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

Adcirca

Products Affected

- ALYQ
- *tadalafil (pah)*

PA Criteria	Criteria Details
Exclusion Criteria	Using tadalafil-PAH formulations for the treatment of erectile dysfunction.
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, 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

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.

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 endarterectomey OR Inoperable (via pulmonary endarterectomey) 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

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	
Required Medical Information	Episodic migraine defined as at least 4 and fewer than 15 migraine days per month and fewer than 15 headache days per month on average during the previous 3-month period. Chronic migraine defined as a headache occurring on 15 or more days per month for more than 3 months, which, on at least 8 days per month, has features of a migraine headache (ICHD-3 beta).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 3 months. Continuation: 1 year

PA Criteria	Criteria Details
Other Criteria	For initial requests: (I) Individual has a diagnosis of one of the following: (a) Episodic migraine OR (b) Chronic migraine AND (II) Individual is using for migraine prophylaxis. And (III) Individual has had a trial of and inadequate response or intolerance to a 2-month trial at target or usual effective dose or intolerance to two agents for migraine prophylaxis (at least one agent in any two of the following classes) or has a contraindication to all of the following medications (AAN/AHA 2012/2015, Level A and B evidence, ICSI 2013, high quality evidence, AHS 2019): (a)The following antidepressants: amitriptyline, venlafaxine, nortriptyline, duloxetine or (b) One of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol or (c) The following calcium channel blocker: verapamil or (d) One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin or (e) Botox (for chronic migraine). AND If individual is also currently using botulinum toxin for prophylaxis and is going to be using Aimovig and botulinum toxin together (i.e., not switching from one agent to another), the following will apply: (a) Individual has had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with the initial agent AND (b) Individual continues to experience a significant number of migraine headache days or severe migraine days per month requiring additional therapy for migraine prevention. For Renewal requests: (I) Individual has a reduction in the overall number of migraine days or reduction of severe migraine days per month AND (II) Individual has obtained clinical benefit deemed significant by individual or prescriber including any of the following (AHS 2019): (a) 50% reduction in frequency of days with headache or migraine OR (b) Significant decrease in attack duration OR (c) Significant decrease in attack severity OR (d) Improved response to acute treatment OR (e) Reduction in migraine-related disability and improvements in functioning in important areas of life OR (f) Improvements in health related quality of life and reduction in psychological stress due to migraine. AND If individual is using
	concurrently with botulinum toxin for migraine prophylaxis, the following will apply: Individual has had further reduction in the overall number of migraine days or reduction in number of severe migraine days per month compared to monotherapy with the initial agent (either botulinum toxin or CGRP).

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

Akeega

Products Affected

- AKEEGA

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	Individual meets 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.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

Alimta

Products Affected

- *pemetrexed disodium intravenous solution reconstituted 100 mg, 500 mg*

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

Alpha1-Proteinase Inhibitor

Products Affected

- PROLASTIN-C

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Initial use, confirmed 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 confirmation (written or verbal) of 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

Alunbrig

Products Affected

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

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

Amphetamine Salts

Products Affected

- *amphetamine-dextroamphet er*
- *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

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

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 confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Aranesp

Products Affected

- ARANESP (ALBUMIN FREE) INJECTION SOLUTION 100 MCG/ML, 200 MCG/ML, 25 MCG/ML, 40 MCG/ML, 60 MCG/ML
- ARANESP (ALBUMIN FREE) INJECTION SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Initial use, Hemoglobin (Hgb) levels less than 10 g/dL, prior to initiation of therapy (unless otherwise specified) AND the individual iron status reveals, 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 erythropoietin level is less than 500 mU/ml. For tx of anemia due to myelosuppressive chemotherapy, chemo is planned for a minimum of 2 months and the dx is non-myeloid cancer and 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, individual demonstrates continued need for ESA treatment and has confirmation of response to treatment as evidenced by an increase in hemoglobin 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 level is not greater than 11 g/dL for individuals using for myelosuppressive chemotherapy related anemia or myelodysplastic syndrome AND If using for myelosuppressive chemotherapy-related anemia, individual is not using beyond 6 weeks after chemotherapy has completed.
Age Restrictions	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	Dialysis Dependent use: 1 year. All other use: 6 months.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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, mbr has confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AUBAGIO

Products Affected

- AUBAGIO

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

Augtyro

Products Affected

- AUGTYRO

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

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

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

AVASTIN

Products Affected

- AVASTIN

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

Ayvakit

Products Affected

- AYVAKIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Advanced Systemic Mastocytosis (AdvSM), individual has a platelet count of greater than or equal to 50 x 109/L.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Balversa

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has confirmed (written or verbal attestation) disease susceptible to genetic alterations.
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

Banzel

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	1 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

Baraclude

Products Affected

- BARACLUDE 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

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

Benlysta

Products Affected

- BENLYSTA

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

PA Criteria	Criteria Details
Other Criteria	For initial treatment of SLE, individual has a Clinical diagnosis of SLE per the American College of Rheumatology [ACR] criteria AND Unequivocally positive ANA (anti-nuclear antibody) titer greater than or equal to 1:80 or anti-dsDNA (double stranded DNA antibody) greater than or equal to 30 IU/mL AND SLE is active as documented 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 treatment of active lupus nephritis, individual has autoantibody-positive SLE (anti-nuclear antibody (ANA) titer greater than or equal to 1:80 or anti-dsDNA greater than or equal to 30 IU/mL) AND 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 individual?s 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, confirmation (written or verbal attestation) 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]).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

Bosulif

Products Affected

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

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

Botox-Myobloc-Dysport

Products Affected

- BOTOX
- XEOMIN INTRAMUSCULAR SOLUTION RECONSTITUTED 50 UNIT

PA Criteria	Criteria Details
Exclusion Criteria	Botulinum toxin is considered cosmetic as a treatment of skin wrinkles or other cosmetic indications and is not approvable.

PA Criteria	Criteria Details
Required Medical Information	For Cervical Dystonia (spasmodic torticollis) of mod or greater severity when: mbr is requesting initial tx AND HX of recurrent clonic and/or tonic involuntary contractions of 1 or more of the following muscles: sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles AND sustained head tilt and/or abnormal posturing with limited range of motion in the neck AND duration of the condition is greater than 6 months. Subsequent injections for the tx of cervical dystonia of mod or greater severity when all the following is met: Individual is requesting subsequent injections AND response to initial tx confirmed in medical records. For initial use in chronic migraine, PT has 15 or more headache- days/month for more than 3 months which on at least 8 days per month has features of a migraine HA (ICHD-3) AND Individual has had trial of/inadequate response to a 2 month trial at target or usual effective dose or intolerance to 2 agents for migraine prophylaxis (at least 1 agent in any 2 of the following classes) or has contraindication to all of the following meds (AAN/AHA 2012/2015, Level A and B evidence, ICSI 2013, high quality evidence, AHS 2021): 1 of these antidepressants: amitriptyline, venlafaxine nortriptyline, duloxetine OR 1 of these beta blockers: metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol OR the following CCB: verapamil OR 1 of these antiepileptics: valproate sod, divalproex sod, topiramate, gabapentin. AND If mbr is currently using a (CGRP) agent for chronic migraine prophylaxis, and is going to be using the CGRP agent and botulinum toxin together (i.e. not switching from one agents to another), the following must apply: (1) has had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with the CGRP agent AND (2) continues to experience a significant number of migraine headache days or severe migraine days per month.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial Chronic migraine: 6 months, Renewal: 1 Year. All others 1 Year.

PA Criteria	Criteria Details
Other Criteria	For Continuing tx of chronic migraine HA, mbr has completed an initial 6 month trial and has a reduction in overall number of migraine days or reduction in number of severe migraine days/month AND individual has obtained clinical benefit deemed significant by individual or prescriber including any of the following (AHS 2019 2021): (1) 50% reduction in freq of days with HA or migraine OR (2) Significant decrease in attack duration OR (3) Significant decrease in attack severity OR (4) Improved response to acute treatment OR (5) Reduction in migraine-related disability and improvements in functioning in important areas of life OR (6) Improvements in health related quality of life and reduction in psychological stress due to migraine. AND IF using concurrently with a CGRP agent for migraine prophylaxis, the following must apply: has had further reduction in the overall number of migraine days or reduction in the number of severe migraine days per month compared to monotherapy with the initial agent (either botulinum toxin or the CGRP agent). Treatment of primary hyperhidrosis. Treatment of secondary hyperhidrosis. Treatment of significant drooling in patients who are unable to tolerate scopolamine. Treatment neurogenic overactive bladder (also referred to as detrusor overactivity or detrusor sphincter dyssynergia) that is inadequately controlled with anticholinergic therapy. Treatment of idiopathic overactive bladder in adults who are unresponsive to or intolerant of a trial of anticholinergic therapy. Treatment of Hirschsprung disease and associated functional obstruction caused by the inability of the internal anal sphincter to relax after prior surgical tx.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Braftovi

Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Written or verbal attestation has been provided for either BRAF V600E or V600K genetic mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Brukinsa

Products Affected

- BRUKINSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has no prior BTK inhibitor usage.
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

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 confirmation of 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

Calquence

Products Affected

- CALQUENCE

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

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). For Continuation use, there is confirmation of clinically significant improvement or stabilization in plasma ammonia level.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

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

Chenodal

Products Affected

- CHENODAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	2 years. Requests to continue therapy beyond 24 months (2 years) should not be approved.
Other Criteria	Individual is using for gallstone dissolution AND has a well-opacifying gallbladder with radiolucent stones AND has an increased surgical risk due to systemic disease or advanced age. For continuation, Repeat imaging studies show partial dissolution of gallstone(s).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Cholbam

Products Affected

- CHOLBAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Initial use of the following: For diagnosis of bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs), Diagnosis is confirmed by any of the following (NORD 2020): (1) Fast atom bombardment-mass spectrometry (FABS-MS) OR (2) Electrospray ionization-mass spectrometry (ESI-MS) OR (3) Gas chromatography-mass spectrometry (GC-MS) OR (4) Molecular genetic testing. For diagnosis of peroxisomal disorders (PDs) [including but not limited to Zellweger spectrum disorders (ZSD)], Individual has one of the following present: (A) Manifestations of liver disease for example, jaundice, hepatomegaly) OR (B) Steatorrhea OR (C.) Complications from decreased fat soluble vitamin (such as but not limited to, vitamin D and K) absorption (for example, rickets, hypocalcemia, bleeding). For Continuation use, Individual has had a clinical improvement (symptoms, lab values) in liver function and/or cholestasis and has not developed a complete biliary obstruction.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

Chorionic Gonadotropin

Products Affected

- *chorionic gonadotropin intramuscular*
- NOVAREL INTRAMUSCULAR SOLUTION RECONSTITUTED 5000 UNIT
- PREGNYL

PA Criteria	Criteria Details
Exclusion Criteria	Use in the following: Infertility treatments (Including use with IVF, ART), Obesity, Weight loss, Stimulation of spermatogenesis in males, Treatment of anovulation in females with infertility, Ovulation induction in females.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Individual is using for Pre-pubertal cryptorchidism not caused by anatomical obstruction in males OR Hypogonadotropic hypogonadism from pituitary deficiency in males.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Cinryze

Products Affected

- CINRYZE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hereditary angioedema (HAE) is confirmed (written or verbal) 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 6 years of age or older.
Prescriber Restrictions	
Coverage Duration	Initial: 6 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 of prophylactic care, there is confirmation of 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

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

Copaxone

Products Affected

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

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

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

Corlanor

Products Affected

- CORLANOR ORAL SOLUTION
- CORLANOR ORAL TABLET
- *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 confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

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 MG/ML, 75 MG/0.5ML
- COSENTYX SENSOREADY (300 MG)
- COSENTYX SENSOREADY PEN
- COSENTYX SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of 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 significantly impact daily function (such as, palms, soles of feet, head/neck, or genitalia). Individual is using for the treatment of Non-radiographic Axial Spondyloarthritis (nr-axSpA) with objective signs of inflammation.
Age Restrictions	For plaque psoriasis, 6 years of age or older. For Enthesitis-Related Arthritis (ERA), 4 years of age or older. For Psoriatic Arthritis, 2 years of age or older. 18 years of age or older for all other indications.
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	For initial use: moderate to severe Ankylosing Spondylitis (AS), individual had an inadequate response to/intolerant of or has a contraindication to ONE conventional therapy [such as, NSAIDs or nonbiologic DMARDS such as sulfasalazine. For chronic moderate to severe plaque psoriasis (Ps), individual had an inadequate response to/intolerant of or has contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine or methotrexate). For moderate to severe Psoriatic Arthritis (PsA), individual has had an inadequate response to/intolerant of or has a contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine or leflunomide)] (ACR 2019). For Non-radiographic Axial Spondyloarthritis (nr-axSpA), individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine, methotrexate)] (ACR 2019). For Enthesitis-Related Arthritis (ERA), individual has moderate to severe ERA AND has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [such as NSAIDs or nonbiologic DMARDs]. For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Cotellic

Products Affected

- COTELLIC

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 unresectable or metastatic melanoma, Individual is using in combination with Zelboraf (vemurafenib) with or without Tecentriq (atezolizumab).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Cresemba

Products Affected

- CRESEMBA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual initiated treatment in an inpatient setting and requires continued treatment of invasive aspergillosis or mucormycosis or an organism susceptible to isavuconazonium in an outpatient setting. For invasive aspergillosis individual has an inadequate response/intolerance to or contraindication to voriconazole or liposomal amphotericin B (Patterson 2016). For invasive mucormycosis individual has had an inadequate response/intolerance to or contraindication to amphotericin B (CDC-Mucormycosis). Individual has human immunodeficiency virus (HIV) infection and is using to treat esophageal candidiasis refractory to oral itraconazole and/or fluconazole (AHFS).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Crinone

Products Affected

- CRINONE

PA Criteria	Criteria Details
Exclusion Criteria	Progesterone supplementation or replacement as part of an Assisted Reproductive Technology (ART) treatment for infertile women with progesterone deficiency, Progesterone supplementation/deficiency.
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

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. Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
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	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Part B Prerequisite	No

D.H.E Inj

Products Affected

- *dihydroergotamine mesylate injection*

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.

PA Criteria	Criteria Details
Other Criteria	For migraine attacks with aura in individuals meeting the following International Headache Society (IHS) diagnostic criteria (must meet criteria A-D): A) At least 2 or more headache attacks AND B) Aura consisting of at least 1 of the following fully reversible aura sx: 1. visual symptoms (such as, flickering lights, spots or lines) OR 2. Sensory symptoms (for example, pins and needles, numbness) OR 3. Speech and/or language (for example, aphasia) OR 4. Motor (for example, weakness) OR 5. Brainstem (for example, ataxia or vertigo) OR 6. Retinal (for example, blindness) AND C) At least 3 of the following characteristics: a) At least 1 aura sx develops gradually over 5 or more minutes or b) 2 or more aura sx occur in succession or c) Each individual aura lasts 5 to 60 minutes or d) At least 1 aura sx is unilateral or e) At least 1 aura sx is positive (scintillations and pins and needles are examples of positive sx of aura) or f) The aura is accompanied or followed within 60 minutes, by headache AND D) Individuals headache is not attributed to another headache disorder (for example, transient ischemic attack). For migraine attacks without aura in adults meeting the following IHS diagnostic criteria: 1) At least 5 or more headache attacks AND 2) Headaches lasting 4-72 hrs (untreated or unsuccessfully treated) AND 3) Headache has at least 2 or more of the following: i) Unilateral location ii) Pulsating quality iii)Moderate or severe pain intensity iv) Aggravation by or causing avoidance of routine physical activity (such as, walking or climbing stairs) AND 4) Individuals headache is accompanied by 1 or more of the following: i) Nausea, vomiting or both ii) Photophobia or phonophobia AND 5) Individuals headache is not attributed to another headache disorder (for example, transient ischemic attack). For cluster headache episodes in adults meeting the following IHS diagnostic criteria: A) At least 5 or more attacks B) Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes if untreated AND C) Headache is accompanied by at least 1 or both of the following: 1. One or more of the following sx or signs, ipsilateral to the headache: (i) conjunctival injection and/or

PA Criteria	Criteria Details
	lacrimation (ii) nasal congestion and/or rhinorrhea (iii) eyelid edema (iv) forehead and facial sweating (v) miosis and ptosis OR 2. A sense of restlessness or agitation AND D) Attacks have a frequency from one every other day to 8 per day for more than half of the time the disorder is active AND E) Individual's headache is not attributed to another headache disorder. DHE may also be approved: For Status migrainosus or rebound withdrawal type of headaches.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

Darzalex

Products Affected

- DARZALEX
- DARZALEX FASPRO

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

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

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

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

Doxil

Products Affected

- *doxorubicin hcl liposomal*

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

Duavee

Products Affected

- DUAVEE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Age 18 through age 75
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using for ONE of the following: Treatment of moderate to severe vasomotor symptoms associated with menopause OR Individual is using for prevention of postmenopausal osteoporosis AND is using solely for prevention of osteoporosis and has had a trial of and inadequate response or intolerance or has a contraindication to non-estrogen agents for osteoporosis.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Dupixent

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial dx of mod-severe asthma as demon by (NHLBI 2020): (a) pretx FEV1 less than or equal to 80% predicted AND (b) FEV1 reversibility of at least 12% and 200ml after albuterol (salbutamol) admin. For initial dx of chronic rhinosinusitis with nasal polyposis (CRSwNP), dx is confirmed by (AAO-HNSF 2015): (a) Anterior rhinoscopy or (b) Nasal endoscopy or (c) CT scan. For initial use in atopic derm (AD), individual has tried one of the following and tx failed to achieve and maintain remission of low or mild disease activity: Topical calcineurin inhibitors (TCI) or Phototherapy (UVB or PUVA) or Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) OR has contraindications to topical calcineurin inhibitors AND Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) AND unable to use Phototherapy. For initial EoE, dx is confirmed (NCT03633617) by 15 or more intraepithelial eos/hpf AND Symp of dysphagia AND tried a course of (PPIs) (Hirano,2020) OR tried a course glucocorticoids (Hirano, 2020).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Other Criteria	For initial tx of Asthma, (A) indv has one of the following: (i) has a blood eosinophil count (in the absence of other potential causes of eosinophilia, including HES, neoplastic dz, and known or suspected parasitic infection) gtr than or equal to 150 cells/microliter at initiation AND (ii) has had a 3 month trial and inadeq resp or intolerance to combo controller therapy (med-to-high dose inhaled steroids plus long acting beta2 -agonists, leukotriene modifiers, theophylline or oral steroids) (ERS/ATS 2013). OR (iii) has oral steroid dependent asthma AND (iv) has had a 3 month trial and inadequate resp or intol to high dose inhaled steroid with daily oral glucocorticoids given in combo with a controller medication (either a long-acting beta2-agonist, or leukotriene receptor antagonist, or theophylline) (ERS/ATS 2013) AND (B) indv has exp two or more asthma exacerbations in the prior 12 months req use of a systemic steroid or temp inc in the mbrs usual maint dosage of oral steroids. For cont tx of asthma: (a) mbr has exp one or more of the following: (i) Dec utilization of rescue meds OR (ii) Dec freq of exacerbations (defined as worsening of asthma that req an incr in inhaled steroid dose or tx with systemic steroids) OR (iii) Inc in predicted FEV1 from pretx baseline OR (iv) Red in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing. For initial dx CRSwNP, mbr has had a recent trial and inadequate resp to maint intranasal steroid (AAO-HNSF 2015) AND had trial, inadequate resp or intolerance to or has CI to the following: (a) Systemic steroids or (b) Sino-nasal surgery AND is using dupilumab as add on therapy to maint intranasal steroid. For initial PN mbr has 20 or more PN lesions (NCT04202679) AND meets one of the following (1 or 2): (1) tried at least a two wk course of med to sup-potent top steroids or such top steroids are not app (NCT04202679) or are not indicated due to severe HSR or concomitant clinical situations, (NCT04202679): lesions located in sensitive areas OR has steroid-induced atrophy OR hx of long-term or uninterrupted topical steroid use. OR (2) tried a course of TCI for

PA Criteria	Criteria Details
	two weeks has failed to achieve and maintain remission of low or mild dz activity state or TCI are not appropriate (NCT04202679) OR not indicated due to severe HSR or concomitant clinical situations: hx of or active malignant or pre-malignant skin conditions OR Netherton's Syndrome or other skin diseases that can increase the risk of systemic absorption of TCI OR considered to be immunocompromised, including those on systemic immunosuppressive meds on an ongoing basis. For cont use for CRSwNP/EoE/PN/AD, confirmed clinically significant imp or stabilization in clinical signs and symptoms of dz.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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.

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

Elidel

Products Affected

- *pimecrolimus*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 2 years of age and older.
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

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

Elitek

Products Affected

- ELITEK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual is receiving treatment in a setting appropriate for providing necessary monitoring and supportive care for tumor lysis syndrome AND Individual has not received a course of Elitek therapy in the past.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	30 DAYS.
Other Criteria	Individual has been diagnosed with leukemia, lymphoma or other hematologic malignancy with risk factors for tumor lysis syndrome AND Individual is receiving chemotherapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Empliciti

Products Affected

- EMPLICITI

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

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

Enbrel

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
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 JIA individual is 2 years of age or older. For plaque psoriasis, 4 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	For Initial use: moderate to severe Ankylosing Spondylitis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapies: [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019). For Moderate to severe Chronic Plaque Psoriasis, individual has had inadequate response to, is intolerant of, or has a contraindication to phototherapy OR ONE other systemic therapies (such as, methotrexate, acitretin, or cyclosporine). 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 or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine). For moderate to severe Polyarticular JIA, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDs such as methotrexate] (ACR 2019). For moderate to severe Psoriatic Arthritis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine or leflunomide)] (AAD 2019). For Continuation use: there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Enhertu

Products Affected

- ENHERTU

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has unresectable or metastatic Her2-positive (HER2+) breast cancer OR Her2+ gastric/gastroesophageal junction adenocarcinoma confirmed (written or verbal) by either Immunohistochemistry (IHC) is 3+ OR In situ hybridization (ISH) positive.
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

Entyvio

Products Affected

- ENTYVIO PEN
- ENTYVIO SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For SQ use, individual is 18 years of age or older for UC/CD.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For initial SQ use in UC/CD, mbr has completed intravenous induction doses with Entyvio and is using subcutaneous Entyvio for maintenance therapy OR has been stabilized on intravenous Entyvio maintenance therapy and is switching to maintenance therapy with subcutaneous Entyvio. For Continuation use: mbr has been receiving and is maintained on a stable dose of Entyvio AND there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Entyvio IV

Products Affected

- ENTYVIO INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For IV use, individual is 6 years of age or older (Conrad 2016, Singh 2016) for UC/CD.
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	For Initial IV use in: (A) CD, individual has had an inadequate response to or is intolerant to conventional therapy (such as systemic corticosteroids or immunosuppressants such as thiopurines or mtx) OR has a contraindication to systemic corticosteroids or thiopurines or methotrexate. OR (B) UC, individual has had an inadequate response to or is intolerant of Conventional Therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as methotrexate]) OR has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines. AND for UC/CD, individual has had a trial and an inadequate response or is intolerant to Humira (adalimumab) OR Stelara (ustekinumab). For the above indications, if the TNF agent (Humira (adalimumab)/Stelara (ustekinumab)) is not acceptable due to Individuals age. Entyvio may be allowed without trial of preferred TNF. For Continuation use: mbr has been receiving and is maintained on a stable dose of Entyvio AND there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Epclusa

Products Affected

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

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

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

Epogen and Procrit

Products Affected

- EPOGEN INJECTION SOLUTION 10000 UNIT/ML, 2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML
- PROCRIT

PA Criteria	Criteria Details
Exclusion Criteria	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Required Medical Information	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 indv 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.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Dialysis Dependent use: 1 year. All other use: 6 months.

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

Erbitux

Products Affected

- ERBITUX

PA Criteria	Criteria Details
Exclusion Criteria	Erbitux is used in combination with other anti-VEGF agents (e.g., bevacizumab). Erbitux is used in more than one line of therapy.
Required Medical Information	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis. For stage IV, kras wild type colon, rectal, colorectal, appendix, or anal adenocarcinoma when used as a single agent or as part of combination therapy. For squamous cell carcinoma of the Head and/or Neck cancer, Erbitux is used in combination with radiation therapy, for the treatment of locally or regionally advanced disease. Or as a single agent for the treatment of patients with recurrent or metastatic disease for whom prior platinum-based therapy has failed. Or in combination with platinum-based therapy with 5-FU (fluorouracil) as first-line treatment for individuals with recurrent locoregional disease or metastatic SCCHN. OR as a single agent or in combination therapy with or without radiation therapy for any of the following indications, unresectable locoregional recurrence or second primary in individuals who have received prior radiation therapy OR resectable locoregional recurrence in individuals who have not received prior radiation therapy OR distant metastases.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

Erivedge

Products Affected

- ERIVEDGE

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	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation, individual does not show evidence of progressive disease while on vismodegib therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Erleada

Products Affected

- ERLEADA

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

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
Age Restrictions	anaphylaxis to prior treatment with E. Coli-derived asparaginase.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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) is confirmed (written or verbal) 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 confirming 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 confirmation (written or verbal) of 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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Exjade

Products Affected

- *deferasirox*

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

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

Fabrazyme

Products Affected

- FABRAZYME

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial use, Diagnosis of Fabry disease is confirmed with either of the following: (a) Documentation (written or verbal) of complete deficiency or less than 5% of mean normal alpha-galactosidase A enzyme activity in leukocytes, dried blood spots or serum (plasma) analysis or (b) Documented (written or verbal) galactosidase alpha gene mutation by gene sequencing.
Age Restrictions	Individual is 8 years of age or older.
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	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Part B Prerequisite	No

Faslodex

Products Affected

- *fulvestrant intramuscular solution prefilled syringe*

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

Fentora

Products Affected

- *fentanyl citrate buccal*

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 (such as, 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.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

Ferriprox

Products Affected

- *deferiprone*
- FERRIPROX ORAL SOLUTION
- FERRIPROX ORAL TABLET 1000 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

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

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

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 confirmed (written or verbal) 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 (for example, 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

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

Flector Patch

Products Affected

- *diclofenac epolamine external*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	Individual is using for the treatment of acute pain from one of the following: (a) Minor strain OR (b) Sprain OR (c) Contusion.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Forteo

Products Affected

- FORTEO SUBCUTANEOUS SOLUTION PEN-INJECTOR 600 MCG/2.4ML
- *teriparatide subcutaneous solution pen-injector 600 mcg/2.4ml, 620 mcg/2.48ml*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial use, 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 young adult reference population OR a Clinical diagnosis based on a history of a low trauma fracture (fragility fracture) at high risk for fracture OR associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5mg or greater of prednisone for at least 3 months) at high risk for fracture.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	For initial use, Individual meets one of the following: (A) Individual has been refractory to a trial of an a oral bisphosphonate therapy OR (B) Intolerance or contraindications to oral bisphosphonate as defined by having at least one of the following: 1. Hypersensitivity to TWO oral bisphosphonates (one of which must be alendronate) 2. Inability to sit or stand upright for at least 30 minutes, 3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, etc.). 4. Uncorrected hypocalcemia. 5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents and zoledronic acid or creatinine clearance less than 30 mL/min for risedronate and ibandronate. (C) Individual is a postmenopausal female 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, or 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. For continued use, there is confirmation (written or verbal) of clinically significant response to therapy (including but not limited to confirmation of no new fractures reduction of fractures, or no worsening vertebral fractures, or no clinically significant adverse reaction) AND has been on therapy less 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

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

Fruzaqla

Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

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	Individual is using as a single agent.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Gattex

Products Affected

- GATTEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 7 months, Continuation: 1 Year.
Other Criteria	For initial use, in the diagnosis of Short Bowel Syndrome (SBS) individual is dependent on parenteral nutrition (PN) support, requires PN at least 3 times per week, AND individual is unable to: (NCT02682381, clinicaltrials.gov) A) reduce PN volume by at least 10% over the previous 3 months OR B) advance oral/enteral feeding support by at least 10% over the previous 3 months. For continued use, individual has experienced improvement as compared to baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Gauchers

Products Affected

- VPRIV

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Type 1 Gaucher is confirmed by either (Weinreb 2004, Wang 2011): Deficiency in Glucocerebrosidase activity as measured in white blood cells or skin fibroblasts OR genotype tests indicating mutation of two alleles of the glucocerebrosidase genome. And indiv has clinically significant manifestations of gauchers (Andersson 2005, Weinreb 2004) including for type 1,3: [Adults] skeletal disease (such as but not limited to avascular necrosis, Erlenmeyer flask deformity, osteopenia or pathological fracture) OR presents with 2 or more of the following: clinically significant hepatomegaly/splenomegaly, hgb at least 1 gm/dl below lower limit for normal for age and sex, platelet counts less than or equal to 120,000 mm3. [Children] clinical manifestations such as but not limited to hepatomegaly, splenomegaly, anemia, thrombocytopenia, skeletal disease or growth failure (Andersson 2005) OR Type 3 gauchers is confirmed by genotype testing indicating mutation of 2 alleles of the glucocerebrosidase genome (Kaplan 2013, Wang 2011) And has clinically significant manifestations of gauchers listed above in type 1 AND Neurological findings are consistent with type 3 gaucher disease based on neurological evaluation including brain imaging[MRI or CT and EEG].
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Other Criteria	Continuation use, there is confirmation of 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

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

Gazyva

Products Affected

- GAZYVA

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.

PA Criteria	Criteria Details
Other Criteria	Gazyva may be approved for treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma for any of the following: In combination with bendamustine for first-line treatment in individuals without del(17p)/TP53 mutation OR In combination with chlorambucil for first-line treatment in individuals without del(17p)/TP53 mutation who have significant comorbidity or age greater than 65 OR In combination with ibrutinib for first-line treatment in individuals without del(17p)/TP53 mutation who have significant comorbidity or age greater than 65 OR In combination with acalabrutinib for first line treatment in individuals with or without del (17p)/TP53 mutation or In combination with Venclexta (venetoclax) for the first line treatment in individuals with or without del (17p)/TP53 mutation OR as first-line single agent in individuals who are frail or with del (17p)/TP53 mutation OR as a single agent for the treatment of relapsed/refractory disease without del (17p)/TP53 mutation. 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

Gilenya

Products Affected

- *fingolimod hcl*
- GILENYA ORAL CAPSULE 0.25 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	I. Individual has had a trial and inadequate response or intolerance to one of the following: Avonex (interferon beta-1a), Betaseron (interferon beta-1b), MSB Tecfidera, MSB Copaxone, MSB Aubagio OR II. Individual has high disease activity despite treatment with a disease modifying drug (including Aubagio, Avonex, Bafiertam, Extavia, Kesimpta, Plegridy, Rebif, Betaseron, 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, Copaxone/Glatiramer/Glatopa, Extavia, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, 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).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

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

Gilotrif

Products Affected

- GILOTRIF

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

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

GLP 1

Products Affected

- BYDUREON BCISE
- BYETTA 10 MCG PEN SUBCUTANEOUS SOLUTION PEN-INJECTOR
- BYETTA 5 MCG PEN SUBCUTANEOUS SOLUTION PEN-INJECTOR
- 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
- VICTOZA SUBCUTANEOUS SOLUTION PEN-INJECTOR

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.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

Granix

Products Affected

- GRANIX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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 x 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 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).

PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has trial and inadequate response to Zarxio (filgrastim-sndz). To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT) (AHFS). 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

Harvoni

Products Affected

- HARVONI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation is provided for a diagnosis of chronic Hepatitis C virus (CHC) infection, which includes 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 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

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Hetlioz

Products Affected

- *tasimelteon*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Initial use, individual has a dx of non-24-hour sleep-wake disorder OR has confirmed dx (written or verbal) of Smith-Magenis Syndrome (SMS) based on one of the following: (a) Demonstration of a 17p11.2 deletion OR (b) Detection of mutation in RAI1 gene.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continued use, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to, increase in nighttime sleep, decrease in daytime nap time, improvement in sleep quality).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HP Acthar

Products Affected

- ACTHAR
- ACTHAR GEL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For West Syndrome, infant or child less than 2 years of age.
Prescriber Restrictions	
Coverage Duration	3 MONTHS.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

HRM Age AU

Products Affected

- ASCOMP-CODEINE
- *benztropine mesylate injection*
- *benztropine mesylate oral*
- BIJUVA
- *butalbital-apap-caff-cod oral capsule 50-325-40-30 mg*
- *butalbital-asa-caff-codeine*
- *carbinoxamine maleate oral solution*
- *carbinoxamine maleate oral tablet 4 mg*
- *chlorzoxazone oral tablet 500 mg*
- *clemastine fumarate oral tablet 2.68 mg*
- COMBIPATCH
- *cyclobenzaprine hcl oral tablet 10 mg, 5 mg*
- *cyproheptadine hcl oral syrup*
- *digox oral tablet 250 mcg*
- *digoxin injection*
- *digoxin oral tablet 250 mcg*
- *disopyramide phosphate oral*
- ELESTRIN
- *ergoloid mesylates oral*
- *estradiol transdermal gel*
- *estradiol transdermal patch twice weekly*
- *estradiol transdermal patch weekly*
- *estradiol-norethindrone acet*
- ESTROGEL
- EVAMIST
- FYAVOLV
- *guanfacine hcl oral*
- JINTELI
- *megestrol acetate oral suspension 625 mg/5ml*
- MENEST
- MENOSTAR
- *meperidine hcl oral tablet 50 mg*
- *meprobamate*
- MIMVEY
- *norethindrone-eth estradiol*
- NP THYROID
- PREMARIN ORAL
- PREMPHASE
- PREMPRO
- *promethazine hcl rectal suppository 12.5 mg, 25 mg*
- PROMETHEGAN
- TENCON ORAL TABLET 50-325 MG
- *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.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

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

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	GH tx used for reconstruction should not continue when BA =16 yr (M), or = 14 yr (F) is reached OR Epiphyseal fusion has occurred OR Mid-parenteral height is achieved. Child over 12: an X-ray report with evidence that epiphyses have closed or SMR of 3 or more.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Required Medical Information	Initial Requests, For idiopathic GHD, has signs/sym of GHD, GV 2 SD below age-appropriate mean or ht 2.25 SD below age-appropriate mean and A subnormal (SubNL) response (less than10ng/ml)to 2GH stim tests OR Neonates with hypoglycemia and clinical/hormone evidence of hypopit and low GH (less than 10ng/ml)OR 2other pit hormone deficiencies and low IGF-1 OR mbr has cranial irradiation with low IGF1 and normal thyroid tests. Child born SGA(birth wt or length 2 or more SD below the mean for gest age),Child fails to manifest catch up growth by age 4yr(ht 2 or more SD below the mean for age,gender)AND Other causes for SS have been ruled out. Transitioning adolescent: completed linear growth(growth rate of less than 2cm/yr) AND either of the following: A)GH tx has been stopped at least a month and GHD reconfirmed by: 1)idiopathic isolated GHD(SubNL response to 2 GH stim tests OR SubNL response (GH conc of less than10 ng/mL)to 1 provocative test and low IGF-I/IGFBP-3) OR 2) multiple pit hormone deficiency,(SubNL response to 1 provocative GH test and/or low IGF-I/IGFBP-3 or 3) with cranial irradiation, low IGF with normal thyroid OR B) any of the following:known genetic mutation assoc with def GH production/secretion or Hypothalamic-pit tumor/structural defect or 3 other pit hormone deficiencies. Adult GHD confirmed/reconfirmed:SubNL response in adults to 2 GH stim tests (GH conc of less than or equal to 5ng/ml when using insulin induced hypoglycemia OR GH conc of less than or equal to 4.1ng/ml when using arginine)OR SubNL response to 1 stim test for adults with hypothalamic or pit dz and 1 pit hormone deficits OR 3 other pit hormone deficiencies. Initial requests for therapy in child: For Reconstructive GH tx, if either mean ht is at least 2.25 but less than 2.5SD below the mean for age, gender and GV is less than the 10th percentile over 1yr OR mean ht is at least 2.5SD below the mean for age, gender for conditions known responsive to GH.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	For Continuation therapy: in child (including reconstructive tx) when following are met: individual evaluated AND growth rate remains above 2.5cm/year (does not apply to children with prior documented hypopituitarism) (Grimberg2016). GH in adults, GHD is reconfirmed as noted above. GH for Adolescents with childhood onset GHD who have completed linear growth.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Humira

Products Affected

- HUMIRA (2 PEN) SUBCUTANEOUS AUTO-INJECTOR KIT 40 MG/0.4ML, 40 MG/0.8ML, 80 MG/0.8ML
- 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, 40 MG/0.4ML, 40 MG/0.8ML
- HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT 40 MG/0.8ML
- HUMIRA-CD/UC/HS STARTER SUBCUTANEOUS AUTO-INJECTOR KIT 80 MG/0.8ML
- HUMIRA-CD/UC/HS STARTER SUBCUTANEOUS PEN-INJECTOR KIT 80 MG/0.8ML
- HUMIRA-PED>/=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 Crohn?s disease. Patient must be at least 2 years old for JIA and uveitis. Individual must be at least 6 years of age for Crohn?s disease. Individual must be at least 12 years old for HS. Individual must be 5 years of age or older for UC.
Prescriber Restrictions	
Coverage Duration	1 Year.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

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

PA Criteria	Criteria Details
	For chronic, progressive, treatment-refractory Sarcoidosis (Sweiss 2014), individual has had an inadequate response to, is intolerant of or has a contraindication to systemic corticosteroids AND nonbiologic DMARDs (such as methotrexate or azathioprine). For moderate to severe Hidradenitis Suppurativa (Hurley stage II or Hurley stage III disease) AND has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as oral antibiotics). For continued use, there is confirmation (verbal or written) of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Ibrance

Products Affected

- IBRANCE

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

Iclusig

Products Affected

- ICLUSIG

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

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) isocitratedehydrogenase-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

Ilaris

Products Affected

- ILARIS SUBCUTANEOUS SOLUTION

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	For cryopyrin-associated periodic syndromes age 4 years and older and for systemic juvenile idiopathic arthritis 2 years of age and older.
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	For AOSD/SJIA, individual has had an inadequate response to, intolerant of, or has a medical contraindication to ONE corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs) AND may be used alone or in combination with corticosteroids, methotrexate or NSAIDs. For FMF, individual has active type 1 FMF disease with genetic confirmation (written or verbal) of the diagnosis (MEFV gene exon 10 mutation) and confirmed recurrent, active disease (that is, at least one flare per month) and has failed to respond to, or is intolerant of colchicine therapy. For HIDS/MKD, individual has HIDS with genetic confirmation (written or verbal) of the diagnosis by deoxyribonucleic acid (DNA) analysis or enzymatic studies (that is, mutations in the MVK gene or markedly reduced mevalonate kinase activity) and confirmed prior history of greater than or equal to three febrile acute flares within a 6-month period when not receiving prophylactic treatment. For TRAPS, genetic confirmation (written or verbal) of the diagnosis (TNFRSF1A gene mutation) and has chronic or recurrent disease activity defined as six flares in a 12-month period. For Continuation use, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Imbruvica

Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 280 MG, 420 MG, 560 MG 70 MG
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET 140 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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Imfinzi

Products Affected

- IMFINZI

PA Criteria	Criteria Details
Exclusion Criteria	Has received treatment with another anti-PD-1 or anit-PD-L1 agent. Individual is receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.
Required Medical Information	For non-small cell lung cancer and biliary tract cancer individual has Eastern Cooperative Oncology Group performance status 0-2. For unresectable hepatocellular carcinoma, individual has Eastern Cooperative Oncology Group performance status 0-1
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For locally advanced, unresectable non-small cell lung cancer (NSCLC), disease has not progressed after definitive chemoradiation or is using until disease has progressed or individual has reached a maximum of 12 months of treatment and is using as consolidation therapy. For extensive stage Small Cell Lung Cancer, Individual is using as first line therapy in combination with etoposide and either cisplatin or carboplatin for four (4) cycles (followed by maintenance Imfinzi monotherapy).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

H1350_PBM24151_C EFFECTIVE DATE 12/01/2024
H9656_PBM24335_C

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

Ingrezza

Products Affected

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

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	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Part B Prerequisite	No

Inlyta

Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Written or verbal attestation is provided for histological confirmation 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

Inqovi

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has intermediate to high-risk myelodysplastic syndrome (MDS) or chronic myelomonocytic leukemia (CMML) disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

Interferons for MS

Products Affected

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Intuniv

Products Affected

- *guanfacine hcl er*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual is using for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD).
Age Restrictions	Individual is 6 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

Iressa

Products Affected

- *gefitinib*

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 diagnosis of recurrent, advanced, or metastatic Non-small cell lung cancer (NSCLC).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

IVIG

Products Affected

- GAMUNEX-C
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 2 GM/20ML, 2.5 GM/50ML, 30 GM/300ML, 5 GM/100ML

PA Criteria	Criteria Details
Exclusion Criteria	

PA Criteria	Criteria Details
Required Medical Information	For INIT Autoimmune (AI) MC blistering dx, when mbr had inadeq response/intolerance/contraindication (CI) to other tx such as steroids/ISx. For INIT AI neutropenia, active INFECT is excluded as cause. For INIT tx of 1 neurologic DZ: A) Lambert-Eaton myasthenic syndrome when having muscle weakness AND dx confirmed w/characteristic electrodiagnostic finding using nerve conduction tests, repetitive nerve stimulation (RNS), exercise testing or single fiber EMG (SFEMG) or presence of AB directed against voltage-gated Ca channels B) For MG and dx confirmed by presence of AB against the ach receptor or muscle specific tk or characteristic ED findings using RNS or SFEMG AND using for exacerbation or acute MG crisis or short-term therapy as ISx tx is taking effect or MAINT therapy of MG when mbr had inadeq response/intolerance/CI to Pyridostigmine, Corticosteroids and Non-steroidal ISx. C) CIDP when muscle weakness or sensory dysfx is caused by neuropathy in more than 1 limb and evidence of demyelinating neuropathy confirmed by EFNS/PNS or AAN guidelines or CSF analysis and other polyneuropathies. D) For MMN, dx is confirmed by EFNS/PNS 2010/AANEM 2003 guidelines. E) Stiff-person synd when mbr had inadeq response/intolerance/CI to other treatments such as benzodiazepines or baclofen. For cont use of above dx A-E, clinically/objective sig improvement in neurological sx on phys exam and cont need is shown by clinical effect. For INIT AE, dx is confirmed by specific autoab assoc with AE and Clinical present inc neuro sx (i.e, memory deficits, seizures, movement disorders, speech disturbances, behav changes, or psych symptoms) and Alternative etiologies of encephalitis syndrome have been ruled out, such as infectious etiologies, other neuro disorders, or other AI conditions.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	Tx of primary (PI) when hx of recurrent (SI) req ABX tx AND lack of/inadeq response to immunization AND no evidence of renal (nephrotic synd) and GI as causes of HGG AND INIT pre-tx total serum IgG below the lower limit of age adj lab ref range or more than 2SD below age adj mean. OR Use for ONE: A) B-cell CLL w/ hx of recur bacterial or active INFECT not responding to antimicrobial therapy and HGG w/ total IgG less than 500mg/dL B) MM with 1) hx of clinically severe INFECT or active clinically severe INFECT and HGG or 2) total IgG less than 400mg/dL C) HIV infected children to prevent opportunistic bacterial infection w/HGG (IgG less than 400mg/dL) or recurrent INFECT D) PARVO B19 chronic INFECT and severe anemia assoc w/BM suppression. OR using in context of transplant (TX) for ONE: 1) HSCT 2) Solid organ transplantation (TP) including prior desensitization for TP for suppression of panel reactive anti-HLA antibody (AB) in ppl with high panel reactive AB (PRA/cPRA) levels to HLA or in mbr w/hx of high levels of donor-specific AB or TX recipients at risk of CMV 3) TX recipients exp AB-mediated rejection w/donor-specific AB. OR for tx of AI DZ: A) ITP w/either active bleed or platelet count less than 30,000 mcL B) Fetal alloimmune TCP w/AB to paternal platelet antigen in maternal serum and ONE: Previously affected PREG, family hx of maternofetal alloimmune TCP or fetal blood sample shows TCP C) Isoimmune hemolytic dx of newborn, tx of severe hyperbilirubinemia D) Dermatomyositis (DMM) or polymyositis when mbr had inadeq response/intolerance/CI to other tx, e.g., corticosteroids, non-steroidal IS agents AND Dx confirmed having at least 4 sx: weak trunk/proximal extremities, high serum CK or aldolase levels, unexplainable muscle pain, electromyography findings, anti-Jo-1 AB, arthralgia/arthritis w/out joint destruction, sign of systemic inflamm, e.g.,fever/elevated C-reactive protein/high SED rate or inflamm myositis seen on muscle biopsy AND using for DMM and skin lesions present or E) AI Encephalitis (AE), eval for neoplasm associated w/AE. For CONT use of AE/AI MC blistering dx/dermatomyositis or polymyositis, is

PA Criteria	Criteria Details
	clinically sig improv in symptoms on phys exam and need is demon by clinical effect (i.e, pos response, stable on current dose, or worsening of symptoms occurs from a dose dec or inc in dose intervals, or prev dc resulted in relapse and Cancer screening continues.For MOG-related NMOSD confirmed (written or verbal) to be seropositive for MOG AB and is seronegative for aquaporin-4 (AQP4) AB and is using as induction treatment for an acute episode after an inadeq response/intolerance/CI to corticosteroids or has further relapse after maintenance treatment with corticosteroids and non-steroidal IS. For cont MOG-related NMOSD use, mbr exp clinical response.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

Jadenu

Products Affected

- *deferasirox*
- *deferasirox granules*

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

Jakafi

Products Affected

- JAKAFI

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

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 for mantle cell lymphoma.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Jynarque

Products Affected

- JYNARQUE ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For autosomal dominant polycystic kidney disease (ADPKD), individual is at risk of rapidly progressing disease consistent with Mayo class IC, ID or IE (Chebib 2018).
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

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	For metastatic breast cancer, individual has previously received trastuzumab (or trastuzumab biosimilars) and a taxane, separately or in combination. AND has either received prior therapy for metastatic disease OR developed disease recurrence during or within six (6) months of completing adjuvant therapy. Kadcyla is only used as a single agent. FOR early non-metastatic breast cancer for residual invasive disease in the breast or axilla after surgery after receiving at least 6 cycles (16 weeks) of neoadjuvant therapy containing a taxane (with or without anthracycline) and trastuzumab (or trastuzumab biosimilars).
Indications	All Medically-accepted Indications.
Off Label Uses	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Part B Prerequisite	No

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 a confirmed (verbal or written attestation) 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 confirmation (verbal or written attestation) of 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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Keytruda

Products Affected

- KEYTRUDA INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Previous treatment with another anti-PD-1 or anti-PD-L1 agent. Receiving therapy for an autoimmune disease or chronic condition requiring treatment with an systemic immunosuppressant.
Required Medical Information	Current ECOG (Eastern Cooperative Oncology Group) performance status of 0-2. Written or verbal attestation is provided for confirmation of (known or unknown) mutations where applicable based on use/diagnosis. For high risk non-muscle invasive (T1, high grade Ta, and/or carcinoma in situ [CIS]) Urothelial Carcinoma of the Bladder with or without papillary tumors (Label, NCT02625961) AND has Bacillus Calmette-Guerin (BCG)-unresponsive disease defined as one of the following: (a) Persistent disease despite adequate BCG therapy (adequate defined as administration of at least 5 doses of an initial induction course plus either at least 2 doses of maintenance therapy or at least 2 doses of a second induction course) or (b) dz recurrence after an initial tumor-free state following adequate BCG therapy (adequate defined as administration of at least 5 doses of an initial induction course plus either at least 2 doses of maintenance therapy or at least 2 doses of a second induction course) or (c) T1 disease (i.e., tumor has spread to the connective tissue, but not the muscle) following a single induction course of BCG AND is ineligible for cystectomy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Other Criteria	For melanoma, 1st line in untreated dz or 2nd line in dz progression while receiving or since completing most recent therapy. For colorectal cancer, monotherapy, primary tx as single agent for dMMR/MSIH and previous adjuvant FOLFOX or Cape OX w/in past 12mon or subsequent therapy as single agent if nivolumab or pembrolizumab not previously given following oxaliplatin-irinotecan and fluropyrimidine based therapy or oxaliplatin-irinotecan OR first line tx as single agent for dMMR/MSIH. For adv/metastatic NSCLC, used as 1st line, monotherapy, cytologically confirmed stage III or IV, tumor expresses PD_L1 gene on at least 1% or grtr of tumor cells. For 1st line adv/ recrnt /metastatic nonsquamous NSCLC, used in combo w/pemetrexed and carboplatin, cytologically confirmed stage IIIb or IV. For 1st line adv/recrnt/metastatic squamous NSCLC, used in combo with carboplatin and nab/paclitaxel and cytologically confirmed stage IV and has not undergone prev systemic tx for dz. For CONT/MAINT of adv, recrnt /metastatic nonsquamous NSCLC, used in combo w/pemetrexed if part of 1st line pembrolizumab/pemetrexed and platinum based regimen and achieved tumor response or stable dz after initial cytotoxic therapy. For CONT/MAINT therapy of adv, recrnt /metastatic squamous NSCLC, used as single agent, given 1st line as part of pembrolizumab/carboplatin/paclitaxel regimen, achieved tumor response or stable dz after initial cytotoxic therapy. For adv,recrnt, metastatic NSCLC, Used 2nd line, monotherapy, tumors w/ PD-L1 gene expression level greater than/equal to 1% w/demonstrated dz progression or after platinum-containing chemo, ALK or EGFR genomic tumor aberrations present and dz progression on FDA approved therapy for aberrations prior to receiving pembrolizumab. For Merkel-cell carcinoma (MCC), used as monotherapy, Presence of metastatic or recurrent locoregional MCC determined to be not amendable to definitive surgery or radiation therapy. For unresectable or metastatic solid tumors (dMMR/MSIH only), used as monotherapy. For hepatocellular
	carcinoma, used as single agent, demonstrated dz progression or intolerance on or after tx w/an approved 1st line agent.
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

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	
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

Korlym

Products Affected

- KORLYM
- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of Cushing?s 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: 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 Cushing?s Syndrome OR disease persists or recurs following surgery intended to correct the cause of endogenous Cushing?s 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

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

Krazati

Products Affected

- KRAZATI

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

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 individual is showing signs of continuing improvement as evidenced by maintaining acceptable blood phenylalanine levels.
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

Kyprolis

Products Affected

- KYPROLIS

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

Lazcluze

Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

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

Lenvima

Products Affected

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

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Letairis

Products Affected

- *ambrisentan oral tablet 10 mg, 5 mg*

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

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 x 10to the power of 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.

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

Levoleucovorin

Products Affected

- *levoleucovorin calcium intravenous solution reconstituted 50 mg*
- *levoleucovorin calcium pf*

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

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

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

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

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

Lorbrena

Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

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

Lotronex

Products Affected

- *alosetron 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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Lumakras

Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 320 MG

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 NSCLC, individual has confirmed (written or verbal) disease progression after one or more prior lines of systemic therapy and using as monotherapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Lumizyme

Products Affected

- LUMIZYME

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial use, infantile-onset Pompe disease, dx is confirmed (written or verbal) with acid alpha-glucosidase deficiency (GAA) activity in skin fibroblasts of less than 1% of the normal mean or by GAA gene sequencing AND Documentation (written or verbal attestation) of symptoms (for example respiratory and/or skeletal muscle weakness) AND confirmed evidence of hypertrophic cardiomyopathy. For initial use, non- infantile onset (late-onset) Pompe disease, dx is confirmed (written or verbal) by GAA enzyme assay which shows reduced enzyme activity less than 40% of the lab specific normal mean value AND Documentation (written or verbal attestation) of second GAA enzyme activity assay in a separate sample (from purified lymphocytes, fibroblasts or muscle) or by GAA gene sequencing AND forced vital capacity (FVC) 30 - 79% of predicted value AND ability to walk 40 meters on a 6-minute walk test (assistive devices permitted) AND muscle weakness in the lower extremities.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation, individual is using to treat infantile-onset Pompe, for non-infantile onset (late-onset) Pompe, individual is responding to therapy (including improvement, stabilization, or slowing of disease progression).

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

Lupron Depot

Products Affected

- *leuprolide acetate (3 month)*
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)
- LUPRON DEPOT-PED (1-MONTH) INTRAMUSCULAR KIT 11.25 MG, 15 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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. 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 a pubertal response to a gonadotropin hormone (GnRH) agonist test or a pubertal level of a third generation luteinizing hormone (LH) assay 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.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Gender Dysphoria in Adolescents (greater than or equal to 10 years of age and less than 18 years of age) (Hembree 2009)m 2017): Fulfills the DSM V criteria for gender dysphoria (American Psychiatric Assoc 2013) AND has experienced puberty to at least Tanner stage 2 (Hembree 2009, 2017) AND has (early) pubertal changes that have resulted in an increase of their gender dysphoria (Hembree 2009, 2017) AND does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment (Hembree 2009, 2017) AND has psychological and social support during treatment (Hembree 2009, 2017) AND demonstrates knowledge and understanding of the expected outcomes of GnRH analog treatment(Hembree 2009, 2017).
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

Lynparza

Products Affected

- LYNPARZA ORAL TABLET

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

Lytgobi

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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

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

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

Mekinist

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	BRAF V600E or V600K mutation results must be confirmed (written or verbal attestation).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Mektovi

Products Affected

- MEKTOVI

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

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

Methylphenidate

Products Affected

- *methylphenidate hcl er (cd)*
- *methylphenidate hcl er (la) oral capsule extended release 24 hour 10 mg, 20 mg, 30 mg, 40 mg, 60 mg*
- *methylphenidate hcl er (osm) oral tablet extended release 18 mg, 27 mg, 36 mg, 54 mg*
- *methylphenidate hcl er (xr)*
- *methylphenidate hcl er oral tablet extended release 20 mg*
- *methylphenidate hcl er oral tablet extended release 24 hour 18 mg, 27 mg, 36 mg, 54 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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Modafinil

Products Affected

- *modafinil oral tablet 100 mg, 200 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Narcolepsy type 1: confirmed 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. 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: confirmed 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. 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.
Age Restrictions	
Prescriber Restrictions	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Coverage Duration	1 Year.
Other Criteria	For obstructive sleep apnea/hypopnea syndrome objectively confirmed by polysomnography (PSG) or home testing with portable monitor showing one of the following (AASM 2017, ICDSD-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) confirmed 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) confirmed 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 confirmed 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

PA Criteria	Criteria Details
	overnight polysomnogram is 15 minutes or less 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.
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	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Mozobil

Products Affected

- MOZOBIL
- *plerixafor*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Using in combination with granulocyte colony stimulating factor (G-CSF) (such as Neupogen, Nivestym, Zarxio or Granix) and after stem cell mobilization and collection, a subsequent autologous hematopoietic stem cell transplant is anticipated.
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	3 months.
Other Criteria	Individual may use a maximum of up to four consecutive doses of plerixafor (Mozobil) injections per cycle for up to 2 cycles. Individual is using Mozobil (plerixafor) for autologous hematopoietic stem cell (HSC) mobilization as part of the development of an FDA-approved ex vivo gene therapy (e.g. Zynteglo).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Myalept

Products Affected

- MYALEPT

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

Naglazyme

Products Affected

- NAGLAZYME

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Mucopolysaccharidosis VI is confirmed (written or verbal) : (a) an increase in dermatan sulfate in the urine and decrease in the activity of N-acetylgalactosamine-4-sulfatase (arylsulfatase B) enzyme as measured in fibroblasts or leukocytes combined with normal enzyme activity level of another sulfatase OR (b) N-acetylgalactosamine-4-sulfatase (arylsulfatase B) gene mutation confirmed (written or verbal attestation).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Continuation use, there is documentation (written or verbal attestation) of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to reduction in urinary GAG excretion, reduction in hepatosplenomegaly, improvement in pulmonary function, improvement in walking distance and/or improvement in fine or gross motor function) compared to the predicted natural history trajectory of disease.
Indications	All Medically-accepted Indications.
Off Label Uses	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Part B Prerequisite	No

Namenda Line

Products Affected

- *memantine hcl er*
- *memantine hcl oral solution 2 mg/ml*
- *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

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

Nexavar

Products Affected

- *sorafenib tosylate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Confirmed (verbal or written attestation) results of FLT3-ITD mutation with acute myeloid leukemia, relapsed/refractory disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Noxafil

Products Affected

- NOXAFIL ORAL SUSPENSION
- *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

NP CSF SA Agents

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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 x 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/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).

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

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

PA Criteria	Criteria Details
Other Criteria	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 myleosuppressive 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

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 Human Growth Hormone

Products Affected

- GENOTROPIN MINIQUICK SUBCUTANEOUS PREFILLED SYRINGE
- GENOTROPIN SUBCUTANEOUS CARTRIDGE
- HUMATROPE INJECTION CARTRIDGE
- NUTROPIN AQ NUSPIN 10 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- NUTROPIN AQ NUSPIN 20 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- NUTROPIN AQ NUSPIN 5 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- SAIZEN INJECTION SOLUTION RECONSTITUTED 5 MG
- ZOMACTON

PA Criteria	Criteria Details
Exclusion Criteria	GH tx used for reconstruction should not continue when BA =16 yr (M), or = 14 yr (F) is reached OR Epiphyseal fusion has occurred OR Mid-parenteral height is achieved. Child over 12: an X-ray report with evidence that epiphyses have closed or SMR of 3 or more.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Required Medical Information	Initial Requests: For idiopathic GHD, has signs/sym of GHD, GV 2 SD below age-appropriate mean or ht 2.25 SD below age-appropriate mean and A subnormal (SubNL) response (less than10ng/ml)to 2GH stim tests OR Neonates with hypoglycemia and clinical/hormone evidence of hypopit and low GH (less than 10ng/ml)OR 2other pit hormone deficiencies and low IGF-1 OR mbr has cranial irradiation with low IGF1 and normal thyroid tests. Child born SGA(birth wt or length 2 or more SD below the mean for gest age),Child fails to manifest catch up growth by age 4yr(ht 2 or more SD below the mean for age,gender)AND Other causes for SS have been ruled out. Transitioning adolescent: completed linear growth(growth rate of less than 2cm/yr) AND either of the following: A)GH tx has been stopped at least a month and GHD reconfirmed by: 1)idiopathic isolated GHD(SubNL response to 2 GH stim tests OR SubNL response (GH conc of less than10 ng/mL)to 1 provocative test and low IGF-I/IGFBP-3) OR 2) multiple pit hormone deficiency,(SubNL response to 1 provocative GH test and/or low IGF-I/IGFBP-3 or 3) with cranial irradiation, low IGF with normal thyroid OR B) any of the following:known genetic mutation assoc with def GH production/secretion or Hypothalamic-pit tumor/structural defect or 3 other pit hormone deficiencies. Adult GHD confirmed/reconfirmed:SubNL response in adults to 2 GH stim tests (GH conc of less than or equal to 5ng/ml when using insulin induced hypoglycemia OR GH conc of less than or equal to 4.1ng/ml when using arginine)OR SubNL response to 1 stim test for adults with hypothalamic or pit dz and 1 pit hormone deficits OR 3 other pit hormone deficiencies. Initial requests for therapy in child: For Reconstructive GH tx, if either mean ht is at least 2.25 but less than 2.5SD below the mean for age, gender and GV is less than the 10th percentile over 1yr OR mean ht is at least 2.5SD below the mean for age, gender for conditions known responsive to GH.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	For Non-Preferred Growth hormone agents, individual has had trial of TWO preferred GH agents (Norditropin AND Omnitrope) or preferred GH agent is not FDA-approved and does not have an accepted off-label use per CMS recognized compendia for the prescribed indication and the requested non-preferred agent is. For Continuation therapy: in child (including reconstructive tx) when following are met: individual evaluated AND growth rate remains above 2.5cm/year (does not apply to children with prior documented hypopituitarism) (Grimberg2016). GH in adults, GHD is reconfirmed as noted above. GH for Adolescents with childhood onset GHD who have completed linear growth.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NP LA Opioid

Products Affected

- BELBUCA
- *buprenorphine transdermal*
- *hydromorphone hcl er oral tablet extended release 24 hour*
- *methadone hcl oral tablet*
- *morphine sulfate er beads*
- *morphine sulfate er oral capsule extended release 24 hour 10 mg, 100 mg, 20 mg, 30 mg, 50 mg, 60 mg, 80 mg*
- *morphine sulfate er oral tablet extended release 100 mg, 15 mg, 200 mg, 30 mg, 60 mg*
- *oxymorphone hcl er*
- *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.

PA Criteria	Criteria Details
Other Criteria	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 na?ve 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.
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

Nucala

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For severe eosinophilic asthma: In the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease and known or suspected parasitic infections, the individual has a blood eosinophil count that is either greater than or equal to 150 cells/microliter (cells/mm3) at initiation of therapy OR greater than or equal 300 cells/mm3 in the prior 12 months. Evidence of asthma is demonstrated by the following (NAEPP 2008): The individual has a pretreatment forced expiratory volume in 1 second (FEV1) less than 80% predicted AND FEV1 reversibility of at least 12% and 200mL after albuterol (salbutamol) administration. For initial severe eosinophilic asthma, mbr had a 3-mon trial/inadeq response or intolerance to combo controller therapy (high dose inhaled corticosteroids plus LA beta2-agonist, leukotriene modifiers, long-acting muscarinic antagonists or oral corticosteroids) (GINA 2022) AND exp 2 or more asthma exacerbations in past 12 mon requiring use of a systemic corticosteroid or temp increase in the mbr usual maint. dose of oral corticosteroids (ERS/ATS 2013). For Continuation of individuals w/severe eosinophilic asthma, tx resulted in clinical improv in one or more of the following: i) Decreased utilization of rescue meds OR ii) decreased freq of exacerbation (defined as worsening of asthma that requires an inc in inhaled corticosteroid dose or tx w/systemic corticosteroid) OR iii) increase in percent predicted FEV1 from pretreatment baseline OR iv) A reduction in reported asthma-related sx, including asthmatic symptoms upon awakening, coughing, fatigue, SOB, sleep disturbance or wheezing.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Age Restrictions	For eosinophilic asthma: 6 years old or older. For eosinophilic granulomatosis with polyangitis (EGPA) and chronic rhinosinusitis with nasal polyps (CRSwNP): 18 years old or older. For hypereosinophilic syndrome (HES): 12 years old or older.
Prescriber Restrictions	
Coverage Duration	Initial: 6 months, Continuation: 1 Year.

PA Criteria	Criteria Details
Other Criteria	For initial EGPA, has been dx for at least 6 months or greater and 1) a history or presence of asthma and 2) blood eosinophil level greater than or equal to 10% of leucocytes or AEC of greater than 1000 cells/mm3 (in absence of other potential causes of eosinophilia, including HES, neoplastic dz and known or suspected parasitic INF) and 3) presence of 2 or more features of EGPA (such as, biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil-rich granulomatosis inflamm, neuropathy, mono or poly (motor deficit or nerve conduction abnormality), pulmonary infiltrates, non-fixed, sino-nasal abnormality, cardiomyopathy, glomerulonephritis, alveolar hemorrhage, palpable purpura or antineutrophil cytoplasmic antibody positive status AND 4) mbr is on concurrent oral corticosteroid therapy (Wechsler 2017). For EGPA Continuation, tx has resulted in the achievement of remission at some point during tx, defined as: Birmingham Vasculitis Activity Score, version 3, of 0 (on a scale from 0 to 63) and receipt of prednisolone or prednisone at a dose of 4mg or less per day. For HES, mbr has been dx for at least 6 mon AND had trial/inadeq response to oral corticosteroids AND mbr experienced 2 or more HES flares w/in the past 12 mon requiring escalation in therapy (increase in oral corticosteroid dose or increase/addition of immunosuppressive or cytotoxic therapy) AND has blood eosinophil count greater than or equal to 1000 cells/mm3. For HES continuation, tx resulted in clinically significant improvement or stabilization in clinical signs/sx of disease (including but not limited to decrease or absence of HES flares, improvement in fatigue). For CRSwNP, there is presence of nasal polyps demonstrated on either a) anterior rhinoscopy OR b) nasal endoscopy OR c) computed tomography AND mbr had trial/inadeq response to MAINT intranasal corticosteroids AND is refractory to or is ineligible or intolerant to systemic corticosteroids OR sinonasal surgery AND mbr is requesting Nucala as add-on therapy to MAINT intranasal corticostetroids. For CRSwNP continuation therapy, tx resulted in
	clinically significant improvement in clinical signs and sx of disease (including but not limited to improvement in nasal congestion or reduced nasal polyp size) AND continues to use Nucala in combo w/ MAINT intranasal corticosteroids.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

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, Pioro et al. 2010), multiple sclerosis (AAN 2019, Pioro et al, 2010), stroke (2016 AHA/ASA)].
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Nulojix

Products Affected

- NULOJIX

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

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	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Part B Prerequisite	No

Nurtec

Products Affected

- NURTEC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For the acute treatment of migraine headaches, Individual has had a trial of and inadequate response or intolerance to two oral triptans (AHS 2021) OR has one of the following cardiovascular or non-coronary vascular contraindications to use of triptans: (a) Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal?s angina) or (b) History of stroke or transient ischemic attack (TIA) or (c) Peripheral vascular disease or (d) Ischemic bowel disease or (e) Uncontrolled hypertension.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial req for migraine prophy: 3 mon. Renewal for prophy: 1 Yr. Acute tx: 1 Yr.

PA Criteria	Criteria Details
Other Criteria	For initial use in prevention of episodic migraine headaches, mbr has a dx of episodic migraine defined as at least 4 and fewer than 15 migraine days per month and fewer than 15 HA days per month on average during the previous 3 month period (ICHD-3) AND is using agent for migraine prophy. AND If mbr is also currently using botulinum toxin for prophy and is going to be using Nurtec ODT and botulinum toxin together (i.e., not switching from one agent to another), the following must apply: (1) Individual has had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with botulinum toxin use AND (2) continues to experience a significant number of migraine headache days or severe migraine days per month requiring additional therapy for migraine prevention. AND has had a trial and inadequate response to a 30 day trial at target or usual effective dose or intolerance to two agents for migraine prophylaxis (at least one agent in any two of the following classes) or has a contraindication to all of the following medications (AAN/AHA 2012/2015, Level A and B evidence, ICSI 2013, high quality evidence, AHS 2021): a) The following antidepressants: amitriptyline, venlafaxine, nortriptyline, duloxetine OR b) One of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol OR c) the following calcium channel blocker, verapamil OR d) One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin OR e) Botox (for chronic migraine). For Continued use for migraine prophylaxis, mbr has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month AND has obtained clinical benefit deemed significant by individual or prescriber including any of the following (AHS 2021): (a) 50% reduction in frequency of days with headache or migraine OR (b) Significant decrease in attack duration OR (c) Significant decrease in attack severity OR (d) Improved response to acute treatment OR (e) Reduction in migraine-related disability and improvements in functioning in important areas of life OR (f) Improvements in health

PA Criteria	Criteria Details
	related quality of life and reduction in psychological stress due to migraine AND If individual is using concurrently with botulinum toxin for migraine prophylaxis, the following must apply: Individual has had further reduction in the overall number of migraine days or reduction in number of severe migraine days per month compared to monotherapy with botulinum toxin.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Nuvigil

Products Affected

- *armodafinil oral tablet 150 mg, 200 mg, 250 mg, 50 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Narcolepsy type 1: confirmed 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. 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: confirmed 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. 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.
Age Restrictions	
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	1 Year.
Other Criteria	For obstructive sleep apnea/hypopnea syndrome objectively confirmed by polysomnography (PSG) or home testing with portable monitor showing one of the following (AASM 2017, ICDSD-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) confirmed 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) confirmed 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 confirmed 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

PA Criteria	Criteria Details
	overnight polysomnogram is 15 minutes or less 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.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

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

Ofev

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Initial: dx of idiopathic pulmonary fibrosis (IPF) is confirmed (verbal or written) by (Raghu 2018): 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 AND Individual has pulmonary function tests within prior 60 days confirming Forced Vital Capacity (% FVC) greater than or equal to 50%. For dx systemic sclerosis-associated interstitial lung disease (SSc-ILD), mbr has been confirmed (verbal or written) by chest high resolution computed tomography (HRCT) scan showing fibrosis affecting greater than or equal to 10% of the lungs and individual has pulmonary function tests within prior 60 days confirming Forced Vital Capacity (%FVC) greater than or equal to 40%. For dx of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype, mbr has been confirmed (written or verbal) by chest (HRCT) scan showing fibrosis affecting greater than or equal to 10% of the lungs AND progressive disease has been confirmed by one of the following within the last 24 months while on treatment: (a) FVC decline of greater than or equal to 10% OR (b) 2 of the following: (1) FVC decline greater than or equal to 5% and less than 10% or (2) Worsening respiratory symptoms or (3) Increased fibrosis on HRCT AND individual has pulmonary function tests within prior 60 days confirming FVC greater than or equal to 45%.
Age Restrictions	

PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Continuation, there is confirmation (written or verbal) of 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

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

Ojemda

Products Affected

- OJEMDA ORAL SUSPENSION RECONSTITUTED
- OJEMDA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For LGG, individual has a BRAF fusion or rearrangement, or BRAF V600 mutation.
Age Restrictions	Individual is 6 months of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual requires systemic therapy and have progressed following ONE prior treatment or have no satisfactory alternative treatment options AND is using as a single agent.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

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

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 has achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy AND is unable to complete intensive curative therapy (e.g. allogeneic hematopoietic stem cell transplant) 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

Opdivo

Products Affected

- OPDIVO

PA Criteria	Criteria Details
Exclusion Criteria	Receiving therapy for an autoimmune disease or chronic condition requiring treatment with an immunosuppressant. Previous treatment with another anti-PD-1 or anti-PD-L1 agent.
Required Medical Information	Current ECOG performance status 0-2. For NSCLC, SCCHN, Urothelial carcinoma, ESCC, Melanoma, confirmation (verbal or written) of disease progression. Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	For unresectable or metastatic melanoma: used as a single agent or in combination with Yervoy, as first-line therapy for untreated melanoma OR used as a single agent or in combination with Yervoy, as second-line or subsequent therapy for disease progression while receiving or since completing most recent therapy. For resected advanced melanoma for up to 12 months of adjuvant therapy when individual has resected state IIIB, IIIC or stage IV disease. For recurrent/metastatic NSCLC when: agent is used in combination with ipilmumab and two (2) cycles of platinum-double chemotherapy AND does not have presence of actionable molecular markers. For intermediate or poor risk renal cell carcinoma, agent used as single agent OR used in combination with ipilmumab for four cycles followed by nivolumab, as subsequent therapy if no checkpoint blockade (PD-1, PD-L1 or CTLA-4) antibody treatment has been previously administered. For malignant pleural or peritoneal mesothelioma, used as a single agent, or in combination with ipilmumab for subsequent therapy. For merkel cell carcinoma (MCC), used as a single agent and Presence of metastatic or recurrent locoregional MCC determined to be not amenable to definitive surgery or radiation therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Part B Prerequisite	No

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

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.
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 meets the initial criteria AND 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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Orkambi

Products Affected

- 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 confirms (verbal or written attestation) the individual has two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.
Age Restrictions	Individual is 1 year age or older
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation requests, there is confirmation (verbal or written attestation) of 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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

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

Otezla

Products Affected

- OTEZLA ORAL TABLET
- OTEZLA ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For pediatric Ps, Individual has chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2020): (a) Plaque Ps involving greater than three percent (3%) body surface area (BSA) OR (b) Plaque Ps involving less than three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).
Age Restrictions	For pediatric Ps, individual is 6 to 17 years of age. All other indications, Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	For Psoriatic Arthritis (PsA), Individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDS (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]. For plaque psoriasis (Ps), Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine or methotrexate) OR individual had an inadequate response to, is intolerant of , or has a contraindication to ONE of the following topical therapies for psoriasis (Gold 2022): Medium to high potency topical steroid Tazarotene, Vitamin D analogs (calcitriol, calcipotriene, or calcipotriene/betamethasone combination agents), Topical calcineurin inhibitors (tacrolimus or pimecrolimus), Anthralin. For pediatric Ps, member weighing at least 20 kg AND has had an inadequate response to or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate) OR has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate. For Behcets disease, Individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [such as topical or systemic corticosteroid, immunosuppressants, colchicine, or NSAIDs].
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

OxyContin

Products Affected

- *oxycodone hcl er oral tablet er 12 hour abuse-deterrent 10 mg, 20 mg, 40 mg, 80 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 11 years of age or older
Prescriber Restrictions	
Coverage Duration	Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

PA Criteria	Criteria Details
Other Criteria	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). Individual is not opioid na?ve 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 and tolerating a minimum daily opioid dose of at least 20mg oxycodone orally or its equivalent. 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 plan.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Pegfilgrastim Agents

Products Affected

- FULPHILA
- NEULASTA ONPRO
- NEULASTA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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 x 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 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).

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

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

Perjeta

Products Affected

- PERJETA

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.

PA Criteria	Criteria Details
Other Criteria	For metastatic breast cancer use Perjeta will be used in combination with trastuzumab (or trastuzumab biosimilars) AND either docetaxel or paclitaxel. AND combination chemotherapy with Perjeta (pertuzumab) will be used as single line anti-HER2 chemotherapy for metastatic disease until progression AND if docetaxel or paclitaxel treatment is contraindicated upon initiation or discontinued (for example, related to toxicity), treatment with pertuzumab and trastuzumab may continue OR individual has early stage, locally advanced or inflammatory breast cancer AND is using in one of the following ways: neoadjuvant therapy (prior to surgery) AND primary tumor is larger than 2cm or individual is lymph node positive (clinically evident by palpation or imaging) OR adjuvant systemic therapy and the cancer is at a high risk of recurrence AND used in combination with trastuzumab (or trastuzumab biosimilars)and with one of the following: docetaxel with or without carboplatin or paclitaxel AND pertuzumab is used for a maximum of 18 cycles (12 month course) OR individual is requesting Perjeta in combination with trastuzumab (or trastuzumab biosimilars) for 12 months after completing 6 cycles (18 weeks) of TCHP (docetaxel, carboplatin, trastuzumab (or trastuzumab biosimilars), pertuzumab) for early stage, locally advanced, or inflammatory breast cancer.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

Piqray

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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

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

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.

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 confirmation of 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

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.

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

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

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

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

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.

PA Criteria	Criteria Details
Other Criteria	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).
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

Ravicti

Products Affected

- RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Initial requests, Individual has had a trial and inadequate response or intolerance to sodium phenylbutyrate (Buphenyl) OR Individual has any of the following: (a) Congestive heart failure or (b) Severe renal insufficiency or (c) A clinical state where there is sodium retention with edema. For continuation requests, the confirmation of clinically significant improvement or stabilization in plasma ammonia level.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Reclast

Products Affected

- *zoledronic acid intravenous solution 5 mg/100ml*

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

RELISTOR

Products Affected

- RELISTOR SUBCUTANEOUS SOLUTION 12 MG/0.6ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For non-cancer pain related OIC, Individual must have a previous trial of or insufficient response to polyethylene glycol (generic MiraLax) (AGA 2013) AND a trial and inadequate response or intolerance to a preferred agent (Movantik/Amitiza) OR the preferred agent (Movantik/Amitiza) is not acceptable due to concomitant clinical situations, warnings or contraindications, such as but not limited to the following: Individual has disruption to the blood-brain barrier and may be at increased risk for opioid withdrawal and/or reduced analgesia (Movantik) OR Individual is taking strong CYP3A4 inhibitors and may be at increased risk for opioid withdrawal and/or reduced analgesia (Movantik). For OIC with advanced illness, individual is receiving palliative care AND must have a previous trial of or insufficient response to polyethylene glycol (generic MiraLax) (AGA 2013).
Indications	All Medically-accepted Indications.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

Remicade

Products Affected

- *infliximab*
- REMICADE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For chronic moderate to severe plaque psoriasis: Greater than 3% of body surface area with plaque psoriasis OR Less than or equal to 3% 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	For Crohn's Disease or Ulcerative colitis, 6 yr of age or older. For JIA, 2 yr of age or older. For all other indications 18 yr of age.
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	For initial use: RA, MTX titrated to maximally tolerated dose (ACR 2021) OR if MTX is not tolerated or contraindicated, individual had an inadequate response to, is intolerant of or has contraindication to other conventional therapy (sulfasalazine, leflunomide or hydroxychloroquine. For moderate to severe Crohn's Disease, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such as 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressants [such as thiopurines or methotrexate]). For moderate to severe Ulcerative Colitis, individual an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such as 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressants [such as thiopurines]). For Ankylosing Spondylitis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [such as NSAIDs, or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019)]. For Psoriatic Arthritis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiological DMARDs (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]. For chronic plaque psoriasis, individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or ONE other systemic therapy (such as methotrexate, acetretin, or cyclosporine). For PJIA, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE Conventional Therapy [nonbiologic DMARD (such as methotrexate)]. For chronic, recurrent, treatment-refractory or vision- threatening, non-infectious uveitis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such as corticosteroids or immunosuppressants [for example, azathioprine, cyclosporine, or methotrexate]). For Sarcoidosis (Baughman 2006), mbr has had an inadequate response to, is intolerant of, or has a contraindication to systemic corticosteroids AND has had an
	inadequate response to, is intolerant of, or has a contraindication to nonbiologic DMARDs (such as methotrexate or azathioprine). For Continuation use there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

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

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

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	
Required Medical Information	For NSCLC, MTC, Thyroid cancer, Solid Tumors, written or verbal attestation is provided for RET mutation status.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Revatio

Products Affected

- *sildenafil citrate oral suspension reconstituted*
- *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

Revatio IV

Products Affected

- *sildenafil citrate intravenous*

PA Criteria	Criteria Details
Exclusion Criteria	Individuals requesting for the treatment of erectile dysfunction.
Required Medical Information	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	For initial sildenafil INJ requests, individual is temporarily unable to take oral dose forms and requires continued therapy. For continuation requests, 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) AND individual is unable to take oral dose forms and requires continued injection therapy.
Indications	All Medically-accepted Indications.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

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	
Required Medical Information	For mds, confirmed [verbal or written] deletion of 5q (del5q) cytogenetic abnormality with or without additional cytogenic abnormalities.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 YEAR.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Rezlidhia

Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial use, individual has AML, and written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis. Individual has an ECOG performance status of 0- 2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months, Continuation: 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

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

Rinvoq

Products Affected

- RINVOQ
- RINVOQ LQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For RA, UC, AS, NR-axSpA, Individual is 18 years of age or older. For Atopic Dermatitis, individual is 12 years of age or older. For PJIA, PsA, individual is 2 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	For initial use: moderate to severe RA meets (a + c, or b + c), (a) individual has had an inadequate response to MTX titrated to maximally tolerated dose (ACR 2021) OR (b) if MTX is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE other conventional therapy (i.e., sulfasalazine, leflunomide, or hydroxychloroquine) AND (c) has had a trial and inadequate response or intolerance to ONE tumor necrosis antagonist agent. For PsA, individual has had inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDS (such as MTX, sulfasalazine cyclosporin or leflunomide)] AND has had a trial and inadequate response or intolerance to ONE tumor necrosis factor (TNF) antagonist agent. For Atopic Dermatitis, a non-corticosteroid systemic immunosuppressant (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) has failed to achieve and maintain remission of low or mild disease activity state or are contraindicated AND Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state or is contraindicated OR a Biologic therapy (such as dupilumab or tralokinumab) has failed to achieve and maintain remission of low or mild disease activity state or are contraindicated. For UC, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]) AND individual has had a trial and inadequate response or intolerance to one tumor necrosis factor (TNF) antagonist agents. For AS/NR-axSpA, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] AND has had a trial and inadequate response or intolerance to ONE tumor necrosis factor (TNF) antagonist agents. For Continuation requests, there is confirmation (written or verbal) of clinically significant
	improvement or stabilization in clinical signs and symptoms of disease.
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

Rozlytrek

Products Affected

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

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	For metastatic non-small cell lung cancer (NSCLC), 18 years of age or older.
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

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Rybrevant

Products Affected

- RYBREVANT

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	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

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

Sabril

Products Affected

- *vigabatrin*
- VIGADRONE
- 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

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

SANCUSO

Products Affected

- SANCUSO

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 and inadequate response or intolerance to EITHER generic ondansetron or oral granisetron OR individual is unable to take oral medications due to the following: (A)The presence of head and neck cancer OR (B)Mucositis due to recent radiation to the head and neck area.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Sarclisa

Products Affected

- SARCLISA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has a diagnosis of multiple myeloma AND has not received treatment with isatuximab or another anti-CD38 agent such as daratumumab) AND (A) has relapsed or refractory disease following treatment with at least two prior lines of therapy including lenalidomide and a proteasome inhibitor (for example, bortezomib, carfilzomib, or ixazomib). Or (B) has relapsed or refractory disease following treatment with one to three prior lines of therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using in combination with pomalidomide and dexamethasone or carfilzomib and dexamethasone.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Scemblix

Products Affected

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

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	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

Serostim

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial requests for Serostim require that individual has HIV-associated wasting syndrome or cachexia, defined as one of following (Schambelan 1996): (A) Unintentional weight loss greater than or less than 10% of baseline weight OR (B) weight less than 90% of the lower limit of ideal body weight. The individual's weight loss cannot be explained by a concurrent illness other than HIV infection AND must be simultaneously treated with antiretroviral therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation, individual's weight loss cannot be explained by a concurrent illness other than HIV infection AND must be simultaneously treated with antiretroviral therapy AND demonstrate clinical effect (for example, patient has had a clinically significant improvement in body weight, lean body mass, or physical endurance from baseline with treatment).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

H1350_PBM24151_C EFFECTIVE DATE 12/01/2024
H9656_PBM24335_C

Signifor IR

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of Cushing?s disease has been confirmed (verbal or written attestation) by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (such as 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

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

Sivextro

Products Affected

- SIVEXTRO INTRAVENOUS
- SIVEXTRO ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has been diagnosed with acute bacterial skin and skin structure infection (ABSSSI) defined as one of the following (FDA, 2013): Cellulitis/erysipelas OR Wound infection OR Major cutaneous abscess. AND Individual has at least 1 regional or 1 systemic sign of infection as defined by: Lymphadenopathy OR temperature greater than or equal to 38 degrees Celsius OR White blood cell count greater than or equal to 10,000 per microliter OR White blood cell count less than 4000 per microliter OR Greater than 10% of immature neutrophils AND is caused by methicillin-resistant Staphylococcus aureus (MRSA).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	30 days
Other Criteria	Individual has had a trial and inadequate response or intolerance to of or has contraindications to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to: Trimethoprim/sulfamethoxazole (TMP/SMX), doxycycline, vancomycin, daptomycin, televancin, clindamycin) (IDSA 2014) OR Individual started treatment with intravenous antibiotic(s) in the hospital and requires continued outpatient therapy for an organism susceptible to Sivextro (tedizolid).

H1350_PBM24151_C EFFECTIVE DATE 12/01/2024
H9656_PBM24335_C

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

Skyrizi

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of chronic moderate to severe (that is, extensive or disabling) plaque psoriasis (Ps) with either of the following (AAD 2019): 1. Patient has greater than 3% body surface area (BSA) with plaque psoriasis OR 2. less than or equal to 3% BSA with plaque psoriasis involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	For initial use: dx of chronic plaque psoriasis (Ps), individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or any ONE systemic therapy (such as acitretin, cyclosporine, or methotrexate). For moderate to severe Psoriatic Arthritis (PsA), individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine or leflunomide)]. For moderate to severe Crohn?s disease (CD), Individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such as systemic corticosteroids or immunosuppressants [such as thiopurines or methotrexate]). For Continuation use: there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.
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	
Required Medical Information	Dx of Actinic Keratosis
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

Somatuline Depot

Products Affected

- *lanreotide acetate*
- SOMATULINE DEPOT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of acromegaly has been confirmed (verbal or written attestation) 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

Somavert

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Dx of acromegaly has been confirmed (verbal or written attestation) 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 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

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

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

Sprycel

Products Affected

- *dasatinib*
- SPRYCEL

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

Stelara

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of 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 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. For Plaque Psoriasis (Ps), Psoriatic Arthritis (PsA), age 6 and older.
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	For initial use: chronic plaque psoriasis, individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or any ONE systemic therapy (for example acitretin, methotrexate, cyclosporine). For psoriatic arthritis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy ([nonbiologic DMARDS] such as methotrexate, sulfasalazine, cyclosporine, or leflunomide). For Crohns disease, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such systemic corticosteroids, or immunosuppressants [such as thiopurines or methotrexate]). For Ulcerative Colitis, individual has had an inadequate response to, is intolerant of, or has a ONE contraindication to conventional therapy (such as 5- Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]). For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

Strensiq

Products Affected

- STRENSIQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Total serum alkaline phosphatase level is below the lower limit of normal for the individual?s age and gender at diagnosis (Whyte 2012) and plasma pyridoxal 5'-phosphate levels are greater than the upper limit of normal at the time of diagnosis (Whyte 2012).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 3 months. Continuation: 1 year

PA Criteria	Criteria Details
Other Criteria	For initial treatment of perinatal/infantile onset hypophosphatasia (HPP) and had onset of symptoms prior to 6 months of age OR has a diagnosis of juvenile-onset HPP and had onset of disease at less than or equal to 18 years of age. AND has one or more of the following: (a) Radiographic evidence of poor bone mineralization including flared and frayed metaphyses, severe/ generalized osteopenia, or widened growth plates (Whyte 2012) or (b) Genetic test results that confirm infantile HPP or (c) one of the following: (1) History or presence of nontraumatic postnatal fracture healing or (2) History of elevated serum calcium or (3) Functional craniosynostosis with decreased head circumference growth or (4) Nephrocalcinosis or (5) Rachitic chest deformity or (6) Respiratory compromise or (7) Vitamin B6-responsive seizures or (8) Failure to thrive. For Continuation of Therapy: There is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to respiratory status, radiographic findings, growth) following asfotase alfa therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

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

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

Synagis

Products Affected

- SYNAGIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual is using when the following are met: A) Maximum of Five (5) doses of palivizumab for infants during the first RSV season within the first year of life: Born before 29 weeks, 0 days gestation (up to and including 28 weeks, 6 days) and younger than 12 months of age at the start of the RSV season OR Chronic lung disease (CLD) of prematurity defined as birth at less than 32 weeks, 0 days gestation and a requirement for greater than 21% oxygen for at least 28 days after birth OR Hemodynamically significant congenital heart disease (CHD) (including infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension OR infants with anatomic pulmonary abnormalities (i.e., tracheal ring) or a neuromuscular condition that impairs the ability to clear secretions from the upper airway because of ineffective cough OR Cystic fibrosis with clinical evidence of chronic lung disease or nutritional compromise (weight for length less than tenth percentile). B) Maximum of five (5) doses of palivizumab for children younger than 24 months of age with any of the following: Profoundly immunocompromised, including severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, undergoing organ or hematopoietic stem cell transplant, or an absolute lymphocyte count of less than 100 cell/mm3 OR undergoing cardiac transplantation.
Age Restrictions	

PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	5 Months.
Other Criteria	C) An additional dose of palivizumab may be allowed for children younger than 24 months of age who have approval for a course of treatment and who undergo cardiopulmonary bypass for a surgical procedure. D) A maximum of 5 doses of palivizumab prophylaxis may be approved for children during their second RSV season (the second RSV season may fall in the first or second year of life) with any of the following: (i) for preterm infant born at less than 32 weeks, 0 days gestation who required at least 28 days of oxygen after birth and continues to require medical intervention within 6 months of the start of the second RSV season (including supplemental oxygen, chronic corticosteroid therapy, or diuretics) or (ii) Cystic fibrosis with severe lung disease (history of hospitalization, abnormal chest x-ray or CT scan) or weight for length less than tenth percentile.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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 a pubertal response to a gonadotropin hormone (GnRH) agonist test or a pubertal level of a third generation luteinizing hormone (LH) assay 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

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 with test results confirmed 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

Tafinlar

Products Affected

- TAFINLAR ORAL CAPSULE
- TAFINLAR ORAL TABLET SOLUBLE

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

Tagrisso

Products Affected

- TAGRISSO

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

Talzenna

Products Affected

- TALZENNA ORAL CAPSULE 0.1 MG, 0.25 MG, 0.35 MG, 0.5 MG, 0.75 MG, 1 MG

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 mCRPC, 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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Tarceva

Products Affected

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

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

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

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

Tasmar

Products Affected

- *tolcapone*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Tazorac

Products Affected

- *tazarotene external cream 0.1 %*
- *tazarotene external gel*

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Tazverik

Products Affected

- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Epithelioid Sarcoma, individual has a histologically confirmed (written or verbal) diagnosis and has a current ECOG performance status of 0-2. For follicular lymphoma, ECOG performance status of 0-2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Tecentriq

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Individual has received treatment with another anti-PD-1 agent or anti-PD-L1 inhibitor and Individual is receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.
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

Tecfidera

Products Affected

- TECFIDERA ORAL CAPSULE DELAYED RELEASE 120 MG, 240 MG
- TECFIDERA 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	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

Tepmetko

Products Affected

- TEPMETKO

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 recurrent, advanced, or metastatic Non-Small Cell Lung Cancer (NSCLC), individual is using as monotherapy AND has not received treatment with another MET exon 14 skipping-targeted agent.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Other Criteria	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 transgender
	individuals who meet ALL the following criteria: Individual has a diagnosis of gender dysphoria/incongruence or gender identity disorder and goal of treatment is female-to-male gender reassignment.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

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

Tibsovo

Products Affected

- TIBSOVO

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

Topical Androgens

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older. For transgender use, individual is 16 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 transgender AND is using for a diagnosis of gender Dysphoria or gender Identity Disorder AND Goal of treatment is female-to-male gender reassignment. For continuation use, 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.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

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

Topical Tretinoin Agents

Products Affected

- *tretinoin external* *0.04 %, 0.1 %*
- *tretinoin microsphere external gel 0.04 % , 0.1 %*
- *tretinoin microsphere pump external gel*

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

Tracleer

Products Affected

- *bosentan*
- TRACLEER ORAL TABLET SOLUBLE

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Transmucosal Fentanyl Citrate

Products Affected

- *fentanyl citrate buccal*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 16 years of age or older
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual has a diagnosis of active cancer with breakthrough cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain 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 transmucosal fentanyl Citrate for cancer related breakthrough pain.
Indications	All Medically-accepted Indications.
Off Label Uses	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Part B Prerequisite	No

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

Trogarzo

Products Affected

- TROGARZO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using to treat human immunodeficiency virus (HIV) infection AND has a viral load of greater than 1000 copies/mL AND has a history of at least 6 months of antiretroviral treatment AND is receiving a failing antiretroviral regimen or has failed and is off therapy AND has confirmed resistance to at least one antiretroviral agent from three different classes as measured by resistance testing AND Individual is using in combination with other antiretroviral agents and has confirmed full viral sensitivity/susceptibility to at least one antiretroviral agent (other than Trogarzo) as determined by resistance testing.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

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

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

Tukysa

Products Affected

- TUKYSA

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

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

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

Tymlos

Products Affected

- TYMLOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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.

PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation therapy, there is confirmation of 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

Tysabri

Products Affected

- TYSABRI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using as monotherapy for relapsing forms of multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease)). For diagnosis of Crohns disease, Individual has an inadequate response to, or is unable to tolerate conventional CD therapies and TNF inhibitors. For all uses, mbr is enrolled in and meets all conditions of the CD or MS Touch Prescribing Program. AND has had a John Cunningham virus (JCV) antibody test and the results as well as risks and benefits have been discussed and understood.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Tyvaso

Products Affected

- TYVASO
- TYVASO REFILL KIT
- TYVASO STARTER KIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnostic Criteria for PAH: right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than or equal to 25mmhg at rest, a pulmonary capillary wedge pressure (PCWP), mean pulmonary arterial wedge pressure (PAWP), left atrial pressure or left ventricular end diastolic pressure (LVEDP) less than or equal to 15mmhg AND a pulmonary vascular resistance (PVR) greater than 3 wood units. Criteria for Vasodilator Response: a favorable response is defined as a fall in mPAP of at least 10mmhg to an absolute mPAP of less than 40mmhg without a decrease in cardiac output, when challenged with inhaled nitric oxide, intravenous epoprostenol or intravenous adenosine or inhaled iloprost (Badesch 2007, McLaughlin 2009, Simonneau 2019). Diagnostic criteria for PH-ILD: right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than or equal to 25mmhg, a pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mm Hg, AND a pulmonary vascular resistance (PVR) greater than 3 wood units.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	Initial requests for inhalation therapy with Tyvaso for PAH, patient must meet all of the following: meets diagnostic criteria for PAH AND demonstrates an unfavorable acute response to vasodilators AND Individual has New York Heart Association (NYHA) functional class III, or IV symptoms: AND World health Organization (WHO) Group I PAH (idiopathic PAH, PAH associated with connective tissue disorders, PAH associated with congenital heart defects, and all Group 1 subtypes). For PH-ILD, individual meets diagnostic criteria for PH-ILD AND Chest high resolution computed tomography (HRCT) demonstrating diffuse parenchymal lung disease. For continuation, there is confirmation (written or verbal) of 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

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

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

Vancocin

Products Affected

- *vancomycin hcl oral capsule*

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

Vanflyta

Products Affected

- VANFLYTA

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

Vectibix

Products Affected

- VECTIBIX INTRAVENOUS SOLUTION
  100 MG/5ML, 400 MG/20ML

PA Criteria	Criteria Details
Exclusion Criteria	Individual has received prior treatment with cetuximab [Note: a course of cetuximab discontinued because of an adverse reaction is not considered prior treatment] OR Panitumumab is used in combination with other anti-VEGF agents (e.g., bevacizumab) OR Panitumumab is being used for more than one line (course) of therapy.
Required Medical Information	For Stage IV colon, rectal, colorectal, appendiceal or anal adenocarcinoma AND unresectable, advanced or metastatic colorectal cancer 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 Stage IV colon, rectal, colorectal, appendiceal, or anal adenocarcinoma, Used as a single agent or as part of combination therapy for stage IV colon, rectal, colorectal, appendiceal, or anal adenocarcinoma. For unresectable, advanced, or metastatic colorectal cancer, used as a single line of therapy AND in combination with encorafenib AND has demonstrated disease progression after one or more prior lines of systemic therapy AND not used n combination with anti-VEGF agents (bevacizumab, ziv-aflibercept or ramucirumab) AND has not received prior therapy with cetuximab.
Indications	All Medically-accepted Indications.

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

Velcade

Products Affected

- *bortezomib injection solution reconstituted*

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

Vemlidy

Products Affected

- VEMLIDY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 6 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

Venclexta

Products Affected

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

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Ventavis

Products Affected

- VENTAVIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnostic Criteria for PAH: right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than or equal to 25mmhg at rest, a pulmonary capillary wedge pressure (PCWP), mean pulmonary arterial wedge pressure (PAWP), left atrial pressure or left ventricular end diastolic pressure (LVEDP) less than or equal to 15mmhg AND a pulmonary vascular resistance (PVR) greater than 3 wood units. Criteria for Vasodilator Response: a favorable response is defined as a fall in mPAP of at least 10mmhg to an absolute mPAP of less than 40mmhg without a decrease in cardiac output, when challenged with inhaled nitric oxide, intravenous epoprostenol or intravenous adenosine or inhaled iloprost (Badesch 2007, McLaughlin 2009, Simonneau 2019).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	Initial requests for Ventavis, patient must meet all of the following: meets diagnostic criteria for PAH AND demonstrates an unfavorable acute response to vasodilators AND Individual has New York Heart Association (NYHA) functional class III, or IV symptoms: AND World health Organization (WHO) Group I PAH (idiopathic PAH, PAH associated with connective tissue disorders, PAH associated with congenital heart defects, and all Group 1 subtypes). For continuation, there is confirmation (written or verbal) of 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

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.

PA Criteria	Criteria Details
Other Criteria	For Continuation, there is confirmation (written or verbal) of 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.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Verzenio

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For early breast cancer with HR positive/HER2 negative, node positive cancer at high risk of recurrence, individual is only using Verzenio in this combination for a total of 24 months (2 years)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

VIBERZI

Products Affected

- VIBERZI

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 irritable bowel syndrome with diarrhea (IBS-D) AND has had a trial and inadequate response or intolerance to two of the following medications or has a contraindication to all of the following medications: 1. Loperamide OR 2. Antispasmodics (such as dicyclomine) OR 3. Tricyclic antidepressants (AGA 2014).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Vidaza

Products Affected

- *azacitidine*

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

Vimizim

Products Affected

- VIMIZIM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Confirmed (written or verbal attestation) diagnosis of Morquio A syndrome (Hendriksz 2015, Wood 2013) by documented (written or verbal) reduced fibroblast or leukocyte N-acetylgalactosamine-6-sulfatase (GALNS) enzyme activity combined with normal enzyme activity level or another sulfatase or by genetic testing and confirmed (written or verbal) clinical signs and symptoms of Morquio A syndrome (for example, knee deformity, corneal opacity or pectus carinatum) (Hendriksz 2015, Wood 2013).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Continuation, there is confirmation (written or verbal attestation) of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to reduction in urinary GAG excretion, reduction in hepatosplenomegaly, improvement in pulmonary function, improvement in walking distance and/or improvement in fine or gross motor function) compared to the predicted natural history trajectory of disease.
Indications	All Medically-accepted Indications.
Off Label Uses	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Part B Prerequisite	No

Vitrakvi

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 Vitrakvi (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

Vizimpro

Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	genetic mutations test result is confirmed by written or verbal attestation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

Voranigo

Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Astrocytoma, Oligodendroglioma, IDH1/IDH2 mutation status.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	Individual is using Voranigo (vorasidenib) as a single agent.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Vosevi

Products Affected

- VOSEVI

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 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	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.

PA Criteria	Criteria Details
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. For Genotype 1, 1a, Individual has had a trial of and inadequate response to Harvoni (sofosbuvir/ledipasvir) OR Individual is currently on and completing a course of therapy with Vosevi OR has one of the following: (1) Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Harvoni(sofosbuvir/ledipasvir) which is not also in Vosevi OR (2) concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens OR (3) Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed Hepatitis C regimen containing an NS5A inhibitor OR (4) Individual has unique disease characteristic to which the preferred regimen(s) is not recommended (examples include specific genotype subtype, resistance-associated substitution (RAS) or polymorphism) . For Genotype 4, Individual has had a trial of and inadequate response to Harvoni(sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) OR Individual is currently on and completing a course of therapy with Vosevi OR has one of the following: (1) Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Harvoni(sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) which is not also in Vosevi OR (2) concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens OR (3) Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed Hepatitis C regimen containing an NS5A inhibitor OR (4) Individual has a unique disease characteristic to which the preferred regimen(s) is not recommended (examples include specific genotype subtype, resistance-associated substitution (RAS) or polymorphism).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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

Wakix

Products Affected

- WAKIX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Narcolepsy type 1 confirmed by the following (ICSD-3): (1) 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: (a) 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 (b) Multiple Sleep Latency Test (MSLT) with one of the following: (i) Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) OR (ii) At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) OR (c) Cerebrospinal fluid hypocretin-1 deficiency (less than 100 pg/mL or less than one-third of the normative values with the same standardized assay). Narcolepsy type 2 confirmed by the following (ICSD-3): (1) Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months AND (2) Multiple sleep latency test (MSLT) with one of the following: (a) MSLT of less than 8 minutes and evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014) OR (b) At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) AND (3) The absence of cataplexy AND (4) Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam, and PSG.
Age Restrictions	Individual is 18 years of age or older for Narcolepsy type 1. Individual is 6 years of age or older for Narcolepsy type 2.
Prescriber Restrictions	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

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

Welireg

Products Affected

- WELIREG

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	Using Welireg (belzutifan) as monotherapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Xalkori

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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

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

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 by the provider (written or verbal) 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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

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

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

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 medications or has contraindications to all of the following medications (CDC, 2020): (1) Generic Fluoroquinolone (ciprofloxacin, levofloxacin or ofloxacin) OR (2) Azithromycin.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Xolair

Products Affected

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

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Other Criteria	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 2022). Continued treatment beyond 12 months is allowed when treatment has resulted in clinical improvement by one or more of the following: Decreased utilization of rescue 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. For chronic idiopathic urticaria, individual has had trial and inadequate response or intolerance to ONE potent antihistamine (AAAAI/ACAAI 2014). For continued use for CIU, 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 nasal polyps, 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 nasal polyps continuation requests, treatment 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 individual continues to use Xolair in combo with maintenance intranasal corticosteroids.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Xospata

Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has confirmed FMS-like tyrosine kinase 3 (FLT3) mutation (written or verbal attestation is acceptable).
Age Restrictions	18 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

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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Xtandi

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	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

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Yervoy

Products Affected

- YERVOY

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	For small cell lung cancer, unresectable or metastatic melanoma (cutaneous or uveal), colorectal cancer, ESCC, renal cell carcinoma, small bowel adenocarcinoma, malignant pleural or peritoneal mesothelioma, HCC, or NSCLC, individual has an Eastern Cooperative Oncology Group (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.

PA Criteria	Criteria Details
Other Criteria	For the tx of unresectable or metastatic melanoma (cutaneous and uveal): Used in combo with nivolumab as: (a) First-line therapy or (b) Second-line or subsequent therapy for disease progression if nivolumab was not prev used or Ipilimumab is used as a single agent for one of the following: (a) First line therapy as a single course of 4 tx or (b) Second-line or subsequent lines of therapy as a single course of 4 treatments or (c) Retreatment, consisting of a 4-dose limit, for an individual who had no significant systemic toxicity during prior ipilimumab therapy, and whose disease progressed after being stable for greater than 3 mon following completion of a prior course of ipilimumab, and for whom no intervening therapy has been admin. OR used for the adjuvant treatment of cutaneous melanoma in mbr with pathologic involvement of regional lymph nodes of more than 1 millimeter who have undergone complete resection, including lymphadenetomy. For colorectal cancer AND meets one of the following criteria: (a) Primary tx used in combination with nivolumab for unresectable metachronous metastases (deficient mismatch repair/high microsatellite instability [dMMR/MSIH] only) and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 mon or (b) Ipilimumab is used in combo with nivolumab as subsequent therapy for unresectable advanced or metastatic colorectal cancer with dMMR or high microsatellite instability (MSIH) mutations that has progressed following tx with fluoropyrimidine and oxaliplatin or irinotecan. For RCC, when: (a) used in combination with nivolumab, for four cycles followed by single agent nivolumab as first-line therapy for previously untreated RCC or (b) used in subsequent therapy with nivolumab for four cycles followed by single agent nivolumab if no checkpoint blockade (PD-1, PD-L1, or CTLA-4) antibody tx has been previously administered and (c)Histologic confirmation of RCC with clear-cell component. For stage IV/recurrent NSCLC when: used in combo with nivolumab and 2 cycles of platinum-doublet chemotherapy AND does not have
	presence of actionable molecular markers. For small bowel adenocarcinoma AND has advanced or metastatic disease (deficient mismatch repair/microsatellite instability [dMMR/MSI-H] only) AND using as initial or subsequent therapy as monotherapy or in combo with nivolumab.

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

Yonsa

Products Affected

- YONSA

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

Zarxio

Products Affected

- ZARXIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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 x 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 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).

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

PA Criteria	Criteria Details
Other Criteria	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 myleosuppressive 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 leukapheresis, as an adjunct to peripheral blood/hematopoietic

PA Criteria	Criteria Details
	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

Zavesca

Products Affected

- *miglustat*
- YARGESA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Presence of type 1 Gaucher disease is confirmed 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 (such as 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 mm3.
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year.

PA Criteria	Criteria Details
Other Criteria	Enzyme replacement therapy with Cerezyme, ELELYSO or VPRIV is not a therapeutic option for reasons such as 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 confirmation (written or verbal attestation) of 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

Zejula

Products Affected

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

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

Zelboraf

Products Affected

- ZELBORAF

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

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

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

Zometa

Products Affected

- *zoledronic acid intravenous concentrate*
- *zoledronic acid intravenous solution 4 mg/100ml*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Individual has bone metastases documented on imaging or bone pain associated with imaging-documented metastases from breast, prostate, lung, kidney, thyroid, or other solid tumors.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For Breast cancer, prevention of bone loss secondary to adjuvant hormone therapy OR Hypercalcemia of malignancy OR treatment of Multiple myeloma OR Prevention of osteoporosis during androgen deprivation therapy in prostate cancer OR Bone disease associated with Langerhans Cell Histiocytosis.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

Zydelig

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	For continuation, Individual has achieved and sustained continuing clinical benefit (e.g., complete response, partial response, or stable disease) AND Results are confirmed (written or verbal attestation is acceptable).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Zykadia

Products Affected

- ZYKADIA ORAL TABLET

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

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

Zyvox

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Confirmed vancomycin-resistant enterococcus faecium (VRE) infection. Confirmed methicillin-resistant S. aureus (MRSA) infection AND individual has had a trial and inadequate response or intolerance to an alternative antibiotic that the microorganism is susceptible to (examples of alternative antibiotics may include, but are not limited to: vancomycin, TMP-SMX, clindamycin, doxycycline, tetracycline (IDSA 2011). Isolates of MRSA have a vancomycin minimum inhibitory concentration (MIC) of greater than 2 (IDSA 2011).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	30 days. 1 year for MDR-TB, XDR-TB,
Other Criteria	If Individual started treatment with Zyvox in the hospital and requires continued outpatient therapy for an organism susceptible to linezolid. For diagnosis of pulmonary multidrug-resistant tuberculosis (MDR-TB) or pulmonary extensively drug-resistant tuberculosis (XDR-TB) (WHO 2019), linezolid will be used in combination with other anti-infectives (WHO 2019).
Indications	All Medically-accepted Indications.
Off Label Uses	

H1350_PBM24151_C
H9656_PBM24335_C

EFFECTIVE DATE 12/01/2024

PA Criteria	Criteria Details
Part B Prerequisite	No

English: We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at 1-800-627-1188 (TTY: 711). Someone who speaks English can help you. This is a free service.

Form Approved
OMB# 0938-1421

Spanish: Tenemos servicios de intérprete sin costo alguno para responder cualquier pregunta que pueda tener sobre nuestro plan de salud o medicamentos. Para hablar con un intérprete, por favor llame al 1-800-627-1188 (TTY: 711). Alguien que hable español le podrá ayudar. Este es un servicio gratuito.

Chinese Mandarin: 我们提供免费的翻译服务，**帮**助**您**解答**关**于健康或药物保险的任何疑 问。如果**您**需要此翻译服务，请致电 1-800-627-1188 (TTY: 711)。我们的中文工作人员很乐意**帮**助**您**。这是一项免费服务。

Chinese Cantonese: **您**對我們的健康或藥物保險可能存有疑問，請此我們提供免費的翻譯 服務。如需翻譯服務，請致電 1-800-627-1188 (TTY: 711)。我們講中文的人員將樂意為**您**提供幫助。這 是一項免費服務。

Tagalog: Mayroon kaming libreng serbisyo sa pagsasaling-wika upang masagot ang anumang mga katanungan ninyo hinggil sa aming planong pangkalusugan o panggamot. Upang makakuha ng tagasaling-wika, tawagan lamang kami sa 1-800-627-1188 (TTY: 711). Maaari kayong tulungan ng isang nakakapagsalita ng Tagalog. Ito ay libreng serbisyo.

French: Nous proposons des services gratuits d'interprétation pour répondre à toutes vos questions relatives à notre régime de santé ou d'assurance-médicaments. Pour accéder au service d'interprétation, il vous suffit de nous appeler au 1-800-627-1188 (TTY: 711). Un interlocuteur parlant Français pourra vous aider. Ce service est gratuit.

Vietnamese: Chúng tôi có dịch vụ thông dịch miễn phí để trả lời các câu hỏi về chương sức khỏe và chương trình thuốc men. Nếu quí vị cần thông dịch viên xin gọi 1-800-627-1188 (TTY: 711) sẽ có nhân viên nói tiếng Việt giúp đỡ quí vị. Đây là dịch vụ miễn phí .

German: Unser kostenloser Dolmetscherservice beantwortet Ihren Fragen zu unserem Gesundheits- und Arzneimittelplan. Unsere Dolmetscher erreichen Sie unter 1-800-627-1188 (TTY: 711). Man wird Ihnen dort auf Deutsch weiterhelfen. Dieser Service ist kostenlos.

Korean: 당사는 의료 보험 또는 약품 보험에 관한 질문에 답해 드리고자 무료 통역 서비스를 제공하고 있습니다. 통역 서비스를 이용하려면 전화 1-800-627-1188 (TTY: 711) 번으로 문의해 주십시오. 한국어를 하는 담당자가 도와 드릴 것입니다. 이 서비스는 무료로 운영됩니다.

Russian: Если у вас возникнут вопросы относительно страхового или медикаментного плана, вы можете воспользоваться нашими бесплатными услугами переводчиков. Чтобы воспользоваться услугами переводчика, позвоните нам по телефону 1-800-627-1188 (TTY: 711). Вам окажет помощь сотрудник, который говорит по-русски. Данная услуга бесплатная.

Arabic: إننا نقدم خدمات المترجم الفوري المجانية للإجابة عن أي أسئلة تتعلق بالصحة أو جدول الأدوية لدينا. للحصول على مترجم فوري، ليس عليك سوى الاتصال بنا على 1-800-627-1188 (TTY: 711). سيقوم شخص ما يتحدث العربية بمساعدتك. هذه خدمة مجانية.

Hindi: हमारे स्वास्थ्य या दवा की योजना के बारे में आपके किसी भी प्रश्न के जवाब देने के लिए हमारे पास मुफ़्त दुभाषिया सेवाएँ उपलब्ध हैं. एक दुभाषिया प्राप्त करने के लिए, बस हमें 1-800-627-1188 (TTY: 711). पर फ़ोन करें. कोई व्यक्ति जो हिन्दी बोलता है आपकी मदद कर सकता है. यह एक मुफ़्त सेवा है.

Italian: È disponibile un servizio di interpretariato gratuito per rispondere a eventuali domande sul nostro piano sanitario e farmaceutico. Per un interprete, contattare il numero 1-800-627-1188 (TTY: 711). Un nostro incaricato che parla Italianovi fornirà l'assistenza necessaria. È un servizio gratuito.

Portuguese: Dispomos de serviços de interpretação gratuitos para responder a qualquer questão que tenha acerca do nosso plano de saúde ou de medicação. Para obter um intérprete, contacte-nos através do número 1-800-627-1188 (TTY: 711). Irá encontrar alguém que fale o idioma Português para o ajudar. Este serviço é gratuito.

French Creole: Nou genyen sèvis entèprèt gratis pou reponn tout kesyon ou ta genyen konsènan plan medikal oswa dwòg nou an. Pou jwenn yon entèprèt, jis rele nou nan 1-800-627-1188 (TTY: 711). Yon moun ki pale Kreyòl kapab ede w. Sa a se yon sèvis ki gratis.

Polish: Umożliwiamy bezpłatne skorzystanie z usług tłumacza ustnego, który pomoże w uzyskaniu odpowiedzi na temat planu zdrowotnego lub dawkowania leków. Aby skorzystać z pomocy tłumacza znającego język polski, należy zadzwonić pod numer 1-800-627-1188 (TTY: 711). Ta usługa jest bezpłatna.

Japanese: 当社の健康 健康保険と薬品 処方薬ランに関するご質問にお答えするため に、無料の通訳サービスがありますございます。通訳ご用命になるには、
1-800-627-1188 (TTY: 711)
にお電話ください。日本語を話す人 者 が支援たします。これは無料のサー ビスです。

Bantu: ICITONDERWA: Nimba uvuga Ikirundi, uzohabwa serivisi zo gufasha mu ndimi, ku buntu. Woterefona 1-800-627-1188 (TTY: 711).

Farsi: توجه: اگر به زبان فارسی گفتگو می کنید، تسهیالت زبانی بصورت رایگان برای شما فراهم می باشد. با 1-800-627-1188 (TTY: 711) تماس بگیرید.

Nepali: ध्यान दिनुहोस्: तपाईंले नेपाली बोल्नुहुन्छ भने तपाईंको निम्ति भाषा सहायता सेवाहरू निःशुल्क रूपमा उपलब्ध छ । फोन गर्नुहोस् 1-800-627-1188 (टिटिविइ: 711) ।

Romanian: ATENȚIE: Dacă vorbiți limba română, vă stau la dispoziție servicii de asistență lingvistică, gratuit. Sunați la 1-800-627-1188 (TTY: 711).

Serbo-Croatian: OBAVJEŠTENJE: Ako govorite srpsko-hrvatski, usluge jezičke pomoći dostupne su vam besplatno. Nazovite 1-800-627-1188 (TTY: Telefon za osobe sa oštećenim govorom ili sluhom: 711).