

2024 CONNECTED CLARITY Prior Authorization Criteria

# Actimmune

**Products Affected**

- ACTIMMUNE

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

# Adcirca

## Products Affected

- ALYQ
- *tadalafil (pah)*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Using tadalafil-PAH formulations for the treatment of erectile dysfunction.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

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# Adempas

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## Products Affected

- ADEMPAS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

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

# AFINITOR

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## 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

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 3 months. Continuation: 1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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</p>
	<p>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).</p>
<b>Indications</b>	All Medically-accepted Indications.

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Akeega

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## Products Affected

- AKEEGA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has the applicable mutations based on use/diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Alecensa

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## Products Affected

- ALECENSA

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

# Alimta

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## Products Affected

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

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

# Alpha1-Proteinase Inhibitor

## Products Affected

- PROLASTIN-C

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

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# Alunbrig

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## Products Affected

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

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

# Ampyra

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## Products Affected

- *dalfampridine er*

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

# Apokyn

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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.</p>
<b>Age Restrictions</b>	

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

# Arcalyst

## Products Affected

- ARCALYST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	For continued use, mbr has confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AUBAGIO

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## Products Affected

- AUBAGIO

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

# Augtyro

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## 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

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## Products Affected

- AURYXIA

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

# Auvelity

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## Products Affected

- AUVELITY

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

# AVASTIN

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## 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

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## 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 10 <sup>9</sup> /L.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# Balversa

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has confirmed (written or verbal attestation) disease susceptible to genetic alterations.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	Individual is using as a single agent.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Banzel

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## 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

- BARACLUDGE ORAL SOLUTION
- *entecavir*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Bavencio

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## Products Affected

- BAVENCIO

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

# Benlysta

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## 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
<b>Other Criteria</b>	<p>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]).</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Besremi

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## Products Affected

- BESREMI

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

# Bosulif

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation is provided for confirmation of mutations or disease progression where applicable based on use/diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 YEAR.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Botox-Myobloc-Dysport

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**Products Affected**

- BOTOX
- XEOMIN INTRAMUSCULAR SOLUTION RECONSTITUTED 50 UNIT

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

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial Chronic migraine: 6 months, Renewal: 1 Year. All others 1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Braftovi

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## 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

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## Products Affected

- BRUKINSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has no prior BTK inhibitor usage.
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Buphenyl

## Products Affected

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

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

# Cabometyx

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## 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

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## 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

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

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# Cayston

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## Products Affected

- CAYSTON

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

# Chantix

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Chenodal

## Products Affected

- CHENODAL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	2 years. Requests to continue therapy beyond 24 months (2 years) should not be approved.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Cholbam

## Products Affected

- CHOLBAM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Chorionic Gonadotropin

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Individual is using for Pre-pubertal cryptorchidism not caused by anatomical obstruction in males OR Hypogonadotropic hypogonadism from pituitary deficiency in males.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Cinryze

## Products Affected

- CINRYZE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is 6 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 6 months, Continuation: 1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

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# Cometriq

## Products Affected

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

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

# Copaxone

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## 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

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## Products Affected

- COPIKTRA

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

# Corlanor

## Products Affected

- CORLANOR ORAL SOLUTION
- CORLANOR ORAL TABLET
- *ivabradine hcl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Cosentyx

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Cotellic

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## Products Affected

- COTELLIC

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	For unresectable or metastatic melanoma, Individual is using in combination with Zelboraf (vemurafenib) with or without Tecentriq (atezolizumab).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Cresemba

## Products Affected

- CRESEMBA

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

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# Crinone

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## Products Affected

- CRINONE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Progesterone supplementation or replacement as part of an Assisted Reproductive Technology (ART) treatment for infertile women with progesterone deficiency, Progesterone supplementation/deficiency.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Cyramza

## Products Affected

- CYRAMZA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	For urothelial cancer, 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# D.H.E Inj

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## 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
<b>Other Criteria</b>	<p>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).</p> <p>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).</p> <p>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</p>

PA Criteria	Criteria Details
	<p>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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Daliresp

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## 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

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## Products Affected

- DARZALEX
- DARZALEX FASPRO

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

# Daurismo

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Dificid

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## Products Affected

- DIFICID

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

# Doxil

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## 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

# DPP4

## Products Affected

- *alogliptin benzoate oral tablet 12.5 mg, 25 mg, 6.25 mg, 25-15 mg, 25-30 mg, 25-45 mg*
- *alogliptin-metformin hcl*
- *alogliptin-pioglitazone oral tablet 12.5-30*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	Individual has had a trial and inadequate response or intolerance to metformin (AACE/ACE 2020) OR Individual has a contraindication to metformin therapy [including but not limited to, renal insufficiency (eGFR less than 45 mL/min/1.73 m <sup>2</sup> )] AND Individual has had a trial and inadequate response or intolerance to ONE of the following: Januvia (sitagliptin), Tradjenta (linagliptin), Janumet (sitagliptin/metformin), Janumet XR (sitagliptin/metformin), Jentadueto (linagliptin/metformin), OR Jentadueto XR (linagliptin/metformin).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Duavee

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## Products Affected

- DUAVEE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Age 18 through age 75
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 dermatitis (AD), individual has tried one of the following and 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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

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PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For initial tx of Asthma, (A) indiv 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) indiv 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.</p> <p>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</p>

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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Duragesic Patch

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## Products Affected

- *fentanyl*

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

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

# Elidel

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## Products Affected

- *pimecrolimus*

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

# ELIGARD\_GNRH

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## Products Affected

- ELIGARD

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

# Elitek

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## Products Affected

- ELITEK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	30 DAYS.
<b>Other Criteria</b>	Individual has been diagnosed with leukemia, lymphoma or other hematologic malignancy with risk factors for tumor lysis syndrome AND Individual is receiving chemotherapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Empliciti

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## Products Affected

- EMLICITI

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

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## Products Affected

- EMSAM

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

# Enbrel

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Enhertu

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## Products Affected

- ENHERTU

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	For breast cancer use, Individual is using Enhertu as monotherapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Entyvio

## Products Affected

- ENTYVIO PEN
- ENTYVIO SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	For SQ use, individual is 18 years of age or older for UC/CD.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Entyvio IV

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## 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
<b>Other Criteria</b>	<p>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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Epidiolex

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## 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

# Epiduo Agents

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## Products Affected

- *adapalene-benzoyl peroxide external gel*  
0.1-2.5 %

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	For dx of acne, Individual has had a prior trial and inadequate response to the following: (a) One preferred topical retinoid agent AND (b) One topical benzoyl peroxide agent.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Epogen and Procrit

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	

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

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

# Erbitux

## Products Affected

- ERBITUX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Erbitux is used in combination with other anti-VEGF agents (e.g., bevacizumab). Erbitux is used in more than one line of therapy.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Erivedge

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## Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	For continuation, individual does not show evidence of progressive disease while on vismodegib therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Erleada

## Products Affected

- ERLEADA

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

# Erwinase

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## Products Affected

- RYLAZE

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

# Esbriet

## Products Affected

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

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

# Evenity

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## Products Affected

- EVENITY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Individual meets one of the following: (A) Individual has been refractory to a trial of a bisphosphonate therapy OR (B) Intolerance or contraindications to a bisphosphonate as defined by having at least one of the following: 1. Hypersensitivity to TWO 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. 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 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. Individual has utilized Evenity (romosozumab-aqqg) for a total duration of less than 12 months in their lifetime. Individual has been refractory to, is intolerant of, or has a contraindication to one of the following: Prolia (denosumab) OR Forteo/Bonsity (teriparatide) OR Tymlos (abaloparatide).</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Exjade

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## 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

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## Products Affected

- EXKIVITY

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

# Fabrazyme

## Products Affected

- FABRAZYME

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is 8 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Fasenra

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 6 years of age or older.
Prescriber Restrictions	
Coverage Duration	Initial: 6 months, Continuation: 1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For Initial use, individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting beta2 agonists, leukotriene modifiers, theophylline or oral corticosteroids) (GINA 2022) AND has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid or temporary increase in the individuals usual maintenance dosage of oral corticosteroids (ERS/ATS, 2013) AND has a blood eosinophil count (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection) greater than or equal to 150 cells/microliter (150 cells/mm<sup>3</sup>) at initiation of therapy. For Continuation use, treatment has resulted in clinical improvement in one or more of the following: (a) decreased utilization of rescue medications OR (b) decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in inhaled corticosteroid dose or treatment with systemic corticosteroids) OR (c) increase in percent predicted FEV1 from pretreatment baseline OR (d) reduction in reported asthma-related symptoms, such as, but not limited to asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Faslodex

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Ferriprox

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## 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

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## 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

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## Products Affected

- FINTEPLA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Individual is using for weight loss/reduction.
<b>Required Medical Information</b>	Diagnosis: Lennox-Gastaut syndrome (LGS), Dravet Syndrome (DS).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Firazyr

## Products Affected

- *icatibant acetate*
- SAJAZIR SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE

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

# Firmagon

## Products Affected

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

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

# Flector Patch

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## Products Affected

- *diclofenac epolamine external*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	Individual is using for the treatment of acute pain from one of the following: (a) Minor strain OR (b) Sprain OR (c) Contusion.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 (AAACE/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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Fotivda

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## Products Affected

- FOTIVDA

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

# Fruzaqla

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 7 months, Continuation: 1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Gauchers

## Products Affected

- VPRIV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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 mm<sup>3</sup>. [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].</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

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

# Gavreto

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## Products Affected

- GAVRETO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	Individual is using as monotherapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Gazyva

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## Products Affected

- GAZYVA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 Venclaxta (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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Gilenya

## Products Affected

- *fingolimod hcl*
- GILENYA ORAL CAPSULE 0.25 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	

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

# Gilotrif

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## Products Affected

- GILOTRIF

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

# Gleevec

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## Products Affected

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

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

# Gleostine

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## 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

# 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
<b>Exclusion Criteria</b>	Individual is using for weight loss.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	For Type 2 Diabetes.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Granix

## Products Affected

- GRANIX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Febrile neutropenic Individuals who are at high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than <math>0.1 \times 10</math> to the power of <math>9/L</math>) 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 <math>450/?L</math>) 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 <math>1500mm^3</math>), poor renal function (GFR less than <math>60mL/min</math>), liver dysfunction (liver function tests at least 2x upper limit of normal or bilirubin gr than <math>2.0 mg/dL</math>) (Lyman 2014) (Aagaard 2018), recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc) (Lyman 2014, Aagaard 2018), History of active infection within previous 60 days (Lyman 2014, Aagaard 2018), Current open wound and chemotherapy cannot be delayed (Lyman 2014, Aagaard 2018).</p>
<b>Age Restrictions</b>	

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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)).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Harvoni

## Products Affected

- HARVONI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Hepsera

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## Products Affected

- *adefovir dipivoxil*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Hetlioz

## Products Affected

- *tasimelteon*

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

# HP Acthar

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## Products Affected

- ACTHAR
- ACTHAR GEL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	For West Syndrome, infant or child less than 2 years of age.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 MONTHS.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# 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*
- *chlordiazepoxide-clidinium*
- *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*
- DOTTI
- *doxepin hcl oral tablet*
- 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	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.

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

# Human Growth Hormone

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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.

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>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 than 10ng/ml) to 2GH stim tests OR Neonates with hypoglycemia and clinical/hormone evidence of hypopit and low GH (less than 10ng/ml) OR 2 other 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 than 10 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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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 $\geq$ 40KG UC STARTER
- HUMIRA-PSORIASIS/UVEIT STARTER

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 [nonbiologic 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 immunosuppressants [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 immunosuppressants [azathioprine, cyclosporine, or methotrexate]).</p>

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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Ibrance

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## 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

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## 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

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## Products Affected

- IDHIFA ORAL TABLET 100 MG, 50 MG

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

# Ilaris

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## Products Affected

- ILARIS SUBCUTANEOUS SOLUTION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
<b>Age Restrictions</b>	For cryopyrin-associated periodic syndromes age 4 years and older and for systemic juvenile idiopathic arthritis 2 years of age and older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Imbruvica

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## 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

# Imfinzi

## Products Affected

- IMFINZI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Has received treatment with another anti-PD-1 or anti-PD-L1 agent. Individual is receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

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# Increlex

## Products Affected

- INCRELEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	For Continuation of treatment with Increlex (mecasermin), Final adult height has not been reached.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Ingrezza

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 3 months. Continuation: 1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Inlyta

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## Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation is provided for histological confirmation where applicable based on use/diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 YEAR.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Inqovi

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## Products Affected

- INQOVI

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

# Inrebic

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## Products Affected

- INREBIC

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

# Interferons for MS

## Products Affected

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

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

# Intuniv

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## Products Affected

- *guanfacine hcl er*

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

# Iressa

## Products Affected

- *gefitinib*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	Individual has a diagnosis of recurrent, advanced, or metastatic Non-small cell lung cancer (NSCLC).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ITRACONAZOLE

## Products Affected

- *itraconazole oral capsule*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	For fingernail/toenail onychomycosis 12 weeks. For all other indications 1 year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

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# 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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.</p>

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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</p>

PA Criteria	Criteria Details
	<p>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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Iwilfin

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## 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

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## Products Affected

- *deferasirox*
- *deferasirox granules*

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

# Jakafi

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## Products Affected

- JAKAFI

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

# Jaypirca

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## Products Affected

- JAYPIRCA ORAL TABLET 100 MG, 50 MG

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

# Jynarque

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## Products Affected

- JYNARQUE ORAL TABLET

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

# Kadcyla

## Products Affected

- KADCYLA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Kalydeco

## Products Affected

- KALYDECO ORAL PACKET
- KALYDECO ORAL TABLET

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

# Keytruda

## Products Affected

- KEYTRUDA INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

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PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 fluopyrimidine 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</p>
	<p>carcinoma, used as single agent, demonstrated dz progression or intolerance on or after tx w/an approved 1st line agent.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Korlym

## Products Affected

- KORLYM
- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 6 months, Continuation: 1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

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# Koselugo

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## Products Affected

- KOSELUGO

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

# Krazati

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## Products Affected

- KRAZATI

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

# Kuvan

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial 8 weeks, 1 year for continuation
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Kyprolis

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## Products Affected

- KYPROLIS

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

# Lazcluze

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## Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

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

# Letairis

## Products Affected

- *ambrisentan oral tablet 10 mg, 5 mg*

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

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# Leukine

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## Products Affected

- LEUKINE INJECTION SOLUTION RECONSTITUTED

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Adjunctive tx and individual as a high risk for infection-associated complications. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. For acute myeloid leukemia and using shortly after completion of induction or repeat induction chemo of AML. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500mm<sup>3</sup> 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- gggk) 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).</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Levoleucovorin

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## Products Affected

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

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

# Lidocaine 4

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## Products Affected

- *lidocaine hcl external solution*

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

# Lidocaine 5

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## Products Affected

- *lidocaine external ointment 5 %*

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

# Lidoderm Patch

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## 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

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## Products Affected

- LONSURF

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

# Lorbrena

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## Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

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

# Lotronex

## Products Affected

- *alosetron hcl*

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

# Lumakras

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## Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 320 MG

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

# Lumizyme

## Products Affected

- LUMIZYME

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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).

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For Prostate cancer: Clinically localized dz with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) or higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Other advanced, recurrent, or metastatic disease.</p> <p>For Gynecology Uses: Initial treatment/retreatment of endometriosis OR Preoperative tx as adjunct to surgical tx of uterine fibroids (leiomyoma uteri), May be used to reduce size of fibroids to allow for a vaginal procedure, prior to surgical tx (myomectomy or hysterectomy) in patients with confirmed anemia (Letheby et al. 2001, 2017). To induce amenorrhea in women (such as but not limited to menstruating women diagnosed with severe thrombocytopenia or aplastic anemia). Using for endometrial thinning prior to endometrial ablation for dysfunctional uterine bleeding. For Endocrine Uses: central Precocious puberty, defined as beginning of secondary sexual characteristics before age 8 in girls and before age 9 in boys and dx has been confirmed (written or verbal) by 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.</p> <p>For Ovarian Cancer (including fallopian tube cancer and primary peritoneal cancer): Hormonal therapy for clinical relapse in individuals with stage II-IV granulosa cell tumors or Hormonal therapy for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer as a single agent for persistent dz or recurrence.</p>
<b>Age Restrictions</b>	

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PA Criteria	Criteria Details
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Lupron Kit IR

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## Products Affected

- *leuprolide acetate injection*

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

# Lynparza

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## Products Affected

- LYNPARZA ORAL TABLET

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

# Lytgobi

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## Products Affected

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

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

# Mavyret

## Products Affected

- MAVYRET ORAL PACKET
- MAVYRET ORAL TABLET

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

# Megace Suspension HRM

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## Products Affected

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

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

# Megace Tabs HRM

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## Products Affected

- *megestrol acetate oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 YEAR.
<b>Other Criteria</b>	Individual has advanced, inoperable, recurrent breast cancer and using for palliative management. Individual has endometrial/uterine cancer and is using for palliative management.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Mekinist

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## 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

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## Products Affected

- MEKTOVI

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

# Mepron

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## Products Affected

- *atovaquone oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Intolerance to trimethoprim-sulfamethoxazole (TMP-SMX)
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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*
- *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*
- **QUILLIVANT XR ORAL SUSPENSION RECONSTITUTED ER**

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

# Modafinil

## Products Affected

- *modafinil oral tablet 100 mg, 200 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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).</p> <p>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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

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

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

# Mounjaro

## Products Affected

- MOUNJARO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Individual is using for weight loss.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Mozobil

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## Products Affected

- MOZOBIL
- *plerixafor*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Myalept

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Namenda Line

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual has a diagnosis of moderate to severe dementia of the Alzheimers type.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Nerlynx

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## Products Affected

- NERLYNX

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

# Nexavar

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## Products Affected

- *sorafenib tosylate*

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

# Ninlaro

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## 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

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 3 months. Continuation: 1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Noxafil

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## Products Affected

- NOXAFIL ORAL SUSPENSION
- *posaconazole oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For an individual who requires continued therapy for an organism susceptible to Posaconazole who is transitioning from inpatient treatment to an outpatient setting.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Febrile neutropenic Individuals who are at high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than <math>0.1 \times 10^9/L</math>) 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 1500mm<sup>3</sup>), poor renal function (GFR less than 60mL/min) , liver dysfunction (liver function tests at least 2x upper limit of normal or bilirubin gr than 2.0 mg/dL) (Lyman 2014) (Aagaard 2018), recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc) (Lyman 2014, Aagaard 2018). History of active infection within previous 60 days(Lyman 2014, Aagaard 2018). Current open wound and chemotherapy cannot be delayed (Lyman 2014, Aagaard 2018).</p>
<b>Age Restrictions</b>	

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PA Criteria	Criteria Details
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	<p>Individual has had a trial and inadequate response to intolerance to Zarxio (Filgrastim-sndz). Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. Using for adjunctive tx for FN and has been prophylactic therapy with GCSF agent or has not received prophylactic therapy with a GCSF and who are at high risk for infection-associated complications. Use in individuals with acute myeloid leukemia (AML) shortly after the completion of induction or repeat induction chemotherapy, or after the completion of consolidation chemotherapy for AML. For tx of moderate to severe aplastic anemia. Tx of severe neutropenia in individuals with hairy cell leukemia. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm<sup>3</sup> or experiencing recurrent infection. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. For tx of (non-chemotherapy) drug-induced neutropenia. For tx of low neutrophil counts in individuals with glycogen storage disease type 1b. For tx of neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected. After accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy] (such as Hematopoietic Syndrome of Acute Radiation Syndrome). After hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed. To mobilize progenitor cells into peripheral blood for collection by</p>

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

# NP Human Growth Hormone

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## 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
<b>Exclusion Criteria</b>	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.

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>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 than 10ng/ml) to 2GH stim tests OR Neonates with hypoglycemia and clinical/hormone evidence of hypopit and low GH (less than 10ng/ml) OR 2 other 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 than 10 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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

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

# NP LA Opioid

## Products Affected

- BELBUCA
- *buprenorphine transdermal*
- *hydrocodone bitartrate er oral capsule extended release 12 hour*
- *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 capsule extended release 24 hour 100 mg, 200 mg, 300 mg*
- *tramadol hcl (er biphasic) oral tablet extended release 24 hour*
- *tramadol hcl er*

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

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

# Nubeqa

## Products Affected

- NUBEQA

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

# Nucala

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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/mm<sup>3</sup>) at initiation of therapy OR greater than or equal 300 cells/mm<sup>3</sup> 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 (FEV<sub>1</sub>) less than 80% predicted AND FEV<sub>1</sub> 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 FEV<sub>1</sub> from pretreatment baseline OR iv) A reduction in reported asthma-related sx, including asthmatic symptoms upon awakening, coughing, fatigue, SOB, sleep disturbance or wheezing.</p>

PA Criteria	Criteria Details
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 6 months, Continuation: 1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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/mm<sup>3</sup> (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/mm<sup>3</sup>. 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</p>
	<p>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.</p>
<b>Indications</b>	All Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Nuedexta

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## Products Affected

- NUEDEXTA

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

# Nulojix

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## Products Affected

- NULOJIX

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

# Nuplazid

## Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial:3 months, Maintenance: 1 Year
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Nurtec

## Products Affected

- NURTEC

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial req for migraine prophylaxis: 3 mon. Renewal for prophylaxis: 1 Yr. Acute tx: 1 Yr.

PA Criteria	Criteria Details
<p><b>Other Criteria</b></p>	<p>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 prophylaxis. AND If mbr is also currently using botulinum toxin for prophylaxis 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</p>
	<p>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.</p>

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

# Nuvigil

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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).</p> <p>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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

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

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

# Odomzo

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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%.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

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

# Ogsiveo

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## 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

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## Products Affected

- OJEMDA ORAL SUSPENSION RECONSTITUTED
- OJEMDA ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For LGG, individual has a BRAF fusion or rearrangement, or BRAF V600 mutation.
<b>Age Restrictions</b>	Individual is 6 months of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Ojjaara

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Onureg

## Products Affected

- ONUREG

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

# Opdivo

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## Products Affected

- OPDIVO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 ipilimumab 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 ipilimumab 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 ipilimumab 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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Opsumit

## Products Affected

- OPSUMIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Orfadin

## Products Affected

- *nitisinone*

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

# Orgovyx

## Products Affected

- ORGOVYX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial and Continuation 6 months.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Orkambi

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## Products Affected

- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is 1 year age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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]).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Orserdu

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## 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

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## Products Affected

- OTEZLA ORAL TABLET
- OTEZLA ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	For pediatric Ps, individual is 6 to 17 years of age. All other indications, Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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].</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Oxandrin

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## 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

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## Products Affected

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

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure). 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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Pegfilgrastim Agents

## Products Affected

- FULPHILA
- NEULASTA ONPRO
- NEULASTA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

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

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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)).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Pemazyre

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## Products Affected

- PEMAZYRE

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

# Perjeta

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## Products Affected

- PERJETA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Phesgo

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## Products Affected

- PHESGO

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

# Piqray

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## Products Affected

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

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

# Pomalyst

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## 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

# Praluent

## Products Affected

- PRALUENT SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For (A) Heterozygous Familial Hypercholesterolemia (HeFH) confirmed by: 1.Presence of a mutation in LDLR, apolipoprotein B (ApoB), PCSK9 or ARH adaptor protein gene (LDLRAP1) gene OR 2. World Health Organization (WHO)/Dutch Lipid Network Criteria with score of gtr than 8 points OR (B) History of Clinical Atherosclerotic Cardiovascular Disease (ASCVD), including one of the following: 1.Acute coronary syndromes 2.Coronary Artery Disease (CAD) 3. History of myocardial infarction (MI) 3.Stable or unstable angina 4.Coronary or other arterial revascularization 5.Stroke 6.Transient ischemic attack (TIA) 7.Peripheral arterial disease (PAD). OR (C) Primary hyperlipidemia alone or in combination with other lipid lowering agents. OR (D) using prophylactically for Established CVD. For (E). Homozygous Familial Hypercholesterolemia (HoFH) confirmed by: 1.Presence of two (2) mutant alleles at the LDLR, apoB, PCSK9 or ARH adaptor gene locus OR 2.untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) AND one of the following: i.Cutaneous or tendonous xanthoma before age of 10 years OR ii.Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than190 mg/dL).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 6 months, Continuation: 1 Year.

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PA Criteria	Criteria Details
<b>Other Criteria</b>	For initial request, individual meets one of the following: (A) Individual is on high intensity statin therapy, or statin therapy at the maximum tolerated dose, where high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher OR (B) Individual is statin intolerant OR (C) Individual has a condition that is a contraindication for statin therapy including but not limited to active liver disease, unexplained persistent elevation of serum hepatic, or pregnancy or (D) Statin associated rhabdomyolysis after a trial of one statin. Individual also has had a trial and titration of a Repatha (evolocumab) and has achieved suboptimal lipid lowering response despite at least 90 days of Repatha (evolocumab) therapy. For continuation, Individual continues to use in combination with maximally tolerated statin (unless contraindication or individual is statin intolerant) AND there is confirmation (verbal or written attestation) of LDL reduction.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Prolia

## Products Affected

- PROLIA SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	For Osteoporosis 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

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

# Promacta

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## 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
<b>Other Criteria</b>	<p>For initial therapy: 1) Diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP) AND individual has platelet count of less than 30 x 10<sup>9</sup>/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 10<sup>9</sup>/L (Olnes et al., 2012.Desmond et al., 2014) AND individual has had a prior trial and insufficient response to an immunosuppressive therapy [such as, anti-thymocyte globulin (ATG)] OR 3) individual is using as first-line treatment in combination with standard immunosuppressive therapy 4) Treatment of thrombocytopenia in individual with hepatitis C AND individual has thrombocytopenia that prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. For continuation therapy, for ITP, severe aplastic anemia or thrombocytopenia in individuals with Hep C, individual has demonstrated a response to therapy as evidenced by increased platelet counts AND to maintain an adequate platelet count (50-200 x 10<sup>9</sup>/L) to decrease the risk of bleeding OR for MDS, individual has demonstrated a clinically significant response to therapy, such as an increase in platelet counts, decrease in bleeding events, or reduction in need for platelet transfusions .</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Protopic

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## Products Affected

- *tacrolimus external ointment*

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

# Purixan

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## 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

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## 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

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## Products Affected

- *quinine sulfate oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

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

# Ranexa

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## Products Affected

- *ranolazine er*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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

# Reclast

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Remicade

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## Products Affected

- *infliximab*
- REMICADE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 PJI, 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</p>
	<p>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.</p>
<b>Indications</b>	All Medically-accepted Indications.

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Repatha

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## 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

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## Products Affected

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

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

# Revatio

## Products Affected

- *sildenafil citrate oral suspension reconstituted*
- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Individuals requesting for the treatment of erectile dysfunction.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

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# Revatio IV

## Products Affected

- *sildenafil citrate intravenous*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Individuals requesting for the treatment of erectile dysfunction.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Revlimid

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## Products Affected

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

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

# Rezlidhia

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## Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 6 months, Continuation: 1 year
<b>Other Criteria</b>	For Continued use, there is confirmation of clinically significant improvement (e.g. no disease progression) or stabilization of disease.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Rezurock

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## Products Affected

- REZUROCK

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

# Rinvoq

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## Products Affected

- RINVOQ
- RINVOQ LQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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</p>
	improvement or stabilization in clinical signs and symptoms of disease.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Rozlytrek

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
<b>Age Restrictions</b>	For metastatic non-small cell lung cancer (NSCLC), 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	Individual is using as monotherapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Rubraca

## Products Affected

- RUBRACA

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

# Rybrevant

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## Products Affected

- RYBREVANT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	Using Rybrevant as a single agent And has not progressed on prior therapy with Rybrevant.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Rydapt

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## Products Affected

- RYDAPT

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

# Sabril

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## 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

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## 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

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## Products Affected

- SANCUSO

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

# Sarclisa

## Products Affected

- SARCLISA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	Individual is using in combination with pomalidomide and dexamethasone or carfilzomib and dexamethasone.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Scemblix

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Serostim

## Products Affected

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

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

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# Signifor IR

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## Products Affected

- SIGNIFOR

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

# Sirturo

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## Products Affected

- SIRTURO

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

# Sivextro

## Products Affected

- SIVEXTRO INTRAVENOUS
- SIVEXTRO ORAL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	30 days
<b>Other Criteria</b>	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).

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



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

# Solaraze

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## Products Affected

- *diclofenac sodium external gel 3 %*

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

# Somatuline Depot

## Products Affected

- *Ianreotide acetate*
- SOMATULINE DEPOT

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

# Somavert

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## Products Affected

- SOMAVERT

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

# Spravato

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## Products Affected

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

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

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

# Sprycel

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## Products Affected

- *dasatinib*
- SPRYCEL

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

# Stelara

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	Individual is 18 years of age or older. For Plaque Psoriasis (Ps), Psoriatic Arthritis (PsA), age 6 and older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

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

# Stivarga

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## Products Affected

- STIVARGA

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

# Strensiq

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## Products Affected

- STRENSIQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 3 months. Continuation: 1 year

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

# Stromectol

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## 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

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## 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

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## Products Affected

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

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

# Synagis

## Products Affected

- SYNAGIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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/mm<sup>3</sup> OR undergoing cardiac transplantation.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

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PA Criteria	Criteria Details
<b>Coverage Duration</b>	5 Months.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Synarel Nasal Solution

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## Products Affected

- SYNAREL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Endometriosis: 6 months, all other indications: 1 year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Tabrecta

## Products Affected

- TABRECTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	Individual is using Tabrecta (capmatinib) as monotherapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Tafinlar

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## Products Affected

- TAFINLAR ORAL CAPSULE
- TAFINLAR ORAL TABLET SOLUBLE

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

# Tagrisso

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## 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

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## 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

# Tarceva

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## Products Affected

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

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

# Targretin

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## 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

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## Products Affected

- TASIGNA

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

# Tasmar

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## Products Affected

- *tolcapone*

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

# Tazorac

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	May not be approved for cosmetic purposes such as, but not limited to the following: Cosmetic purposes, Photoaging, Wrinkles, Hyperpigmentation, Sun damage, or Melasma.
<b>Required Medical Information</b>	For psoriasis, individual has up to 20% of body surface area involvement.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Tazverik

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## Products Affected

- TAZVERIK

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

# Tecentriq

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## Products Affected

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

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

# Tecfidera

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## Products Affected

- TECFIDERA ORAL CAPSULE  
DELAYED RELEASE 120 MG, 240 MG
- TECFIDERA ORAL CAPSULE  
DELAYED RELEASE THERAPY PACK

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

# Tecvayli

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## Products Affected

- TECVAYLI

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

# Tepmetko

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## Products Affected

- TEPMETKO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Thalomid

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## 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

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## Products Affected

- TIBSOVO

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

# Topical Acne Antibiotic

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## Products Affected

- *clindamycin-tretinoin*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For dx of Acne, Individual has had a prior trial and inadequate response to the following: (1) One preferred generic topical tretinoin agent AND (2) One preferred generic erythromycin/benzoyl peroxide combination agent OR (3) One preferred generic clindamycin/benzoyl peroxide combination agent.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Topical Androgens

## Products Affected

- *testosterone transdermal gel 1.62 %, 10 mg/act (2%), 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%)*
- *testosterone transdermal solution*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age or older. For transgender use, individual is 16 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Topical Doxepin Agents

## Products Affected

- *doxepin hcl external*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	For dx moderate pruritis associated with atopic dermatitis (AAD 2014), (1) Individual has had a trial of and inadequate response or intolerance to one topical corticosteroid OR Topical corticosteroid use is not acceptable due to the following concomitant clinical conditions: (a) Individual has atopic dermatitis recalcitrant to topical corticosteroids OR (b) has atopic dermatitis lesions in sensitive areas (such as face, anogenital area or skin folds) OR (c) has steroid-induced atrophy OR (d) has history of long-term or uninterrupted topical steroid use. AND (2) Individual has had a trial of and inadequate response or intolerance to one of the following: (a) A topical calcineurin inhibitor OR (b) Eucrisa (crisaborole). For dx moderate pruritis associated with lichen simplex chronicus, Individual has had a trial of and inadequate response or intolerance to one topical corticosteroid.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Tracleer

## Products Affected

- *bosentan*
- TRACLEER ORAL TABLET SOLUBLE

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

# Transmucosal Fentanyl Citrate

## Products Affected

- *fentanyl citrate buccal*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 16 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Trodelvy

## Products Affected

- TRODELVY

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

# Trogarzo

## Products Affected

- TROGARZO

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

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# Truqap

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## Products Affected

- TRUQAP

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

# Truseltiq

## Products Affected

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

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

# Tukysa

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## 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

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## Products Affected

- TURALIO ORAL CAPSULE 125 MG

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

# Tykerb

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## Products Affected

- *lapatinib ditosylate*

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

# Tymlos

## Products Affected

- TYMLOS

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

PA Criteria	Criteria Details
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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

# Tyvaso

## Products Affected

- TYVASO
- TYVASO REFILL KIT
- TYVASO STARTER KIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

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

# Ubrelvy

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## Products Affected

- UBRELVY ORAL TABLET 100 MG, 50 MG

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

# Uceris

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## 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

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## 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*
- *vancomycin hcl oral solution reconstituted 25 mg/ml*

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

# Vanflyta

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## Products Affected

- VANFLYTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has the applicable mutations based on use/diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Vectibix

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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 in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept or ramucirumab) AND has not received prior therapy with cetuximab.
<b>Indications</b>	All Medically-accepted Indications.

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Velcade

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## 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

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## Products Affected

- VEMLIDY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 6 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Venclexta

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## Products Affected

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

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

# Ventavis

## Products Affected

- VENTAVIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

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

# Verquvo

## Products Affected

- VERQUVO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.

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

# Verzenio

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## 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

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## Products Affected

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

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

# VIBERZI

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## Products Affected

- VIBERZI

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

# Vidaza

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# Vittrakvi

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	For Vittrakvi (larotrectinib) oral solution requests, individual is unable to swallow the oral capsule dose form due to a clinical condition, but not limited to the following: (a) Dysphagia OR (b) individual?s age.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Vizimpro

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## Products Affected

- VIZIMPRO

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

# Vonjo

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## Products Affected

- VONJO

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

# Voranigo

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## 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

# Vosevi

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## Products Affected

- VOSEVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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).</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VOTRIENT

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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.</p>
<b>Age Restrictions</b>	<p>Individual is 18 years of age or older for Narcolepsy type 1. Individual is 6 years of age or older for Narcolepsy type 2.</p>
<b>Prescriber Restrictions</b>	

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

# Welireg

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## Products Affected

- WELIREG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	Using Welireg (belzutifan) as monotherapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Xalkori

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## Products Affected

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

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

# XENAZINE

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 3 months. Continuation: 1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

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# Xgeva

## Products Affected

- XGEVA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	For Hypercalcemia of malignancy, Refractory to recent (within the last 30 days) treatment with intravenous bisphosphonate therapy (for example, pamidronate, zoledronic acid).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Xifaxan - HE

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## Products Affected

- XIFAXAN ORAL TABLET 550 MG

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

# Xifaxan 200mg

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## Products Affected

- XIFAXAN ORAL TABLET 200 MG

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

# Xolair

## Products Affected

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

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Initial Treatment: For moderate to severe persistent asthma, individual has had a minimum of 3 month trial and inadequate response or intolerance to ONE combination controller therapy (high dose of inhaled corticosteroids plus long-acting beta-2 agonists, Leukotriene modifiers, theophylline or oral corticosteroids)(GINA 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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Xospata

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## Products Affected

- XOSPATA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has confirmed FMS-like tyrosine kinase 3 (FLT3) mutation (written or verbal attestation is acceptable).
<b>Age Restrictions</b>	18 years of age and older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Xtandi

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## Products Affected

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

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

# Yervoy

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## Products Affected

- YERVOY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 lymphadenectomy.</p> <p>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</p>
	<p>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.</p>
<b>Indications</b>	All Medically-accepted Indications.

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Yonsa

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Febrile neutropenic Individuals who are at high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than <math>0.1 \times 10</math> to the power of <math>9/L</math>) 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 <math>450/?L</math>) 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 <math>1500mm^3</math>), poor renal function (GFR less than <math>60mL/min</math>) , liver dysfunction (liver function tests at least 2x upper limit of normal or bilirubin gr than <math>2.0 mg/dL</math>) (Lyman 2014) (Aagaard 2018), recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc) (Lyman 2014, Aagaard 2018). History of active infection within previous 60 days(Lyman 2014, Aagaard 2018). Current open wound and chemotherapy cannot be delayed (Lyman 2014, Aagaard 2018).</p>
<b>Age Restrictions</b>	

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PA Criteria	Criteria Details
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.
<b>Other Criteria</b>	<p>Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. Using for adjunctive tx for FN and has been prophylactic therapy with GCSF 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 mm<sup>3</sup> or experiencing recurrent infection. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. For tx of (non-chemotherapy) drug-induced neutropenia. For tx of low neutrophil counts in individuals with glycogen storage disease type 1b. For tx of neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected. After accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy] (such as Hematopoietic Syndrome of Acute Radiation Syndrome). After hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed. To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic</p>

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)).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# Zavesca

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## Products Affected

- *miglustat*
- YARGESA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 mm <sup>3</sup> .
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year.

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

# Zejula

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## Products Affected

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

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

# Zelboraf

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## Products Affected

- ZELBORAF

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

# Zepzelca

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## Products Affected

- ZEPZELCA

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

# Zolinza

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## 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

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## Products Affected

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

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

# Zydelig

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## 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

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## Products Affected

- ZYKADIA ORAL TABLET

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

# Zytiga

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## 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	30 days. 1 year for MDR-TB, XDR-TB,
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	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 pagsasalang-wika upang masagot ang anumang mga katanungan ninyo hinggil sa aming planong pangkalusugan o panggamot. Upang makakuha ng tagasalang-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 quý vị cần thông dịch viên xin gọi 1-800-627-1188 (TTY: 711) sẽ có nhân viên nói tiếng Việt giúp đỡ quý 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 대해 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 मुफ्त दुभाषिया सेवाएँ उपलब्ध हैं। एक दुभाषिया प्राप्त करने के लिए, बस हमें 1-800-627-1188 (TTY: 711) पर फोन करें। कोई व्यक्ति जो हिन्दी बोलता है आपकी मदद कर सकता है। यह एक मुफ्त 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 Italiano vi 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 bezpłatnie 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。通訳 ご用意になるには、1-800-627-1188 (TTY: 711) にお電話ください。日本語を話す人が支援いたします。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:** دی نک یم وگتفگ یسراف نابز هب رگا: هجوت، یم مهارف امش یارب ناگیار تروصب ی نابز تالی هست دی ریگب سامت 1-800-627-1188 (TTY: 711) اب دشاب.

**Nepali:** ध्यान दनुहोस्: तपाइंले नेपाली बोलनुहुन्छ भने तपाइंको नमिती भाषा सहायता सेवाहरू निःशुल्क रूपमा उपलब्ध छ । फोन गर्नुहोस् 1-800-627-1188 (टिडिडिडि: 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).