Priority Health

2026 Priority Health Medicare Prior Authorization Criteria

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

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Y0056_NCMS500050402613N_C 09152025 H8379_NCMS500050402614O_C 09152025 2025 PH_35317-7.1 09/25

ACTHAR

Products Affected

- ACTHAR
- ACTHAR GEL

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ACTIMMUNE

Products Affected

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient's body surface area (BSA)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ADALIMUMAB-ADAZ

Products Affected

- *adalimumab-adaz subcutaneous solution auto-injector 40 mg/0.4ml, 80 mg/0.8ml* *40 mg/0.4ml*
- *adalimumab-adaz subcutaneous solution prefilled syringe 10 mg/0.1ml, 20 mg/0.2ml,*

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment. For approvals of shortened-interval dosing in Crohn's disease and ulcerative colitis, documentation of the following: (1) Two of the following: symptoms, imaging showing active disease, fecal calprotecin greater than 120, CRP greater than or equal to 300, and (2) inadequate drug trough levels, and (3) initial response to therapy.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ADEMPAS

Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	FOR PULMONARY ARTERIAL HYPERTENSION (PAH): Documentation that the patient has pulmonary arterial hypertension (WHO Group 1) confirmed by right heart catheterization must be provided. FOR CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH): Documentation that the patient has CTEPH (WHO Group 4) - and - CTEPH is classified as inoperable or as persistent/recurrent after pulmonary endarterectomy must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AIMOVIG

Products Affected

- AIMOVIG

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other CGRP antagonist therapy.
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 1 year. Reauth: 2 years. Dosing must align with FDA labeling.
Other Criteria	For migraine prevention reauthorization requests: Must provide documentation of a decrease in migraine days per month with use of Aimovig.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AKEEGA

Products Affected

- AKEEGA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ALECENSA

Products Affected

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ALUNBRIG

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ambrisentan

Products Affected

- *ambrisentan*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AMITRIPTYLINE

Products Affected

- *amitriptyline hcl oral*

PA Criteria	Criteria Details
Exclusion Criteria	The criteria only apply to patients 65 years and older.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Coverage requires the following: (1) Prescriber acknowledges that the benefit of therapy outweighs the potential risks for this patient, and (2) Prescriber has considered therapy changes if the patient is using more than one anticholinergic drug in combination. Note: Due to safety concerns, this medication is considered potentially inappropriate in older adults, and is best avoided, prescribed at lower dose, or used with caution.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AMVUTTRA

Products Affected

- AMVUTTRA

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with TTR stabilizers (e.g., tafamidis) or TTR-lowering agents (e.g. Onpattro).
Required Medical Information	INITIAL COVERAGE OF HATTR-PN: Medical records supporting the request must be provided and include all of the following: (1) Patient has a transthyretin (TTR) mutation (e.g., V30M) - AND - (2) Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb - AND - (3) Patient has clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.). INITIAL COVERAGE OF ATTR-CM: Documentation of the following is required: (1) Patient has had trial with failure or intolerance, or has a contraindication to tafamidis (Vyndaqel, Vyndamax) - AND (2) Patient has New York Heart Association (NYHA) class 1 , 2, or 3 heart failure with current clinical manifestations or prior hospitalization for HF - AND - (3) Patient has an echocardiogram (ECHO) or cardiac magnetic resonance (CMR) imaging demonstrating cardiac involvement (i.e., increased left ventricular wall thickness) - AND - (4) diagnosis confirmed by tissue biopsy, genetic testing, or radionuclide imaging (99mTc-PYP, 99mTc-DPD, or 99mTc-HMDP scan) - AND - (5) if the diagnosis was confirmed by radionuclide imaging, coverage also requires documentation of Grade 2 or 3 cardiac uptake.
Age Restrictions	Must be age 18 or older.
Prescriber Restrictions	
Coverage Duration	One year initial and reauthorization.

PA Criteria	Criteria Details
Other Criteria	Amvuttra will not be approved if the patient has primary (light-chain) amyloidosis. REAUTHORIZATION OF HATTR-PN: Documentation demonstrating a positive clinical response to Amvuttra compared to baseline must be provided (e.g., improved neuropathy symptoms, motor function, quality of life, slowing of disease progression). REAUTHORIZATION OF ATTR-CM: Documentation demonstrating a positive clinical response to Amvuttra compared to baseline must be provided (e.g., reduced cardiovascular-related hospitalizations, improved function, improved quality of life).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

aprepitant

Products Affected

- *aprepitant*

PA Criteria	Criteria Details
Exclusion Criteria	Aprepitant is not covered in the following situations: (1)treatment of established nausea and vomiting, and (2) for chronic continuous use.
Required Medical Information	For post-op nausea/vomiting: Provide date of surgery.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan year authorization with limit of one 30-day fill for post-op nausea/vomiting
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ARCALYST

Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For the treatment of recurrent pericarditis: Must have documentation supporting a trial and failure (defined as inadequate response) with an NSAID in combination with colchicine.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ARIKAYCE

Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial review, sputum culture supporting the diagnosis of Mycobacterium avium complex (MAC) lung disease must be submitted.
Age Restrictions	
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	Initial approval for 6 months. Reauthorization for 12 months.
Other Criteria	For initial review, documentation of failure to obtain negative sputum cultures after a minimum of 6 months of a multidrug background regimen therapy for MAC lung disease must be provided. For reauthorization, documentation of a negative sputum culture obtained within the last 30 days must be provided. Criteria will be applied consistent with current ATS/IDSA guidelines.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

aripiprazole odt

Products Affected

- *aripiprazole oral tablet dispersible*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ARIPIPRAZOLE ORAL SOLUTION

Products Affected

- *aripiprazole oral solution*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have tried and have a documented intolerance or contraindication to aripiprazole TABLET and either olanzapine ODT or risperidone ODT.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

armodafinil

Products Affected

- *armodafinil*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

asenapine

Products Affected

- *asenapine maleate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as an inadequate response) with two of the following generic drugs used for at least 28 days each: aripiprazole, olanzapine, quetiapine, risperidone, ziprasidone, or lurasidone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AUGTYRO

Products Affected

- AUGTYRO ORAL CAPSULE 160 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AUSTEDO

Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR
- AUSTEDO XR PATIENT TITRATION ORAL TABLET EXTENDED RELEASE THERAPY PACK 12 & 18 & 24 & 30 MG

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with tetrabenazine or Ingrezza.
Required Medical Information	TARDIVE DYSKINESIA (TD) INITIAL REQUESTS: (1) the patient is using Austedo for TD that is not associated with dopamine receptor blocking, OR (2) the patient is using Austedo for TD associated with the use of dopamine receptor blocking agents and symptoms have persisted despite stopping or reducing the dose of the dopamine blocking agent, OR (3) stopping or reducing the dose of the dopamine blocking agent is not possible.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 1 year. Reauth: 2 years.
Other Criteria	UNDER CMS REVIEW
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AUVELITY

Products Affected

- AUVELITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of prior therapies and responses to treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years. Dosing must follow the FDA-approved labeling.
Other Criteria	Must try and fail (defined as an inability to improve depressive symptoms after at least 4 weeks of treatment) with an SSRI or SNRI and 1 atypical antidepressant (e.g., bupropion, mirtazapine).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AVMAPKI-FAKZYNJA

Products Affected

- AVMAPKI FAKZYNJA CO-PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AVONEX

Products Affected

- AVONEX PEN INTRAMUSCULAR AUTO-INJECTOR KIT
- AVONEX PREFILLED INTRAMUSCULAR PREFILLED SYRINGE KIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AYVAKIT

Products Affected

- AYVAKIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BALVERSA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BENLYSTA

Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used with another biologic drug or Lupkynis.
Required Medical Information	For SLE initial requests: Must have a SELENA-SLEDAI score of 6 or more before starting Benlysta AND either an anti-dsDNA antibody greater than 30 IU/ml or ANA greater than 1:80. For LN initial requests: Must have a confirmed diagnosis of SLE AND a kidney biopsy confirming class 3, 4, and/or 5 disease.
Age Restrictions	
Prescriber Restrictions	Prescriber must be a specialist in treating the condition or have consulted with a specialist.
Coverage Duration	1 year initial. 2 years reauthorization.
Other Criteria	For SLE initial requests: Must be taking two of the following drugs together for at least 12 weeks each: a steroid, immunosuppressant, and/or hydroxychloroquine - AND - For SLE reauthorization: Must have evidence of clinical improvement with Benlysta. For lupus nephritis (LN) initial requests: Must be receiving standard therapy for LN (e.g., mycophenolate or azathioprine plus a steroid) - AND - For LN reauthorization: Must have evidence of clinical improvement with Benlysta, including improved or stable eGFR.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BESREMI

Products Affected

- BESREMI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years. Dosing must follow the FDA-approved labeling.
Other Criteria	Must trial and fail hydroxyurea (defined as an intolerance and/or persistence or recurrence of disease).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BETASERON

Products Affected

- BETASERON SUBCUTANEOUS KIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

bexarotene

Products Affected

- *bexarotene oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BEXAROTENE GEL

Products Affected

- *bexarotene external*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Must first try tazarotene.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

bosentan

Products Affected

- *bosentan oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BOSULIF

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BRAFTOVI

Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have documentation of BRAF V600 mutation status.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BRIVIACT

Products Affected

- BRIVIACT ORAL SOLUTION
- BRIVIACT ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as inadequate seizure control) with generic levetiracetam and at least 1 other generic anticonvulsant for the condition.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BRUKINSA

Products Affected

- BRUKINSA ORAL CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For CLL/SLL, marginal zone lymphoma, mantle cell lymphoma, and Waldenström Macroglobulinemia where NCCN Guidelines give the same category of recommendation: Your prescriber must provide rationale supporting why Calquence or Imbruvica cannot be used in place of Brukinsa.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CABOMETYX

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

calcipotriene/betamethasone suspension

Products Affected

- *calcipotriene-betameth diprop external suspension*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure with a generic topical steroid for the scalp (such as fluocinonide solution, clobetasol solution, clobetasol shampoo) in combination with generic calcipotriene solution. Failure is defined as an inadequate response in treating the condition.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CALQUENCE

Products Affected

- CALQUENCE ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CAPLYTA

Products Affected

- CAPLYTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	Must be age 18 or older.
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	For schizophrenia: Patient must have tried and failed (defined as taking the medication as prescribed without an adequate response or with intolerance) two of the following generic atypical antipsychotics: aripiprazole, ziprasidone, olanzapine, risperidone, quetiapine. For depressive episodes associated with bipolar 1 disorder: Patient must have tried and failed (defined above) one of the following generic products: quetiapine or olanzapine (with fluoxetine) - AND - Patient must have tried and failed (defined above) generic lurasidone. For depressive episodes associated with bipolar 2 disorder: Patient must have tried and failed (defined above) quetiapine.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CAPRELSA

Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CARGLUMIC ACID

Products Affected

- *carglumic acid oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CAYSTON

Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

clobazam

Products Affected

- *clobazam oral suspension 2.5 mg/ml*
- *clobazam oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Patient must first try one generic anticonvulsant. Clobazam suspension may only be used in patients where tablets are contraindicated (e.g., dysphagia).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CLOZAPINE ODT

Products Affected

- *clozapine oral tablet dispersible*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient has had prior trial AND a documented contraindication (e.g. dysphagia) to generic clozapine tablet.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

COBENFY

Products Affected

- COBENFY
- COBENFY STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as an inadequate response) with two generic atypical antipsychotics used for at least 28 days each.
Age Restrictions	Must be age 18 or older.
Prescriber Restrictions	Must be prescribed by, or in consultation with, a specialist for the condition being treated.
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

colistimethate sodium

Products Affected

- *colistimethate sodium (cba)*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(1) The drug is being used intravenously (IV) or intramuscularly (IM). Administration through nebulization is not covered (CMS-approved compendia do not support inhalation/nebulization of colistimethate), AND (2) the infection is proven, or strongly suspected, to be caused by susceptible bacteria based on the following required documentation: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by or in consultation with an infectious disease specialist.
Coverage Duration	One year.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

COMETRIQ

Products Affected

- COMETRIQ (100 MG DAILY DOSE) ORAL KIT 80 & 20 MG
- COMETRIQ (140 MG DAILY DOSE) ORAL KIT 3 X 20 MG & 80 MG
- COMETRIQ (60 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

COPIKTRA

Products Affected

- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CORTROPHIN

Products Affected

- CORTROPHIN

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

COSENTYX

Products Affected

- COSENTYX (300 MG DOSE)
- COSENTYX SENSOREADY (300 MG)
- COSENTYX SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 75 MG/0.5ML
- COSENTYX UNOREADY

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Two years. Dosing must follow the FDA-approved labeling.
Other Criteria	For ankylosing spondylitis and non-radiographic axial spondyloarthritis (NRAS): Must try and fail (defined above) one nonsteroidal antiinflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For ERA: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - have aggressive disease that necessitates initial biologic therapy. For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

COTELLIC

Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CRESEMBA

Products Affected

- CRESEMBA ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For invasive aspergillosis, documentation to support an inability to use generic voriconazole for the condition must be provided.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CYSTADROPS

Products Affected

- CYSTADROPS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CYSTARAN

Products Affected

- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DALFAMPRIDINE ER

Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
Exclusion Criteria	Patient must not have history of seizure and creatinine clearance must be greater than 50 ml per min.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	UNDER CMS REVIEW
Other Criteria	Baseline timed 25-foot walk (T25FW), patient must be currently ambulatory. Reauthorization requires documentation of stability and/or improvement in walking speed.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DANZITEN

Products Affected

- DANZITEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DASATINIB

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DAURISMO

Products Affected

- DAURISMO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Diabetic Supplies

Products Affected

- *assure id insulin safety syr 29g x 1/2" 1 ml*
- *bd autoshield duo*
- *bd pen needle 29g x 12mm*
- *bd pen needle micro u/f*
- *bd pen needle micro ultrafine*
- *bd pen needle mini u/f*
- *bd pen needle mini ultrafine*
- *bd pen needle nano 2nd gen*
- *bd pen needle nano u/f*
- *bd pen needle nano ultrafine*
- *bd pen needle orig ultrafine*
- *bd pen needle original u/f*
- *bd pen needle short u/f*
- *bd pen needle short ultrafine*
- *comfort assist insulin syringe 29g x 1/2" 1 ml*
- *cvs gauze sterile pad 2"x2"*
- *embecta autoshield duo*
- *embecta pen needle nano*
- *embecta pen needle nano 2 gen*
- *embecta pen needle ultrafine*
- *global alcohol prep ease*
- *novofine pen needle*
- *novofine plus pen needle*
- *preferred plus insulin syringe 28g x 1/2" 0.5 ml*
- *reli-on insulin syringe 29g 0.3 ml*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DIACOMIT

Products Affected

- DIACOMIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(1) Patient has a diagnosis of seizures associated with Dravet syndrome AND (2) Patient is not currently controlled on current therapy (defined as experiencing generalized tonic clonic or clonic seizures within the past 28 days) AND (3) Patient taking concomitant clobazam therapy.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by or in consultation with a specialist (i.e. neurologist, epileptologist).
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DICHLORPHENAMIDE

Products Affected

- *dichlorphenamide*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

dihydroergotamine nasal spray

Products Affected

- *dihydroergotamine mesylate nasal*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation to support (1) a trial and failure (defined as inability to improve symptoms or condition) of one non-oral triptan drug (e.g., sumatriptan nasal spray or injection) AND (2) a trial and failure (defined above) of Nurtec ODT.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

dimethyl fumarate

Products Affected

- *dimethyl fumarate oral*
- *dimethyl fumarate starter pack oral capsule delayed release therapy pack*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DRIZALMA

Products Affected

- DRIZALMA SPRINKLE ORAL CAPSULE DELAYED RELEASE SPRINKLE 20 MG, 30 MG, 60 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

droxidopa

Products Affected

- *droxidopa*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year initial and reauthorization.
Other Criteria	Patient must first try midodrine. For reauthorization: Must have documentation of a positive clinical response (e.g., sustained decrease in dizziness).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DUPIXENT

Products Affected

- DUPIXENT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/1.14ML, 300 MG/2ML
- DUPIXENT SUBCUTANEOUS SOLUTION PEN-INJECTOR 200 MG/1.14ML, 300 MG/2ML
- DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/0.67ML, 200

MG/1.14ML, 300 MG/2ML

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs or Janus Kinase Inhibitor (JAKis).
Required Medical Information	INITIAL COVERAGE OF ASTHMA: Documentation of the following: (1) Patient has oral corticosteroid-dependent asthma, OR (2) patient has an eosinophilic phenotype defined by an elevated blood eosinophil count of 150 or more cells per microliter at therapy initiation or 300 or more cells per microliter in the past 12 months, AND (3) Patient has tried and failed 1 ICS/LABA inhaler in the past 6 months (failure is defined as an inability to improve the condition on the required therapy for at least 4 weeks). REAUTHORIZATION OF ASTHMA: Must have documentation of clinical benefit compared to baseline (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). INITIAL COVERAGE OF EOSINOPHILIC ESOPHAGITIS (EOE): Documentation of the following: (1) Patient has a diagnosis confirmed by esophageal biopsy defined by at least 15 eosinophils per high power field (HPF), AND (2) patient's current weight is at least 15 kg, AND (3) Patient has symptoms of esophageal dysfunction, AND (4) Patient has tried and failed (defined as an inadequate response) a proton pump inhibitor or a swallowed topical steroid (e.g., fluticasone, budesonide) for at least 2 months. REAUTHORIZATION OF EOE: Must have documentation of a positive response including a reduction in eosinophil count or esophageal symptoms (e.g., less dysphagia).
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	1 year initial and 2 years reauth. Dose must follow the FDA-approved labeling.
Other Criteria	UNDER CMS REVIEW
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EBGLYSS

Products Affected

- EBGLYSS

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs or Janus Kinase Inhibitors (JAKis) for the condition.
Required Medical Information	For initial coverage of atopic dermatitis, documentation of the following is required: (1) Confirmation of moderate to severe atopic dermatitis - AND - (2) Trial and failure (defined as an inadequate response) to Rinvoq - AND - (3) Trial and failure (defined as an inadequate response) to Dupixent.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Initial: 1 year limited to 4 doses the first month and 2 doses each month thereafter. 2-year reauth.
Other Criteria	For reauthorization of atopic dermatitis, documentation of the following is required: (1) Positive clinical response compared to baseline (e.g., less exacerbations, improved symptoms, less steroid use) - AND - Patient is using Ebglyss at the maintenance dose of every 4 weeks or patient is using Ebglyss every 2 weeks due to an inadequate response with dosing every 4 weeks.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ELTROMBOPAG

Products Affected

- *eltrombopag olamine oral packet 12.5 mg, 25 mg*
- *eltrombopag olamine oral tablet 12.5 mg, 25 mg, 50 mg, 75 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Use of eltrombopag to normalize platelet counts is not covered.
Required Medical Information	Documentation supporting the request including current platelet count must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	UNDER CMS REVIEW
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	Yes
Prerequisite Therapy Required	Yes

EMGALITY

Products Affected

- EMGALITY
- EMGALITY (300 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other CGRP antagonist therapy.
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year. Cluster reauth: 1 year. Migraine reauth: 2 years. Dosing must align with FDA labeling.
Other Criteria	For migraine prevention reauthorization requests: Must provide documentation of a decrease in migraine days per month with use of Emgality. For cluster headache reauthorization requests: Must provide documentation of a decrease in the frequency or intensity of cluster headaches with Emgality.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EMSAM

Products Affected

- EMSAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation supporting the trial and failure (defined as an inadequate improvement in depressive symptoms) with two of the following generic antidepressants is required: SNRIs, SSRIs, mirtazapine, or bupropion.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ENBREL

Products Affected

- ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5ML
- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 25 MG/0.5ML, 50 MG/ML
- ENBREL SURECLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	UNDER CMS REVIEW
Other Criteria	For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Enbrel concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

ENBREL MINI

Products Affected

- ENBREL MINI

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	UNDER CMS REVIEW
Other Criteria	For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Enbrel concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

ENDARI

Products Affected

- ENDARI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Must try and fail hydroxyurea. Fail is defined as continuing to have pain episodes despite appropriately dosed hydroxyurea or having any intolerance to hydroxyurea.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EOHILIA

Products Affected

- EOHILIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(1) Diagnosis of EOE confirmed by esophageal biopsy, defined as at least 15 eosinophils per high power field (HPF) - and - (2) Must have continued symptoms of EOE despite trial of a proton pump inhibitor for at least 2 months - and (3) - Trial with one topical generic corticosteroid (i.e., fluticasone, budesonide) for at least 2 months with continued symptoms.
Age Restrictions	Must be age 11 years or older.
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated (gastroenterologist, allergist)
Coverage Duration	1 year authorization with a limit of 12 weeks of treatment.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EPCLUSA

Products Affected

- EPCLUSA ORAL PACKET 150-37.5 MG, 200-50 MG
- EPCLUSA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have chronic hepatitis C infection.
Age Restrictions	For pellets only, must be age 3 - 21 years old.
Prescriber Restrictions	
Coverage Duration	Duration of therapy will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Must have documentation to support that the use of Epclusa is consistent with current AASLD/IDSA guidance.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

EPIDIOLEX

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure with at least 2 generic anticonvulsants for the condition.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EPRONTIA

Products Affected

- EPRONTIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure with generic topiramate sprinkles and at least 1 other generic anticonvulsant for the condition.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ERIVEDGE

Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ERLEADA

Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

erlotinib

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ESLICARBAZEPINE

Products Affected

- *eslicarbazepine acetate oral tablet 200 mg, 400 mg, 600 mg, 800 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as inadequate seizure control) with at least 2 generic anticonvulsants for the condition.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EUCRISA

Products Affected

- EUCRISA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Approve in patients who have tried and failed a prescription strength topical steroid for the current condition being treated. If a topical steroid is not appropriate for the patient, approve in patients who have tried a generic topical calcineurin inhibitor for the current condition being treated.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EULEXIN

Products Affected

- EULEXIN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Coverage requires a trial with generic flutamide or bicalutamide.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EVENITY

Products Affected

- EVENITY

PA Criteria	Criteria Details
Exclusion Criteria	Cumulative use of Evenity of more than 12 months is not covered.
Required Medical Information	Documentation supporting one of the following: (1) Trial and failure, intolerance, or contraindication to alendronate, risedronate, or ibandronate - AND - either zoledronic acid or Prolia, OR (2) a very high risk of fracture defined as a T-score of -3.0 or less, a T-score of -2.5 or less with a fragility fracture, or a history of severe or multiple fragility fractures regardless of T-score.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by endocrinologist.
Coverage Duration	Up to 12 months total therapy. Dosing must follow FDA-approved labeling.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

everolimus

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

EVRYSDI

Products Affected

- EVRYSDI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For spinal muscular atrophy (SMA), documentation of the genetic test confirming the diagnosis must be provided.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by a neurologist or in consultation with a neurologist with experience treating SMA.
Coverage Duration	Initial - 12 months, reauthorization - 12 months
Other Criteria	UNDER CMS REVIEW
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FANAPT

Products Affected

- FANAPT
- FANAPT TITRATION PACK A
- FANAPT TITRATION PACK B ORAL TABLET
- FANAPT TITRATION PACK C ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as an inadequate response) with two of the following generic drugs that have support for the requested condition and each used for at least 28 days: aripiprazole, olanzapine, quetiapine, risperidone, ziprasidone, or lurasidone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FASENRA

Products Affected

- FASENRA PEN
- FASENRA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 10 MG/0.5ML, 30 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs.
Required Medical Information	For initial coverage of severe eosinophilic asthma, documentation of the following is required: (1) An elevated blood eosinophil count of greater than or equal to 150 cells per microliter within 6 weeks (prior to the immediate start of treatment with Fasenra) - OR - greater than or equal to 300 cells per microliter in the previous 12 months, AND (2) Trial with failure of 1 ICS/LABA inhaler in the past 6 months (failure is defined as an inability to improve the condition on the required therapy for at least 4 weeks). For reauthorization of severe eosinophilic asthma: (1) Must have documentation of clinical benefit with Fasenra compared to baseline (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). For initial coverage of eosinophilic granulomatosis with polyangiitis (EGPA): Documentation supporting the patient has non-severe EGPA (defined as absence of life or organ-threatening manifestations) must be provided. For reauthorization of EGPA, must have documentation of clinical benefit with Fasenra compared to baseline (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use).
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	1 year initial and 2 years reauth. Dosing must follow the FDA-approved labeling.
Other Criteria	Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

FINGOLIMOD

Products Affected

- *fingolimod hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FINTEPLA

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as inadequate seizure control) with two of the following: clobazam, valproic acid, topiramate.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FOTIVDA

Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FRUZAQLA

Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FYCOMPA

Products Affected

- FYCOMPA ORAL SUSPENSION
- FYCOMPA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as inadequate seizure control) with at least 2 generic anticonvulsants for the condition.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GATTEX

Products Affected

- GATTEX

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	No

GAVRETO

Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GEFITINIB

Products Affected

- *gefitinib*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GILOTRIF

Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

glatiramer

Products Affected

- *glatiramer acetate subcutaneous solution prefilled syringe 20 mg/ml, 40 mg/ml*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GLATOPA

Products Affected

- GLATOPA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 20 MG/ML, 40 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GOMEKLI

Products Affected

- GOMEKLI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GROWTH HORMONE

Products Affected

- NORDITROPIN FLEXPRO SUBCUTANEOUS SOLUTION PEN-INJECTOR
- OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE
- OMNITROPE SUBCUTANEOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	FOR CHILDREN: must submit an untreated growth velocity curve with a minimum of 1 year of growth data showing a growth velocity of less that 10th % for bone age and gender, growth plates must be open, bone age must be a minimum of 1 year behind chronological age (unless GHD is related to pituitary surgery, radiation therapy, or with precocious puberty), must have a documented GH deficiency via 2 growth hormone stimulation tests below 10ng/ml or GH stimulation test level less than 15 ng/ml + IGF-1 and IGF-PB3 levels below normal for bone age and sex, decreased muscle tone by exam. FOR ADULTS with a diagnosis of GHD: Must have confirmation of GHD by meeting one of the following: (1) A suboptimal response using an appropriate GH-stimulation test, (2) Child-onset GHD with confirmed persistent GHD, or (3) patient has all the following: (a) documented pituitary or hypothalamic disease (e.g., brain tumor with previous brain irradiation), (b)greater than or equal to 3 pituitary hormone deficiencies (thyroid-stimulating hormone (TSH), corticotropin (ACTH), and gonadotropins), and (c) low insulin-like growth factor-1 (IGF-1). If IGF-1 value is indeterminate, a suboptimal response on an appropriate GH-stimulation test required.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by an endocrinologist, gastroenterologist, or nephrologist.
Coverage Duration	One year

PA Criteria	Criteria Details
Other Criteria	FOR CHILDREN: Diagnosis of Growth Hormone Deficiency-height must be less than the 5th% fir age/sex. Diagnosis of Turner's syndrome-height must be less than 10th%. Diagnosis of Pre-transplant chronic renal insufficiency-height must be less than 5th% for age/sex and patient must be receiving weekly dialysis or SCR less than 2 mg/dL. FOR CHILDREN: must not have constitutional growth delay, or acute or chronic catabolic illness. FOR ADULTS, the following conditions are not covered: treatment of reduced growth hormone related to aging, Turner's syndrome or cystinosis. For reauthorization in adults and children: Above normal IGF-1 level requires provider attestation that dose will be decreased and therapy will be managed to obtain a level within normal range.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

HADLIMA

Products Affected

- HADLIMA PUSHTOUCH SUBCUTANEOUS SOLUTION AUTO-INJECTOR 40 MG/0.4ML, 40 MG/0.8ML
- HADLIMA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 40 MG/0.4ML, 40 MG/0.8ML

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment. For approvals of shortened-interval dosing in Crohn's disease and ulcerative colitis, documentation of the following: (1) Two of the following: symptoms, imaging showing active disease, fecal calprotecin greater than 120, CRP greater than or equal to 300, and (2) inadequate drug trough levels, and (3) initial response to therapy.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Haegarda

Products Affected

- HAEGARDA

PA Criteria	Criteria Details
Exclusion Criteria	Haegarda is not covered if any of the following are met: (1) use in combination with an angiotensin-converting enzyme inhibitor (ACEI), (2) use in combination with other preventative therapies for HAE (e.g., Orladeyo, Takhyzro), and/or (3) used for the treatment of acute attacks.
Required Medical Information	Requires submission of C4, C1-INH protein, and C1-INH function lab results confirming diagnosis.
Age Restrictions	Must be age 6 or older.
Prescriber Restrictions	Prescriber is an allergist, immunologist, hematologist, or other specialist experienced in treating HAE.
Coverage Duration	1 year initial and reauth
Other Criteria	For reauthorization: Must also have documentation showing a decrease in the frequency of attacks.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

HUMIRA

Products Affected

- HUMIRA (2 PEN)
- HUMIRA (2 SYRINGE) SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML
- HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT 40 MG/0.8ML
- HUMIRA-CD/UC/HS STARTER
- HUMIRA-PED>/=40KG UC STARTER
- HUMIRA-PSORIASIS/UVEIT STARTER

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment. Dosing must follow the FDA-approved labeling. For approvals of shortened-interval dosing in Crohn's disease and ulcerative colitis, documentation of the following: (1) Two of the following: symptoms, imaging showing active disease, fecal calprotecin greater than 120, CRP greater than or equal to 300, and (2) inadequate drug trough levels, and (3) initial response to therapy.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Two years
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IBRANCE

Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

icatibant acetate

Products Affected

- *icatibant acetate subcutaneous solution prefilled syringe*
- SAJAZIR SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of an angiotensin-converting enzyme inhibitor (ACEI) is not covered.
Required Medical Information	Documentation of C4, C1-INH protein, and C1-INH function lab results confirming diagnosis.
Age Restrictions	Must be age 18 or older.
Prescriber Restrictions	Prescriber is an allergist, immunologist, hematologist, or other specialist experienced in treating HAE.
Coverage Duration	6 months, initial and reauthorization.
Other Criteria	For reauthorization: Must have documentation showing use of previously approved syringes AND a favorable clinical response (decrease in the duration of attacks, quick onset of symptom relief, resolution of symptoms, decrease in attack frequency or severity).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ICLUSIG

Products Affected

- ICLUSIG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IDHIFA

Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of IDH2 (isocitrate dehydrogenase-2) mutation must be submitted.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

imatinib mesylate

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IMBRUVICA

Products Affected

- IMBRUVICA ORAL CAPSULE
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years. Dosing must follow the FDA-approved labeling.
Other Criteria	Criteria will be applied consistent with current NCCN guidance. Reauthorization for GVHD: Must have documentation of clinical benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IMKELDI

Products Affected

- *imkeldi*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Coverage requires that the patient is unable to swallow or appropriately use the generic imatinib tablet formulation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IMPAVIDO

Products Affected

- IMPAVIDO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One month
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

INCRELEX

Products Affected

- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	Increlex is not covered in patients with closed epiphyses.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

INLYTA

Products Affected

- INLYTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

INQOVI

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	Yes
Prerequisite Therapy Required	No

INREBIC

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Must have tried and failed (defined as an intolerance or inability to improve the condition) Jakafi.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ITOVEBI

Products Affected

- ITOVEBI ORAL TABLET 3 MG, 9 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IVIG

Products Affected

- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA
- GAMUNEX-C

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(1) A current weight and requested dose, AND (2) Dosing must follow FDA-approved labeling, or have documentation supporting that the requested dose follows accepted standards of medical practice, AND (3) Patient's dose has been weight-adjusted if the BMI is 30 or more or the actual body weight is 20% higher than the member's ideal body weight, AND (4) Medical records supporting the request, including support for the diagnosis and dose have been provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. FOR MYASTHENIA GRAVIS: Patient must be experiencing acute myasthenic crisis with decompensation. Use of IVIG for chronic or routine use is not covered (there is a lack of evidence to support use of IVIG in stable MG).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IWILFIN

Products Affected

- IWILFIN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

JAKAFI

Products Affected

- JAKAFI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Criteria will be applied consistent with current NCCN guidance. Reauthorization for GVHD: Must have documentation of clinical benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

JAYPIRCA

Products Affected

- JAYPIRCA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medical records supporting that the use of Jaypirca follows current NCCN recommendations must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Use of Jaypirca must follow current NCCN recommendations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

JYLAMVO

Products Affected

- JYLAMVO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JYNARQUE

Products Affected

- JYNARQUE ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	FOR HYPONATREMIA: (1) Documentation that confirms the patient has hypervolemic or euvolemic hyponatremia defined as a serum sodium less than 125 mEq/L or less-marked hyponatremia that is symptomatic and nonresponsive to fluid restriction (including patients with SIADH or heart failure), and (2) Jynarque is being used at a quantity of up to 60 mg per day in line with the FDA-approved labeling. FOR AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD): (1) Patient is at risk of rapidly progressing, and (2) Jynarque is being used at a quantity of up to 120 mg per day in line with the FDA-approved labeling.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Hyponatremia: 30 days, ADPKD: 2 years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KALYDECO

Products Affected

- KALYDECO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have laboratory confirmation of ivacaftor-responsive mutation in the CFTR gene.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KERENDIA

Products Affected

- KERENDIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial treatment, eGFR greater than or equal to 25ml/min/1.73m2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	UNDER CMS REVIEW
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

KISQALI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KISQALI FEMARA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KOSELUGO

Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KRAZATI

Products Affected

- *krazati*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medical records supporting that the use of Krazati follows current NCCN recommendations must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Use of Krazati must follow current NCCN recommendations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

lapatinib

Products Affected

- *lapatinib ditosylate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LAZCLUZE

Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LENALIDOMIDE

Products Affected

- *lenalidomide*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LENVIMA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIDOCAINE PATCH

Products Affected

- *lidocaine external patch 5 %*
- LIDOCAN
- LIDOCAN III
- TRIDACAINE II
- TRIDACAINE III
- TRIDACAINE XL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Medically accepted indications for lidocaine 5% patch include relief of pain associated with postherpetic neuralgia (PHN), diabetic neuropathy, and cancer-related neuropathic pain.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIVTENCITY

Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Baseline CMV DNA level confirming diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	8 weeks
Other Criteria	Must not be used concomitantly with other CMV antivirals (e.g., ganciclovir, valganciclovir). Dosing must follow FDA-approved labeling. Must have documented trial and failure with ganciclovir, valganciclovir, cidofovir or foscarnet. For reauthorization, documentation of response (e.g., CMV DNA level) must be provided.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LONSURF

Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LORBRENA

Products Affected

- LORBRENA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LUMAKRAS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LUPRON DEPOT

Products Affected

- LUPRON DEPOT (1-MONTH) INTRAMUSCULAR KIT 3.75 MG
- LUPRON DEPOT (3-MONTH) INTRAMUSCULAR KIT 11.25 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LYNPARZA

Products Affected

- LYNPARZA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LYTGOBI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MARPLAN

Products Affected

- MARPLAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation supporting the trial and failure (defined as an inadequate improvement in depressive symptoms) with two of the following generic antidepressants is required: SNRIs, SSRIs, mirtazapine, or bupropion.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MATULANE

Products Affected

- MATULANE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEKINIST

Products Affected

- MEKINIST ORAL TABLET 0.5 MG, 2 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEKINIST ORAL SOLUTION

Products Affected

- MEKINIST ORAL SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Coverage requires that the patient is unable to swallow the tablet formulation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEKTOVI

Products Affected

- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have documentation of BRAF V600 mutation status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MERCAPTOPURINE

Products Affected

- *mercaptopurine oral suspension*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MIFEPRISTONE

Products Affected

- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Must be prescribed by an endocrinologist.
Coverage Duration	One year.
Other Criteria	For reauthorization of previously approved requests: Must provide documentation of improvement in hyperglycemia control with mifepristone.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

modafinil

Products Affected

- *modafinil oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MOUNJARO

Products Affected

- MOUNJARO SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	No

NAYZILAM

Products Affected

- NAYZILAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NERLYNX

Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months total therapy
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NEXLETOL

Products Affected

- NEXLETOL

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used along with PCSK9 inhibitors (e.g., Repatha), Juxtapid.
Required Medical Information	Must submit most recent LDL-C level. Must submit documentation of prior therapies and responses to treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Patient must meet the following: (1) Patient has tried one high-intensity statin (or if a high-intensity strength statin is not tolerated, a maximally-tolerated statin is acceptable), along with ezetimibe for at least 4 weeks and LDL-C remains greater than or equal to 70mg/dL OR (2) Patient has tried ezetimibe for at least 4 weeks with LDL-C greater than or equal to 70mg/dL and is statin intolerant defined as trying at least two different statins and experiencing statin-related symptoms on both agents.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NEXLIZET

Products Affected

- NEXLIZET

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used along with PCSK9 inhibitors (e.g., Repatha), Juxtapid.
Required Medical Information	Must submit most recent LDL-C level. Must submit documentation of prior therapies and responses to treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Patient must meet the following: (1) Patient has tried one high-intensity statin (or if a high-intensity strength statin is not tolerated, a maximally-tolerated statin is acceptable), along with ezetimibe for at least 4 weeks and LDL-C remains greater than or equal to 70mg/dL OR (2) Patient has tried ezetimibe for at least 4 weeks with LDL-C greater than or equal to 70mg/dL and is statin intolerant defined as trying at least two different statins and experiencing statin-related symptoms on both agents.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NINLARO

Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

nitisinone

Products Affected

- *nitisinone*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NIVESTYM

Products Affected

- NIVESTYM INJECTION SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NORTRIPTYLINE

Products Affected

- *nortriptyline hcl oral*

PA Criteria	Criteria Details
Exclusion Criteria	The criteria only apply to patients 65 years and older.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Coverage requires the following: (1) Prescriber acknowledges that the benefit of therapy outweighs the potential risks for this patient and (2) Prescriber has considered therapy changes if the patient is using more than one anticholinergic drug in combination. Note: Due to safety concerns, this medication is considered potentially inappropriate in older adults, and is best avoided, prescribed at lower dose, or used with caution.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUBEQA

Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUEDEXTA

Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medical records supporting the request, including documentation of the diagnosis, must be provided.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by a neurologist.
Coverage Duration	Two years
Other Criteria	Coverage requires a diagnosis of pseudobulbar affect caused by an underlying neurological condition (ex. amyotrophic lateral sclerosis, multiple sclerosis, stroke). For reauthorization, documentation that Nuedexta caused a decrease in the number of episodes of laughing or crying compared to baseline must be provided.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NULIBRY

Products Affected

- NULIBRY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Confirmed diagnosis of MoCD Type A by genetic testing. Documentation of genetic testing results must be submitted.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with a physician who specializes in the treatment of inherited metabolic disorders.
Coverage Duration	Initial 1 year. Reauthorization 2 years
Other Criteria	For reauthorization requests, must also provide documentation demonstrating a beneficial response to therapy compared to pretreatment baseline in one or more of the following: neurological function, gross motor function, and/or developmental milestones.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUPLAZID

Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NURTEC

Products Affected

- NURTEC

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other CGRP antagonist therapy.
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 1 year. Reauth: 1 year. Dosing must align with FDA labeling.
Other Criteria	FOR EPISODICE MIGRAINE PREVENTION REAUTHORIZATION: (1) Must have at least 4 but less than 15 migraine headache days per month, AND (2) Must provide documentation of a decrease in migraine days per month with use of Nurtec ODT.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

OCALIVA

Products Affected

- OCALIVA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation supporting the following is required: (1) a diagnosis of primary biliary cholangitis (PBC) that includes an alkaline phosphatase (ALP) level at least 1.5 times the upper limit of normal (ULN) AND the presence of antimitochondrial antibodies (AMA) at a titer of 1:40 or more, AND (2) a trial of ursodiol at a dose of 13 to 15 mg/kg/day for at least 12 months without normalization of alkaline phosphatase (ALP) or an intolerance to ursodiol therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ODOMZO

Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OFEV

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For all indications, must have documentation of High Resolution Computed Tomography (HRCT) confirming diagnosis.
Age Restrictions	
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	One year initial. Two years reauth. Dosing must follow the FDA-approved labeling.
Other Criteria	FOR IDIOPATHIC PULMONARY FIBROSIS (IPF): Prescriber must rule out other known causes of interstitial lung disease - AND - must have presence of a UIP pattern on HRCT in patients not subjected to surgical lung biopsy. FOR CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE WITH PROGRESSIVE PHENOTYPE: Forced Vital Capacity (FVC) decline must be at least 10% - OR - at least 5% with one of the following: worsening respiratory symptoms OR worsening fibrosis on imaging. FOR REAUTHORIZATION OF ALL PREVIOUSLY APPROVED INDICATIONS: Must have documentation of improvement in condition.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OGSIVEO

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OJEMDA

Products Affected

- OJEMDA ORAL SUSPENSION RECONSTITUTED
- OJEMDA ORAL TABLET 100 MG, 100 MG (16 PACK), 100 MG (24 PACK)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For oral suspension, coverage requires that patient is unable to swallow the tablet formulation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year. Limited to 1 box per 28 days, based on requested strength.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OJJAARA

Products Affected

- *ojjaara*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Criteria will be applied consistent with current NCCN guidance.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ONUREG

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OPIPZA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation to support an inability to use generic aripiprazole orally disintegrating tablet (ODT) and generic aripiprazole oral solution in place of Opipza must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OPSUMIT

Products Affected

- OPSUMIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	FOR PULMONARY ARTERIAL HYPERTENSION (PAH): Documentation that the patient has pulmonary arterial hypertension (WHO Group 1) confirmed by right heart catheterization must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OPSYNVI

Products Affected

- OPSYNVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	FOR PULMONARY ARTERIAL HYPERTENSION (PAH): Documentation that the patient has pulmonary arterial hypertension (WHO Group 1) confirmed by right heart catheterization must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORENITRAM

Products Affected

- ORENITRAM
- ORENITRAM MONTH 1
- ORENITRAM MONTH 2
- ORENITRAM MONTH 3

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	FOR PULMONARY ARTERIAL HYPERTENSION (PAH): Documentation that the patient has pulmonary arterial hypertension (WHO Group 1) confirmed by right heart catheterization must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORGOVYX

Products Affected

- ORGOVYX

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	Yes
Prerequisite Therapy Required	No

ORKAMBI

Products Affected

- ORKAMBI ORAL PACKET
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have laboratory confirmation of homozygous F508del mutation in the cystic fibrosis transmembrane regulator (CFTR) gene
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORSERDU

Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medical records supporting that the use of Orserdu follows current NCCN recommendations must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Use of Orserdu must follow current NCCN recommendations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OTEZLA

Products Affected

- OTEZLA ORAL TABLET
- OTEZLA ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Two years. Dosing must follow the FDA-approved labeling.
Other Criteria	For PsO: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g. methotrexate, cyclosporine, acitretin). For oral ulcers associated with Behcet's disease: Must try and fail (defined above) one other systemic therapy (e.g., colchicine, thalidomide, interferon alpha, tumor necrosis factor inhibitors) for the condition.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

OXERVATE

Products Affected

- OXERVATE

PA Criteria	Criteria Details
Exclusion Criteria	More than 8-weeks of treatment per lifetime will not be covered.
Required Medical Information	Documentation confirming diagnosis of Stage 2 (persistent epithelial defect) or stage 3 (corneal ulcer) neurotrophic keratitis such as through slit lamp examination.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, an ophthalmologist.
Coverage Duration	8 weeks total treatment. Dosing must follow the FDA-approved labeling.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OZEMPIC

Products Affected

- OZEMPIC (0.25 OR 0.5 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 2 MG/3ML
- OZEMPIC (1 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 4 MG/3ML
- OZEMPIC (2 MG/DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	No

PANRETIN

Products Affected

- PANRETIN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Must first try and fail (defined as an intolerance or inability to improve the condition) with imiquimod 5% cream.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PAROXETINE

Products Affected

- *paroxetine hcl*

PA Criteria	Criteria Details
Exclusion Criteria	The criteria only apply to patients 65 years and older.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Coverage requires the following: (1) Prescriber acknowledges that the benefit of therapy outweighs the potential risks for this patient, and (2) Prescriber has considered therapy changes if the patient is using more than one anticholinergic drug in combination. Note: Due to safety concerns, this medication is considered potentially inappropriate in older adults, and is best avoided, prescribed at lower dose, or used with caution.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PAROXETINE MESYLATE

Products Affected

- *paroxetine mesylate*

PA Criteria	Criteria Details
Exclusion Criteria	The criteria only apply to patients 65 years and older.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Coverage requires the following: (1) Prescriber acknowledges that the benefit of therapy outweighs the potential risks for this patient, and (2) Prescriber has considered therapy changes if the patient is using more than one anticholinergic drug in combination. Note: Due to safety concerns, this medication is considered potentially inappropriate in older adults, and is best avoided, prescribed at lower dose, or used with caution.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PAZOPANIB

Products Affected

- *pazopanib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PEMAZYRE

Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

penicillamine

Products Affected

- *penicillamine oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	For cystinuria, documentation that treatment with conservative measures (e.g. high fluid intake, sodium and protein restriction, urinary alkalization) were ineffective, not tolerated, or contraindicated. Quantity limited to dosage as supported by the FDA-approved label.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PERAMPANEL

Products Affected

- *perampanel*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PHENOBARBITAL

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PIQRAY

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PIRFENIDONE

Products Affected

- *pirfenidone oral capsule*
- *pirfenidone oral tablet 267 mg, 801 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For all indications, must have documentation of High Resolution Computed Tomography (HRCT) confirming diagnosis.
Age Restrictions	
Prescriber Restrictions	Prescriber is or has consulted with a pulmonologist.
Coverage Duration	Two years
Other Criteria	For idiopathic pulmonary fibrosis (IPF): (1) The patient's diagnosis must be confirmed by a surgical lung biopsy or by the presence of a UIP pattern on a HRCT, and (2) the prescriber must rule out other known causes of interstitial lung disease. For reauthorization requests: Documentation of improvement in condition with use of pirfenidone must be provided.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PLEGRIDY

Products Affected

- PLEGRIDY
- PLEGRIDY STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

POMALYST

Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PREVYMIS

Products Affected

- PREVYMIS ORAL PACKET
- PREVYMIS ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	200 days
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PROLASTIN-C

Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have an FEV1 less than 80 percent predicted - AND - a serum AAT level less than 11 micromoles per liter (80 milligrams per deciliter if measured by radial immunodiffusion or 50 milligrams per deciliter if measure by nephelometry).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

protriptyline

Products Affected

- *protriptyline hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as inadequate response) with 2 of the following generic antidepressants: SSRIs, SNRIs, bupropion, mirtazapine, or trazodone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

QINLOCK

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RADICAVA ORS

Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months. Limited to 70 mLs the first 28 days and 50 mLs every 28 days thereafter.
Other Criteria	For initial requests, documentation of the following is required: (1) A diagnosis of definite or probable amyotrophic lateral sclerosis (ALS) as defined by the revised El Escorial/Arlie House criteria, AND (2) a diagnosis of ALS for 2 years or less (please provide date of diagnosis), AND (3) retention of most activities of daily living defined as having a baseline score of at least 2 points on each of the 12 items of the revised ALS Functional Rating Scale (ALSFRS-R) (i.e., a minimum score of 24), AND (4) normal respiratory function defined as a percent-predicted forced vital capacity (% FVC) greater than or equal to 80%. For reauthorization requests, documentation of the following is required: (1) Radicava is slowing the progression of ALS as determined by an improved or stable ALFRS-R score or other supporting clinical documentation.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RALDESY

Products Affected

- RALDESY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Coverage requires that the patient meet the following: (1) the patient is unable to swallow the generic trazodone tablet - and - (2) the patient has tried and failed (defined as depression symptoms not improving) at least one generic oral solution for depression (such as escitalopram oral solution, sertraline oral concentrate, nortriptyline oral solution).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RELISTOR

Products Affected

- RELISTOR ORAL
- RELISTOR SUBCUTANEOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Patient must not have mechanical gastrointestinal obstruction.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	UNDER CMS REVIEW
Other Criteria	Must try and fail (defined as an inadequate response or intolerance) to lactulose.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

REPATHA

Products Affected

- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must submit most recent LDL-C level.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Patient must meet one of the following: (1) Patient has tried a high intensity statin (i.e., atorvastatin 40 mg to 80 mg daily or rosuvastatin 20 mg to 40 mg daily) and LDL-C remains above 70mg/dL, OR (2) if a high-intensity strength statin is not tolerated, the patient has tried a the maximally tolerated statin dose and LDL-C remains above 70mg/dL, OR (3) Patient has tried two different statins and experienced statin-related symptoms on both agents.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RETEVMO

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REVCOVI

Products Affected

- REVCOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must provide trough plasma ADA activity and trough dAXP levels. Must provide patient's current weight and requested dose.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year initial and reauthorization.
Other Criteria	Provider attestation that treatment will follow FDA-approved labeling with dose adjusted to maintain trough ADA activity over 30 mmol/hr/L, trough dAXP level under 0.02 mmol/L, and/or to maintain adequate immune reconstitution based on clinical assessment of the patient.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REVUFORJ

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REXULTI

Products Affected

- REXULTI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

REZDIFFRA

Products Affected

- REZDIFFRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial requests, documentation supporting the following is required: (1) A diagnosis of metabolic dysfunction-associated steatohepatitis (MASH), AND (2) moderate to advanced liver fibrosis that is consistent with a fibrosis stage of F2 or F3 confirmed by biopsy or non-invasive tests (NITs), AND (3) current weight, AND (4) the patient is using Rezdiffra at a dose aligned with the FDA-approved labeling (i.e., 80 mg/day if weight is less than 100 kg, and 100 mg/day if weight is 100 kg or more), AND (5) a provider attestation that Rezdiffra will be used in conjunction with diet and exercise as per its FDA labeling.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation, with a gastroenterologist or hepatologist.
Coverage Duration	One year initial and reauthorization.
Other Criteria	For reauthorization, documentation supporting the following is required: (1) current ALT and/or fibrosis score supporting that the patient's liver disease has not worsened (worsening of liver disease is defined as a consistent increase in ALT or fibrosis progression assessed by biopsy or NITs), AND (2) current weight, AND (3) the patient is using Rezdiffra at a dose aligned with the FDA-approved labeling (i.e., 80 mg/day if weight is less than 100 kg, and 100 mg/day if weight is 100 kg or more), AND (4) a provider attestation that Rezdiffra will be used in conjunction with diet and exercise as per its FDA labeling.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

REZLIDHIA

Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZUROCK

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year initial and continuation.
Other Criteria	Other criteria will be applied consistent with current NCCN guidance. Reauthorization for GVHD: Must have documentation of clinical benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RINVOQ

Products Affected

- RINVOQ LQ
- RINVOQ ORAL TABLET EXTENDED RELEASE 24 HOUR 15 MG, 30 MG, 45 MG

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	1 year initial (AD). 2 year initial (others). 2 year reauth (all). Dose must follow FDA labeling
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ROMVIMZA

Products Affected

- ROMVIMZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ROZLYTREK

Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ROZLYTREK PELLET PACK

Products Affected

- ROZLYTREK ORAL PACKET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient has had prior trial with AND is unable to use Rozlytrek oral capsule formulation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RUBRACA

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as an intolerance or inadequate response) with Lynparza.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RUFINAMIDE

Products Affected

- *rufinamide*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RYBELSUS

Products Affected

- RYBELSUS
- RYBELSUS (FORMULATION R2)

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	No

RYDAPT

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For diagnosis of acute myeloid leukemia (AML), patient must have FLT3 mutation-positive disease as detected by an FDA-approved test.
Age Restrictions	Must be age 18 or older
Prescriber Restrictions	
Coverage Duration	One year.
Other Criteria	For diagnosis of AML, patient must be using Rydapt in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SCEMBLIX

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For PH+ CML-CP with T315I mutation, documentation confirming mutation must be provided.
Age Restrictions	Must be 18 years of age or older.
Prescriber Restrictions	Must be prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	1 year. 20mg limit to 60 tabs per 30 days. 40mg limit to 240 tabs per 30 days.
Other Criteria	For PH+ CML-CP with T315I mutation, your prescriber must provide rationale supporting why Iclusig cannot be used in place of Scemblix.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SECUADO

Products Affected

- SECUADO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as an inadequate response) with two of the following generic drugs used for at least 28 days each: aripiprazole, olanzapine, quetiapine, risperidone, ziprasidone, or lurasidone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SELARSDI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Two years. Dosing must follow the FDA-approved labeling.
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SIGNIFOR

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Patient must be too ill for pituitary surgery or patient must have had surgery that failed to completely removed the tumor. Patient must have a documented trial with ketoconazole to reduce cortisol secretion.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SILDENAFIL CITRATE

Products Affected

- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SIRTURO

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	24 weeks
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SKYRIZI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Two years. Dosing must follow the FDA-approved labeling.
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SODIUM OXYBATE

Products Affected

- SODIUM OXYBATE

PA Criteria	Criteria Details
Exclusion Criteria	Patient must not be receiving sedative hypnotics with sodium oxybate. Patient must not suffer from succinic semialdehyde dehydrogenase deficiency.
Required Medical Information	Documentation of prior therapies and responses to treatment. Documentation of MSLT and polysomnography confirming diagnosis of narcolepsy.
Age Restrictions	
Prescriber Restrictions	Prescriber must be a sleep specialist or neurologist.
Coverage Duration	Two years
Other Criteria	UNDER CMS REVIEW
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SOMAVERT

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SORAFENIB

Products Affected

- *sorafenib tosylate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SPRITAM

Products Affected

- SPRITAM ORAL TABLET DISINTEGRATING SOLUBLE 1000 MG, 250 MG, 500 MG, 750 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure with generic levetiracetam and at least 1 other generic anticonvulsant for the condition.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

STELARA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Two years.
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

STIVARGA

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SUNITINIB MALATE

Products Affected

- *sunitinib malate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SYMDEKO

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have laboratory confirmation of homozygous F508del mutation or have at least one tezacaftor/ivacaftor-responsive mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.
Age Restrictions	Must be age 6 or older.
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SYMPAZAN

Products Affected

- SYMPAZAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient has had prior trial with AND has a documented contraindication (e.g. dysphagia) to BOTH generic clobazam tablet AND clobazam oral suspension.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year initial and reauthorization.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TABRECTA

Products Affected

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

tadalafil 2.5mg and 5mg (Cialis)

Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Patient must have tried and failed either 6 months of finasteride or 3 months of dutasteride and must have tried and failed 28 days of alfuzosin, doxazosin, tamsulosin, or terazosin.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

tadalafil 20mg (Adcirca)

Products Affected

- *tadalafil (pah)*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAFINLAR

Products Affected

- TAFINLAR ORAL CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAFINLAR TABLET FOR ORAL SUPSENSION

Products Affected

- TAFINLAR ORAL TABLET SOLUBLE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Coverage requires that the patient is unable to swallow the tablet formulation.
Age Restrictions	Must be less than 18 years old.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAGRISSO

Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TALZENNA

Products Affected

- TALZENNA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TASIGNA

Products Affected

- TASIGNA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TASIMELTEON

Products Affected

- *tasimelteon*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAVNEOS

Products Affected

- TAVNEOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	Must be 18 years of age or older.
Prescriber Restrictions	Must be prescribed by or in consultation with a specialist for the condition.
Coverage Duration	Initial 6 months. Reauthorization 12 months.
Other Criteria	UNDER CMS REVIEW
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

tazarotene cream

Products Affected

- *tazarotene external cream 0.1 %*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAZVERIK

Products Affected

- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TEPMETKO

Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TERIFLUNOMIDE

Products Affected

- *teriflunomide*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TERIPARATIDE

Products Affected

- TERIPARATIDE SUBCUTANEOUS SOLUTION PEN-INJECTOR 560 MCG/2.24ML

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	Documentation supporting one of the following: (1) Trial and failure, intolerance, or contraindication to alendronate, risedronate, or ibandronate - AND - zoledronic acid, OR (2) a very high risk of fracture defined as a T-score of -3.0 or less, a T-score of -2.5 or less with a fragility fracture, or a history of severe or multiple fragility fractures regardless of T-score.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by endocrinologist.
Coverage Duration	UNDER CMS REVIEW
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	Yes
Prerequisite Therapy Required	Yes

testosterone gel

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	Yes
Prerequisite Therapy Required	No

testosterone solution

Products Affected

- *testosterone transdermal solution*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	Yes
Prerequisite Therapy Required	No

tetrabenazine

Products Affected

- *tetrabenazine oral tablet 12.5 mg, 25 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with Austedo or Ingrezza.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	CYP2D6 genotype must be provided for doses greater than 50mg/day.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

THALOMID

Products Affected

- THALOMID ORAL CAPSULE 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TIBSOVO

Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have documentation of IDH1 mutation status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

tolvaptan

Products Affected

- *tolvaptan oral tablet*
- *tolvaptan oral tablet therapy pack*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	FOR HYPONATREMIA: (1) Documentation that confirms the patient has hypervolemic or euvolemic hyponatremia defined as a serum sodium less than 125 mEq/L or less-marked hyponatremia that is symptomatic and nonresponsive to fluid restriction (including patients with SIADH or heart failure), and (2) tolvaptan is being used at a quantity of up to 60 mg per day in line with the FDA-approved labeling. FOR AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD): (1) Patient is at risk of rapidly progressing, and (2) tolvaptan is being used at a quantity of up to 120 mg per day in line with the FDA-approved labeling.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Hyponatremia: 30 days, ADPKD: 2 years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOPIRAMATE SOLUTION

Products Affected

- *topiramate oral solution*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRELSTAR

Products Affected

- TRELSTAR MIXJECT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as inadequate response) with Eligard or leuprolide 22.5 mg depot.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TRETINOIN CAPSULES

Products Affected

- *tretinoin oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRIKAFTA

Products Affected

- TRIKAFTA ORAL TABLET THERAPY PACK
- TRIKAFTA ORAL THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For diagnosis of cystic fibrosis, must provide documentation of a F508del mutation or at least one mutation responsive to Trikafta.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

trimipramine maleate

Products Affected

- *trimipramine maleate oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as inadequate response) with 2 of the following generic antidepressants: SSRIs, SNRIs, bupropion, mirtazapine, or trazodone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TRULICITY

Products Affected

- TRULICITY SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRUQAP

Products Affected

- TRUQAP ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	For PIK3CA mutations, must first try Piqray.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TRYNGOLZA

Products Affected

- TRYNGOLZA

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	No

TUKYSA

Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TURALIO

Products Affected

- TURALIO ORAL CAPSULE 125 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TYENNE

Products Affected

- TYENNE SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, Janus Kinase Inhibitor (JAKis), or Ofev.
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided. For systemic sclerosis- related interstitial lung disease (SSc-ILD) , must also have documentation of High Resolution Computed Tomography (HRCT) confirming diagnosis.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Two years. Dosing must follow FDA-approved labeling.
Other Criteria	For RA and JIA: Must have documentation supporting a trial and failure of (defined as an intolerance or inability to improve symptoms) two of the following: a preferred adalimumab product, Rinvoq, Xeljanz/Xeljanz XR, or Enbrel. For systemic sclerosis- related interstitial lung disease (SSc-ILD) reauthorization: Must have documentation of improvement in condition.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

USTEKINUMAB

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Two years
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VALCHLOR

Products Affected

- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For limited/localized skin involvement, must have tried topical steroids and either topical tazarotene or topical imiquimod. For generalized skin involvement, must have tried topical steroids.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VALTOCO

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VANFLYTA

Products Affected

- VANFLYTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VENCLEXTA

Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VERQUVO

Products Affected

- VERQUVO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided. Documentation of an ejection fraction less than 45% assessed within the past 12 months must be provided.
Age Restrictions	Must be at least 18 years old.
Prescriber Restrictions	Must be prescribed by, or in consultation with, a cardiologist.
Coverage Duration	Two years
Other Criteria	Patient has symptomatic worsening chronic heart failure (NYHA class 2 to 4) - AND - has been hospitalized for heart failure in the past 6 months or treated with outpatient IV diuretic therapy for heart failure in the past 3 months AND - has tried and failed (defined as an intolerance or inability to improve symptoms) maximally tolerated doses of the following medications in combination: an ACEI, ARB, or ARNi (such as enalapril or Entresto) - AND - bisoprolol, carvedilol or metoprolol ER - AND - spironolactone or other diuretic.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VERSACLOZ

Products Affected

- VERSACLOZ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient has had prior trial with AND has a documented contraindication (e.g. dysphagia) to BOTH generic clozapine tablet AND generic clozapine orally disintegrating tablet (ODT).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VERZENIO

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

vigabatrin

Products Affected

- *vigabatrin*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For refractory complex partial seizures: Must have documentation supporting a trial and failure (defined as inadequate seizure control) with at least 2 other generic anticonvulsants for the condition.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

vigadrone

Products Affected

- *vigadrone*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For refractory complex partial seizures: Must have documentation supporting a trial and failure (defined as inadequate seizure control) with at least 2 other generic anticonvulsants for the condition.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VIGAFYDE

Products Affected

- VIGAFYDE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Must be 2 years of age or younger (max age 2 years).
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VITRAKVI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VIZIMPRO

Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VONJO

Products Affected

- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Criteria will be applied consistent with current NCCN guidance.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VORANIGO

Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

voriconazole

Products Affected

- *voriconazole intravenous*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VOWST

Products Affected

- VOWST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of at least 2 recurrent episodes of CDI (3 or more total CDI episodes) after failure of appropriate antibiotic treatments.
Age Restrictions	Patient must be 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year. Limited to 1 treatment course (12 capsules over 3 days).
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VOYDEYA

Products Affected

- VOYDEYA

PA Criteria	Criteria Details
Exclusion Criteria	Voydeya is not covered in combination with Fabhalta or Empaveli.
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	Must be 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	One year initial and reauthorization.
Other Criteria	For reauthorization: (1) must be actively receiving treatment with Ultomiris/Soliris, AND (2) must have documentation of improvement in EVH symptoms (e.g., fatigue, dyspnea), AND (3) must have a sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VRAYLAR

Products Affected

- VRAYLAR ORAL CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as an inadequate response) with two of the following generic drugs that have support for the requested condition and each used for at least 28 days: aripiprazole, olanzapine, quetiapine, risperidone, ziprasidone, or lurasidone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VYNDAMAX

Products Affected

- VYNDAMAX

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with TTR-lowering agents (e.g., Amvuttra, Onpattro).
Required Medical Information	INITIAL COVERAGE OF ATTR-CM: Documentation of the following: (1) New York Heart Association (NYHA) class 1 , 2, or 3 heart failure, AND (2) an echocardiogram (ECHO) or cardiac magnetic resonance (CMR) imaging demonstrating cardiac involvement (i.e., increased left ventricular wall thickness), AND (3) diagnosis confirmed by tissue biopsy, genetic testing, or radionuclide imaging (99mTc-PYP, 99mTc-DPD, or 99mTc-HMDP scan), AND (4) if the diagnosis was confirmed by radionuclide imaging, coverage also requires documentation of Grade 2 or 3 cardiac uptake.
Age Restrictions	Must be age 18 or older.
Prescriber Restrictions	
Coverage Duration	One year initial and reauthorization.
Other Criteria	Vyndamax will not be approved if the patient has primary (light-chain) amyloidosis. FOR REAUTHORIZATION OF ATTR-CM: Coverage requires documentation of a positive clinical response to Vyndamax compared to baseline (e.g., reduced cardiovascular-related hospitalizations, improved function, improved quality of life).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VYNDAQEL

Products Affected

- VYNDAQEL

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with TTR-lowering agents (e.g., Amvuttra, Onpattro).
Required Medical Information	INITIAL COVERAGE OF ATTR-CM: Documentation of the following: (1) New York Heart Association (NYHA) class 1 , 2, or 3 heart failure, AND (2) an echocardiogram (ECHO) or cardiac magnetic resonance (CMR) imaging demonstrating cardiac involvement (i.e., increased left ventricular wall thickness), AND (3) diagnosis confirmed by tissue biopsy, genetic testing, or radionuclide imaging (99mTc-PYP, 99mTc-DPD, or 99mTc-HMDP scan), AND (4) if the diagnosis was confirmed by radionuclide imaging, coverage also requires documentation of Grade 2 or 3 cardiac uptake.
Age Restrictions	Must be age 18 or older.
Prescriber Restrictions	
Coverage Duration	One year initial and reauthorization.
Other Criteria	Vyndaqel will not be approved if the patient has primary (light-chain) amyloidosis. FOR REAUTHORIZATION OF ATTR-CM: Coverage requires documentation of a positive clinical response to Vyndaqel compared to baseline (e.g., reduced cardiovascular-related hospitalizations, improved function, improved quality of life).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

WELIREG

Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

WINREVAIR

Products Affected

- WINREVAIR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial requests, documentation of the following is required: (1) Must have a confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1, by right heart catheterization, AND (2) Must have WHO functional class II or III symptoms, AND (3) Must have tried and failed (defined as an inability to improve the condition) of dual therapy with a phosphodiesterase inhibitor (e.g., sildenafil or tadalafil) AND an endothelin receptor antagonist (e.g., ambrisentan or bosentan), AND (4) Winrevair will be initiated as add on therapy to at least 2 other PAH agents (e.g. ERA, PDE5i, Prostaglandins).
Age Restrictions	Must be 18 years of age or older.
Prescriber Restrictions	Must be prescribed by or in consultation with a specialist for the condition.
Coverage Duration	One year initial. Two years reauthorization.
Other Criteria	For reauthorization requests: Documentation must be provided demonstrating that the patient has had a beneficial response to Winrevair compared to pretreatment baseline in one or more of the following: improvement in WHO functional class, risk status, or 6MWD.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XALKORI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XATMEP

Products Affected

- XATMEP

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Must try and fail (defined as an intolerance or inability to improve the condition) generic methotrexate.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XCOPRI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have documentation supporting a trial and failure (defined as inadequate seizure control) with at least 2 generic anticonvulsants for the condition.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XDEMVY

Products Affected

- XDEMVY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of Demodex blepharitis confirmed by the presence of mites on examination by light microscopy or presence of collarettes on slit lamp examination.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XELJANZ

Products Affected

- XELJANZ ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Two years. Dosing must follow the FDA-approved labeling.
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XELJANZ SOLUTION

Products Affected

- XELJANZ ORAL SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Two years. Dosing must follow the FDA-approved labeling.
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XELJANZ XR

Products Affected

- XELJANZ XR

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Two years. Dosing must follow the FDA-approved labeling.
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XERMELO

Products Affected

- XERMELO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must be experiencing 4 or more bowel movements per day.
Age Restrictions	Must be 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XGEVA

Products Affected

- XGEVA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	For all medically-accepted indications (except for Giant Cell Tumor of the bone, and for bone metastases from breast, prostate, and lung cancer), must first try zoledronic acid. Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	Yes
Prerequisite Therapy Required	No

XIFAXAN

Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	For IBS-D, no more than a total of three, 14-day treatment courses are covered. Xifaxan COVERAGE FOR SMALL INTESTINAL BACTERIAL OVER-GROWTH (SIBO) IS NOT PROVIDED.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year (all). IBS-D limited to three, 14-day treatment courses. TD limited to three days.
Other Criteria	For travelers diarrhea (TD): Coverage requires a trial and failure (defined as an intolerance or inability to improve the condition) with azithromycin. For hepatic encephalopathy: Coverage requires a trial and failure (defined above) with lactulose.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XOLAIR

Products Affected

- XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs.
Required Medical Information	Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. INITIAL COVERAGE OF ASTHMA: Documentation of the following is required: (1) A baseline IgE level of at least 30 IU/mL (baseline is defined as before treatment with Xolair or another therapy that lowers IgE levels), AND (2) a baseline (defined above) positive skin test or in vitro reactivity to a perennial aeroallergen, AND (3) Patient's current weight, AND (4) Trial and failure of 1 ICS/LABA inhaler in the past 6 months (failure is defined as an inability to improve the condition on the required therapy for at least 4 weeks). REAUTHORIZATION OF ASTHMA: (1) Must have documentation of clinical benefit with Xolair compared to baseline (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use), AND (2) the patient's current weight and baseline IgE level must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	1 year initial and 2 years reauth. Dosing must follow the FDA-approved labeling.

PA Criteria	Criteria Details
Other Criteria	INITIAL COVERAGE OF FOOD ALLERGY REQUESTS: Documentation of the following is required: (1) Patient has a diagnosis of an IgE-mediated food allergy confirmed by both a positive in vitro test for IgE to the specified foods AND a positive skin prick test to the specified foods, AND (2) Patient has a clinical history of a significant allergic reaction to the specified foods, AND (3) Patient has a baseline IgE level of at least 30 IU/mL (baseline is defined as before treatment with Xolair or another therapy that lowers IgE levels), AND (4) Xolair will be used in conjunction with a food allergen-avoidant diet, AND (5) Patient's current weight, AND (6) Patient is at least 1 year of age. REAUTHORIZATION OF FOOD ALLERGY REQUESTS: (1) Xolair must continue to be used in conjunction with a food allergen-avoidant diet, AND (2) the patient's current weight and baseline IgE level must be provided. INITIAL COVERAGE OF CHRONIC URTICARIA (CU): Documentation of the following is required: (1) Patient has a confirmed diagnosis of chronic urticaria defined as urticaria occurring for more than 6 weeks, AND (2) Trial and failure (defined as an inability to improve symptoms) with one H1 antihistamine. REAUTHORIZATION OF CU: (1) Must have documentation of clinical benefit with Xolair compared to baseline (e.g., improved symptoms). INITIAL COVERAGE OF NASAL POLYP REQUESTS: Documentation of the following is required: (1) Patient has a baseline IgE level of at least 30 IU/mL (baseline is defined as before treatment with Xolair or another therapy that lowers IgE levels), AND (2) Patient's current weight, AND (3) trial and failure (defined as an inability to adequately improve symptoms) with an intranasal steroid, AND (4) Patient will continue to use an intranasal steroid along with Xolair. REAUTHORIZATION OF NASAL POLYP REQUESTS: (1) The patient will continue to use an intranasal steroid along with Xolair, AND (2) Must have documentation of clinical benefit with Xolair compared to baseline (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use), AND (3) the patient's current weight and baseline IgE level must be provided.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XOSPATA

Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XPOVIO

Products Affected

- XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 50 MG
- XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 10 MG, 40 MG
- XPOVIO (40 MG TWICE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (60 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 60 MG
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (80 MG TWICE WEEKLY)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XTANDI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

YESINTEK

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Two years. Dosing must follow the FDA-approved labeling.
Other Criteria	UNDER CMS REVIEW
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

YORVIPATH

Products Affected

- YORVIPATH SUBCUTANEOUS SOLUTION PEN-INJECTOR 168 MCG/0.56ML, 294 MCG/0.98ML, 420 MCG/1.4ML

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZEJULA

Products Affected

- ZEJULA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZELBORAF

Products Affected

- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZOLINZA

Products Affected

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZONISADE

Products Affected

- ZONISADE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For doses above 400 mg per day, documentation confirming need for further seizure reduction is required.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Must have tried generic zonisamide capsules with inability to swallow capsule - AND - must have tried and failed (defined as an inability to improve the condition) one other generic antiseizure medication.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZTALMY

Products Affected

- ZTALMY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(1) Must provide confirmation of CDKL5 deficiency based on genetic testing, (2) Must provide patient's current weight.
Age Restrictions	Must be 2 years of age or older.
Prescriber Restrictions	Must be prescribed by a neurologist.
Coverage Duration	Two years
Other Criteria	UNDER CMS REVIEW
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZURZUVAE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Confirmation of diagnosis of postpartum depression.
Age Restrictions	Must be 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	One year. Limited to one treatment course per year.
Other Criteria	Must follow current ACOG recommendations which require the patient to be in the postpartum period (ie, within 12 months postpartum) for depression that has onset in the third trimester or within 4 weeks postpartum.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZYDELIG

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZYKADIA

Products Affected

- ZYKADIA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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