

2025 HEALTHSUN Prior Authorization Criteria

Actimmune

Products Affected

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Adempas

Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Pulmonary Arterial Hypertension, individual has a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units. AND Individual has WHO functional class II- IV symptoms. For CTEPH a right-heart catheterization showing a mPAP greater than 25 mm Hg caused by thromboemboli in the pulmonary arterial system (ACCF/AHA 2009).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

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PA Criteria	Criteria Details
Other Criteria	For Initial use, for diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 AND has WHO functional class II-IV symptoms. For diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4 AND has WHO functional class II-IV symptoms AND using for one of the following: Persistent or recurrent pulmonary hypertension after at least 180 days following surgical treatment with pulmonary endarterectomy OR Inoperable (via pulmonary endarterectomy) CTEPH. For continued use, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AED Agents

Products Affected

- DILANTIN ORAL CAPSULE 30 MG
- EPRONTIA
- FYCOMPA ORAL SUSPENSION
- FYCOMPA ORAL TABLET
- LAMICTAL XR ORAL KIT
- SPRITAM ORAL TABLET
- DISINTEGRATING SOLUBLE 1000 MG, 250 MG, 500 MG, 750 MG
- SUBVENITE
- 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
- ZONISADE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has had a trial of and inadequate response or intolerance to ONE of the following preferred agents: Carbamazepine, Clonazepam/ODT, Clorazepate, Diazepam, Divalproex, Ethosuximide, Felbamate, Gabapentin, Lacosamide, Lamotrigine IR, Levetiracetam IR, Oxcarbazepine, Phenytoin, Primidone, Tiagabine, Topiramate IR, Valproate sodium, Valproic acid, Zonisamide OR the preferred agent is not FDA-approved for the prescribed indication.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No

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AFINITOR

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	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Aimovig

Products Affected

- AIMOVIG SUBCUTANEOUS
SOLUTION AUTO-INJECTOR 140
MG/ML, 70 MG/ML

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

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Akeega

Products Affected

- AKEEGA

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

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Alecensa

Products Affected

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Alpha1-Proteinase Inhibitor

Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Initial use, verified alpha-1 antitrypsin level is less than or equal to 11micro-mol/L (approximately equivalent to 80mg/dL measured by radial immunodiffusion or 57 mg/dL measured by nephelometry) (ATS/ERS 2003, Stoller 2017). Individual has clinically evident emphysema (or chronic obstructive pulmonary disease [COPD]).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Continued use, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decreased frequency of exacerbations, slowed rate of FEV1 decline, preservation of CT scan lung density or improvement in symptom burden).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Alunbrig

Products Affected

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

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

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Amphetamine Salts

Products Affected

- *amphetamine-dextroamphetamine*
- *amphetamine-dextroamphetamine oral tablet 10 mg, 12.5 mg, 15 mg, 20 mg, 30 mg, 5 mg, 7.5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For dx ADHD, 3 years of age or older for immediate release. For Narcolepsy, 6 years of age or older for immediate release
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Ampyra

Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For renewal, individual achieved and sustained clinically significant improvement in ambulation related functional status.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial approval 12 weeks, renewal 1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Apokyn

Products Affected

- *apomorphine hcl subcutaneous*

PA Criteria	Criteria Details
Exclusion Criteria	Erectile Dysfunction (ED) use
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For initial use in PD, individual is using in conjunction with an antiemetic (excluding 5HT3 antagonist agents) during initiation period. For continuation, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Arcalyst

Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis. For initial use, for DIRA, disease is in remission from previous anakinra treatment. For Recurrent Pericarditis (RP), individual is using for treatment of RP or reduction in risk of recurrence AND has a history of at least two pericarditis episodes (i.e. presents with at least the third episode) (Klein 2021).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continued use, individual has been receiving and is maintained on a stable dose of Arcalyst AND mbr has clinically significant improvement or stabilization in clinical signs and symptoms of disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Augtyro

Products Affected

- AUGTYRO

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

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Auryxia

Products Affected

- AURYXIA

PA Criteria	Criteria Details
Exclusion Criteria	Individual has a diagnosis of an iron overload syndrome (for example, hemochromatosis) or has a diagnosis of iron deficiency anemia associated with chronic kidney disease (CKD) stages 3, 4, or 5 and is not on dialysis [Not Part D].
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Austedo

Products Affected

- AUSTEDO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Initial: 3 months. Continuation: 1 year
Other Criteria	For initial requests, Individual has a diagnosis of chorea associated with Huntington?s disease. Has a diagnosis of Tardive dyskinesia confirmed (written or verbal attestation) by the following DSM-5 AND (a.) At least 30 days of stable (drug, dose) medication exposure (either typical or first generation antipsychotic agents [such as, chlorpromazine, haloperidol, fluphenazine], atypical or second-generation antipsychotic agents [such as, clozapine, risperidone, olanzapine, quetiapine, aripiprazole], or certain dopamine receptor-blocking drugs used in treatment of nausea and gastroparesis [such as, prochlorperazine, promethazine, metoclopramide]) and (b.) Presence of involuntary athetoid or choreiform movements. For continuation requests, Individual has experienced an improvement in symptoms deemed to be clinically significant by the provider (written or verbal attestation) based on stabilization or improvement in Abnormal Involuntary Movement Scale (AIMS) score (for TD) or total maximal chorea score (for Huntington?s disease).

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Auvelity

Products Affected

- AUVELITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For MDD.
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Ayvakit

Products Affected

- AYVAKIT

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

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Balversa

Products Affected

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

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

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Banzel

Products Affected

- *rufinamide oral suspension*
- *rufinamide oral tablet 200 mg, 400 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis.
Age Restrictions	Individual is 1 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has had a trial of and inadequate response or intolerance to ONE of the following preferred agents: Carbamazepine, Clonazepam/ODT, Clorazepate, Diazepam, Divalproex, Ethosuximide, Felbamate, Gabapentin, Lacosamide, Lamotrigine IR, Levetiracetam IR, Oxcarbazepine, Phenytoin, Primidone, Tiagabine, Topiramate IR, Valproate sodium, Valproic acid, Zonisamide OR the preferred agent is not FDA-approved for the prescribed indication.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Baraclude

Products Affected

- BARACLUDGE ORAL SOLUTION
- *entecavir*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has a diagnosis of Chronic Hepatitis B virus (HBV) infection and has not been previously treated with lamivudine (AASLD 2016) OR is using as prophylaxis for hepatitis B reactivation in the setting of immune suppression (AGA 2015) or in combination with hepatitis C direct-acting antiviral therapy (AASLD 2017) OR Individual is a solid organ transplant recipient and using as prophylaxis for hepatitis B reactivation post (AASLD 2018).
Age Restrictions	2 years of age and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Bavencio

Products Affected

- BAVENCIO

PA Criteria	Criteria Details
Exclusion Criteria	Receiving treatment with another anti PD-1 agent or anti PD-L1 agent. Receiving therapy for an autoimmune disease or chronic condition requiring treatment with systemic immunosuppressant.
Required Medical Information	Current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 for metastatic merkel cell carcinoma, advanced RCC, endometrial carcinoma, and locally advanced or metastatic urothelial carcinoma
Age Restrictions	Individual is 12 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Benlysta

Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months. Continuation: 1 Year.

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PA Criteria	Criteria Details
Other Criteria	<p>For initial tx (IV or Subcutaneous), individual has a diagnosis of SLE per the American College of Rheumatology [ACR] criteria AND has positive ANA titer greater than or equal to 1:80 or anti-dsDNA greater than or equal to 30 IU/mL AND disease is active as shown by a SELENA-SLEDAI score greater than or equal to 6 while on current treatment regimen AND SLE remains active while on corticosteroid, antimalarials, and/or immunosuppressants for at least the last 30 days AND is using in combination with standard therapy (for example, corticosteroids, antimalarials, and/or immunosuppressants [but not other biologics or IV cyclophosphamide]). For Initial tx (IV or Subcutaneous) of active lupus nephritis, individual has Class III, IV, or V lupus nephritis showing active or chronic lesions, and confirmed by renal biopsy AND has a urinary protein to creatinine ratio of greater than or equal to 1 AND did not have disease progression to lupus nephritis while on Benlysta therapy for SLE without LN AND disease remains active while on corticosteroids, antimalarials, or immunosuppressants (alone or as combination therapy) for at least the last 30 days AND is using in combination with standard therapy (for example, corticosteroids, antimalarials, and/or immunosuppressants [but not other biologics or IV cyclophosphamide]). For continuation of therapy (IV or Subcutaneous), verification of previous improvement in disease activity following treatment with belimumab indicating a therapeutic response including lack of disease progression to lupus nephritis while on Benlysta if initially only using for SLE without LN AND there is no evidence of active central nervous system lupus. AND individual is using in combination with standard therapy (for example, corticosteroids, antimalarials, and/or immunosuppressants [but not other biologics or IV cyclophosphamide]).</p>
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Besremi

Products Affected

- BESREMI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

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	PENDING CMS REVIEW
Required Medical 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

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Braftovi

Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

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

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Bronchitol

Products Affected

- BRONCHITOL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has a prescription for a short-acting bronchodilator and will be administering prior to every dose of mannitol AND has had a trial and inadequate response or intolerance to inhaled hypertonic saline (Mogayzel 2013).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Brukinsa

Products Affected

- BRUKINSA

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

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Buphenyl

Products Affected

- *sodium phenylbutyrate oral powder 3 gm/tsp*
- *sodium phenylbutyrate oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Using as adjunctive therapy for chronic management of hyperammonemia
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation, there is clinically significant improvement or stabilization in plasma ammonia level.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Cabometyx

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Calquence

Products Affected

- CALQUENCE

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

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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	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Carbaglu

Products Affected

- *carglumic acid oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For initial use, (A) member has a diagnosis of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) AND Using as adjunctive therapy with other ammonia lowering therapies OR (B) has a diagnosis of chronic hyperammonemia due to the deficiency of the hepatic enzyme NAGS AND Using as maintenance therapy OR (C) Individual is using as adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MA) and using as adjunctive therapy with other ammonia lowering therapies. For Continuation use, there is clinically significant improvement or stabilization in plasma ammonia level.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No

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Cayston

Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	7 years of age or older
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Chantix

Products Affected

- *varenicline tartrate (starter)*
- *varenicline tartrate oral tablet 0.5 mg, 1 mg, 1 mg (56 pack)*
- *varenicline tartrate(continue)*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Cialis BPH

Products Affected

- *tadalafil oral tablet 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has a diagnosis of benign prostatic hyperplasia (BPH) and is using to treat the signs and symptoms of BPH.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has had a trial and inadequate response or intolerance to TWO of the following agents: Alfuzosin, Doxazosin, Silodosin, Tamsulosin, or Terazosin.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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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	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Copiktra

Products Affected

- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For continuation, confirmation (verbal or written) of continuing clinical benefit (e.g., complete response, partial response or stable disease).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 YEAR.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Corlanor

Products Affected

- CORLANOR ORAL SOLUTION
- *ivabradine hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For dx NYHA class II-IV (Adult) HF, individual is 18 years of age or older. For NYHA class II-IV (Pediatric) HF due to CM, individual is less than 18 years of age.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For INITIAL use: (A) For adult use, Individual is using for the treatment of New York Heart Association (NYHA) class II, III or IV heart failure symptoms AND has a left ventricular ejection fraction less than or equal to 35% AND will be utilizing in combination with a beta-blocker (bisoprolol, carvedilol, metoprolol succinate) OR has a contraindication or intolerance to beta-blocker therapy AND is in normal sinus rhythm AND individual has a resting heart rate greater than or equal to 70 beats per minute. OR (B) For pediatric use, Individual is using for the treatment of New York Heart Association (NYHA) class II, III, or IV heart failure symptoms due to dilated cardiomyopathy AND has a left ventricular ejection fraction less than or equal to 45% AND is in normal sinus rhythm AND individual has an elevated resting heart rate. For Continuation use there is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Cosentyx

Products Affected

- COSENTYX (300 MG DOSE) SOLUTION PREFILLED SYRINGE 150
- COSENTYX SENSOREADY (300 MG) MG/ML, 75 MG/0.5ML
- COSENTYX SENSOREADY PEN
- COSENTYX SUBCUTANEOUS

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

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Cotellic

Products Affected

- COTELLIC

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

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Cyramza

Products Affected

- CYRAMZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For urothelial cancer, an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. Individual has the applicable mutations based on use/diagnosis. For hepatocellular carcinoma, individual has a Child-Pugh Class A score.
Age Restrictions	For urothelial cancer, 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For locally advanced, unresectable or metastatic urothelial cancer originating from bladder, urethra, ureter or renal pelvis and using in combination with docetaxel AND disease has progressed after platinum-containing chemotherapy (cisplatin or carboplatin) AND individual has received treatment with no more than one immune checkpoint inhibitor (such as, atezolizumab, avelumab, durvalumab, nivolumab or pembrolizumab) AND has received treatment with no more than one prior systemic chemotherapy regimen in the relapsed or metastatic setting AND individual has not received prior systemic taxane therapy in any setting (neoadjuvant, adjuvant or metastatic).
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No

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Cystagon

Products Affected

- CYSTAGON

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Daliresp

Products Affected

- *roflumilast*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using in combination with a long-acting bronchodilator.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Daraprim

Products Affected

- *pyrimethamine oral*

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

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EFFECTIVE DATE 01/01/2025

Darzalex

Products Affected

- DARZALEX FASPRO
- DARZALEX INTRAVENOUS SOLUTION
400 MG/20ML

PA Criteria	Criteria Details
Exclusion Criteria	Has received treatment with daratumumab or another anti-CD38 agent
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Daurismo

Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 75 years old or older OR has comorbidities that preclude use of intensive induction chemotherapy.
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

DHE Nasal Agents

Products Affected

- *dihydroergotamine mesylate nasal*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has had a trial of and inadequate response or intolerance to up to TWO of the following oral agents: Almotriptan, eletriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan OR If oral triptan agents are not acceptable due to concomitant clinical conditions, such as but not limited to the following: (A) Individual is unable to take oral medications due to one of the following: (1) Individual experiences nausea and vomiting due to migraines OR (2) requires a more rapid onset of action due to short aura time period OR (3) cannot swallow tablets and there are no preferred ODT (oral disintegrating tablet) formulations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Diacomit

Products Affected

- DIACOMIT ORAL CAPSULE 250 MG, 500 MG
- DIACOMIT ORAL PACKET 250 MG, 500 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For dx of seizures associated with Dravet Syndrome AND is taking in combination with clobazam AND has responded inadequately to TWO previous antiepileptic drugs (e.g. valproic acid, topiramate, clobazam) (Wirrell 2017, Ziobro 2018).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Dificid

Products Affected

- DIFICID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	30 Days
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Dimethyl Fumarate

Products Affected

- *dimethyl fumarate oral capsule delayed release 120 mg, 240 mg*
- *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	1 Year.
Other Criteria	Individual has a diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Dupixent

Products Affected

- 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	PENDING CMS REVIEW
Required Medical 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

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EFFECTIVE DATE 01/01/2025

Duragesic Patch

Products Affected

- *fentanyl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 2 years of age or older
Prescriber Restrictions	
Coverage Duration	Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

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PA Criteria	Criteria Details
Other Criteria	<p>For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure) AND Individual is not opioid naive as noted by the following: (a) Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting opioid analgesic to another long-acting opioid analgesic OR (c) already receiving at least 60 mg/day of oral morphine, 30 mg/day of oral oxycodone, 8 mg/day of oral hydromorphone, 60 mg/day of oral hydrocodone or an equianalgesic dose of another opioid. For continued use, (I) individual has a diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (II) diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR (III) Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline AND prescriber has consulted with individual regarding risks of opioid therapy AND clear treatment goals have been defined and outlined as part of overall pain.</p>
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Elidel

Products Affected

- *pimecrolimus*

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

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ELIGARD_GNRH

Products Affected

- ELIGARD

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Other advanced, recurrent, or metastatic disease. OR for castration-recurrent disease OR Progressive castration-na?ve disease OR Used as androgen deprivation therapy as a single agent or in combination with antiandrogen.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Emsam

Products Affected

- EMSAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has no known contraindications to the use of a monoamine oxidase inhibitor (MAOI).
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Enbrel

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For chronic moderate to severe plaque psoriasis with either of the following: Individual has greater than 3% of body surface area with plaque psoriasis OR less than or equal to 3% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).
Age Restrictions	Individual is 18 years of age or older, except for the diagnosis of JIA and plaque psoriasis. For PsA and JIA, individual is 2 years of age or older. For plaque psoriasis, 4 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.

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PA Criteria	Criteria Details
Other Criteria	<p>For Initial use: moderate to severe Ankylosing Spondylitis, individual has had an inadequate response to, or is intolerant of, ONE conventional therapies: [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019) OR has a contraindication to NSAIDs or sulfasalazine. For Moderate to severe Chronic Plaque Psoriasis, individual has had inadequate response to, or is intolerant of, phototherapy OR ONE other systemic therapies (such as, methotrexate, acitretin, or cyclosporine) has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate. For moderate to severe Rheumatoid Arthritis, individual has had an inadequate response to, methotrexate titrated to maximally tolerated dose (ACR 2021) OR If methotrexate is not tolerated, individual has had an inadequate response to, or is intolerant of, ONE other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine) OR has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine. For moderate to severe Polyarticular JIA, individual has had an inadequate response to, or is intolerant of, ONE conventional therapy [nonbiologic DMARDs such as methotrexate] (ACR 2019) OR has a contraindication to methotrexate. For moderate to severe Psoriatic Arthritis, individual has had an inadequate response to, or is intolerant of, ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine or leflunomide)] (AAD 2019) OR has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide. For Continuation use: there is clinically significant improvement or stabilization in clinical signs and symptoms of the disease AND has been receiving and is maintained on a stable dose of etanercept.</p>
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Endari

Products Affected

- *L-glutamine oral packet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial, individual has a diagnosis of sickle cell anemia with following: (A) Diagnosis of HbSS or HbS/beta0- thalassemia AND (B) At least two episodes of sickle cell crises (SCC) in the last 12 months.
Age Restrictions	Individual is 5 years of age or older
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation, individual experienced a reduction in acute complications of sickle cell disease (e.g. reduction in the number of vaso-occlusive episodes, acute chest syndrome episodes) since initiating Endari (L-glutamine).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Enhertu

Products Affected

- ENHERTU

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Her2-positive (HER2+) breast cancer OR Her2+ gastric/esophageal and esophagogastric junction cancers confirmed (written or verbal) by either Immunohistochemistry (IHC) is 3+ OR In situ hybridization (ISH) positive. Individual has the applicable mutations based on use/diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For breast cancer use, Individual is using Enhertu as monotherapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Epclusa

Products Affected

- EPCLUSA ORAL PACKET 150-37.5 MG, 200-50 MG
 - EPCLUSA ORAL TABLET 200-50 MG, 400-100 MG
- *sofosbuvir-velpatasvir*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Epidiolex

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For tx of seizures associated with Lennox-Gastaut syndrome or Dravet Syndrome, Individual has responded inadequately to two previous antiepileptic drugs (e.g., valproic acid, topiramate, clobazam) (Hancock 2013. Wirrell 2017. Ziobro 2018). Individual is using for tuberous sclerosis complex.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Epogen and Procrit

Products Affected

- PROCRIT UNIT/ML, 4000 UNIT/ML, 40000
- RETACRIT INJECTION SOLUTION UNIT/ML
10000 UNIT/ML, 10000 UNIT/ML(1ML),
2000 UNIT/ML, 20000 UNIT/ML, 3000

PA Criteria	Criteria Details
Exclusion Criteria	

PA Criteria	Criteria Details
Required Medical Information	<p>For initial use of EPO: Baseline Hemoglobin (Hgb) levels are less than 10 g/dL AND baseline evaluation of the individual iron status is adequate as defined by one of the following: transferrin saturation 20% or greater OR ferritin 80 ng/mL or greater OR bone marrow demonstrates adequate iron stores. And individual is using for one of the following: For MDS, endogenous EPO level is less than or equal to 500 mU/ml. For anemia related to zidovudine (ZDV) in HIV-infected mbr when the dose of ZDV is less than or equal to 4200 mg per week, endogenous EPO level is less than or equal 500 mU/ml. For tx of anemia due to myelosuppressive chemotherapy known to produce anemia when the following are met: chemo is planned for a minimum of 2 months and the dx is non-myeloid cancer and the anticipated outcome is not cure. For anemia associated with CKD ON dialysis use is to achieve and maintain hgb levels within the range of 10 to 11 g/dL. For anemia associated with CKD NOT ON dialysis, use is to achieve and maintain hgb levels of 10 g/dL. For continued use, mbr demonstrates continued need for ESA tx and has confirmation of response to tx as evidenced by an inc in HGB levels from baseline AND is using the lowest ESA dose necessary to avoid transfusions AND meets one of the following criteria: (a) HGB level is not greater than 11 g/dL for CKD individuals on dialysis, or greater than 10 g/dL for CKD non-dialysis, unless otherwise specified (for example, pediatric individuals with CKD where target Hgb levels is within the range of 10 to 12 g/dL) OR (b) HGB is not greater than 11 g/dL for indiv using for myelosuppressive chemotherapy related anemia or myelodysplastic syndrome (NCCN) OR HGB level is not greater than 12 g/dL for ZDV-related anemia in patients with HIV AND if using for myelosuppressive chemotherapy-related anemia, individual is not using beyond 6 weeks after chemotherapy has completed.</p>
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Dialysis Dependent use: 1 year. All other use: 6 months.

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PA Criteria	Criteria Details
Other Criteria	For ESA use for elective, non-cardiac, non-vascular surgery to reduce the need for allogenic blood transfusions AND Baseline Hgb level is greater than 10 g/dL and less than or equal to 13 g/dL AND is at high risk for perioperative transfusions with significant, anticipated blood loss AND Baseline iron status is adequate as defined by one of the following: (i) Transferrin saturation 20% or greater OR (ii) Ferritin 80 ng/mL or greater OR (iii) Bone marrow demonstrates adequate iron stores.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Eraxis

Products Affected

- ERAXIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has a diagnosis of Candidemia or certain other forms of Candida infection OR esophageal candidiasis OR member is transitioning from inpatient treatment to an outpatient setting and requires continued therapy for an organism susceptible to anidulafungin.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Erivedge

Products Affected

- ERIVEDGE

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

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Erleada

Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)] OR Has had a bilateral orchiectomy. For non-metastatic castration-resistant prostate cancer (nmCRPC), Individual has a PSA doubling time (PSADT) less than or equal to 10 months.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Erwinase

Products Affected

- RYLAZE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has developed a confirmed (written or verbal) systemic allergic reaction or anaphylaxis to prior treatment with E. Coli-derived asparaginase.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Esbriet

Products Affected

- *pirfenidone oral tablet 267 mg, 534 mg, 801 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial use for Diagnosis of idiopathic pulmonary fibrosis (IPF) demonstrated by: Exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity AND High resolution computed tomography (HRCT) with or without lung tissue sampling. Individual has pulmonary function tests within prior 60 days demonstrating a Forced Vital Capacity (% FVC) greater than or equal to 50%.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continued use, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decreased frequency of exacerbations, slowed rate of FVC decline or improvement in respiratory symptom burden).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Exjade

Products Affected

- *deferasirox oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 2 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Exkivity

Products Affected

- EXKIVITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has not progressed on prior therapy with Exkivity (mobocertinib) AND is using as monotherapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Fasenra

Products Affected

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

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

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EFFECTIVE DATE 01/01/2025

Fentora

Products Affected

- *fentanyl citrate buccal tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has a diagnosis of active cancer (including but not limited to metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (provide diagnosis) AND has had a trial and inadequate response or intolerance to fentanyl citrate lozenge (generic Actiq) AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR At least 60mg of oral hydrocodone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking fentanyl citrate for cancer related breakthrough pain.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

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Fetzima

Products Affected

- FETZIMA
- FETZIMA TITRATION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For MDD, individual has had a trial of TWO of the following: Desvenlafaxine, fluoxetine, fluvoxamine, escitalopram, citalopram, paroxetine, sertraline, mirtazapine, venlafaxine, or bupropion.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Fintepla

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	Individual is using for weight loss/reduction.
Required Medical Information	Diagnosis: Lennox-Gastaut syndrome (LGS), Dravet Syndrome (DS).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has a diagnosis of seizures associated with Lennox-Gastaut syndrome or Dravet Syndrome AND has responded inadequately to two previous antiepileptic drugs (Lagae 2019, Wirrell 2017, Ziobro 2018).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Firazyr

Products Affected

- *icatibant acetate*
- SAJAZIR SUBCUTANEOUS SOLUTION
PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Prophylaxis for HAE attacks.
Required Medical Information	Dx of HAE to be verified by a C4 level below the lower limit of normal (as defined by laboratory testing) and either a C1 inhibitor antigenic level below the lower limit of normal (as defined by lab testing) or a C1 inhibitor functional level below the lower limit of normal (as defined by the lab testing).
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has a history of moderate or severe attacks such as airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, or painful facial distortion and using Icatibant for acute HAE attacks.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Firmagon

Products Affected

- FIRMAGON (240 MG DOSE)
- FIRMAGON SUBCUTANEOUS SOLUTION RECONSTITUTED 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Used for progressive castration-na?ve disease or for castration-recurrent disease OR Other advanced, recurrent, or metastatic disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Forteo

Products Affected

- *teriparatide*
- *teriparatide (recombinant)*

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

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Fotivda

Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For RCC, individual has received at least two prior systemic therapies AND at least one prior systemic therapy included a vascular endothelial growth factor receptor tyrosine kinase inhibitor (VEGFR TKI), such as axitinib, cabozantinib, lenvatinib, sunitinib, or pazopanib (Rini 2020).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Fruzaqla

Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

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

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Galafold

Products Affected

- GALAFOLD

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial use, Individual has a diagnosis of Fabry disease as defined with either complete deficiency or less than 5% of mean normal alpha-galactosidase A (a-Gal A) enzyme activity in leukocytes, dried blood spots or serum (plasma) analysis OR galactosidase alpha (GLA) gene mutation by gene sequencing. Individual has an amendable GLA gene variant based on the human embryonic kidney-293 assay.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For initial use, Individual has one or more symptoms or physical findings attributable to Fabry disease (ACMG), such as but not limited to: (a) Burning pain in the extremities (acroparesthesias), or (b) Cutaneous vascular lesions (angiokeratomas), or (c) Corneal verticillata (whorls), or (d) Decreased sweating (anhidrosis or hypohidrosis), or (e) Personal or family history of exercise, heat, or cold intolerance, or (f) Personal or family history of kidney failure. For continued use, Individual has had a positive therapeutic response to treatment.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No

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Gattex

Products Affected

- GATTEX

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

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Gavreto

Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has written or verbal confirmation of RET fusion (or rearrangement) positive tumors. For NSCLC, individual has not received treatment with another RET rearrangement positive-targeted agent, such as cabozantinib, vandetanib, or selpercatinib (NCT03037385).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using as monotherapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Gazyva

Products Affected

- GAZYVA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has the applicable mutations based on use/diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For the treatment of follicular lymphoma, using in combination with ONE of the following combination therapies regimens and as monotherapy for up to 24 months or until disease progression, following the listed combination therapy regimens: cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP regimen) or cyclophosphamide, vincristine, and prednisone (CVP regimen) or bendamustine.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Gilenya

Products Affected

- *fingolimod hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<p>I. Individual has had a trial and inadequate response (including but not limited to clinical relapse, new or enlarged lesions on MRI or disability progression) or intolerance to one of the following: Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Glatiramer Acetate/Glatopa, Dimethyl Fumarate, or Teriflunomide OR II. Individual has high disease activity despite treatment with a disease modifying drug (including Aubagio, Avonex, Bafiertam, Extavia, Kesimpta, Plegridy, Ponvory Rebif, Betaseron, Briumvi Lemtrada, Mavenclad, Mayzent, Ocrevus, Copaxone/Glatiramer/Glatopa, Tecfidera, Tysabri, Vumerity and Zeposia) defined as the following: At least 1 relapse in the previous year while on therapy AND At least 9 T2-hyperintense lesions in cranial MRI OR At least 1 Gadolinium-enhancing lesion. OR III. Individual is treatment naive (no previous history of use of disease modifying drugs such as Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone/Glatiramer/Glatopa, Extavia, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Ponvory Rebif, Tecfidera, Tysabri, Vumerity and Zeposia) AND IV. Individual has rapidly evolving severe relapsing multiple sclerosis defined as the following: Two or more disabling relapses in 1 year AND One or more Gadolinium-enhancing lesions on brain MRI. OR V. Individual is between 10-17 years of age and has a diagnosis relapsing MS (RMS).</p>
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Gilotrif

Products Affected

- GILOTRIF

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

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Glatiramer Agents

Products Affected

- *glatiramer acetate subcutaneous solution* MG/ML, 40 MG/ML
prefilled syringe 20 mg/ml, 40 mg/ml
- GLATOPA SUBCUTANEOUS
SOLUTION PREFILLED SYRINGE 20

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Gleevec

Products Affected

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

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

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EFFECTIVE DATE 01/01/2025

Gleostine

Products Affected

- GLEOSTINE ORAL CAPSULE 10 MG, 100 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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GLP 1

Products Affected

- OZEMPIC (0.25 OR 0.5 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 2 MG/1.5ML, 2 MG/3ML
- OZEMPIC (1 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 2 MG/1.5ML, 4 MG/3ML
- OZEMPIC (2 MG/DOSE)
- RYBELSUS ORAL TABLET 14 MG, 3 MG, 7 MG
- TRULICITY

PA Criteria	Criteria Details
Exclusion Criteria	Individual is using for weight loss.
Required Medical Information	Documentation (written) has been provided for diagnosis. Attestation has been provided that diagnosis has been verified by history of: (A) Hemoglobin A1c (A1C) greater than or equal to 6.5% OR (B) Fasting Plasma Glucose (FPG) greater than or equal to 126 mg/dl (after fasting for at least 8 hours) OR (C) 2 hour plasma glucose greater than or equal to 200mg/dl as part of an oral glucose tolerance test (75g oral glucose after fasting for at least 8 hours) OR (D) Symptoms of hyperglycemia (including polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dl.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Type 2 Diabetes.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Hadlima

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Chronic moderate to severe plaque psoriasis with either of the following: Patient has greater than 3% of body surface area with plaque psoriasis OR Less than or equal to 3% of body surface area with plaque psoriasis involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia) AND agent is used to reduce signs/symptoms OR to induce/maintain clinical response.
Age Restrictions	Individual is 18 years of age or older for all indications except JIA, uveitis, UC, Hidradenitis Suppurativa (HS) and Crohns disease. Individual is 2 years old for JIA and uveitis. Individual is 6 years of age for Crohns disease. Individual is 12 years old for HS. Individual is 5 years of age or older for UC.
Prescriber Restrictions	
Coverage Duration	1 Year.

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PA Criteria	Criteria Details
Other Criteria	<p>For initial use: For RA, mbr has had an inadequate response to MTX titrated to maximally tolerated dose (ACR 2021) OR If MTX is not tolerated, individual has had an inadequate response to, or is intolerant of, ONE other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine) OR has a contraindication(CI) to MTX, sulfasalazine, leflunomide, and hydroxychloroquine. For Psoriatic Arthritis, mbr has had an inadequate response to, or is intolerant of, ONE conventional therapy [non-biologic DMARDs (such as methotrexate, sulfasalazine or leflunomide)] OR has a CI to MTX, sulfasalazine, cyclosporine, and leflunomide. For Ankylosing Spondylitis (AS), mbr has had an inadequate response to, or is intolerant of, ONE conventional therapy (such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine) OR has a CI to NSAIDs or sulfasalazine. For Crohn's disease, mbr has had an inadequate response to, or is intolerant of, ONE conventional therapy (e.g. systemic corticosteroids, or immunosuppressants) OR has a CI to systemic corticosteroids or thiopurines or MTX. For plaque psoriasis, mbr has had an inadequate response to, or is intolerant of, phototherapy or ONE other systemic therapy (e.g. methotrexate, acitretin, or cyclosporine) OR has a CI to phototherapy, acitretin, cyclosporine, and MTX. For Polyarticular Juvenile Idiopathic Arthritis (PJIA), mbr has had an inadequate response to, or is intolerant of, ONE conventional therapy [nonbologic DMARDs (such as methotrexate)] (ACR 2011) OR has a CI to MTX. For Ulcerative Colitis (UC), mbr has had an inadequate response to, or is intolerant of, ONE conventional therapy (such as 5-ASA products, systemic corticosteroids, or immunosuppressants [such as thiopurines]) OR has a CI to 5-ASA products or systemic corticosteroids or thiopurines. For uveitis, mbr has chronic, recurrent, treatment-refractory or vision-threatening disease and has had an inadequate response to, or is intolerant of, conventional therapy (such as corticosteroids or immunosuppressants [azathioprine, cyclosporine, or MTX]) OR has a CI to corticosteroids, azathioprine, cyclosporine, and MTX. For</p>

PA Criteria	Criteria Details
	<p>chronic, progressive, treatment-refractory Sarcoidosis (Sweiss 2014), mbr has had an inadequate response to, or is intolerant of nonbiologic DMARDs (such as methotrexate or azathioprine) OR has a CI to MTX and azathioprine. For Hidradenitis Suppurativa (Hurley stage II or Hurley stage III disease) AND has had an inadequate response to, or is intolerant of, conventional therapy (such as oral antibiotics) OR has a CI to oral antibiotics. For continued use, there is clinically significant improvement or stabilization in clinical signs and symptoms of the disease AND has been receiving and is maintained on a stable dose of adalimumab-bwwd.</p>
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Hepsera

Products Affected

- *adefovir dipivoxil*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	12 years of age and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has had a previous trial and inadequate response or intolerance to or has a contraindication to an alternative antiviral agent with a higher genetic barrier to resistance for Hepatitis B [such as entecavir or tenofovir] (AASLD 2016).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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HRM Age

Products Affected

- *amoxapine*
- *chlordiazepoxide-amitriptyline*
- *clomipramine hcl oral*
- *desipramine hcl oral*
- *doxepin hcl oral capsule*
- *doxepin hcl oral concentrate*
- *imipramine hcl oral*
- *imipramine pamoate*
- *perphenazine-amitriptyline*
- *phenobarbital oral elixir*
- *phenobarbital oral tablet 100 mg, 15 mg, 16.2 mg, 30 mg, 32.4 mg, 60 mg, 64.8 mg, 97.2 mg*
- *protriptyline hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prescriber must acknowledge this is a high risk medication (HRM) (as identified by American Geriatric Society) for individuals greater than 65 and medication benefits outweigh potential risk for this individual.
Age Restrictions	Individuals that are 64 years of age or younger are NOT subject to the prior authorization requirements. Prior Authorization applies to individuals that are 65 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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HRM Age AU

Products Affected

- BAC
- *benztropine mesylate oral*
- BIJUVA
- *butalbital-acetaminophen oral tablet 50-325 mg*
- *butalbital-apap-caffeine oral capsule*
- *butalbital-apap-caffeine oral tablet 50-325-40 mg*
- *carbinoxamine maleate oral solution*
- *chlordiazepoxide-clidinium*
- *chlorzoxazone oral tablet 500 mg*
- *clemastine fumarate oral tablet 2.68 mg*
- CLIMARA PRO
- *cyclobenzaprine hcl oral tablet 10 mg, 5 mg*
- *cyproheptadine hcl oral syrup*
- *digox oral tablet 250 mcg*
- *digoxin oral tablet 250 mcg*
- *dipyridamole oral*
- *disopyramide phosphate oral*
- *ergoloid mesylates oral*
- ESGIC ORAL CAPSULE
- *indomethacin oral capsule 25 mg, 50 mg*
- *ketorolac tromethamine oral*
- *megestrol acetate oral suspension 625 mg/5ml*
- *meperidine hcl injection solution 100 mg/ml, 25 mg/ml, 50 mg/ml*
- *meperidine hcl oral solution*
- *meperidine hcl oral tablet 50 mg*
- *meprobamate*
- *pentazocine-naloxone hcl*
- PREMARIN ORAL
- PROMETHEGAN
- *trihexyphenidyl hcl oral solution*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prescriber must acknowledge this is a high risk medication (HRM) (as identified by American Geriatric Society) for individuals greater than 65 and medication benefits outweigh potential risk for this individual.
Age Restrictions	Individuals that are 64 years of age or younger are NOT subject to the prior authorization requirements. Prior Authorization applies to individuals that are 65 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Human Growth Hormone

Products Affected

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

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

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Humira

Products Affected

- HUMIRA (2 PEN) SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.4ML, 40 MG/0.8ML, 80 MG/0.8ML
- HUMIRA (2 SYRINGE) SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML
- HUMIRA-CD/UC/HS STARTER SUBCUTANEOUS PEN-INJECTOR KIT 80 MG/0.8ML
- HUMIRA-PED \geq 40KG UC STARTER
- HUMIRA-PSORIASIS/UVEIT STARTER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Chronic moderate to severe plaque psoriasis with either of the following: Patient has greater than 3% of body surface area with plaque psoriasis OR Less than or equal to 3% of body surface area with plaque psoriasis involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia) AND agent is used to reduce signs/symptoms OR to induce/maintain clinical response.
Age Restrictions	Individual is 18 years of age or older for all indications except JIA, uveitis, UC, Hidradenitis Suppurativa (HS) and Crohns disease. Individual is 2 years old for JIA and uveitis. Individual is 6 years of age for Crohns disease. Individual is 12 years old for HS. Individual is 5 years of age or older for UC.
Prescriber Restrictions	
Coverage Duration	1 Year.

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PA Criteria	Criteria Details
Other Criteria	<p>For initial use: For RA, mbr has had an inadequate response to MTX titrated to maximally tolerated dose (ACR 2021) OR If MTX is not tolerated, individual has had an inadequate response to, or is intolerant of, ONE other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine) OR has a contraindication(CI) to MTX, sulfasalazine, leflunomide, and hydroxychloroquine. For Psoriatic Arthritis, mbr has had an inadequate response to, or is intolerant of, ONE conventional therapy [non-biologic DMARDs (such as methotrexate, sulfasalazine or leflunomide)] OR has a CI to MTX, sulfasalazine, cyclosporine, and leflunomide. For Ankylosing Spondylitis (AS), mbr has had an inadequate response to, or is intolerant of, ONE conventional therapy (such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine) OR has a CI to NSAIDs or sulfasalazine. For Crohn's disease, mbr has had an inadequate response to, or is intolerant of, ONE conventional therapy (e.g. systemic corticosteroids, or immunosuppressants) OR has a CI to systemic corticosteroids or thiopurines or MTX. For plaque psoriasis, mbr has had an inadequate response to, or is intolerant of, phototherapy or ONE other systemic therapy (e.g. methotrexate, acitretin, or cyclosporine) OR has a CI to phototherapy, acitretin, cyclosporine, and MTX. For Polyarticular Juvenile Idiopathic Arthritis (PJIA), mbr has had an inadequate response to, or is intolerant of, ONE conventional therapy [nonbologic DMARDs (such as methotrexate)] (ACR 2011) OR has a CI to MTX. For Ulcerative Colitis (UC), mbr has had an inadequate response to, or is intolerant of, ONE conventional therapy (such as 5-ASA products, systemic corticosteroids, or immunosuppressants [such as thiopurines]) OR has a CI to 5-ASA products or systemic corticosteroids or thiopurines. For uveitis, mbr has chronic, recurrent, treatment-refractory or vision-threatening disease and has had an inadequate response to, or is intolerant of, conventional therapy (such as corticosteroids or immunosuppressants [azathioprine, cyclosporine, or MTX]) OR has a CI to corticosteroids, azathioprine, cyclosporine, and MTX. For</p>

PA Criteria	Criteria Details
	<p>chronic, progressive, treatment-refractory Sarcoidosis (Sweiss 2014), mbr has had an inadequate response to, or is intolerant of nonbiologic DMARDs (such as methotrexate or azathioprine) OR has a CI to MTX and azathioprine. For Hidradenitis Suppurativa (Hurley stage II or Hurley stage III disease) AND has had an inadequate response to, or is intolerant of, conventional therapy (such as oral antibiotics) OR has a CI to oral antibiotics. For continued use, there is clinically significant improvement or stabilization in clinical signs and symptoms of the disease AND has been receiving and is maintained on a stable dose of adalimumab.</p>
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Ibrance

Products Affected

- IBRANCE

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

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Iclusig

Products Affected

- ICLUSIG

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

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EFFECTIVE DATE 01/01/2025

Idhifa

Products Affected

- IDHIFA ORAL TABLET 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has confirmed (written or verbal attestation) isocitrate dehydrogenase-2 (IDH2) mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Imbruvica

Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 560 MG
70 MG
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET 420 MG,

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Increlex

Products Affected

- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial treatment of growth failure associated with severe primary IGF-1 deficiency as defined by: Height standard deviation score of less than or equal to -3.0 AND Basal IGF-1 standard deviation score of less than or equal to -3.0 AND normal or elevated growth hormone levels (greater than 10ng/mL on standard GH stimulation tests) are present OR GH gene deletion who have development of neutralizing antibodies to GH.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Continuation of treatment with Increlex (mecasermin), Final adult height has not been reached.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Ingrezza

Products Affected

- INGREZZA ORAL CAPSULE 40 MG, 60 MG, 80 MG
- INGREZZA ORAL CAPSULE THERAPY PACK
- INGREZZA ORAL CAPSULE SPRINKLE 40 MG, 60 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial use in Tardive dyskinesia confirmed by the following (DSM-5): A) Individual has had a stable (drug, dose) medication exposure (either typical or first generation antipsychotic agents [such as, chlorpromazine, haloperidol, fluphenazine], atypical or second-generation antipsychotic agents [such as, clozapine, risperidone, olanzapine, quetiapine, aripiprazole], or certain dopamine receptor-blocking used in treatment of nausea and gastroparesis [such as prochlorperazine, promethazine, metoclopramide] AND B) Presence of involuntary athetoid or choreiform movements. Diagnosis of chorea associated with Huntington's disease.
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Initial: 3 months. Continuation: 1 year
Other Criteria	For continued use, individual has experienced an improvement in symptoms deemed to be clinically significant by the provider based on stabilization or improvement in Abnormal Involuntary Movement Scale (AIMS) score (for TD) or total maximal chorea score (for Huntington's disease).
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Inlyta

Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

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

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Inqovi

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Inrebic

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Interferons for MS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Iressa

Products Affected

- *gefitinib*

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

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ITRACONAZOLE

Products Affected

- *itraconazole oral capsule*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	For fingernail/toenail onychomycosis 12 weeks. For all other indications 1 year.
Other Criteria	For second-line non-onychomycosis indications include tinea infections (including, but limited to tinea versicolor, tinea cruris, tinea corporis, tinea pedis, tinea manuum, and tinea capitis) where the individual has had a trial and inadequate response or intolerance to at least one prior topical therapy: ciclopirox, clotrimazole, ketoconazole, econazole, or nystatin. OR Individual is transitioning from inpatient treatment to an outpatient setting and requires continued therapy for an organism susceptible to itraconazole for a non-onychomycosis use.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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IVIG

Products Affected

- GAMUNEX-C INJECTION SOLUTION 1 GM/10ML GM/200ML, 2 GM/20ML, 20 GM/200ML, 5 GM/50ML
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 10 GM/100ML, 10

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

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Iwilfin

Products Affected

- IWILFIN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Jadenu

Products Affected

- *deferasirox oral tablet 90 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For dx non-transfusion-dependent thalassemia (NTDT) syndrome, 10 years of age or older. For dx of chronic iron overload, 2 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Jakafi

Products Affected

- JAKAFI

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

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Jaypirca

Products Affected

- JAYPIRCA ORAL TABLET 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual is using as a single agent. Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Kadcyla

Products Affected

- KADCYLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Tumor(s) have been evaluated with an assay validated to predict HER2 positive (HER2+) protein overexpression. Individuals are considered HER2 positive (HER2+) as confirmed by one of the following, immunohistochemistry (IHC) 3+ or In Situ hybridization (ISH) positive.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Kalydeco

Products Affected

- KALYDECO ORAL PACKET
- KALYDECO ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial use, individual has a diagnosis of cystic fibrosis (CF) AND has mutation-positive result in the cystic fibrosis transmembrane conductance regulator (CFTR) gene and the mutation type is provided and responsive to Kaldeco.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation requests, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in FEV1, decrease in pulmonary exacerbations, improvement in BMI or improvement of respiratory symptoms [cough, sputum production, difficulty breathing]).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Kisqali

Products Affected

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

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EFFECTIVE DATE 01/01/2025

Korlym

Products Affected

- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of Cushings has been verified by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (including but not limited to: 24-hour urinary free cortisol (UFC) test, Dexamethasone suppression test (DST), Late-night salivary cortisol (LNSC) test) that are indicative of a positive test.
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Initial: 6 months. Continuation: 1 Year.
Other Criteria	Initial therapy: Individual is not a candidate for surgery that is expected to correct the cause of endogenous Cushings Syndrome OR disease persists or recurs following surgery intended to correct the cause of endogenous Cushings Syndrome. For continuation of therapy: Individual continues to meet the initial request approval criteria AND has experienced an improvement in or stabilization of glucose control as assessed by fasting serum glucose test, oral glucose tolerance test or hemoglobin A1c test.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Koselugo

Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Krazati

Products Affected

- KRAZATI

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

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EFFECTIVE DATE 01/01/2025

Kuvan

Products Affected

- JAVYGTOR
- *sapropterin dihydrochloride oral packet*
- *sapropterin dihydrochloride oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial requests, Individual has Dx of Hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4) responsive PKU. For continued use, has Dx of Hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4) responsive PKU AND. There is a positive response to therapy as evidenced by reduction in blood PHE levels from baseline.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial 8 weeks, 1 year for continuation
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

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	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Letairis

Products Affected

- *ambrisentan*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial use, Individual has diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units. AND Individual has WHO functional class II- IV symptoms.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation use, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Leukine

Products Affected

- LEUKINE INJECTION SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individuals who are at high risk for infection-associated complications demonstrated by any of the following: Expected prolonged (greater than 10 day) and profound (less than $0.1 \times 10^9/L$) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infection, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Prior episode of febrile neutropenia, Hospitalized at the time of the development of fever.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

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PA Criteria	Criteria Details
Other Criteria	<p>Adjunctive tx and individual as a high risk for infection-associated complications. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. For acute myeloid leukemia and using shortly after completion of induction or repeat induction chemo of AML. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500mm³ or experiencing recurrent/resistant infection. For mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation. For acceleration of myeloid reconstitution after autologous or allogenic bone marrow transplantation or peripheral blood progenitor cell transplantation. For delayed neutrophil recovery/graft failure after autologous or allogenic bone marrow transplantation. Used to increase survival in individual exposed to myelosuppressive doses of radiation such as Hematopoietic Syndrome of Acute Radiation Syndrome. For malignant melanoma as an adjuvant treatment following surgery for stage III or IV melanoma in those at high risk for recurrence. For relapsed/refractory high-risk neuroblastoma AND using in combination with Danyelza (naxitamab- gqgk) OR is using in combination with dinutuximab (Unituxin), 13-cis-retinoic acid (i.e. isotretinoin) and with or without interleukin-2 (IL-2) (i.e. aldesleukin) AND achieved a partial response to first-line multi-agent, multi-modality therapy (i.e. induction combination chemotherapy, or myeloablative consolidation chemotherapy followed by autologous stem cell transplant).</p>
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Lidocaine 4

Products Affected

- *lidocaine hcl external solution*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using for anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Lidocaine 5

Products Affected

- *lidocaine external ointment 5 %*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using for anesthesia of accessible mucous membranes of the oropharynx (such as back of the tongue, soft palate, side and back walls of the throat, and the tonsils) OR is using for relief of pain and itching due to minor cuts, minor scrapes, minor skin irritations, minor burns, and insect bites.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Lidoderm Patch

Products Affected

- *lidocaine external patch 5 %*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Livtency

Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using to treat cytomegalovirus (CMV) infection or disease AND is a hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT) recipient AND is refractory to treatment with ganciclovir, valganciclovir, cidofovir or foscarnet.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Lonsurf

Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Lorbrena

Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

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

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EFFECTIVE DATE 01/01/2025

Lotronex

Products Affected

- *alose tron hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual is a Female with Severe diarrhea-predominant Irritable Bowel Syndrome (IBS) defined as including diarrhea and 1 or more of the following: Frequent and severe abdominal pain/discomfort, Frequent bowel urgency or fecal incontinence, Disability or restriction of daily activities due to IBS. Member is female AND Member has chronic symptoms of IBS that have persisted for 6 months or longer AND does not have an anatomic or biochemical abnormality of the gastrointestinal tract.
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has a trial and inadequate response or intolerance TWO (2) of the following medications: (a) Loperamide (b) antispasmodics (for example, dicyclomine), or (c) tricyclic antidepressants (AGA 2021).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Lumakras

Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 320 MG

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

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Lupron Depot

Products Affected

- *leuprolide acetate (3 month)*
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<p>For Prostate cancer: Clinically localized dz with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) or higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Other advanced, recurrent, or metastatic disease.</p> <p>For Gynecology Uses: Initial treatment/retreatment of endometriosis OR Preoperative tx as adjunct to surgical tx of uterine fibroids (leiomyoma uteri), May be used to reduce size of fibroids to allow for a vaginal procedure, prior to surgical tx (myomectomy or hysterectomy) in patients with confirmed anemia (Letheby et al. 2001, 2017). To induce amenorrhea in women (such as but not limited to menstruating women diagnosed with severe thrombocytopenia or aplastic anemia). Using for endometrial thinning prior to endometrial ablation for dysfunctional uterine bleeding. For Endocrine Uses: central Precocious puberty, defined as beginning of secondary sexual characteristics before age 8 in girls and before age 9 in boys and dx has been confirmed (written or verbal) by one of the following: pubertal response to a GnRH agonist test OR A pubertal level of:(1) a third generation LH assay OR (2) pediatric LH assay OR (3) ultra-sensitive LH assay OR (4) assay that can detect levels less than 0.2 AND has been confirmed (written or verbal) by assessment of bone age versus chronological age. For Ovarian Cancer (including fallopian tube cancer and primary peritoneal cancer): Hormonal therapy for clinical relapse in individuals with stage II-IV granulosa cell tumors or Hormonal therapy for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer as a single agent for persistent dz or recurrence.</p>

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Gender Dysphoria/incongruence (Coleman 2022) mbr has experienced puberty to at least Tanner stage 2 (Hembree 2017, Coleman 2022)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Lupron Kit IR

Products Affected

- *leuprolide acetate injection*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) or higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Other advanced, recurrent, or metastatic disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Lybalvi

Products Affected

- LYBALVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Lynparza

Products Affected

- LYNPARZA ORAL TABLET

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

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EFFECTIVE DATE 01/01/2025

Lytgobi

Products Affected

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

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EFFECTIVE DATE 01/01/2025

Mavyret

Products Affected

- MAVYRET ORAL PACKET
- MAVYRET ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a genotype and a positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2017).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Megace Suspension HRM

Products Affected

- *megestrol acetate oral suspension 40 mg/ml, 400 mg/10ml, 800 mg/20ml*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual is using for the treatment of cachexia, or unexplained weight loss in individuals with HIV/AIDS. Prescriber must acknowledge this is a high risk medication (HRM) [as identified by American Geriatric Society] for individuals greater than 65 and medication benefits outweigh potential risk for this individual.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Megace Tabs HRM

Products Affected

- *megestrol acetate oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prescriber must acknowledge this is a high risk medication (HRM) [as identified by American Geriatric Society] for individuals greater than 65 and medication benefits outweigh potential risk for this individual.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 YEAR.
Other Criteria	Individual has advanced, inoperable, recurrent breast cancer and using for palliative management. Individual has endometrial/uterine cancer and is using for palliative management.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Mekinist

Products Affected

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

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

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EFFECTIVE DATE 01/01/2025

Mektovi

Products Affected

- MEKTOVI

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

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EFFECTIVE DATE 01/01/2025

Mepron

Products Affected

- *atovaquone oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Intolerance to trimethoprim-sulfamethoxazole (TMP-SMX)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Methylphenidate

Products Affected

- *methylphenidate hcl er (cd) oral capsule extended release 10 mg, 20 mg, 40 mg, 50 mg, 60 mg*
- *methylphenidate hcl er (osm) oral tablet extended release 18 mg, 27 mg, 36 mg, 54 mg*
- *methylphenidate hcl er oral tablet*
- *extended release 20 mg*
- *methylphenidate hcl oral solution 10 mg/5ml, 5 mg/5ml*
- *methylphenidate hcl oral tablet*
- *methylphenidate hcl oral tablet chewable 10 mg, 2.5 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual is using for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) or Narcolepsy.
Age Restrictions	For ADHD, 6 years of age and older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Modafinil

Products Affected

- *modafinil oral tablet 100 mg, 200 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<p>For Narcolepsy type 1: defined by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following: 1. Clear cataplexy (defined as more than one episode of generally brief usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness) AND 2. Multiple Sleep Latency Test (MSLT) showing one of the following: a. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014) OR b. MSL less than 8min of at least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) OR 3. Cerebrospinal fluid hypocretin-1 deficiency (less than 100pg/mL or less than one-third of the normative values with the same standardized assay). For Narcolepsy type 2: defined by 1. Multiple sleep latency test (MSLT) with one of the following: a. Mean sleep latency of less than 8 minutes with and evidence of two sleep-onset rapid eye movement periods (SOREMPs) ICSD-3, 2014) OR b. MSL less than 8min of at least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) AND 2. The absence of cataplexy AND 3. Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and Polysomnography.</p>
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	1 Year.
Other Criteria	<p>For obstructive sleep apnea/hypopnea syndrome objectively verified by polysomnography (PSG) or home testing with portable monitor showing one of the following (AASM 2017, ICDS-3): 1. Greater than 15 obstructive events (defined as apneas, hypopneas plus respiratory event related arousal) per hour of sleep OR 2. Greater than 5 obstructive events per hour of sleep and individual reports any of the following: a. Unintentional sleep episodes during wakefulness or b. Daytime sleepiness or c. Unrefreshing sleep or d. Fatigue or e. Insomnia or f. Waking up breath holding, gasping or choking or g. Bed partner describing loud snoring, breathing interruptions or both or h. Presence of comorbid conditions including hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation or type 2 diabetes mellitus AND 3. Has an Epworth Sleepiness Scale score greater than or equal to 10. For Shift-Work Sleep Disorder (SWSD) defined by all of the following: 1. No other medical disorder or mental disorder accounts for the symptoms AND 2. Symptoms do not meet criteria for any other sleep disorder (i.e. jet lag) AND 3. Symptoms have occurred for at least 3 months, AND 4. Individual has one of the following: a. Individual has excessive sleepiness or insomnia associated with a work period that occurs during the usual sleep phase OR b. Polysomnography demonstrates loss of a normal sleep-wake pattern (such as, disturbed chronobiological rhythmicity). For idiopathic hypersomnia (IH) defined by the following (ICSD-3, Kahn 2015, AASM 2021): 1. Daily periods of irresistible need to sleep or daytime lapses into sleep for more than 3 months AND 2. Absence of cataplexy AND Insufficient sleep syndrome ruled out (if deemed necessary, by lack of improvement of sleepiness after an adequate trial of increased nocturnal time in bed, preferably verified by at least 1 week of wrist actigraphy) AND 3. Multiple Sleep Latency Test (MSLT) shows the following: a. Fewer than 2 sleep-onset rapid eye movement periods (SOREMPs) OR b. No SOREMPs if the REM sleep latency period on the preceding overnight polysomnogram is 15 minutes or less</p>

PA Criteria	Criteria Details
	<p>AND 5. The presence of at least one of the following: a. MSLT showing a mean sleep latency of 8 minutes or less OR b. Total 24-hour sleep time of 660 minutes or longer (typically 12-14 hours) on 24-hour polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in association with a sleep log (averaged over at least 7 days with unrestricted sleep) AND 6. Hypersomnolence or MSLT findings are not better explained by another sleep disorder, medical or neurologic disorder, mental disorder, medication use, or substance abuse.</p>
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Mounjaro

Products Affected

- MOUNJARO

PA Criteria	Criteria Details
Exclusion Criteria	Individual is using for weight loss.
Required Medical Information	Documentation (written) has been provided for diagnosis. Attestation has been provided that diagnosis has been verified by history of: (A) Hemoglobin A1c (A1C) greater than or equal to 6.5% OR (B) Fasting Plasma Glucose (FPG) greater than or equal to 126 mg/dl (after fasting for at least 8 hours) OR (C) 2 hour plasma glucose greater than or equal to 200mg/dl as part of an oral glucose tolerance test (75g oral glucose after fasting for at least 8 hours) OR (D) Symptoms of hyperglycemia (including polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dl.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Type 2 Diabetes.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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MSB Antipsychotics

Products Affected

- FANAPT ORAL TABLET 1 MG, 10 MG, 12 MG, 2 MG, 4 MG, 6 MG, 8 MG
- FANAPT TITRATION PACK
- REXULTI
- SECUADO
- VRAYLAR ORAL CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has had a trial of and inadequate response or intolerance to ONE of the following generic oral atypical antipsychotic: Aripiprazole, Asenapine tablets, Lurasidone, Olanzapine, Paliperidone ER, Quetiapine IR, Risperidone, or Ziprasidone OR the preferred generics are not FDA approved and do not have an accepted off-label use for the prescribed indication and the non-preferred agent does.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Namenda Line

Products Affected

- *memantine hcl er*
- *memantine hcl oral tablet 10 mg, 28 x 5 mg & 21 x 10 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individuals that are 50 years of age or older are NOT subject to the prior authorization requirements. Prior Authorization applies to individuals that are 49 years of age or younger.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of moderate to severe dementia of the Alzheimers type.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Nayzilam

Products Affected

- NAYZILAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 12 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Nerlynx

Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has HER2- overexpressed/amplified confirmed by one of the following: (A) Immunohistochemistry (IHC) is 3+ or (B) In situ hybridization (ISH) positive.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Nexavar

Products Affected

- *sorafenib tosylate*

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

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Ninlaro

Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	For multiple myeloma, individual received at least two prior therapies, including immunomodulatory agent and a proteasome inhibitor AND demonstrated disease progression on or within 60 days of completion therapy AND Ninlaro is given as part of a treatment regimen containing dexamethasone and pomalidomide.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Northera

Products Affected

- *droxidopa oral capsule 100 mg, 200 mg, 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Initial: 3 months. Continuation: 1 year
Other Criteria	For initial use, individual has had a trial and inadequate response or intolerance to one prior symptomatic nOH pharmacologic therapy (which may include midodrine or fludrocortisone [AHFS]). For continued use, individual has experienced a positive clinical response with droxidopa use (e.g., sustained decrease in dizziness).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Noxafil

Products Affected

- *posaconazole oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For an individual who requires continued therapy for an organism susceptible to Posaconazole who is transitioning from inpatient treatment to an outpatient setting.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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NP CSF SA Agents

Products Affected

- NEUPOGEN INJECTION SOLUTION
300 MCG/ML, 480 MCG/1.6ML
- NEUPOGEN INJECTION SOLUTION
PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<p>Febrile neutropenic Individuals who are at high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than $0.1 \times 10^9/L$) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infections, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Prior episode of febrile neutropenia, Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have risk factors for FN including any of the following: age greater than 65 years, Poor performance status (ECOG status 3-4) or HIV infection (in particular, those with low CD4 counts (less than or eq 450/microL) but chemotherapy still indicated (Lyman 2014), Prior radiation therapy (within previous 1 year) (Terbuch 2018) (Fujiwara 2017) (Shigeta 2015), Bone marrow involvement by tumor producing cytopenias, persistent neutropenia (ANC less than 1500mm³), poor renal function (GFR less than 60mL/min) , liver dysfunction (liver function tests at least 2x upper limit of normal or bilirubin gr than 2.0 mg/dL) (Lyman 2014) (Aagaard 2018), recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc) (Lyman 2014, Aagaard 2018). History of active infection within previous 60 days(Lyman 2014, Aagaard 2018). Current open wound and chemotherapy cannot be delayed (Lyman 2014, Aagaard 2018).</p>

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

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PA Criteria	Criteria Details
Other Criteria	<p>Individual has had a trial and inadequate response to intolerance to Zarxio (Filgrastim-sndz). Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. Using for adjunctive tx for FN and has been prophylactic therapy with GCSF agent or has not received prophylactic therapy with a GCSF and who are at high risk for infection-associated complications. Use in individuals with acute myeloid leukemia (AML) shortly after the completion of induction or repeat induction chemotherapy, or after the completion of consolidation chemotherapy for AML. For tx of moderate to severe aplastic anemia. Tx of severe neutropenia in individuals with hairy cell leukemia. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm³ or experiencing recurrent infection. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. For tx of (non-chemotherapy) drug-induced neutropenia. For tx of low neutrophil counts in individuals with glycogen storage disease type 1b. For tx of neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected. After accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy] (such as Hematopoietic Syndrome of Acute Radiation Syndrome). After hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed. To mobilize progenitor cells into peripheral blood for collection by</p>

PA Criteria	Criteria Details
	leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT). Use as an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant. For autologous hematopoietic stem cell (HSC) mobilization as part of the development of an FDA-approved ex vivo gene therapy (e.g. Zynteglo (betibeglogene autotemcel)).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NP IVIG

Products Affected

- BIVIGAM INTRAVENOUS SOLUTION 5 GM/10ML
- FLEBOGAMMA DIF INTRAVENOUS SOLUTION 10 GM/200ML
- GAMMAGARD INJECTION SOLUTION 1 GM/10ML, 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA
- GAMMAKED INJECTION SOLUTION 1 GM/10ML
- GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 5 GM/50ML
- PRIVIGEN INTRAVENOUS SOLUTION 10 GM/100ML, 20 GM/200ML, 5 GM/50ML

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

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NP LA Opioid

Products Affected

- *buprenorphine transdermal* 60 mg
- *methadone hcl oral tablet*
- *morphine sulfate er oral tablet extended release 100 mg, 15 mg, 200 mg, 30 mg,*
- *tramadol hcl (er biphasic) oral tablet extended release 24 hour*
- *tramadol hcl er*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

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PA Criteria	Criteria Details
Other Criteria	<p>For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure) AND for initial therapy, individual is not opioid naive as noted by the following: (a) Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting opioid analgesic to another long-acting opioid analgesic. For continued use, (I) individual has a diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (II) diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR (III) Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline AND Prescriber has consulted individual regarding risks of opioid therapy AND clear treatment goals have been defined and outline as part of overall plan.</p>
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NP Pegfilgrastim Agents

Products Affected

- UDENYCA

PA Criteria	Criteria Details
Exclusion Criteria	

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

PA Criteria	Criteria Details
Required Medical Information	<p>Individual has had a trial and inadequate response to intolerance to Neulasta/Neulasta Onpro (Pegfilgrastim) AND Adjunctive tx of Febrile neutropenia and has not received prophylactic therapy with Pegfilgrastim agents and has high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1×10 to the power of 9/L) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infections, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Prior episode of febrile neutropenia, Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have risk factors for FN including any of the following: age greater than 65 years, Poor performance status (ECOG status 3-4) or HIV infection (in particular, those with low CD4 counts (less than or eq 450/uL) but chemotherapy still indicated (Lyman 2014), Prior radiation therapy (within previous 1 year) (Terbuch 2018) (Fujiwara 2017) (Shigeta 2015), Bone marrow involvement by tumor producing cytopenias, persistent neutropenia (ANC less than 1500mm³), poor renal function (GFR less than 60mL/min), liver dysfunction (liver function tests at least 2x upper limit of normal or bilirubin gr than 2.0 mg/dL) (Lyman 2014) (Aagaard 2018), recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc) (Lyman 2014, Aagaard 2018). History of active infection within previous 60 days(Lyman 2014, Aagaard 2018). Current open wound and chemotherapy cannot be delayed (Lyman 2014, Aagaard 2018).</p>
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

PA Criteria	Criteria Details
Other Criteria	Individual with nonmyeloid malignancy is using for Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. For use after accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome). For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution OR when engraftment is delayed or has failed. For autologous hematopoietic stem cell (HSC) mobilization as part of the development of an FDA-approved ex vivo gene therapy (e.g. Zynteglo (betibeglogene autotemcel)).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Nubeqa

Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(1) Individual has Metastatic hormone-sensitive prostate cancer (mHSPC) OR (2) Individual has a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC) AND has a PSA doubling time (PSADT) less than or equal to 10 months AND (3) One of the following: (a) individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (Degarelix)] OR (b) Has had a bilateral orchiectomy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Nucala

Products Affected

- NUCALA SUBCUTANEOUS SOLUTION MG/0.4ML
AUTO-INJECTOR
- NUCALA SUBCUTANEOUS SOLUTION
PREFILLED SYRINGE 100 MG/ML, 40
- NUCALA SUBCUTANEOUS SOLUTION
RECONSTITUTED

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Nuedexta

Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using for the treatment of amyotrophic lateral sclerosis (ALS) (Orphan indication) OR Individual has a diagnosis of pseudobulbar affect (PBA) AND has a concomitant diagnosis with an unrelated neurologic disease or injury [amyotrophic lateral sclerosis (AAN 2020, Piro et al. 2010), multiple sclerosis (AAN 2019, Piro et al, 2010), stroke (2016 AHA/ASA)].
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

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	Initial:3 months, Maintenance: 1 Year
Other Criteria	Initial therapy: Individual has a diagnosis of Parkinsons disease AND Symptoms of psychosis developed after the PD diagnosis AND Symptoms of psychosis include at least one of the following: (1) Visual hallucinations, (2) Auditory hallucination OR (3) Delusions AND Symptoms have been present for at least one month AND Individual has experienced symptoms at least once weekly. Psychiatric symptoms cannot be attributed to disorders such as schizophrenia, schizoaffective disorder, delusional disorder, or mood disorder with psychotic features, or a general medical condition including delirium. For continued therapy, the individual has had a reduction in symptoms of psychosis compared to baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

PA Criteria	Criteria Details
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Nurtec

Products Affected

- NURTEC

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Octreotide Line

Products Affected

- *octreotide acetate injection solution 100 mcg/ml, 1000 mcg/ml, 200 mcg/ml, 50 mcg/ml, 500 mcg/ml*
- *octreotide acetate subcutaneous*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of acromegaly has been confirmed by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (such as but not limited to: Insulin-like Growth Factor 1 levels, Oral Glucose Tolerance Test with associated Growth Hormone (GH) levels) that are indicative of a positive test.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Odomzo

Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Ofev

Products Affected

- OFEV

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

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	1 year
Other Criteria	Individual has an ECOG performance status of 0-2.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Ojemda

Products Affected

- OJEMDA ORAL SUSPENSION RECONSTITUTED
- OJEMDA ORAL TABLET

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

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1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Ojjaara

Products Affected

- OJJAARA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has hemoglobin less than 10 g/dL (NCT04173494, NCT01969838).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Onfi

Products Affected

- *clobazam oral suspension*
- *clobazam oral tablet 10 mg, 20 mg*
- SYMPAZAN ORAL FILM 10 MG, 20 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis (all ages) and if over 65 years of age or older, Prescriber must acknowledge this is a high risk medication (HRM) [as identified by American Geriatric Society] and medication benefits outweigh potential risk for this individual.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has had a trial of and inadequate response or intolerance to ONE of the following preferred agents: Carbamazepine, Clonazepam/ODT, Clorazepate, Diazepam, Divalproex, Ethosuximide, Felbamate, Gabapentin, Lacosamide, Lamotrigine IR, Levetiracetam IR, Oxcarbazepine, Phenytoin, Primidone, Tiagabine, Topiramate IR, Valproate sodium, Valproic acid, Zonisamide OR the preferred agent is not FDA-approved for the prescribed indication.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Onureg

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has a diagnosis of acute myeloid leukemia (AML), including de novo AML and AML secondary to prior myelodysplastic disease or chronic myelomonocytic leukemia (NCT01757535) AND is used as a single agent.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Opsumit

Products Affected

- OPSUMIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial requests, Individual has diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units. AND Individual has WHO functional class II- IV symptoms.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using for the treatment of chronic thromboembolic pulmonary hypertension (CTEPH) OR Individual is using for the treatment of Fontan-Palliated patients. For continuation therapy, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).
Indications	All Medically-accepted Indications.
Off Label Uses	

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1074448MUMENMUB

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PA Criteria	Criteria Details
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Orfadin

Products Affected

- *nitisinone*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial requests, Individuals plasma tyrosine level is maintained below 500 micromol/L to reduce risk of ocular symptoms, developmental delay, or hyperkeratotic plaques.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Orgovyx

Products Affected

- ORGOVYX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial therapy, Individual presents with ONE of the following disease state presentations: (a) Evidence of biochemical (PSA) or clinical relapse following local primary intervention with curative intent, such as surgery, radiation therapy, cryotherapy, or high-frequency ultrasound and not a candidate for salvage treatment by surgery OR (b) Newly diagnosed androgen-sensitive metastatic disease OR (c) Advanced localized disease unlikely to be cured by local primary intervention with either surgery or radiation with curative intent. AND is using as androgen deprivation therapy AND is using as a single agent.
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Initial and Continuation 6 months.
Other Criteria	For continuation therapy, individual does not show evidence of progressive disease while on therapy AND has serum testosterone level less than 50 ng/dL.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Orkambi

Products Affected

- ORKAMBI ORAL PACKET
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial use, individual has a diagnosis of cystic fibrosis (CF) AND mutation testing demonstrates the individual has two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.
Age Restrictions	Individual is 1 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation requests, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in FEV1, decrease in pulmonary exacerbations, improvement in BMI or improvement of respiratory symptoms [cough, sputum production, difficulty breathing]).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Orserdu

Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual is using as a single agent.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Otezla

Products Affected

- OTEZLA ORAL TABLET
- OTEZLA ORAL TABLET THERAPY PACK

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Oxandrin

Products Affected

- *oxandrolone oral tablet 10 mg, 2.5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Oxervate

Products Affected

- OXERVATE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has a diagnosis of stage 2 or stage 3 neurotrophic keratitis in one or both eyes, as shown by the presence of one of the following: (A) Persistent epithelial defect(s) OR (B) Corneal ulcer(s).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has evidence of decreased corneal sensitivity in at least one corneal quadrant AND has failed one or more conventional non-surgical treatments for neurotrophic keratitis such as artificial tears, gels, or ointments.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Pegfilgrastim Agents

Products Affected

- NEULASTA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<p>Adjunctive tx of Febrile neutropenia and has not received prophylactic therapy with Pegfilgrastim agents and has high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1×10^9 to the power of 9/L) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infections, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Prior episode of febrile neutropenia, Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have risk factors for FN including any of the following: age greater than 65 years, Poor performance status (ECOG status 3-4) or HIV infection (in particular, those with low CD4 counts (less than or eq 450/?L) but chemotherapy still indicated (Lyman 2014), Prior radiation therapy (within previous 1 year) (Terbuch 2018) (Fujiwara 2017) (Shigeta 2015), Bone marrow involvement by tumor producing cytopenias, persistent neutropenia (ANC less than 1500mm³), poor renal function (GFR less than 60mL/min), liver dysfunction (liver function tests at least 2x upper limit of normal or bilirubin gr than 2.0 mg/dL) (Lyman 2014) (Aagaard 2018), recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc) (Lyman 2014, Aagaard 2018). History of active infection within previous 60 days(Lyman 2014, Aagaard 2018). Current open wound and chemotherapy cannot be delayed (Lyman 2014, Aagaard 2018).</p>

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual with nonmyeloid malignancy is using for Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. For use after accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome). For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution OR when engraftment is delayed or has failed. For autologous hematopoietic stem cell (HSC) mobilization as part of the development of an FDA-approved ex vivo gene therapy (e.g. Zynteglo (betibeglogene autotemcel)).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Pemazyre

Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) OR unresectable locally advanced, or metastatic cholangiocarcinoma AND using as monotherapy AND has confirmed disease progression (written or verbal) after one or more prior lines of systemic therapy. Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Phesgo

Products Affected

- PHESGO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has HER2-positive breast cancer confirmed (verbal or written) by EITHER immunohistochemistry (IHC) of 3+ OR positive In situ hybridization (ISH).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Piqray

Products Affected

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Pomalyst

Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Prevymis

Products Affected

- PREVYMIS ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For allogeneic hematopoietic stem cell transplant (HSCT) recipient, individual is CMV-seropositive and is using to prevent CMV infection or disease AND therapy will be initiated between Day 0 and Day 28 post-transplantation. For kidney transplant recipient, individual is CMV-seronegative and donor is CMV-seropositive AND is using to prevent CMV disease AND therapy will be initiated between Day 0 and Day 7 post-transplantation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Prolia

Products Affected

- PROLIA SUBCUTANEOUS SOLUTION
PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial requests, Osteoporosis is defined as a BMD T-Score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture). Glucocorticoid-induced osteoporosis defined as a bone mineral density (BMD) T score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture) and is initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5mg or greater of prednisone and expected to remain on glucocorticoids for a least 6 months.
Age Restrictions	For Osteoporosis 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 Year.

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

PA Criteria	Criteria Details
Other Criteria	For Initial use: For osteoporosis/ glucocorticoid-induced osteoporosis treatment, individual has had at least ONE osteoporotic (minimal trauma) fracture OR has two or more risk factors for osteoporotic fracture OR Individual has failed or is intolerant to or has a medical contraindication to other available osteoporosis therapies (such as, bisphosphonates). For male receiving androgen deprivation therapy for non- metastatic prostate cancer, individual has had at least ONE osteoporotic (minimal trauma) fracture OR has one or more additional risk factors for osteoporotic fracture. Individual is a postmenopausal (natural or induced) female receiving adjuvant aromatase inhibitor therapy for the treatment of breast cancer. For continuation requests, there is clinically significant response to therapy (including but not limited to confirmation of no new fractures or reduction of fractures, or no worsening vertebral fractures, or no clinically significant adverse reaction) AND IF individual has been on therapy greater than or equal to 24 months of treatment, a repeat BMD demonstrates a stable or increase in BMD.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Promacta

Products Affected

- PROMACTA ORAL PACKET 12.5 MG, 25 MG
- PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months. Continuation: 1 Year.

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1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

PA Criteria	Criteria Details
Other Criteria	<p>For initial therapy: 1) Diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP) AND individual has platelet count of less than 30 x 10⁹/L or active bleeding (ASH, 2011. Hicks et al., 2014) AND has had a prior trial and insufficient response to one of the following: a) corticosteroids OR b) immunoglobulins [for example, intravenous, anti-D] or c) splenectomy OR 2) Diagnosis of severe aplastic anemia AND individual has a platelet count of less than or equal to 30 x 10⁹/L (Olnes et al., 2012.Desmond et al., 2014) AND individual has had a prior trial and insufficient response to an immunosuppressive therapy [such as, anti-thymocyte globulin (ATG)] OR 3) individual is using as first-line treatment in combination with standard immunosuppressive therapy 4) Treatment of thrombocytopenia in individual with hepatitis C AND individual has thrombocytopenia that prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. For continuation therapy, for ITP, severe aplastic anemia or thrombocytopenia in individuals with Hep C, individual has demonstrated a response to therapy as evidenced by increased platelet counts AND to maintain an adequate platelet count (50-200 x 10⁹/L) to decrease the risk of bleeding OR for MDS, individual has demonstrated a clinically significant response to therapy, such as an increase in platelet counts, decrease in bleeding events, or reduction in need for platelet transfusions .</p>
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Protopic

Products Affected

- *tacrolimus external ointment*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual is using as second-line therapy for moderate to severe atopic dermatitis AND has had a trial of and inadequate response or intolerance to one topical prescription strength corticosteroid.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Purixan

Products Affected

- PURIXAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Qinlock

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using as a single agent AND has a ECOG performance status of 0-2.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

quinine

Products Affected

- *quinine sulfate oral*

PA Criteria	Criteria Details
Exclusion Criteria	Treatment or prevention of nocturnal recumbency leg muscle cramps or other related conditions including but not limited to: Leg cramps, muscle cramps, myoclonus, Periodic Movements of Sleep, Periodic Limb Movements of Sleep (PLMS), Restless Leg Syndrome (RLS).
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

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PA Criteria	Criteria Details
Other Criteria	<p>Individual has been diagnosed with uncomplicated malaria caused by one of the following: Plasmodium falciparum known or suspected to be resistant to chloroquine (CDC) OR chloroquine-resistant Plasmodium vivax (CDC) OR an unidentified plasmodial species known or suspected to be resistant to chloroquine (CDC) OR Chloroquine-resistant Plasmodium ovale (CDC) OR Chloroquine-sensitive Plasmodium malariae (CDC) OR Chloroquine-sensitive Plasmodium knowlesi (CDC) OR Chloroquine-sensitive Plasmodium falciparum, Plasmodium vivax or Plasmodium ovale AND one of the following (CDC): (i.) Individual is pregnant OR (ii.) Chloroquine and hydroxychloroquine are not available. Individual is using as interim treatment for severe malaria until intravenous artesunate is available (AHFS, CDC) or using as follow-on treatment after intravenous artesunate. Individual has a diagnosis of been diagnosed with babesiosis caused by Babesia microti and treatment is in conjunction with intravenous or oral clindamycin (AHFS, DrugPoints B IIa).</p>
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Ranexa

Products Affected

- *ranolazine er*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For dx chronic angina, individual has had a trial and inadequate response or intolerance to one of the following formulary agents (ACCF/AHA 2012): (a) Beta-blocker OR (b) Calcium-channel blocker OR (c) Long-acting nitrate.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Regranex

Products Affected

- REGRANEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	Individual is using as adjunctive therapy with good ulcer care practices including, but not limited to sharp debridement of the ulcer
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Repatha

Products Affected

- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Retevmo

Products Affected

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

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Revatio

Products Affected

- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Individuals requesting for the treatment of erectile dysfunction.
Required Medical Information	For initial requests, individual has diagnosis of Pulmonary Arterial Hypertension in adults World Health Organization (WHO) Group I AND Individual has a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units AND Individual has WHO functional class II- IV symptoms.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation requests of PAH for adults, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Revlimid

Products Affected

- *lenalidomide oral capsule 10 mg, 15 mg, 2.5 mg, 20 mg, 25 mg, 5 mg*

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

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Rezlidhia

Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has the applicable mutations based on use/diagnosis. Individual has an ECOG performance status of 0- 2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Continued use, there is confirmation of clinically significant improvement (e.g. no disease progression) or stabilization of disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Rezurock

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 12 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For cGVHD after failure of at least two prior lines of systemic therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Rinvoq

Products Affected

- RINVOQ
- RINVOQ LQ

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Rozlytrek

Products Affected

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

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Rubraca

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For metastatic castration-resistant prostate cancer (mCRPC), with a deleterious BRCA mutation (germline and/or somatic), Individual had been treated with androgen-receptor directed therapy and a taxane-based chemotherapy AND is using a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)) concurrently or have had a bilateral orchiectomy and using as a single agent.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Rybrevant

Products Affected

- RYBREVANT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Using Rybrevant as a single agent And has not progressed on prior therapy with Rybrevant.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Rydapt

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has confirmed written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Sabril

Products Affected

- *vigabatrin oral packet*
 - *vigabatrin oral tablet*
 - VIGADRONE ORAL PACKET
 - VIGADRONE ORAL TABLET
- VIGPODER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For infantile spasm 1 month to 2yr old. For seizure 2 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 YEAR.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Samsca

Products Affected

- *tolvaptan oral tablet 15 mg, 30 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	30 Days
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Sarclisa

Products Affected

- SARCLISA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Savella

Products Affected

- SAVELLA
- SAVELLA TITRATION PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has a clinical diagnosis of fibromyalgia AND symptoms have been present at a similar level for at least 3 months AND mbr has had a trial of and inadequate response or intolerance to TWO of the following medications that are medically accepted or FDA-approved for the treatment of fibromyalgia: (A) tricyclic antidepressants (CF CG 2012, EULAR 2016) OR (B) gabapentin (CF CG 2012) OR (C) cyclobenzaprine (CF CG 2012, EULAR 2016) OR (D) fluoxetine (CF CG 2012) or alternative selective serotonin reuptake inhibitor (SSRI) (Off-label, Clinical Judgement) OR (E) duloxetine OR (F) pregabalin.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Scemblix

Products Affected

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

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Signifor IR

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of Cushings disease has been verified by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (including but not limited to: 24-hour urinary free cortisol (UFC) test, Dexamethasone suppression test (DST), Late-night salivary cortisol (LNSC) test) that are indicative of a positive test.
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Sirturo

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has a diagnosis of pulmonary multidrug-resistant tuberculosis (MDR-TB) or pulmonary extensively drug-resistant tuberculosis (XDR-TB) or pulmonary pre-extensively drug-resistant tuberculosis (pre-XDR-TB) AND the individual is using in combination with other anti-infectives (WHO 2019).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

PA Criteria	Criteria Details
Other Criteria	<p>For initial use: dx of chronic plaque psoriasis (Ps), individual has had an inadequate response to, or is intolerant of phototherapy or any ONE systemic therapy (such as acitretin, cyclosporine, or methotrexate) OR has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate. For moderate to severe Psoriatic Arthritis (PsA), individual has had an inadequate response to, or is intolerant of ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine or leflunomide)] OR has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide. For moderate to severe Crohns disease (CD) IV induction, Individual has had an inadequate response to, or is intolerant of ONE conventional therapy (such as systemic corticosteroids or immunosuppressants [such as thiopurines or methotrexate]) OR has a contraindication to systemic corticosteroids or thiopurines or methotrexate. For CD subcutaneous maintenance therapy, Individual has completed the intravenous induction doses with Skyrizi and will be using subcutaneous Skyrizi for maintenance therapy. For Continuation use: there is clinically significant improvement or stabilization in clinical signs and symptoms of disease AND has been receiving and is maintained on a stable dose of Skyrizi.</p>
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Solaraze

Products Affected

- *diclofenac sodium external gel 3 %*

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

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EFFECTIVE DATE 01/01/2025

Somatuline Depot

Products Affected

- *Ianreotide acetate*
- SOMATULINE DEPOT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of acromegaly has been verified by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (including but not limited to: Insulin-like Growth Factor 1 levels, Oral Glucose Tolerance Test with associated Growth Hormone (GH) levels) that are indicative of a positive test.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Somavert

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Dx of acromegaly has been verified by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (including but not limited to: Insulin-like Growth Factor 1 levels, Oral Glucose Tolerance Test with associated Growth Hormone (GH) levels) that are indicative of a positive test AND member has had an inadequate response to surgery and/or radiation OR Surgery and/or radiation therapy are not an option.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Soriatane

Products Affected

- *acitretin*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For severe psoriasis, if individual is a female of reproductive age, has met one of the following: (A) Individual is unresponsive to other therapies OR (B) has a clinical condition that contraindicates the use of other treatments.
Age Restrictions	For severe psoriasis, individual is greater than 18 years of age.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Spravato

Products Affected

- SPRAVATO (56 MG DOSE)
- SPRAVATO (84 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Initial 3 months, continuation 1 year. MDD with acute suicidal ideation or behavior: 1 year

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EFFECTIVE DATE 01/01/2025

PA Criteria	Criteria Details
Other Criteria	<p>For initial use, individual is using for the tx of depressive sx with major depressive disorder (MDD) with acute suicidal ideation or behavior AND has a dx of MDD without psychotic features according to DSM-5 (Fu 2020, Ionescu 2020) AND is judged to be at risk for suicide by a clinician based on consideration of suicidal behavior, expressed suicidal ideation or overall clinical assessment consistent with significant continuing risk of suicide AND will use Spravato in addition to antidepressant therapy. Individual has been diagnosed with moderate to severe major depressive disorder AND had an inadequate response to the maximum tolerated dose of two antidepressant therapies during the current major depressive episode (MDE) as defined by less than 50% reduction in symptom severity using a standard rating scale that reliably measures depressive symptoms AND will use Spravato in addition to antidepressant therapy. For continuation, individual has had at least a 50% reduction in symptoms of treatment resistant moderate to severe depression compared to baseline using a standard rating scale that reliably measures depressive symptoms AND will use Spravato in addition to antidepressant therapy.</p>
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Sprycel

Products Affected

- SPRYCEL

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

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EFFECTIVE DATE 01/01/2025

Stelara

Products Affected

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

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

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1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Stivarga

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Written or verbal attestation is provided for confirmation of mutations or disease progression where applicable based on use/diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For gastrointestinal stromal tumors (GIST), individual has had progression after monotherapy with imatinib and sunitinib
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Stromectol

Products Affected

- *ivermectin oral*

PA Criteria	Criteria Details
Exclusion Criteria	For the treatment or prophylaxis of COVID-19.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Sutent

Products Affected

- *sunitinib malate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Symdeko

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial use, individual has a diagnosis of cystic fibrosis (CF) AND has a mutation-positive result in the cystic fibrosis transmembrane conductance regulator (CFTR) gene and the mutation type is provided and responsive to Symdeko.
Age Restrictions	Individual is 6 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation requests, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in FEV1, decrease in pulmonary exacerbations, improvement in BMI or improvement of respiratory symptoms [cough, sputum production, difficulty breathing]).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Symlin

Products Affected

- SYMLINPEN 120 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- SYMLINPEN 60 SUBCUTANEOUS SOLUTION PEN-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Type 1 or type 2 diabetes AND taking mealtime insulin therapy AND has failed to achieve glucose control AND HBA1C is less than or equal to 9.
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Synarel Nasal Solution

Products Affected

- SYNAREL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Central precocious puberty (CPP), defined as the beginning of secondary sexual maturation characteristics before age 8 in girls and before age 9 in boys. Dx of CPP has been confirmed by one of the following: (1) a pubertal response to a gonadotropin hormone (GnRH) agonist test or (2) a pubertal level of a third generation luteinizing hormone (LH) assay or (3) a pubertal level of a pediatric luteinizing hormone (LH) assay or (4) a pubertal level of an ultra-sensitive luteinizing hormone (LH) assay or (5) a pubertal level on a luteinizing hormone (LH) assay that can detect levels less than 0.2 AND assessment of bone age versus chronological age.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Endometriosis: 6 months, all other indications: 1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Syprine

Products Affected

- *trientine hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has a diagnosis of Wilsons Disease as confirmed by two of the following (AASLD 2022): (A) Serum ceruloplasmin less than 20 mg/DI (B) Presence of Kayser-Fleischer rings (C) 24-hour urinary copper is greater than 40 mcg/day (D) Liver biopsy findings consistent with Wilsons Disease (E) Genetic testing findings consistent with Wilsons Disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tabrecta

Products Affected

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For recurrent, advanced or metastatic non-small cell lung cancer (NSCLC), Individual has mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors AND individual has not received treatment with another MET exon 14 skipping-targeted agent, such as crizotinib. For metastatic NSCLC, individual has MET exon 14 skipping positive tumors. For advanced or metastatic NSCLC, individual has high level MET amplification (greater than or equal to 10 gene copies) (Wolf 2020).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using Tabrecta (capmatinib) as monotherapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tafinlar

Products Affected

- TAFINLAR ORAL CAPSULE
- TAFINLAR ORAL TABLET SOLUBLE

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tagrisso

Products Affected

- TAGRISSO

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Takhzyro

Products Affected

- TAKHZYRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hereditary angioedema (HAE) is verified by a C4 level below the lower limit of normal as defined by laboratory test AND ANY of the following: (a) C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by lab test (b) C1-INH functional level below the lower limit of normal as defined by lab test or (c) Presence of a known HAE-causing C1-INH mutation.
Age Restrictions	Individual is 2 years of age or older.
Prescriber Restrictions	
Coverage Duration	Initial: 8 months, Continuation: 1 Year.
Other Criteria	Individual has a history of moderate or severe attacks and is using as prophylaxis against acute attacks of hereditary angioedema for short-term use prior to surgery, dental procedures, or intubation OR for long-term prophylaxis to minimize the frequency and/or severity of recurrent attacks. For continued use in prophylactic care individual has had a positive clinical response defined as a clinically significant reduction in the number and/or frequency of HAE attacks occurred.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Talzenna

Products Affected

- TALZENNA

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tarceva

Products Affected

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

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Targretin

Products Affected

- *bexarotene external*
- *bexarotene oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tasigna

Products Affected

- TASIGNA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tasmar

Products Affected

- *tolcapone*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For initial use, using in combination with carbidopa/levodopa. For continuation, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tazorac

Products Affected

- *tazarotene external cream 0.1 %*
- *tazarotene external gel*
- TAZORAC EXTERNAL CREAM 0.05 %

PA Criteria	Criteria Details
Exclusion Criteria	May not be approved for cosmetic purposes such as, but not limited to the following: Cosmetic purposes, Photoaging, Wrinkles, Hyperpigmentation, Sun damage, or Melasma.
Required Medical Information	For psoriasis, individual has up to 20% of body surface area involvement.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For psoriasis, individual has had a prior trial and inadequate response to either of the following (AAD 2009): Any two (2) topical corticosteroids or any one (1) topical corticosteroids plus calcipotriene. For psoriasis use greater than 1 year, efficacy must be documented for continued use. Documentation may include chart notes, consultation notes.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tazverik

Products Affected

- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	ECOG performance status of 0-2. Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tecentriq

Products Affected

- TECENTRIQ INTRAVENOUS SOLUTION 1200 MG/20ML, 840 MG/14ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tecvayli

Products Affected

- TECVAYLI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For MM, current Eastern Cooperative Group (ECOG) performance status of 0-1 AND No prior treatment with any B cell maturation antigen (BCMA) targeted therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tegsedi

Products Affected

- TEGSEDI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has a baseline platelet count greater than or equal to 100 x 10 ⁹ /L AND urinary protein to creatinine ratio (UPCR) less than 1000 mg/g AND Individual has a TTR mutation verified by genotyping.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has diagnosis of hereditary transthyretin (hATTR) amyloidosis or familial amyloid polyneuropathy (FAP) AND associated mild to moderate polyneuropathy. For Continuation, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improved ambulation, improvement in neurologic symptom burden, improvement in activities of daily living) AND most recent platelet count was within the past month and was greater than or equal to 100 x 10 ⁹ /L AND most recent urinary protein to creatinine ratio (UPCR) was within the past month and was less than 1000 mg/g.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tepmetko

Products Affected

- TEPMETKO

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Teriflunomide Agents

Products Affected

- *teriflunomide*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Testosterone Inj

Products Affected

- DEPO-TESTOSTERONE INTRAMUSCULAR SOLUTION 100 MG/ML
- *testosterone cypionate intramuscular solution 100 mg/ml*
- *testosterone enanthate intramuscular solution*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prior to starting testosterone therapy, an initial and a repeat (at least 24 hours apart) morning total testosterone level is provided to confirm a low testosterone serum level indicating one of the following: (1) Individual is 70 years of age or younger with a serum testosterone level of less than 300 ng/dL OR (2) Individual is over 70 years of age with a serum testosterone level of less than 200 ng/dL.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

PA Criteria	Criteria Details
Other Criteria	<p>For initial use of replacement therapy, Individual has a dx of (1) primary hypogonadism (congenital or acquired) such as but not limited to: Cryptorchidism OR Bilateral torsion OR Vanishing testis syndrome OR orchitis OR Orchiectomy OR Klinefelter Syndrome OR Chemotherapy OR Toxic damage from alcohol or heavy metals OR idiopathic primary hypogonadism. Or (2) Hypogonadotropic hypogonadism (congenital or acquired), such as but not limited to: Idiopathic luteinizing hormone-releasing hormone (LHRH deficiency) OR Pituitary-hypothalamic injury AND Individual presents with symptoms associated with hypogonadism, such as but not limited to, at least one of the following: (a) Reduced sexual desire (libido) and activity or (b) Decreased spontaneous erections or (c) Breast discomfort/gynecomastia or (d) Loss of body (axillary and pubic) hair, reduced need for shaving or (e) Very small (especially less than 5 mL) or shrinking testes or (f) Inability to father children or low/zero sperm count or (g) Height loss, low trauma fracture, low bone mineral density or (h) Hot flushes, sweats or (i) Other less specific signs and symptoms including decreased energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, diminished physical or work performance. For Continuation of Testosterone Inj agents for replacement therapy, (a) Individual met all diagnostic criteria for initial therapy and (b) Individual has had serum testosterone level measured in the previous 180 days and (c) Individual has obtained clinical benefits as noted by symptom improvement. For treatment of delayed puberty when ALL the criteria below are met: Individual is using to stimulate puberty and has documented (verbal or written) few to no signs of puberty. For tx of breast cancer when the following are met: Female 1-5 years post-menopause and Individual is using secondarily for advanced inoperable metastatic (skeletal) breast cancer OR Premenopausal female who has benefited from oophorectomy and is considered to have a hormone responsive tumor. For tx of individual with low testosterone and HIV-associated weight loss and wasting. For gender</p>
	<p>dysphoria/incongruence individuals who meet ALL the following criteria: Individual has experienced puberty to at least Tanner Stage 2 AND has a diagnosis of gender dysphoria/incongruence.</p>
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Thalomid

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tibsovo

Products Affected

- TIBSOVO

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Topical Acyclovir

Products Affected

- *acyclovir external ointment*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For limited non-life-threatening mucocutaneous herpes simplex virus infection in an immunocompromised individual OR for genital herpes infection, individual has had a trial and inadequate response or intolerance to one of the following oral antiviral agent (CDC 2021): Acyclovir, Valacyclovir, or Famciclovir.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Topical Androgens

Products Affected

- *testosterone transdermal gel 1.62 %*, 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%)
- *testosterone transdermal solution*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For primary or hypogonadotropic hypogonadism, individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Initial use: Individual has a dx of (1) primary hypogonadism (congenital or acquired) [for example, Cryptorchidism OR Bilateral torsion OR orchitis OR Vanishing testis syndrome OR Orchiectomy OR Klinefelter Syndrome OR Chemotherapy OR Toxic damage from alcohol or heavy metals OR idiopathic primary hypogonadism]. Or (2) Hypogonadotropic hypogonadism (congenital or acquired) [for example, Idiopathic luteinizing hormone-releasing hormone (LHRH deficiency), OR Pituitary-hypothalamic injury.] Individual is using for a diagnosis of gender Dysphoria/incongruence (Coleman 2022) AND has experienced puberty to at least Tanner Stage 2. For continuation use for primary or hypogonadotropic hypogonadism, Individual meets all criteria for initial therapy AND has had serum testosterone level measured in the previous 180 days AND Individual has obtained clinical benefits as noted by symptom improvement.
Indications	All Medically-accepted Indications.

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Topical Onychomycosis

Products Affected

- JUBLIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has a confirmed fungal infection (i.e. physical exam). And has confirmed laboratory evidence of one of the following: (1) Trichophyton rubrum OR (2) Trichophyton mentagrophytes.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has had a trial of and inadequate response or intolerance to oral itraconazole and terbinafine. Or has a, contraindication, drug interaction or concomitant clinical condition (such as but not limited history of liver disease or concerns over hepatotoxicity, history of CHF) which make use of oral itraconazole and terbinafine unacceptable OR Individual has used requested medication within the previous 6 months.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Topical Tretinoin Agents

Products Affected

- *tretinoin external*

PA Criteria	Criteria Details
Exclusion Criteria	Topical tretinoin agents may not be approved for cosmetic purposes such as, but not limited to the following: Photoaging, Wrinkles, Hyperpigmentation, Sun damage, Melasma.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tracleer

Products Affected

- *bosentan*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial therapy, Individual has a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has Pulmonary Arterial Hypertension (WHO Group I), and WHO Functional Class II-IV symptoms. For continuation therapy, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Trelstar Line

Products Affected

- TRELSTAR MIXJECT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Following radical prostatectomy as adjuvant therapy when lymph node metastases are present OR Locally advanced disease OR Other advanced, recurrent, or metastatic disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Trikafta

Products Affected

- TRIKAFTA ORAL TABLET THERAPY PACK
- TRIKAFTA ORAL THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial use, individual has a diagnosis of cystic fibrosis (CF) AND has a mutation-positive result in the cystic fibrosis transmembrane conductance regulator (CFTR) gene and the mutation type is provided and responsive to Trikafta.
Age Restrictions	Individual is 2 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation requests, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in FEV1, decrease in pulmonary exacerbations, improvement in BMI or improvement of respiratory symptoms [cough, sputum production, difficulty breathing]).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Trodelvy

Products Affected

- TRODELVY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has (A) recurrent or metastatic, histologically confirmed triple-negative Breast Cancer (lack of estrogen- and progesterone-receptor expression and no overexpression of HER2) AND has confirmation of disease progression (written or verbal) after two prior therapies. Or (B) locally advanced or metastatic Urothelial Cancer AND has confirmation (written or verbal) of disease progression after platinum-containing chemotherapy and either an anti-PD-1 or anti-PD-L1 agent.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Truqap

Products Affected

- TRUQAP

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has the applicable mutations based on use/diagnosis. Individual is HR positive, HER2 negative breast cancer (defined as IHC 0 or 1 plus or IHC 2 plus/ISH negative).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Truseltiq

Products Affected

- TRUSELTIQ (100MG DAILY DOSE)
- TRUSELTIQ (125MG DAILY DOSE)
- TRUSELTIQ (50MG DAILY DOSE)
- TRUSELTIQ (75MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using as monotherapy AND has confirmed (written or verbal) disease progression after one or more prior lines of systemic therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tukysa

Products Affected

- TUKYSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has the applicable mutations based on use/diagnosis. HER2-positive (HER2+) breast cancer is confirmed by one of the following: (a) Immunohistochemistry (IHC) is 3 + or (b) In situ hybridization (ISH) positive.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Turalio

Products Affected

- TURALIO ORAL CAPSULE 125 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Tykerb

Products Affected

- *lapatinib ditosylate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cancer has been confirmed HER2 positive. HER 2 overexpression confirmed (written or verbal) by one of the following: (a) Immunohistochemistry (IHC) 3+ or (b) In situ hybridization (ISH) positive.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Tymlos

Products Affected

- TYMLOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<p>For initial therapy, Individual is a postmenopausal female or a male using to increase bone density with one of the following: (A) dx of osteoporosis (defined as a bone mineral density [BMD] T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population) OR (B) clinical dx based on history of A low trauma fracture (fragility fracture) at high risk for fracture AND Individual meets one of the following: (a) refractory to a trial of bisphosphonate OR (b) individual is intolerant to or has a contraindication to bisphosphonate therapy as defined by one of the following (1 through 5): (1) Hypersensitivity to TWO bisphosphonates (one of which must be generic alendronate) OR (2) Inability to stand or sit upright for at least 30 minutes OR(3) A pre-existing gastrointestinal disorder (for example, Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, etc.) OR (4) Uncorrected hypocalcemia OR (5) Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents and zoledronic agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate. Or (c) Individual is at very high risk for fracture as defined by one or more of the following (AACE/ACE 2020): Recent fracture (within the past 12 months), Fractures while on approved osteoporosis therapy, Multiple fractures, Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids), Very low T-score (less than -3.0), High risk for falls or history of injurious falls, Very high fracture probability by FRAX (fracture risk assessment tool) (e.g. major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or other validated fracture risk algorithm.</p>

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation therapy, there is clinically significant response to therapy (including but not limited to no new fractures or reduction of fractures, or no worsening vertebral fractures, or no clinically significant adverse reaction) AND if individual has been on therapy greater than or equal to 24 months of treatment, a repeat BMD demonstrates a stable or increase in BMD.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Ubrelvy

Products Affected

- UBRELVY ORAL TABLET 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has had a trial/inadequate response or intolerance to 2 oral triptans (AHS 2021) OR Individual has one of the following CV or non-coronary vascular contraindications to use of triptans: Ischemic coronary artery disease (CAD) including angina pectoris, history of MI, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina), history of stroke or TIA, PVD, ischemic bowel disease, or uncontrolled hypertension.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Uceris

Products Affected

- *budesonide er oral tablet extended release 24 hour*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Uptravi

Products Affected

- UPTRAVI ORAL
- UPTRAVI TITRATION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Pulmonary Arterial Hypertension, individual has a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation therapy, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Valchlor

Products Affected

- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Vancocin

Products Affected

- *vancomycin hcl oral capsule*
- *vancomycin hcl oral solution reconstituted 25 mg/ml, 250 mg/5ml*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual is being treated for enterocolitis caused by Staphylococcal aureus including methicillin-resistant strains. Individual is being treated for clostridium Clostridiodes difficile-associated.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Vanflyta

Products Affected

- VANFLYTA

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

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Venclexta

Products Affected

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

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

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Verquvo

Products Affected

- VERQUVO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial use, individual has experienced one of the following: (A) Heart failure hospitalization within 6 months OR (B) Use of intravenous outpatient diuretics within 3 months AND Individual will be taking Verquvo (vericiguat) in combination with the following (Armstrong 2020): (A) Entresto (sacubitril/valsartan), angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) unless contraindicated or not tolerated AND (B) Beta-blocker (bisoprolol, carvedilol, metoprolol succinate) unless contraindicated or not tolerated.
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Continuation, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in heart failure symptoms, reduction in heart failure related physical limitations, reduction in hospitalizations) AND continues to use Verquvo (vericiguat) in combination with Entresto (sacubitril/valsartan), angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) unless contraindicated or not tolerated AND continues to use Verquvo (vericiguat) in combination with beta-blocker (bisoprolol, carvedilol, metoprolol succinate) therapy unless contraindicated or not tolerated.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Verzenio

Products Affected

- VERZENIO

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

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1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Vfend

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual is currently transitioning from inpatient treatment (hospital/medical facility) to an outpatient (home) setting and requires continued therapy for an organism susceptible to Vfend (voriconazole). Or mbr is using for a FDA approved use or supported by CMS approved compendia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Vittrakvi

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Written or verbal attestation to confirm genetic test results show the tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Vittrakvi (larotrectinib) oral solution requests, individual is unable to swallow the oral capsule dose form due to a clinical condition, but not limited to the following: (a) Dysphagia OR (b) individual?s age.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Vizimpro

Products Affected

- VIZIMPRO

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Vonjo

Products Affected

- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

VOTRIENT

Products Affected

- *pazopanib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
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EFFECTIVE DATE 01/01/2025

Vowst

Products Affected

- VOWST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has had at least three episodes of Clostridiodes difficile infection (initial episode and two recurrences) treated with antibiotic therapy (including Difucid, metronidazole or oral vancomycin) (IDSA/SHEA 2021) AND Current episode of Clostridiodes difficile infection has been verified (written or verbal) with a positive stool test for Clostridiodes difficile toxin AND treatment will be initiated within 2 to 4 days of completing antibiotic treatment for the current Clostridiodes difficile infection episode.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Month.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Vytorin

Products Affected

- *ezetimibe-simvastatin*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has had a trial of up to TWO of the following high intensity statins: (A) Atorvastatin 40mg and 80mg OR (B) Rosuvastatin 20mg and 40 mg OR Individual has had a trial of up to TWO generic statins at the maximally tolerated dose and did not achieve LDL cholesterol goal (AHA/ACC 2018).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Welireg

Products Affected

- WELIREG

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

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EFFECTIVE DATE 01/01/2025

Xalkori

Products Affected

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

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

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1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

XENAZINE

Products Affected

- *tetrabenazine oral tablet 12.5 mg, 25 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 3 months. Continuation: 1 year
Other Criteria	For continuation requests, individual has experienced an improvement in symptoms deemed to be clinically significant by the provider, and if using for Huntingtons disease, there is stabilization or improvement in total maximal chorea score.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Xermelo

Products Affected

- XERMELO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Initial: 3 months. Continuation: 1 year
Other Criteria	For initial therapy: Individual is using in combination with somatostatin analog (SSA) therapy (such as but not limited to, lanreotide (Somatuline Depot), octreotide (Sandostatin)) AND individual has had an inadequate response on a stable dose of SSA monotherapy for at least 3 months. For continuation therapy requests: Individual has previously met the initiation criteria AND if improvements are confirmed after 12 weeks of treatment with Xermelo (telotristat ethyl) when added to SSA therapy AND Individual does not report severe constipation or severe persistent or worsening abdominal pain.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Xgeva

Products Affected

- XGEVA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Skeletally mature adolescent is defined by at least one mature long bone [for example, closed epiphyseal growth plate of the humerus]. Hypercalcemia of malignancy is defined as an albumin corrected serum calcium level greater than 12.5 mg/dL (3.1 mmol/L).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Hypercalcemia of malignancy, Refractory to recent (within the last 30 days) treatment with intravenous bisphosphonate therapy (for example, pamidronate, zoledronic acid).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Xifaxan - HE

Products Affected

- XIFAXAN ORAL TABLET 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For the treatment of small intestinal bacterial overgrowth (ACG 2020).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Xifaxan 200mg

Products Affected

- XIFAXAN ORAL TABLET 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	30 Days.
Other Criteria	For 200mg strength, travelers diarrhea (TD), individual has already been started on the requested agent and needs to complete treatment OR Individual has had a trial and inadequate response or intolerance to one of the following agents (1 or 2) or has contraindications to all of the following agents (both 1 and 2) (CDC, 2024): (1) Generic Fluoroquinolone (ciprofloxacin, levofloxacin or ofloxacin) OR (2) Azithromycin.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Xolair

Products Affected

- XOLAIR SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 150 MG/ML, 300
 AUTO-INJECTOR 150 MG/ML, 300
 MG/2ML, 75 MG/0.5ML
- XOLAIR SUBCUTANEOUS SOLUTION MG/2ML, 75 MG/0.5ML
- XOLAIR SUBCUTANEOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<p>Individual has Moderate to Severe Persistent Asthma AND has a positive skin test or in vitro reactivity to a perennial aeroallergen, AND individual has a pretreatment FEV1 less than 80% predicted AND IgE level is equal to or greater than 30 IU/ml. For nasal polyps, individual had an inadequate response to nasal corticosteroids as add-on maintenance treatment AND individual has a serum IgE level greater than or equal to 30 IU/mL. For IgE mediated food allergy, diagnosis is confirmed via clinical hx of IgE mediated food allergy demonstrated by moderate to severe symptoms (including but not limited to throat tightness, dyspnea/wheezing, clinically significant hypotension, generalized urticaria) or requiring administration of epinephrine or emergency medical care AND positive skin prick test or positive serum IgE test or positive food challenge AND has a serum Immunoglobulin E (IgE) level equal to or greater than 30 IU/mL.</p>
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months. Continuation: 1 Year.

PA Criteria	Criteria Details
Other Criteria	<p>Initial Treatment: For moderate to severe persistent asthma, individual has had a minimum of 3 month trial and inadequate response or intolerance to ONE combination controller therapy (high dose of inhaled corticosteroids plus long-acting beta-2 agonists, Leukotriene modifiers, theophylline or oral corticosteroids)(GINA 2023). Continued treatment beyond 12 months is allowed when treatment has resulted in clinical improvement by one or more of the following: Decreased utilization of reliever medications OR Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids) OR Increase in percent predicted FEV1 from pretreatment baseline OR Reduction in reported asthma- related symptoms, such as, but not limited to, wheezing, shortness of breath, coughing, fatigue, sleep disturbance, or asthmatic symptoms upon awakening. AND continues to use omalizumab in combination with inhaled corticosteroid-based controller therapy For chronic spontaneous urticaria, individual has had trial and inadequate response or intolerance to ONE potent antihistamine (AAAAI/ACAAI 2014). For continued use for CSU, treatment has resulted in clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to itch severity and hive count). For initial request for CRSwNP, the presence of nasal polyps have been demonstrated on one of the following (AAO-HNS2015): a) anterior rhinoscopy b) nasal endoscopy OR c) computed tomography AND individual has had trial and inadequate response to maintenance intranasal corticosteroids AND individual is refractory to or is ineligible or intolerant to the following (AAAAI/ACAAI 2014): a) systemic corticosteroids OR b) sinonasal surgery. For CRSwNP continuation requests, tx with Xolair has resulted clinically significant improvement in clinical signs and symptoms of disease (including but not limited to improvement in nasal congestion or reduced polyp size) AND continues to use Xolair in combo with maintenance intranasal corticosteroids. For</p>
	<p>initial and continued use for IgE mediated food allergy, individual will use omalizumab in combination with food allergen avoidance AND has a prescription for an auto-injectable epinephrine agent.</p>
Indications	All Medically-accepted Indications.

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EFFECTIVE DATE 01/01/2025

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Xospata

Products Affected

- XOSPATA

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Xpovio

Products Affected

- XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 50 MG
- XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 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	For (DLBCL), Individual must not have DLBCL with mucosa-associated lymphoid tissue (MALT) lymphoma, composite lymphoma (Hodgkins and non-Hodgkins lymphoma), primary mediastinal (thymic) large B-cell lymphoma (PMBL), or known central nervous system (CNS) lymphoma (NCT02227251).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Xtandi

Products Affected

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

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

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Xuriden

Products Affected

- XURIDEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Y0114_25_3012943_0000_I_C
1074448MUMENMUB

EFFECTIVE DATE 01/01/2025

Xyrem

Products Affected

- *sodium oxybate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial tx of Narcolepsy type 1 (narcolepsy with cataplexy) defined by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following (ICSD-3): (1) Clear cataplexy (defined as more than one episode of generally brief [less than 2 min]) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness) AND (2) Multiple Sleep Latency Test (MSLT) showing one of the following: (a) MSLT of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) or (b) At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) OR (3) Cerebrospinal fluid hypocretin-1 deficiency (less than 100 pg/mL or less than one-third of the normative values with the same standardized assay).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 3 months. Continuation: 6 months

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PA Criteria	Criteria Details
Other Criteria	<p>For initial tx, of Narcolepsy type 2 (narcolepsy without cataplexy) defined by the following: (1) Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months AND (2) MSLT with one of the following: (a) MSLT of less than 8 minutes and evidence of two SOREMPs (ICSD-3, 2014) or (b) At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight PSG AND (3) absence of cataplexy AND (4) Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and PSG. AND (5) Mbr has had a previous trial of and inadequate response or intolerance to TWO of the following medications: (A) One of the following wakefulness promoting medications: (i) Modafinil or (ii) Nuvigil (armodafinil) AND (B) One of the following stimulants: (i) Methylphenidate (ii) Dextroamphetamine or (iii) Amphetamine/dextroamphetamine salt immediate-release OR (6) Trials of wakefulness promoting agents and stimulant agents are not acceptable due to concomitant clinical situations including but not limited to the following: (1) Cardiovascular disease or (2) Drug interactions. Mbr has idiopathic hypersomnia defined by (1) daily periods of strong need to sleep or daytime lapses into sleep for more than 3 mon. (2) absence of cataplexy (3) Insuff sleep syndrome ruled out (if nec, by lack of improvement of sleepiness after adequate trial of increased nocturnal time in bed, preferably verified by at least 1 wk. of wrist actigraphy) (4) MSLT shows fewer than 2 SOREMPs OR No SOREMPs if the REM sleep latency period on the preceding overnights polysomnogram is 15min or less (5) The presence of at least one: MSLT shows mean sleep latency of 8 min or less OR total 24hr sleep time of 660 min or longer (typically 12-14 hrs) on 24-hr polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in assoc with a sleep log (avg over at least 7 days with unrestricted sleep) AND (6) hypersomolence or MSLT findings are not better explained by another sleep disorder, medical or neurologic disorder, mental disorder, med use or substance abuse.</p>
	<p>For continuation, use has resulted in a reduction in frequency of cataplexy attacks compared to baseline OR use has resulted in a reduction in excessive daytime sleepiness (EDS) as measured by improvement in Epworth Sleepiness Scale (ESS) measurements or Maintenance of Wakefulness Test (MWT) compared to baseline.</p>

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Zarxio

Products Affected

- ZARXIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<p>Febrile neutropenic Individuals who are at high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1×10 to the power of $9/L$) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infections, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Prior episode of febrile neutropenia, Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have risk factors for FN including any of the following: age greater than 65 years, Poor performance status (ECOG status 3-4) or HIV infection (in particular, those with low CD4 counts (less than or eq $450/?L$) but chemotherapy still indicated (Lyman 2014), Prior radiation therapy (within previous 1 year) (Terbuch 2018) (Fujiwara 2017) (Shigeta 2015), Bone marrow involvement by tumor producing cytopenias, persistent neutropenia (ANC less than $1500mm^3$), poor renal function (GFR less than $60mL/min$) , liver dysfunction (liver function tests at least 2x upper limit of normal or bilirubin gr than $2.0 mg/dL$) (Lyman 2014) (Aagaard 2018), recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc) (Lyman 2014, Aagaard 2018). History of active infection within previous 60 days(Lyman 2014, Aagaard 2018). Current open wound and chemotherapy cannot be delayed (Lyman 2014, Aagaard 2018).</p>

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

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PA Criteria	Criteria Details
Other Criteria	<p>Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. Using for adjunctive tx for FN and has been prophylactic therapy with GCSF or has not received prophylactic therapy with a GCSF and who are at high risk for infection-associated complications. Use in individuals with acute myeloid leukemia (AML) shortly after the completion of induction or repeat induction chemotherapy, or after the completion of consolidation chemotherapy for AML. For tx of moderate to severe aplastic anemia. Tx of severe neutropenia in individuals with hairy cell leukemia. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm³ or experiencing recurrent infection. For myelodysplastic syndrome with ring sideroblasts (MDS-RS) or MDS/MPN-RS-T and using in combination with luspatercept-aamt. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. For tx of (non-chemotherapy) drug-induced neutropenia. For tx of low neutrophil counts in individuals with glycogen storage disease type 1b. For tx of neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected. After accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy] (such as Hematopoietic Syndrome of Acute Radiation Syndrome). After hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed. To mobilize progenitor cells into peripheral blood for</p>

PA Criteria	Criteria Details
	<p>collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT). Use as an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant. For tx for hematopoietic cell mobilization in combination with plerixafor. For Wilms Tumor (Nephroblastoma) and using with Regimen M and Regimen I for one of the following courses: Cyclophosphamide and etoposide OR Cyclophosphamide, doxorubicin, and vincristine. For autologous hematopoietic stem cell (HSC) mobilization as part of the development of an FDA-approved ex vivo gene therapy (e.g. Zynteglo (betibeglogene autotemcel)). For hematopoietic cell mobilization for autologous donors in combination with motixafortide.</p>
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Zavesca

Products Affected

- *miglustat*
- YARGESA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Presence of type 1 Gaucher disease is verified by either of the following (Weinreb et al. 2004, Wang et al. 2011): Deficiency in Glucocerebrosidase enzyme activity as measured in white blood cells or skin fibroblasts, OR genotype testing indicating mutation of two alleles of the glucocerebrosidase genome. And patient has clinically significant manifestations of gauchers disease including any of the following: skeletal disease (including but not limited to avascular necrosis, Erlenmeyer flask deformity, osteopenia or pathological fracture) OR patient presents with at least 2 of the following: clinically significant hepatomegaly, clinically significant splenomegaly, hgb at least 1 gram per deciliter below lower limit for normal for age and sex, platelet counts less than or equal to 120,000 mm ³ .
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.

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PA Criteria	Criteria Details
Other Criteria	Enzyme replacement therapy with Cerezyme, ELELYSO and VPRIV is not a therapeutic option for reasons including but limited to any of the following (Label, Weinreb et al. 2005): (a) Medically unmanageable hypersensitivity or (b) Development of therapy-limiting inhibitory antibodies or (c) Poor peripheral or central venous access. For continuation use, there is clinically significant improvement in clinical signs and symptoms of disease (including but not limited to reduction of spleen volume, reduction of liver volume, resolution of anemia, resolution of thrombocytopenia, reduction in fatigue, improvement in skeletal manifestations).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Zejula

Products Affected

- ZEJULA ORAL TABLET 100 MG, 200 MG, 300 MG

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

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Zelboraf

Products Affected

- ZELBORAF

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

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Zepzelca

Products Affected

- ZEPZELCA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has confirmation (verbal or written) of disease progression on or after platinum-based chemotherapy AND has a current ECOG performance of 0-2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using as a single agent for subsequent therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Zolinza

Products Affected

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Zydelig

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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EFFECTIVE DATE 01/01/2025

Zykadia

Products Affected

- ZYKADIA ORAL TABLET

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

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Zytiga

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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Zyvox

Products Affected

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

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

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