Year
Other Criteria	N/A

STELARA

Products Affected

• Stelara

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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) patient meets any of the following: a) 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) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

STIMUFEND

Products Affected

• Stimufend

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

STIVARGA

Products Affected

• Stivarga

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Osteosarcoma, glioblastoma, angiosarcoma, retroperitoneal/intra- abdominal soft tissue sarcoma, rhabdomyosarcoma, soft tissue sarcomas of the extremities, body wall, head and neck, appendiceal adenocarcinoma
Exclusion Criteria	N/A
Required Medical Information	For colorectal cancer: 1) The disease is advanced or metastatic, AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Lonsurf (trifluridine/tipiracil).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

STRENSIQ

Products Affected

• Strensiq

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SUBLOCADE

Products Affected

• Sublocade

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SUNOSI

Products Affected

• Sunosi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SUSVIMO

Products Affected

• Susvimo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SUTENT

Products Affected

• Sunitinib Malate

• Sutent

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Thyroid carcinoma (follicular, medullary, papillary, and oncocytic), soft tissue sarcoma (angiosarcoma, solitary fibrous tumor, and alveolar soft part sarcoma subtypes), recurrent chordoma, thymic carcinoma, lymphoid and/or myeloid neoplasms with eosinophilia and FLT3 rearrangement in chronic or blast phase, pheochromocytoma, paraganglioma, well differentiated grade 3 neuroendocrine tumors
Exclusion Criteria	N/A
Required Medical Information	For renal cell carcinoma (RCC): 1) The disease is relapsed, advanced, or stage IV OR 2) the requested drug is being used as adjuvant treatment for patients that are at high risk of recurrent RCC following nephrectomy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

SYFOVRE

Products Affected

• Syfovre

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SYLVANT

Products Affected

• Sylvant

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

SYMDEKO

Products Affected

• Symdeko

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For cystic fibrosis: The requested medication will not be used in combination with other medications containing ivacaftor.
Age Restrictions	6 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

SYMLIN

Products Affected

• Symlinpen 120

• Symlinpen 60

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

SYMPAZAN

Products Affected

• Sympazan

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Seizures associated with Dravet syndrome
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Seizures associated with Lennox-Gastaut syndrome (LGS): 2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TABRECTA

Products Affected

• Tabrecta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent non-small cell lung cancer (NSCLC), NSCLC with high-level mesenchymal-epithelial transition (MET) amplification, central nervous system (CNS) brain metastases from MET exon-14 mutated NSCLC
Exclusion Criteria	N/A
Required Medical Information	For recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC): Tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TADALAFIL (BPH)

Products Affected

• Tadalafil TABS 5MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Erectile Dysfunction.
Required Medical Information	For benign prostatic hyperplasia (BPH): the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to both of the following: 1) alpha blocker, 2) 5-alpha reductase inhibitor (5-ARI).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	26 weeks
Other Criteria	N/A

TADALAFIL (PAH)

Products Affected

- Adcirca
- Alyq

- Tadalafil TABS 20MG
- Tadliq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TAFINLAR

Products Affected

• Tafinlar

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Langerhans cell histiocytosis, Erdheim-Chester disease.
Exclusion Criteria	N/A
Required Medical Information	For melanoma: 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used as a single agent or in combination with trametinib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For non-small cell lung cancer: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used as a single agent or in combination with trametinib. For papillary, follicular, and oncocytic thyroid carcinoma: 1) The tumor is BRAF V600E-positive, AND 2) The disease is not amenable to radioactive iodine (RAI) therapy, AND 3) the requested drug will be used in combination with trametinib. For Langerhans Cell Histiocytosis and Erdheim-Chester Disease: The disease is positive for a BRAF V600E mutation. For solid tumors: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used in combination with trametinib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TAGRISSO

Products Affected

• Tagrisso

PA Criteria	Criteria Details
ra Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Sensitizing epidermal growth factor receptor (EGFR) mutation-positive recurrent non-small cell lung cancer (NSCLC), brain metastases from sensitizing EGFR mutation-positive NSCLC, leptomeningeal metastases from EGFR mutation-positive NSCLC
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC), the requested drug is used in any of the following settings: 1) The patient meets both of the following: a) patient has metastatic, advanced, or recurrent NSCLC (including brain and/or leptomeningeal metastases from NSCLC) and b) patient has a sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease, OR 2) The patient meets both of the following: a) request is for adjuvant treatment of NSCLC following tumor resection and b) patient has EGFR mutation-positive disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TAKHZYRO

Products Affected

• Takhzyro

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TALTZ

Products Affected

• Taltz

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TALVEY

Products Affected

• Talvey

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TALZENNA

Products Affected

• Talzenna

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent germline breast cancer susceptibility gene (BRCA)-mutated breast cancer
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TARGRETIN TOPICAL

Products Affected

• Bexarotene GEL

• Targretin GEL

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Mycosis fungoides (MF)/Sezary syndrome (SS), chronic or smoldering adult T-cell leukemia/lymphoma (ATLL), primary cutaneous marginal zone lymphoma, primary cutaneous follicle center lymphoma
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TARPEYO

Products Affected

• Tarpeyo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TASCENSO

Products Affected

• Tascenso Odt

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TASIGNA

Products Affected

• Tasigna

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL), gastrointestinal stromal tumor (GIST), myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase, pigmented villonodular synovitis/tenosynovial giant cell tumor, cutaneous melanoma.
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML), including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor for CML, patient is negative for T315I, Y253H, E255K/V, and F359V/C/I mutations. For acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If the patient has experienced resistance to an alternative tyrosine kinase inhibitor for ALL, patient is negative for T315I, Y253H, E255K/V, F359V/C/I and G250E mutations. For gastrointestinal stromal tumor (GIST): 1) Disease is residual, unresectable, recurrent/progressive, or metastatic/tumor rupture, AND 2) Disease has progressed on at least 2 Food and Drug Administration (FDA)-approved therapies (e.g. imatinib, sunitinib, regorafenib, ripretinib). For cutaneous melanoma: 1) Disease is metastatic or unresectable, AND 2) Disease is positive for c-KIT activating mutations, AND 3) Requested drug will be used as subsequent therapy, AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year

Other Criteria	N/Δ
Other Criteria	N/A

TAVALISSE

Products Affected

• Tavalisse

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TAVNEOS

Products Affected

• Tavneos

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For continuation of treatment for severe anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: the patient has experienced benefit from therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TAZAROTENE

Products Affected

• Tazarotene CREA 0.1%

- Tazarotene GEL
- Tazorac

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For plaque psoriasis, the patient meets the following criteria: 1) the patient has less than or equal to 20 percent of affected body surface area (BSA), AND 2) the patient experienced an inadequate treatment response or intolerance to at least one topical corticosteroid OR has a contraindication that would prohibit a trial of topical corticosteroids.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TAZVERIK

Products Affected

• Tazverik

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Epithelioid sarcoma: 16 years of age or older, Follicular lymphoma: 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TECENTRIQ

Products Affected

• Tecentriq

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TECVAYLI

Products Affected

• Tecvayli

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TEGSEDI

Products Affected

• Tegsedi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TEMAZEPAM 30MG - 65

Products Affected

• Restoril CAPS 30MG

• Temazepam CAPS 30MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For short-term treatment of insomnia: 1) The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older.

TEPEZZA

Products Affected

• Tepezza

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

Терметко

Products Affected

• Tepmetko

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent non-small cell lung cancer (NSCLC), NSCLC with high level mesenchymal-epithelial transition (MET) amplification, central nervous system (CNS) cancer including brain metastases and leptomeningeal metastases from MET exon-14 mutated NSCLC
Exclusion Criteria	N/A
Required Medical Information	For recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC): Tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TERIFLUNOMIDE AET

Products Affected

• Aubagio

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TESTOPEL

Products Affected

• Testopel

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TESTOSTERONE AET

Products Affected

- Androderm PT24 2MG/24HR
- Androgel Pump GEL 1.62%
- Natesto

- Testim
- Vogelxo
- Vogelxo Pump

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TESTOSTERONE CYPIONATE INJ

Products Affected

• Depo-testosterone INJ 100MG/ML, 200MG/ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Gender Dysphoria
Exclusion Criteria	N/A
Required Medical Information	For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For gender dysphoria: The patient is able to make an informed decision to engage in hormone therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TESTOSTERONE ENANTHATE INJ

Products Affected

• Testosterone Enanthate INJ

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Gender Dysphoria
Exclusion Criteria	N/A
Required Medical Information	For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For gender dysphoria: The patient is able to make an informed decision to engage in hormone therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TETRABENAZINE

Products Affected

• Tetrabenazine

• Xenazine

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Tic disorders, tardive dyskinesia, hemiballismus, chorea not associated with Huntington's disease.
Exclusion Criteria	N/A
Required Medical Information	For treatment of tardive dyskinesia and treatment of chorea associated with Huntington's disease: The patient has experienced an inadequate treatment response or intolerable adverse event to deutetrabenazine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TETRACYCLINE TAB

Products Affected

• Tetracycline Hydrochlorid

• Tetracycline Hydrochloride TABS

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TEZSPIRE

Products Affected

• Tezspire

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

THALOMID

Products Affected

• Thalomid

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Myelofibrosis-associated anemia, acquired immunodeficiency syndrome (AIDS)-related aphthous stomatitis, Kaposi sarcoma, multicentric Castleman's disease, Rosai-Dorfman disease, Langerhans cell histiocytosis
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TIBSOVO

Products Affected

• Tibsovo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Conventional (grades 1-3) or dedifferentiated chondrosarcoma, central nervous system (CNS) cancers (astrocytoma, oligodendroglioma)
Exclusion Criteria	N/A
Required Medical Information	Patient has disease with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation. For acute myeloid leukemia (AML): 1) patient has newly-diagnosed AML and meets one of the following: a) 75 years of age or older, b) patient has comorbidities that preclude use of intensive induction chemotherapy, OR 2) the requested drug will be used as post-induction therapy following response to induction therapy with the requested drug, OR 3) patient has relapsed or refractory AML. For locally advanced, unresectable, resected gross residual, or metastatic cholangiocarcinoma: the requested drug will be used as subsequent treatment for progression on or after systemic treatment. For CNS cancers: 1) disease is recurrent or progressive, AND 2) patient has oligodendroglioma or astrocytoma.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TIVDAK

Products Affected

• Tivdak

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TLANDO

Products Affected

• Tlando

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TOBI INHALER

Products Affected

• Tobi Podhaler

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Non-cystic fibrosis bronchiectasis
Exclusion Criteria	N/A
Required Medical Information	For cystic fibrosis and non-cystic fibrosis bronchiectasis: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) The patient has a history of Pseudomonas aeruginosa infection or colonization in the airways.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TOBRAMYCIN

Products Affected

- Bethkis
- Kitabis Pak

- Tobi
- Tobramycin NEBU

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Non-cystic fibrosis bronchiectasis
Exclusion Criteria	N/A
Required Medical Information	For cystic fibrosis and non-cystic fibrosis bronchiectasis: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) The patient has a history of Pseudomonas aeruginosa infection or colonization in the airways.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.

TOFIDENCE

Products Affected

• Tofidence

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TOLAK

Products Affected

• Tolak

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TOLSURA

Products Affected

• Tolsura

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TOPICAL DOXEPIN

Products Affected

• Doxepin Hydrochloride CREA

- Prudoxin
- Zonalon

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a topical corticosteroid or a topical calcineurin inhibitor.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A

TOPICAL LIDOCAINE

Products Affected

- Dermacinrx Lidogel
- Glydo
- Lidocaine OINT 5%
- Lidocaine Hcl PRSY

- Lidocaine Hydrochloride EXTERNAL SOLN
- Lidorex
- Pliaglis CREA

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) The requested drug is being used for topical anesthesia, AND 2) If the requested drug will be used as part of a compounded product, then all the active ingredients in the compounded product are Food and Drug Administration (FDA) approved for topical use.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.

TOPICAL TRETINOIN

Products Affected

- Altreno
- Atralin
- Clindamycin Phosphate/tretinoin
- Retin-a CREA
- Retin-a GEL
- Retin-a Micro
- Retin-a Micro Pump

- Tretinoin CREA
- Tretinoin GEL
- Tretinoin Microsphere
- Tretinoin Microsphere Pump
- Twyneo
- Veltin
- Ziana

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

TOREMIFENE

Products Affected

• Fareston

• Toremifene Citrate

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Congenital/acquired QT prolongation (long QT syndrome), uncorrected hypokalemia, or uncorrected hypomagnesemia.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TRAMADOL ORAL SOLUTION

Products Affected

• Qdolo

• Tramadol Hydrochloride SOLN

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TRAZIMERA

Products Affected

• Trazimera

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TRELSTAR

Products Affected

• Trelstar Mixject

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TREMFYA

Products Affected

• Tremfya INJ 100MG/ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For moderate to severe plaque psoriasis (new starts): 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) patient meets any of the following: a) 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) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TREPROSTINIL INJ

Products Affected

• Remodulin

• Treprostinil

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TRIENTINE

Products Affected

• Syprine

• Trientine Hydrochloride

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

TRIKAFTA

Products Affected

• Trikafta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For cystic fibrosis: The requested medication will not be used in combination with other medications containing ivacaftor.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TRINTELLIX

Products Affected

• Trintellix

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For major depressive disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to ONE of the following generic products: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TRIPTODUR

Products Affected

• Triptodur

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TRODELVY

Products Affected

• Trodelvy

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TROKENDI XR

Products Affected

• Trokendi Xr

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TRULICITY

Products Affected

• Trulicity

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	For glycemic control in type 2 diabetes mellitus:10 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TRUQAP

Products Affected

• Truqap

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

TRUXIMA

Products Affected

• Truxima

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TUKYSA

Products Affected

• Tukysa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer
Exclusion Criteria	N/A
Required Medical Information	For colorectal cancer (including appendiceal adenocarcinoma): 1) the patient has advanced, unresectable, or metastatic disease, AND 2) the patient has human epidermal growth factor receptor 2 (HER2)-positive disease, AND 3) the patient has RAS wild-type disease, AND 4) the requested drug will be used in combination with trastuzumab, AND 5) the patient has not previously been treated with a HER2 inhibitor.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TURALIO

Products Affected

• Turalio CAPS 125MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai-Dorfman disease
Exclusion Criteria	N/A
Required Medical Information	For Langerhans cell histiocytosis: 1) disease has colony stimulating factor 1 receptor (CSF1R) mutation. For Erdheim-Chester disease and Rosai-Dorfman disease: 1) disease has CSF1R mutation AND patient has any of the following: a) symptomatic disease OR b) relapsed/refractory disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

TYENNE

Products Affected

• Tyenne

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TYMLOS

Products Affected

• Tymlos

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TYSABRI

Products Affected

• Tysabri

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TYVASO

Products Affected

• Tyvaso

- Tyvaso Refill KitTyvaso Starter Kit

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TYVASO DPI

Products Affected

• Tyvaso Dpi Maintenance Kit

• Tyvaso Dpi Titration Kit

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

TZIELD

Products Affected

• Tzield

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

UBRELVY

Products Affected

• Ubrelvy

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For acute treatment of migraine: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to at least one triptan 5-HT1 receptor agonist.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ULTOMIRIS

Products Affected

• Ultomiris INJ 1100MG/11ML, 300MG/3ML

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

UPLIZNA

Products Affected

• Uplizna

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

UPTRAVI

Products Affected

• Uptravi

• Uptravi Titration Pack

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

UZEDY

Products Affected

• Uzedy

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VABOMERE

Products Affected

• Vabomere

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VABYSMO

Products Affected

• Vabysmo SOLN

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VALCHLOR

Products Affected

• Valchlor

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Chronic or smoldering adult T-cell leukemia/lymphoma (ATLL), Stage 2 or higher mycosis fungoides (MF)/Sezary syndrome (SS), primary cutaneous marginal zone lymphoma, primary cutaneous follicle center lymphoma, CD30-positive lymphomatoid papulosis (LyP), unifocal Langerhans cell histiocytosis (LCH) with isolated skin disease
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

VALTOCO

Products Affected

- Valtoco 10 Mg Dose
- Valtoco 15 Mg Dose

- Valtoco 20 Mg Dose
- Valtoco 5 Mg Dose

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	6 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

VANFLYTA

Products Affected

• Vanflyta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Relapsed or refractory acute myeloid leukemia
Exclusion Criteria	N/A
Required Medical Information	For acute myeloid leukemia (AML): AML is FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (ITD)-positive.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

VECAMYL

Products Affected

• Vecamyl

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VECTIBIX

Products Affected

• Vectibix INJ 100MG/5ML, 400MG/20ML

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VEGZELMA

Products Affected

• Vegzelma

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VEKLURY

Products Affected

• Veklury INJ 100MG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VELCADE

Products Affected

• Bortezomib INJ 1MG, 2.5MG, 3.5MG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

• Velcade

VELSIPITY

Products Affected

• Velsipity

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

VENCLEXTA

Products Affected

• Venclexta

• Venclexta Starting Pack

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Mantle cell lymphoma, blastic plasmacytoid dendritic cell neoplasm (BPDCN), multiple myeloma, relapsed or refractory acute myeloid leukemia (AML), Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, relapsed or refractory systemic light chain amyloidosis with translocation t(11:14), accelerated or blast phase myeloproliferative neoplasms, B-cell acute lymphoblastic leukemia/T-cell acute lymphoblastic leukemia (B-ALL/T-ALL), hairy cell leukemia
Exclusion Criteria	N/A
Required Medical Information	For acute myeloid leukemia (AML): 1) patient has newly-diagnosed AML and meets one of the following: a) 75 years of age or older, b) patient has comorbidities that preclude use of intensive induction chemotherapy, OR 2) patient has poor/adverse risk disease and is a candidate for intensive induction therapy, OR 3) patient has relapsed or refractory AML. For blastic plasmacytoid dendritic cell neoplasm (BPDCN): 1) patient has systemic disease being treated with palliative intent, OR 2) patient has relapsed or refractory disease. For multiple myeloma: 1) the disease is relapsed or progressive, AND 2) the requested drug will be used in combination with dexamethasone, AND 3) patient has t(11:14) translocation. For Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma: 1) patient has previously treated disease that did not respond to primary therapy, OR 2) patient has progressive or relapsed disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

VENTAVIS

Products Affected

• Ventavis

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VEOPOZ

Products Affected

• Veopoz

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VEOZAH

Products Affected

• Veozah

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

VERKAZIA

Products Affected

• Verkazia

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VERSACLOZ

Products Affected

• Versacloz

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the treatment of a severely ill patient with schizophrenia who failed to respond adequately to standard antipsychotic treatment (i.e., treatment-resistant schizophrenia): 1) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Rexulti, Secuado, Vraylar.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

VERZENIO

Products Affected

• Verzenio

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer in combination with fulvestrant or an aromatase inhibitor, or as a single agent if progression on prior endocrine therapy and prior chemotherapy in the metastatic setting. Endometrial cancer, in combination with letrozole for estrogen receptor positive tumor.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

VEVYE

Products Affected

• Vevye

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VIBATIV AET

Products Affected

• Vibativ INJ 750MG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VIBERZI

Products Affected

• Viberzi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VICTOZA AET

Products Affected

• Liraglutide

• Victoza

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VIGABATRIN

Products Affected

- Sabril
- Vigabatrin

- VigadroneVigpoder

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For complex partial seizures (i.e., focal impaired awareness seizures): patient has experienced an inadequate treatment response to at least two antiepileptic drugs for complex partial seizures (i.e., focal impaired awareness seizures).
Age Restrictions	Infantile Spasms: 1 month to 2 years of age. Complex partial seizures (i.e., focal impaired awareness seizures): 2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

VIGAFYDE

Products Affected

• Vigafyde

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VIJOICE

Products Affected

• Vijoice

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VILTEPSO

Products Affected

• Viltepso

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VIMIZIM

Products Affected

• Vimizim

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VITRAKVI

Products Affected

• Vitrakvi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Non-metastatic neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, first-line treatment of NTRK gene fusion-positive solid tumors.
Exclusion Criteria	N/A
Required Medical Information	For all neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, the disease is without a known acquired resistance mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

VIVJOA

Products Affected

• Vivjoa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VIZIMPRO

Products Affected

• Vizimpro

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent non-small cell lung cancer (NSCLC)
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced, or metastatic, and 2) the patient has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

Vonjo

Products Affected

• Vonjo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Accelerated or blast phase myeloproliferative neoplasms
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

VORICONAZOLE

Products Affected

- Vfend SUSR
- Vfend IV

- Voriconazole INJ
- Voriconazole SUSR

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The patient will use the requested drug orally or intravenously.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

Vosevi

Products Affected

• Vosevi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh class B or C)
Required Medical Information	For hepatitis C: Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Criteria will be applied consistent with current AASLD-IDSA guidance.
Other Criteria	N/A

VOTRIENT

Products Affected

• Votrient

• Pazopanib Hydrochloride

PA Criteria	Criteria Details
TA CITICITA	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Thyroid carcinoma (follicular, papillary, oncocytic, or medullary), uterine sarcoma, chondrosarcoma, gastrointestinal stromal tumor
Exclusion Criteria	N/A
Required Medical Information	For renal cell carcinoma: 1) the disease is advanced, relapsed, or stage IV, OR 2) the requested drug will be used for von Hippel-Lindau (VHL)-associated renal cell carcinoma. For gastrointestinal stromal tumor (GIST): 1) the disease is residual, unresectable, recurrent, or metastatic/tumor rupture AND 2) the patient meets one of the following: a) the disease has progressed after at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib), b) the disease is succinate dehydrogenase (SDH)-deficient GIST. For soft tissue sarcoma (STS): the patient does not have an adipocytic soft tissue sarcoma.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

Vowst

Products Affected

• Vowst

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the prevention of recurrence of Clostridioides difficile infection (CDI): 1) The diagnosis of CDI has been confirmed by a positive stool test for C. difficile toxin, AND 2) The requested drug will be administered at least 48 hours after the last dose of antibiotics used for the treatment of recurrent CDI.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A

Voxzogo

Products Affected

• Voxzogo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VOYDEYA

Products Affected

• Voydeya

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VPRIV

Products Affected

• Vpriv

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VTAMA

Products Affected

• Vtama

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VUITY

Products Affected

• Vuity

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VUMERITY

Products Affected

• Vumerity

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VYEPTI

Products Affected

• Vyepti

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VYJUVEK

Products Affected

• Vyjuvek

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VYNDAMAX

Products Affected

• Vyndamax

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VYNDAQEL

Products Affected

• Vyndaqel

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VYONDYS 53

Products Affected

• Vyondys 53

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VYVGART

Products Affected

• Vyvgart

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

Vyvgart Hytrulo

Products Affected

• Vyvgart Hytrulo

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

VYXEOS

Products Affected

• Vyxeos

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

WAINUA

Products Affected

• Wainua

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

WAKIX

Products Affected

• Wakix

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

WELIREG

Products Affected

• Welireg

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

WINLEVI

Products Affected

• Winlevi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

WINREVAIR

Products Affected

• Winrevair

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

XALKORI

Products Affected

• Xalkori

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent non-small cell lung cancer (NSCLC), NSCLC with high-level MET amplification or MET exon 14 skipping mutation, symptomatic or relapsed/refractory anaplastic lymphoma kinase (ALK)-fusion positive Erdheim-Chester Disease, symptomatic or relapsed/refractory (ALK)-fusion positive Rosai-Dorfman Disease, (ALK)-fusion positive Langerhans Cell Histiocytosis, metastatic or unresectable ROS1 gene fusion positive cutaneous melanoma.
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC), the requested drug is used in any of the following settings: 1) the patient has recurrent, advanced or metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following products: Alecensa (alectinib) or Alunbrig (brigatinib), OR 3) the patient has recurrent, advanced or metastatic ROS-1 positive NSCLC, OR 4) the patient has NSCLC with high-level MET amplification or MET exon 14 skipping mutation. For inflammatory myofibroblastic tumor (IMT), the disease is ALK-positive. For anaplastic large cell lymphoma (ALCL): 1) the disease is relapsed or refractory, AND 2) the disease is ALK-positive.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

XDEMVY

Products Affected

• Xdemvy

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

XELJANZ

Products Affected

• Xeljanz

• Xeljanz Xr

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

XEMBIFY

Products Affected

• Xembify

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

XENPOZYME

Products Affected

• Xenpozyme

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

XEOMIN

Products Affected

• Xeomin

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

XERMELO

Products Affected

• Xermelo

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

XGEVA

Products Affected

• Xgeva

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For hypercalcemia of malignancy: condition is refractory to intravenous (IV) bisphosphonate therapy or there is a clinical reason to avoid IV bisphosphonate therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.

XHANCE

Products Affected

• Xhance

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

XIAFLEX

Products Affected

• Xiaflex

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

XIFAXAN

Products Affected

• Xifaxan TABS 550MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Small intestinal bacterial overgrowth syndrome (SIBO)
Exclusion Criteria	N/A
Required Medical Information	For irritable bowel syndrome with diarrhea (IBS-D): 1) The patient has not previously received treatment with the requested drug, OR 2) The patient has previously received treatment with the requested drug, AND a) the patient is experiencing a recurrence of symptoms, AND b) the patient has not already received an initial 14-day course of treatment and two additional 14-day courses of treatment with the requested drug. For small intestinal bacterial overgrowth (SIBO): 1) the patient is experiencing a recurrence after completing a successful course of treatment with the requested drug OR 2) diagnosis has been confirmed by one of the following: a) quantitative culture of upper gut aspirate, b) breath testing (e.g., lactulose hydrogen or glucose hydrogen breath test).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Reduction in risk of overt HE recurrence: 6 months, IBS-D and SIBO: 14 days
Other Criteria	N/A

XIFAXAN200

Products Affected

• Xifaxan TABS 200MG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

XIPERE

Products Affected

• Xipere

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

XOLAIR

Products Affected

• Xolair

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For moderate to severe persistent asthma, initial therapy (tx): 1) Patient (pt) has a positive skin test (or blood test) to at least one perennial aeroallergen, 2) Pt has baseline immunoglobulin E (IgE) level greater than or equal to 30 international units per milliliter (IU/mL), AND 3) Pt has inadequate asthma control despite current tx with both of the following medications: a) Medium-to-high-dose inhaled corticosteroid, AND b) Additional controller (i.e., long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless pt has an intolerance or contraindication to such therapies. For moderate to severe persistent asthma, continuation of tx (COT): Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms (sx) and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. For chronic spontaneous urticaria (CSU), initial tx: 1) Pt has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1 (IL-1)-associated urticarial syndromes (e.g., auto-inflammatory disorders, urticarial vasculitis), 2) Pt has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks, AND 3) Pt remains symptomatic despite H1 antihistamine treatment. For CSU, COT: Pt has experienced a benefit (e.g., improved sx) since initiation of tx. For chronic rhinosinusitis with nasal polyps (CRSwNP): 1) The requested drug is used as add-on maintenance treatment, AND 2) Pt has experienced inadequate treatment response to Xhance (fluticasone). For IgE-mediated food allergy, initial tx: Pt has baseline IgE level greater than or equal to 30 IU/mL. For IgE-mediated food allergy, COT: Pt has experienced a benefit as evidenced by a decrease in hypersensitivity (e.g., moderate to severe skin, respiratory or gastrointestinal sx) to food allergen.
Age Restrictions	CSU: 12 years of age or older. Asthma: 6 years of age or older. CRSwNP: 18 years of age or older. IgE-mediated food allergy: 1 year of age or older

Prescriber Restrictions	N/A
Coverage Duration	CSU initial: 6 months, All others: Plan Year
Other Criteria	N/A

XOLREMDI

Products Affected

• Xolremdi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

XOSPATA

Products Affected

• Xospata

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement
Exclusion Criteria	N/A
Required Medical Information	For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FMS-like tyrosine kinase 3 (FLT3) rearrangement: the disease is in chronic or blast phase.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

XPHOZAH

Products Affected

• Xphozah

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

XPOVIO

Products Affected

• Xpovio

- Xpovio 60 Mg Twice Weekly Xpovio 80 Mg Twice Weekly

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma, Human Immunodeficiency Virus (HIV)-related B-cell lymphoma, high-grade B-cell lymphoma, post-transplant lymphoproliferative disorders
Exclusion Criteria	N/A
Required Medical Information	For multiple myeloma: Patient must have been treated with at least one prior therapy. For B-cell lymphomas: Patient must have been treated with at least two lines of systemic therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

XTANDI

Products Affected

• Xtandi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the treatment of castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer: The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

XURIDEN

Products Affected

• Xuriden

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

XYOSTED AET

Products Affected

• Xyosted

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

XYREM

Products Affected

• Sodium Oxybate

• Xyrem

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the treatment of excessive daytime sleepiness in a patient with narcolepsy, initial request: 1) The diagnosis has been confirmed by sleep lab evaluation, AND 2) The patient meets one of the following criteria: a) if the patient is 17 years of age or younger, the patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate), OR has a contraindication that would prohibit a trial of central nervous system (CNS) stimulant drugs (e.g., amphetamine, dextroamphetamine, methylphenidate), b) If the patient is 18 years of age or older, the patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) wakefulness promoting drug (e.g., armodafinil, modafinil), OR has a contraindication that would prohibit a trial of central nervous system (CNS) wakefulness promoting drugs (e.g., armodafinil, modafinil). For the treatment of cataplexy in a patient with narcolepsy, initial request: The diagnosis has been confirmed by sleep lab evaluation. If the request is for a continuation of therapy, then the patient experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy.
Age Restrictions	7 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a sleep disorder specialist or neurologist
Coverage Duration	Plan Year
Other Criteria	N/A

XYWAV

Products Affected

• Xywav

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

YCANTH

Products Affected

• Ycanth

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

YERVOY

Products Affected

• Yervoy

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

YONDELIS

Products Affected

• Yondelis

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

YONSA

Products Affected

• Yonsa

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

YUPELRI AET

Products Affected

• Yupelri

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZALTRAP

Products Affected

• Zaltrap

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZARXIO

Products Affected

• Zarxio

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Neutropenia in myelodysplastic syndromes (MDS), agranulocytosis, neutropenia in aplastic anemia, human immunodeficiency virus (HIV)-related neutropenia, hematopoietic syndrome of acute radiation syndrome
Exclusion Criteria	N/A
Required Medical Information	If receiving chemotherapy, the requested drug will be administered at least 24 hours after chemotherapy. For prophylaxis or treatment of myelosuppressive chemotherapy-induced febrile neutropenia (FN) patient must meet both of the following: 1) Patient has a solid tumor or non-myeloid cancer, AND 2) Patient has received, is currently receiving, or will be receiving treatment with myelosuppressive anti-cancer therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

ZAVZPRET

Products Affected

• Zavzpret

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZEGERID CAPSULE AET

Products Affected

• Zegerid CAPS

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZEGERID SUSPENSION AET

Products Affected

• Zegerid PACK

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZEJULA

Products Affected

• Zejula TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Uterine leiomyosarcoma
Exclusion Criteria	N/A
Required Medical Information	For uterine leiomyosarcoma: 1) the requested drug is used as second-line therapy AND 2) the patient has BRCA-altered disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ZELBORAF

Products Affected

• Zelboraf

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Non-small cell lung cancer, hairy cell leukemia, central nervous system cancer (i.e., glioma, glioblastoma, pediatric diffuse high-grade glioma), adjuvant systemic therapy for cutaneous melanoma, Langerhans cell histiocytosis.
Exclusion Criteria	N/A
Required Medical Information	For central nervous system (CNS) cancer (i.e., glioma, astrocytoma, glioblastoma, pediatric diffuse high-grade glioma): 1) The tumor is positive for BRAF V600E mutation, AND 2) The requested drug will be used in combination with cobimetinib OR the requested drug is being used for the treatment of pediatric diffuse high-grade glioma. For melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) the requested drug will be used as a single agent, or in combination with cobimetinib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, or b) adjuvant systemic therapy. For Erdheim-Chester Disease and Langerhans Cell Histiocytosis: Tumor is positive for BRAF V600 mutation. For non-small cell lung cancer: 1) The tumor is positive for the BRAF V600E mutation, AND 2) The patient has recurrent, advanced, or metastatic disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ZEMDRI

Products Affected

• Zemdri

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZEPATIER AET

Products Affected

• Zepatier

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZEPOSIA

Products Affected

• Zeposia

- Zeposia 7-day Starter Pack
- Zeposia Starter Kit

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZEPZELCA

Products Affected

• Zepzelca

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZILBRYSQ

Products Affected

• Zilbrysq

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZINPLAVA

Products Affected

• Zinplava

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZIRABEV

Products Affected

• Zirabev

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZOKINVY

Products Affected

• Zokinvy

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZOLINZA

Products Affected

• Zolinza

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Mycosis fungoides (MF)/Sezary syndrome (SS)
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ZOLPIDEM

Products Affected

• Zolpidem Tartrate CAPS

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZONISADE

Products Affected

• Zonisade

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For adjunctive treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom, Xcopri, Spritam OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules).
Age Restrictions	16 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

ZORYVE 0.3% CRM

Products Affected

• Zoryve CREA 0.3%

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZORYVE FOAM

Products Affected

• Zoryve FOAM

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZTALMY

Products Affected

• Ztalmy

PA Criteria	Criteria Details		
Indications	All FDA-approved Indications.		
Off-Label Uses	N/A		
Exclusion Criteria	N/A		
Required Medical Information	N/A		
Age Restrictions	2 years of age or older		
Prescriber Restrictions	N/A		
Coverage Duration	Plan Year		
Other Criteria	N/A		

ZTLIDO AET

Products Affected

• Ztlido

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZURZUVAE

Products Affected

• Zurzuvae

PA Criteria	Criteria Details			
Indications	All FDA-approved Indications.			
Off-Label Uses	N/A			
Exclusion Criteria	N/A			
Required Medical Information	For the treatment of postpartum depression (PPD): diagnosis was confirmed using standardized rating scales that reliably measure depressive symptoms (e.g., Hamilton Depression Rating Scale [HDRS], Edinburgh Postnatal Depression Scale [EPDS], Patient Health Questionnaire 9 [PHQ9], Montgomery-Asberg Depression Rating Scale [MADRS], Beck's Depression Inventory [BDI], etc.).			
Age Restrictions	N/A			
Prescriber Restrictions	N/A			
Coverage Duration	1 month			
Other Criteria	N/A			

ZYDELIG

Products Affected

• Zydelig

PA Criteria	Criteria Details	
Indications	All FDA-approved Indications, Some Medically accepted Indications.	
Off-Label Uses	Small lymphocytic lymphoma (SLL)	
Exclusion Criteria	N/A	
Required Medical Information	For chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL): the requested drug is used as second-line or subsequent therapy.	
Age Restrictions	N/A	
Prescriber Restrictions	N/A	
Coverage Duration	Plan Year	
Other Criteria	N/A	

ZYKADIA

Products Affected

• Zykadia TABS

PA Criteria	Criteria Details			
Indications	All FDA-approved Indications, Some Medically accepted Indications.			
Off-Label Uses	Recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), recurrent, advanced, or metastatic ROS1-positive NSCLC, Erdheim-Chester Disease (ECD) with ALK-fusion, inflammatory myofibroblastic tumor (IMT), brain metastases from NSCLC, relapsed or refractory ALK-positive anaplastic large cell lymphoma (ALCL)			
Exclusion Criteria	N/A			
Required Medical Information	For non-small cell lung cancer (NSCLC): 1) the patient has recurrent, advanced, or metastatic anaplastic lymphoma kinase (ALK)-positive AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following products: Alecensa (alectinib) or Alunbrig (brigatinib) OR 3) ROS1-positive disease. For inflammatory myofibroblastic tumor: the disease is ALK-positive. For brain metastases from NSCLC: the patient has ALK-positive NSCLC. For anaplastic large cell lymphoma (ALCL): the patient has relapsed or refractory ALK-positive disease.			
Age Restrictions	N/A			
Prescriber Restrictions	N/A			
Coverage Duration	Plan Year			
Other Criteria	N/A			

ZYMFENTRA AET

Products Affected

• Zymfentra 2-pen

• Zymfentra 2-syringe

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZYNLONTA

Products Affected

• Zynlonta

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZYNYZ

Products Affected

• Zynyz

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
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

ZYPREXA RELPREVV

Products Affected

• Zyprexa Relprevv

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Tolerability with oral olanzapine has been established.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

PART B VERSUS PART D

Products Affected

- Abelcet
- Acetylcysteine INHALATION SOLN
- Acyclovir Sodium INJ 50MG/ML
- Adriamycin INJ 50MG
- Akynzeo CAPS
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Ambisome
- Amphotericin B INJ
- Amphotericin B Liposome
- Anzemet TABS 50MG
- Aprepitant CAPS
- Astagraf XL
- Atgam
- Azasan
- Azathioprine INJ
- Azathioprine TABS
- Baclofen INJ 20000MCG/20ML, 40MG/20ML, 500MCG/ML, 50MCG/ML
- Bleomycin Sulfate INJ
- Budesonide SUSP
- Cellcept
- Cellcept Intravenous
- Cladribine
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%
- Clinimix 6/5
- Clinimix 8/10
- Clinimix 8/14

- Clinimix E 2.75%/dextrose 5% INJ 570MG/100ML; 316MG/100ML; 33MG/100ML; 5GM/100ML; 515MG/100ML; 132MG/100ML; 165MG/100ML; 201MG/100ML; 159MG/100ML; 51MG/100ML; 110MG/100ML; 454MG/100ML; 154MG/100ML; 261MG/100ML; 187MG/100ML; 138MG/100ML; 117MG/100ML; 112MG/100ML; 116MG/100ML; 116MG/100ML; 110MG/100ML; 11MG/100ML; 110MG/100ML; 11MG/100ML; 110MG/100ML; 110MG/100ML;
- Clinimix E 4.25%/dextrose 10%
- Clinimix E 4.25%/dextrose 5%
- Clinimix E 5%/dextrose 15%
- Clinimix E 5%/dextrose 20%
- Clinimix E 8/10
- Clinimix E 8/14
- Clinisol Sf 15%
- Clinolipid
- Cromolyn Sodium NEBU
- Cyclosporine CAPS
- Cyclosporine INJ
- Cyclosporine Modified
- Cytarabine INJ 100MG/ML
- Cytarabine Aqueous
- Deferoxamine Mesylate
- Depo-medrol
- Desferal INJ 500MG
- Dextrose 25% INJ 250MG/ML
- Dextrose 50%
- Dextrose 70%
- Dilaudid INJ 0.2MG/ML, 1MG/ML, 2MG/ML
- Dobutamine Hcl INJ 250MG/20ML
- Dobutamine Hcl/d5w INJ 5%; 1MG/ML
- Dobutamine Hydrochloride/dextrose 5%
- Dopamine Hydrochloride INJ
- Dopamine Hydrochloride/dextrose
- Dopamine/d5w INJ 5%; 3.2MG/ML

- Doxorubicin Hcl INJ 50MG
- Doxorubicin Hydrochloride INJ 10MG, 200MG/100ML
- Duopa
- Duramorph
- Emend CAPS 80MG
- Emend SUSR
- Emend Tripack
- Engerix-b
- Envarsus Xr
- Epoprostenol Sodium
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Fentanyl Citrate INJ 1000MCG/20ML, 100MCG/2ML, 2500MCG/50ML, 250MCG/5ML, 500MCG/10ML, 50MCG/ML
- Fiasp Pumpcart
- Flolan
- Fluorouracil INJ 1GM/20ML, 2.5GM/50ML, 500MG/10ML, 5GM/100ML
- Gablofen
- Gamastan
- Ganciclovir INJ 500MG, 500MG/10ML
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hydrochloride TABS
- Heplisav-b
- Humulin R U-500 (concentrated)
- Hydromorphone Hcl INJ 10MG/ML, 1MG/ML, 4MG/ML
- Hydromorphone Hydrochloride INJ 0.25MG/0.5ML, 1MG/ML, 2MG/ML, 4MG/ML, 50MG/5ML
- Imovax Rabies (h.d.c.v.)
- Imuran TABS
- Infumorph 200
- Infumorph 500
- Intralipid INJ 20GM/100ML, 30GM/100ML
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate

- Isolyte-s INJ 27MEQ/L; 98MEQ/L; 23MEQ/L; 3MEQ/L; 5MEQ/L; 140MEQ/L
- Isolyte-s Ph 7.4
- Jynneos
- Kabiven
- Khapzory INJ 175MG
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU
- Levalbuterol Hydrochloride NEBU 0.63MG/3ML
- Medrol TABS 16MG, 2MG, 4MG, 8MG
- Methylprednisolone TABS
- Methylprednisolone Acetate INJ 40MG/ML, 80MG/ML
- Methylprednisolone Sodium Succinate
- Methylprednisolone Sodiumsuccinate INJ 40MG
- Milrinone Lactate INJ 10MG/10ML, 20MG/20ML, 50MG/50ML
- Milrinone Lactate In Dextrose
- Mitigo
- Morphine Sulfate INJ 0.5MG/ML, 10MG/ML, 1MG/ML, 2MG/ML, 4MG/ML, 50MG/ML, 5MG/ML, 8MG/ML
- Morphine Sulfate/sodium Chloride INJ 1MG/ML
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil INJ
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Myfortic
- Myhibbin
- Nebupent
- Neoral
- Nulojix
- Nutrilipid
- Omegaven
- Ondansetron Hcl SOLN
- Ondansetron Hcl TABS 24MG
- Ondansetron Hydrochloride TABS

- Ondansetron Odt
- Orapred Odt
- Pediapred SOLN
- Pentamidine Isethionate INHALATION SOLR
- Perikabiven
- Plenamine INJ 147.4MEQ/L;
 2.17GM/100ML; 1.47GM/100ML;
 434MG/100ML; 749MG/100ML;
 1.04GM/100ML; 894MG/100ML;
 749MG/100ML; 1.04GM/100ML;
 1.18GM/100ML; 749MG/100ML;
 1.04GM/100ML; 894MG/100ML;
 592MG/100ML; 749MG/100ML;
 250MG/100ML; 39MG/100ML;
 960MG/100ML
- Prednisolone SOLN
- Prednisolone TABS
- Prednisolone Sodium Phosphate ORAL SOLN 10MG/5ML, 15MG/5ML, 20MG/5ML, 25MG/5ML, 5MG/5ML
- Prednisolone Sodium Phosphate Odt
- Prednisone SOLN
- Prednisone TABS 10MG, 1MG, 2.5MG, 20MG, 50MG, 5MG
- Prednisone Intensol
- Prehevbrio
- Premasol INJ 52MEQ/L;
 1760MG/100ML; 880MG/100ML;
 34MEQ/L; 1760MG/100ML;
 372MG/100ML; 406MG/100ML;
 526MG/100ML; 492MG/100ML;
 492MG/100ML; 526MG/100ML;
 356MG/100ML; 356MG/100ML;
 390MG/100ML; 34MG/100ML;
 152MG/100ML
- Prialt
- Prograf
- Prosol
- Pulmicort
- Rabavert
- Rapamune SOLN
- Rapamune TABS 1MG, 2MG
- Rayos

- Recombivax Hb
- Sandimmune CAPS 100MG, 25MG
- Sandimmune INJ
- Sandimmune SOLN
- Simulect
- Sirolimus SOLN
- Sirolimus TABS
- Smoflipid
- Solu-medrol INJ 1000MG, 125MG, 2GM, 40MG, 500MG
- Tacrolimus CAPS
- Thymoglobulin
- Tpn Electrolytes INJ 29.5MEQ/20ML;
 4.5MEQ/20ML; 35MEQ/20ML;
 5MEQ/20ML; 20MEQ/20ML;
 35MEQ/20ML
- Travasol INJ 52MEQ/L; 1760MG/100ML; 880MG/100ML; 34MEQ/L; 1760MG/100ML; 372MG/100ML; 406MG/100ML; 526MG/100ML; 492MG/100ML; 492MG/100ML; 526MG/100ML; 356MG/100ML; 500MG/100ML; 356MG/100ML; 390MG/100ML; 34MG/100ML; 152MG/100ML
- Trophamine INJ 0.54GM/100ML;
 1.2GM/100ML; 0.32GM/100ML; 0; 0;
 0.5GM/100ML; 0.36GM/100ML;
 0.48GM/100ML; 0.82GM/100ML;
 1.4GM/100ML; 1.2GM/100ML;
 0.34GM/100ML; 0.48GM/100ML;
 0.68GM/100ML; 0.38GM/100ML;
 5MEQ/L; 0.025GM/100ML;
 0.42GM/100ML; 0.2GM/100ML;
 0.24GM/100ML; 0.78GM/100ML
- Varubi TBPK
- Veletri
- Vinblastine Sulfate INJ 1MG/ML
- Vincristine Sulfate INJ 1MG/ML
- Zortress
- Zulresso

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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