

## 2023 Prior Authorization Criteria

Updated 12/01/2023

# ABIRATERONE

### Products Affected

- Abiraterone Acetate

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Node-positive (N1), non-metastatic (M0) prostate cancer
<b>Part B Prerequisite</b>	No

# ACITRETIN

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## Products Affected

- Acitretin

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Psoriasis: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to methotrexate or cyclosporine.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Prevention of non-melanoma skin cancers in high risk individuals, Lichen planus, Keratosis follicularis (Darier Disease)
<b>Part B Prerequisite</b>	No

# ACTIMMUNE

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## Products Affected

- Actimmune

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Mycosis fungoides, Sezary syndrome.
<b>Part B Prerequisite</b>	No

# ADEMPAS

## Products Affected

- Adempas

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. For chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4): 1) Patient has persistent or recurrent CTEPH after pulmonary endarterectomy (PEA), OR 2) Patient has inoperable CTEPH with the diagnosis confirmed by right heart catheterization AND by computed tomography (CT), magnetic resonance imaging (MRI), or pulmonary angiography.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AIMOVIG

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## Products Affected

- Aimovig

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For the preventive treatment of migraine, initial: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants. For preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug, and the patient had a reduction in migraine days per month from baseline.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 3 months, Continuation: Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ALDURAZYME

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## Products Affected

- Aldurazyme

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For mucopolysaccharidosis I (MPS I): Diagnosis of MPS I was confirmed by an enzyme assay demonstrating a deficiency of alpha-L-iduronidase enzyme activity and/or by genetic testing. Patients with Scheie form (i.e., attenuated MPS I) must have moderate to severe symptoms.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved 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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent ALK-positive non-small cell lung cancer (NSCLC), brain metastases from ALK-positive NSCLC.
<b>Part B Prerequisite</b>	No

# ALOSETRON

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## Products Affected

- Alosetron HCl

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For severe diarrhea-predominant irritable bowel syndrome (IBS): 1) The requested drug is being prescribed for a biological female or a person that self-identifies as a female, 2) chronic IBS symptoms lasting at least 6 months, 3) gastrointestinal tract abnormalities have been ruled out, AND 4) inadequate response to one conventional therapy (e.g., antispasmodics, antidepressants, antidiarrheals).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# ALPHA1-PROTEINASE INHIBITOR

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## Products Affected

- Aralast NP Intravenous Solution Reconstituted  
1000 MG, 500 MG
- Prolastin-C
- Zemaira

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For alpha1-proteinase inhibitor deficiency: Patient must have 1) clinically evident emphysema and 2) pretreatment serum alpha1-proteinase inhibitor level less than 11 micromol/L (80 mg/dL by radial immunodiffusion or 50 mg/dL by nephelometry).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ALUNBRIG

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## Products Affected

- Alunbrig

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent ALK-positive non-small cell lung cancer (NSCLC), brain metastases from ALK-positive NSCLC, Inflammatory myofibroblastic tumor (IMT) with ALK translocation.
Part B Prerequisite	No

# AMBRISENTAN

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## Products Affected

- Ambrisentan

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): Diagnosis was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AMPHETAMINES

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## Products Affected

- Amphetamine-Dextroamphet ER
- Amphetamine-Dextroamphetamine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The patient has a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) OR 2) The patient has a diagnosis of narcolepsy confirmed by a sleep study.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan 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

- Apokyn Subcutaneous Solution Cartridge
- Apomorphine HCl Subcutaneous

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For continuation treatment of off episodes in Parkinson's disease: The patient is experiencing improvement on the requested drug.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved 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>	For prevention of gout flares in patients initiating or continuing urate-lowering therapy (e.g., allopurinol) (new starts): 1) two or more gout flares within the previous 12 months, AND 2) inadequate response, intolerance or contraindication to maximum tolerated doses of a non-steroidal anti-inflammatory drug (NSAID) and colchicine, AND 3) concurrent use with urate-lowering therapy. For prevention of gout flares in patients initiating or continuing urate-lowering therapy (e.g., allopurinol) (continuation): 1) patient must have achieved or maintained a clinical benefit (i.e., a fewer number of gout attacks or fewer flare days) compared to baseline, AND 2) continued use of urate-lowering therapy concurrently with the requested drug. For recurrent pericarditis: patient must have had an inadequate response, intolerance or contraindication to maximum tolerated doses of an NSAID and colchicine.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	For prevention of gout flares: 4 months. Other: Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Prevention of gout flares in patients initiating or continuing urate-lowering therapy.
<b>Part B Prerequisite</b>	No

# ARMODAFINIL

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## Products Affected

- Armodafinil

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The patient has a diagnosis of narcolepsy and the diagnosis is confirmed by sleep lab evaluation OR 2) The patient has a diagnosis of Shift Work Disorder (SWD) OR 3) The patient has a diagnosis of obstructive sleep apnea (OSA) and the diagnosis is confirmed by polysomnography.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved 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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# AUSTEDO

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## Products Affected

- Austedo
- Austedo XR
- Austedo XR Patient Titration

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Tourette's syndrome
<b>Part B Prerequisite</b>	No

# AUVELITY

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## Products Affected

- Auvelity

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For Major Depressive Disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to two of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AYVAKIT

## Products Affected

- Ayvakit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For myeloid and lymphoid neoplasms with eosinophilia, the patient meets all of the following criteria: 1) The disease is FIP1L1- PDGFRA rearrangement-positive, AND 2) The disease harbors a PDGFRA D842A mutation, AND 3) The disease is resistant to imatinib. For GIST, the patient meets either of the following criteria: 1) The disease harbors PDGFRA exon 18 mutation, including PDGFRA D842V mutations, OR 2) The requested drug will be used after failure on at least two Food and Drug Administration (FDA)-approved therapies in unresectable, recurrent, or metastatic disease without PDGFRA exon 18 mutation. For systemic mastocytosis: 1) The patient has a diagnosis of indolent systemic mastocytosis or advanced systemic mastocytosis (including aggressive systemic mastocytosis [ASM], systemic mastocytosis with associated hematological neoplasm [SM-AHN], and mast cell leukemia [MCL]) AND 2) The patient has a platelet count of greater than or equal to 50,000/microliter (mcL).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Myeloid and lymphoid neoplasms with eosinophilia, gastrointestinal stromal tumor (GIST) for unresectable, recurrent, or metastatic disease without platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation.
<b>Part B Prerequisite</b>	No

## B VS. D

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### Products Affected

- Abelcet
- Acetylcysteine Inhalation
- Acyclovir Sodium Intravenous Solution
- Albuterol Sulfate Inhalation Nebulization Solution (2.5 MG/3ML) 0.083%, 0.63 MG/3ML, 1.25 MG/3ML, 2.5 MG/0.5ML
- Amphotericin B Intravenous
- Amphotericin B Liposome
- Aprepitant Oral Capsule
- Arformoterol Tartrate
- azaCITIDine
- azaTHIOprine Oral Tablet 50 MG
- Bendeka
- Budesonide Inhalation Suspension 0.25 MG/2ML, 0.5 MG/2ML
- Calcitonin (Salmon) Nasal
- Calcitriol Oral
- CARBOplatin Intravenous Solution
- Cinacalcet HCl
- CISplatin Intravenous Solution 100 MG/100ML, 200 MG/200ML, 50 MG/50ML
- Clinimix/Dextrose (4.25/10)
- Clinimix/Dextrose (4.25/5)
- Clinimix/Dextrose (5/15)
- Clinimix/Dextrose (5/20)
- Clinimix/Dextrose (6/5)
- Clinimix/Dextrose (8/10)
- Clinimix/Dextrose (8/14)
- Clinisol SF
- Clinolipid
- Cromolyn Sodium Inhalation
- Cyclophosphamide Injection
- Cyclophosphamide Intravenous
- Cyclophosphamide Oral Capsule
- Cyclophosphamide Oral Tablet
- cycloSPORINE Intravenous
- cycloSPORINE Modified
- CycloSPORINE Oral Capsule
- Cytarabine Injection Solution
- Dextrose Intravenous Solution 50 %, 70 %
- Diphtheria-Tetanus Toxoids DT
- DOCEtaxel CONCENTRATE 160 MG/8ML Intravenous
- DOCEtaxel CONCENTRATE 80 MG/4ML Intravenous
- DOCEtaxel Intravenous Concentrate 160 MG/8ML, 20 MG/ML, 80 MG/4ML
- DOCEtaxel Intravenous Solution 160 MG/16ML, 20 MG/2ML, 80 MG/8ML
- DOCEtaxel SOLUTION 160 MG/16ML Intravenous
- DOCEtaxel SOLUTION 20 MG/2ML Intravenous
- DOCEtaxel SOLUTION 80 MG/8ML Intravenous
- Doxercalciferol Oral
- DOXOrubicin HCl Intravenous Solution
- DOXOrubicin HCl Liposomal
- Dronabinol
- Ellence
- Engerix-B Injection Suspension 20 MCG/ML
- Engerix-B Injection Suspension Prefilled Syringe
- Etoposide Intravenous Solution 1 GM/50ML, 100 MG/5ML, 500 MG/25ML
- Everolimus Oral Tablet 0.25 MG, 0.5 MG, 0.75 MG, 1 MG
- Fiasp PumpCart
- Fluorouracil Intravenous
- Formoterol Fumarate Inhalation
- Fulvestrant Intramuscular Solution Prefilled Syringe
- GamaSTAN
- Ganciclovir Sodium Intravenous Solution Reconstituted
- Gemcitabine HCl Intravenous Solution 1 GM/26.3ML, 2 GM/52.6ML, 200 MG/5.26ML
- Gemcitabine HCl Intravenous Solution Reconstituted
- Gengraf Oral Capsule 100 MG, 25 MG
- Gengraf Oral Solution
- Granisetron HCl Oral
- Heparin Sodium (Porcine) Injection Solution 1000 UNIT/ML, 10000 UNIT/ML, 20000 UNIT/ML, 5000 UNIT/ML
- Heplisav-B Intramuscular Solution Prefilled

- Syringe
- HumuLIN R U-500 (CONCENTRATED)
  - Ibandronate Sodium
  - Imovax Rabies Intramuscular Suspension Reconstituted
  - Intralipid
  - Intron A Injection Solution Reconstituted
  - Ipratropium Bromide Inhalation
  - Ipratropium-Albuterol
  - Irinotecan HCl
  - Kadcyla
  - Leucovorin Calcium Injection Solution 500 MG/50ML
  - Leucovorin Calcium Injection Solution Reconstituted
  - Levalbuterol HCl Inhalation
  - levOCARNitine Oral Solution
  - levOCARNitine Oral Tablet
  - Lidocaine HCl (PF) Injection Solution 0.5 %, 1 %, 1.5 %
  - Lidocaine HCl Injection Solution 0.5 %, 1 %, 2 %
  - Methotrexate Sodium (PF) Injection Solution 1 GM/40ML, 250 MG/10ML, 50 MG/2ML
  - Methotrexate Sodium Injection Solution 250 MG/10ML, 50 MG/2ML
  - Methotrexate Sodium Injection Solution Reconstituted
  - Morphine Sulfate (PF) Injection Solution 10 MG/ML, 2 MG/ML, 4 MG/ML, 5 MG/ML, 8 MG/ML
  - Morphine Sulfate (PF) Intravenous Solution 1 MG/ML, 10 MG/ML, 2 MG/ML, 4 MG/ML, 8 MG/ML
  - Morphine Sulfate Intravenous Solution 10 MG/ML, 4 MG/ML, 8 MG/ML
  - Mycophenolate Mofetil Oral
  - Mycophenolate Sodium
  - Nulojix
  - Nutrilipid
  - Oxaliplatin
  - PACLitaxel Intravenous Concentrate 100 MG/16.7ML, 150 MG/25ML, 30 MG/5ML, 300 MG/50ML
  - PACLitaxel Protein-Bound Part
  - Pamidronate Disodium Intravenous Solution 30 MG/10ML, 90 MG/10ML
  - Pamidronate Disodium Intravenous Solution 6 MG/ML
  - Paraplatin Intravenous Solution 1000 MG/100ML
  - Paricalcitol Oral
  - PEMEtrexed Disodium Intravenous Solution Reconstituted
  - Pentamidine Isethionate Inhalation
  - Plenamine
  - PreHevbrio
  - Premasol Intravenous Solution 10 %
  - Prograf Oral Packet
  - Prosol
  - RabAvert
  - Recombivax HB
  - SandIMMUNE Oral Solution
  - Sirolimus Oral
  - Tacrolimus Oral
  - TDVAX
  - Tenivac
  - TPN Electrolytes Intravenous Concentrate
  - Travasol
  - TrophAmine Intravenous Solution 10 %
  - vinCRISTine Sulfate Intravenous
  - Vinorelbine Tartrate
  - Zoledronic Acid Intravenous Concentrate
  - Zoledronic Acid Intravenous Solution

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	

PA Criteria	Criteria Details
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	N/A
<b>Other Criteria</b>	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BALVERSA

## Products Affected

- Balversa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For urothelial carcinoma: Disease has susceptible fibroblast growth factor receptor 3 (FGFR3) or fibroblast growth factor receptor 2 (FGFR2) genetic alterations AND the requested drug will be used as subsequent therapy for any of the following: a) locally advanced or metastatic urothelial carcinoma, b) recurrent primary carcinoma of the urethra, c) stage II urothelial carcinoma of the bladder if tumor is present following reassessment of tumor status 2-3 months after primary treatment with bladder preserving concurrent chemoradiotherapy, d) urothelial carcinoma of the bladder with metastatic or local recurrence post cystectomy, or e) urothelial carcinoma of the bladder with muscle invasive local recurrence or persistent disease in a preserved bladder.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent primary carcinoma of the urethra, recurrent or persistent urothelial carcinoma of the bladder.
<b>Part B Prerequisite</b>	No

# BANZEL

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## Products Affected

- Rufinamide

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



# BENLYSTA

## Products Affected

- Benlysta

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	For patients new to therapy: severe active central nervous system lupus.
<b>Required Medical Information</b>	For systemic lupus erythematosus (SLE): 1) Patient is currently receiving a stable standard therapy regimen (e.g., corticosteroid or antimalarial) for SLE OR 2) patient is not currently receiving a stable standard therapy regimen for SLE because the patient experienced an intolerance or has a contraindication to standard therapy regimens. For lupus nephritis: 1) patient is currently receiving a stable standard therapy regimen (e.g., corticosteroid) for lupus nephritis OR 2) patient is not currently receiving a stable standard therapy regimen for lupus nephritis because the patient experienced an intolerance or has a contraindication to standard therapy regimens.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BERINERT

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## Products Affected

- Berinerter

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For hereditary angioedema (HAE): The requested drug is being used for the treatment of acute angioedema attacks. Patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR patient has HAE with normal C1 inhibitor confirmed by laboratory testing. For patients with HAE with normal C1 inhibitor, EITHER 1) Patient tested positive for an F12, angiotensin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosaminase 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation OR 2) Patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month.
<b>Age Restrictions</b>	5 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Short-term preprocedural prophylaxis for hereditary angioedema (HAE) attacks
<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>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BETASERON

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## Products Affected

- Betaseron Subcutaneous Kit

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BEXAROTENE

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## Products Affected

- Bexarotene

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Mycosis fungoides, Sezary syndrome, CD30-positive primary cutaneous anaplastic large cell lymphoma, CD30-positive lymphomatoid papulosis.
<b>Part B Prerequisite</b>	No

# BOSENTAN

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## Products Affected

- Bosentan

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): Diagnosis was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BOSULIF

## Products Affected

- Bosulif

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For chronic myeloid leukemia (CML) or acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, and 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I, G250E, V299L, and F317L. For CML, including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: patient has experienced resistance or intolerance to imatinib or dasatinib.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase
<b>Part B Prerequisite</b>	No

# BRAFTOVI

## Products Affected

- Braftovi Oral Capsule 75 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For colorectal cancer: The patient must meet both of the following criteria: 1) Tumor is positive for BRAF V600E mutation, 2) The requested drug will be used for either of the following: a) as subsequent therapy for advanced or metastatic disease, or b) as primary treatment for unresectable metachronous metastases. For cutaneous melanoma: The patient must meet all of the following criteria: 1) Tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), 2) The requested drug will be used in combination with binimetinib, and 3) The requested drug will be used for either of the following: a) unresectable or metastatic disease, or b) adjuvant systemic therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Adjuvant systemic therapy for cutaneous melanoma
<b>Part B Prerequisite</b>	No



# BRIVIACT

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## Products Affected

- Briviact

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The patient has experienced an inadequate treatment response, intolerance, or contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or contraindication to any of the following: Aptiom, Vimpat, Xcopri, Spritam.
<b>Age Restrictions</b>	1 month of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BRIVIACT INJ

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## Products Affected

- Briviact

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The patient has experienced an inadequate treatment response, intolerance, or contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or contraindication to any of the following: Aptiom, Vimpat, Xcopri, Spritam.
<b>Age Restrictions</b>	1 month of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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>	For marginal zone lymphoma: 1) the requested drug is being used for the treatment of relapsed or refractory disease AND the patient has received at least one anti-CD20-based regimen, OR 2) the requested drug is being used for the treatment of refractory or progressive disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BUDESONIDE CAP

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## Products Affected

- Budesonide Oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For the maintenance of microscopic colitis: patient has had a clinical relapse after cessation of treatment (induction) therapy.
<b>Age Restrictions</b>	Crohn's, treatment: 8 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Microscopic colitis, maintenance: 12 months, all other indications: 3 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Treatment and maintenance of microscopic colitis in adults
<b>Part B Prerequisite</b>	No

# BUPRENORPHINE

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## Products Affected

- Buprenorphine HCl Sublingual

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The requested drug is being prescribed for the treatment of opioid use disorder AND patient meets one of the following: 1) The patient is pregnant or breastfeeding, and the requested drug is being prescribed for induction therapy and/or subsequent maintenance therapy for treatment of opioid use disorder OR 2) The requested drug is being prescribed for induction therapy for transition from opioid use to treatment of opioid use disorder OR 3) The requested drug is being prescribed for maintenance therapy for treatment of opioid use disorder in a patient who is intolerant to naloxone.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BYDUREON

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## Products Affected

- Bydureon BCise

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	10 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BYETTA

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## Products Affected

- Byetta 10 MCG Pen Subcutaneous Solution Pen-Injector
- Byetta 5 MCG Pen Subcutaneous Solution Pen-Injector

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

# CABOMETYX

## Products Affected

- Cabometyx

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For renal cell carcinoma: The disease is advanced, relapsed, or stage IV. For non-small cell lung cancer: 1) the disease is rearranged during transfection (RET) positive AND 2) the disease is recurrent, advanced, or metastatic. For hepatocellular carcinoma: the requested drug will be used as subsequent treatment. For gastrointestinal stromal tumor (GIST): the disease is unresectable, recurrent, or metastatic AND the patient has failed on an FDA-approved therapy (e.g., imatinib, sunitinib, regorafenib, ripretinib). For Ewing sarcoma and osteosarcoma: the requested drug will be used as subsequent therapy. For differentiated thyroid cancer (DTC) (follicular, papillary, Hurthle cell): 1) The disease is locally advanced or metastatic disease, 2) the disease has progressed after a vascular endothelial growth factor receptor (VEGFR)- targeted therapy, AND 3) the patient is refractory to radioactive iodine therapy (RAI) or ineligible for RAI.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Non-small cell lung cancer, Ewing sarcoma, osteosarcoma, gastrointestinal stromal tumor
<b>Part B Prerequisite</b>	No



# CALCIPOTRIENE

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## Products Affected

- Calcipotriene External Ointment
- Calcipotriene External Solution
- Calcitrene
- Enstilar

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For Treatment of Psoriasis: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to a topical steroid.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# CALQUENCE

## Products Affected

- Calquence

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For gastric MALT lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma: the requested drug is being used for the treatment of refractory or progressive disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Waldenstrom macroglobulinemia, lymphoplasmacytic lymphoma, gastric mucosa-associated lymphoid tissue (MALT) lymphoma, non-gastric MALT lymphoma (noncutaneous), nodal marginal zone lymphoma, splenic marginal zone lymphoma
<b>Part B Prerequisite</b>	No

# CAPRELSA

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## Products Affected

- Caprelsa

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Differentiated thyroid carcinoma: papillary, follicular, and Hurthle cell.
<b>Part B Prerequisite</b>	No

# CARBAGLU

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## Products Affected

- Carglumic Acid Oral Tablet Soluble

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For N-acetylglutamate synthase (NAGS) deficiency: Diagnosis of NAGS deficiency was confirmed by enzymatic, biochemical, or genetic testing.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# CAYSTON

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## Products Affected

- Cayston

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For treatment of respiratory symptoms in cystic fibrosis patients: 1) Pseudomonas aeruginosa is present in the patient's airway cultures OR 2) The patient has a history of pseudomonas aeruginosa infection or colonization in the airways.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# CERDELGA

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## Products Affected

- Cerdelga

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For type 1 Gaucher disease (GD1): 1) The diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing, and 2) The patient's CYP2D6 metabolizer status has been established using an FDA-cleared test, and 3) The patient is a CYP2D6 extensive metabolizer, an intermediate metabolizer, or a poor metabolizer.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# CEREZYME

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## Products Affected

- Cerezyme Intravenous Solution Reconstituted  
400 UNIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For Gaucher disease, the diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Type 2 Gaucher disease, Type 3 Gaucher disease
<b>Part B Prerequisite</b>	No

# CLOBAZAM

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## Products Affected

- cloBAZam

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	2 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# CLOMIPRAMINE

## Products Affected

- clomiPRAMINE HCl Oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The requested drug is being prescribed for one of the following: a) Obsessive-Compulsive Disorder (OCD), b) Panic Disorder AND 2) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to any of the following: a) a serotonin and norepinephrine reuptake inhibitor (SNRI), b) a selective serotonin reuptake inhibitor (SSRI) OR 3) The requested drug is being prescribed for Depression AND 4) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to two of the following: a) serotonin and norepinephrine reuptake inhibitors (SNRIs), b) selective serotonin reuptake inhibitors (SSRIs), c) mirtazapine, d) bupropion
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Depression, Panic Disorder
<b>Part B Prerequisite</b>	No

# CLORAZEPATE

## Products Affected

- Clorazepate Dipotassium

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Short-term relief anxiety-1 month, Anxiety Disorders-4 months, All other Diagnoses-Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 65 years of age or older.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# CLOZAPINE ODT

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## Products Affected

- CloZAPine Oral Tablet Dispersible

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# COMETRIQ

## Products Affected

- Cometriq (100 MG Daily Dose) Oral Kit 80 & 20 MG
- Cometriq (60 MG Daily Dose) MG
- Cometriq (140 MG Daily Dose) Oral Kit 3 x 20 MG & 80 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For NSCLC: The requested medication is used for NSCLC when the patient's disease expresses rearranged during transfection (RET) gene rearrangements.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Non-small cell lung cancer (NSCLC), differentiated thyroid carcinoma: papillary, follicular, and Hurthle cell.
<b>Part B Prerequisite</b>	No

# COPIKTRA

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## Products Affected

- Copiktra

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL): the patient has relapsed or refractory disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# COTELLIC

## Products Affected

- Cotellic

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For adjuvant treatment of melanoma, and central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma): The patient must meet both of the following criteria: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), and 2) The requested drug will be used in combination with vemurafenib. For unresectable or metastatic melanoma: The patient must meet both of the following criteria: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), and 2) The requested drug will be used in combination with vemurafenib (with or without atezolizumab).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma), Erdheim-Chester disease, Langerhans cell histiocytosis, Rosai-Dorfman disease
<b>Part B Prerequisite</b>	No

# CYSTADROPS

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## Products Affected

- Cystadrops

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient meets both of the following: 1) Diagnosis of cystinosis was confirmed by ANY of the following: a) the presence of increased cystine concentration in leukocytes, OR b) genetic testing, OR c) demonstration of corneal cystine crystals by slit lamp examination, AND 2) the patient has corneal cystine crystal accumulation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# CYSTAGON

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## Products Affected

- Cystagon

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of nephropathic cystinosis was confirmed by ANY of the following: 1) the presence of increased cystine concentration in leukocytes, OR 2) genetic testing, OR 3) demonstration of corneal cystine crystals by slit lamp examination.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# CYSTARAN

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## Products Affected

- Cystaran

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient meets both of the following: 1) Diagnosis of cystinosis was confirmed by ANY of the following: a) the presence of increased cystine concentration in leukocytes, OR b) genetic testing, OR c) demonstration of corneal cystine crystals by slit lamp examination, AND 2) the patient has corneal cystine crystal accumulation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DALFAMPRIDINE

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## Products Affected

- Dalfampridine ER

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For multiple sclerosis, patient must meet the following: For new starts, prior to initiating therapy, patient demonstrates sustained walking impairment. For continuation of therapy: patient must have experienced an improvement in walking speed OR other objective measure of walking ability since starting the requested drug.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DAURISMO

## Products Affected

- Daurismo

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For acute myeloid leukemia: 1) the requested drug must be used in combination with cytarabine, 2) the patient is 75 years of age or older OR has comorbidities that preclude intensive chemotherapy, and 3) the requested drug will be used as treatment for induction therapy, post-induction therapy, or relapsed or refractory disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Post induction therapy following response to previous therapy with the same regimen for acute myeloid leukemia (AML). Relapsed/refractory AML as a component of repeating the initial successful induction regimen.
<b>Part B Prerequisite</b>	No

# DEFERASIROX

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## Products Affected

- Deferasirox Granules
- Deferasirox Oral Tablet
- Deferasirox Oral Tablet Soluble

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For chronic iron overload due to blood transfusions: pretreatment serum ferritin level is greater than 1000 mcg/L.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DEMSER

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## Products Affected

- metyroSINE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to an alpha-adrenergic antagonist.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DESVENLAFAXINE

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## Products Affected

- Desvenlafaxine Succinate ER

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: a) serotonin and norepinephrine reuptake inhibitors (SNRIs), b) selective serotonin reuptake inhibitors (SSRIs), c) mirtazapine, d) bupropion
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DEXMETHYLPHENIDATE

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## Products Affected

- Dexmethylphenidate HCl

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The patient has a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) OR 2) The requested drug is being prescribed for the treatment of cancer-related fatigue after other causes of fatigue have been ruled out.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Cancer-related fatigue
<b>Part B Prerequisite</b>	No

# DHE NASAL

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## Products Affected

- Dihydroergotamine Mesylate Nasal

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coverage will be denied when used in conjunction with potent CYP3A4 inhibitors (e.g., ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin).
<b>Required Medical Information</b>	The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one triptan 5-HT <sub>1</sub> receptor agonist.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# DIACOMIT

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## Products Affected

- Diacomit

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	6 months of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DIAZEPAM

## Products Affected

- diazePAM Intensol
- diazePAM Oral Solution 5 MG/5ML
- diazePAM Oral Tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Short-term relief anx-1 mo, skeletal muscle spasm-3 mo, Anx Disorders-4 mo, Other Diagnoses-PlanYR
<b>Other Criteria</b>	This Prior Authorization only applies to patients 65 years of age or older.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DOPTelet

## Products Affected

- Doptelet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For thrombocytopenia in patients with chronic liver disease: Untransfused platelet count prior to a scheduled procedure is less than 50,000/mcL. For chronic immune thrombocytopenia (ITP): 1) For new starts: a) Patient has had an inadequate response or is intolerant to prior therapy such as corticosteroids or immunoglobulins, AND b) Untransfused platelet count at any point prior to the initiation of the requested medication is less than 30,000/mcL OR 30,000 to 50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes patient to trauma). 2) For continuation of therapy, platelet count response to the requested drug: a) Current platelet count is less than or equal to 200,000/mcL OR b) Current platelet count is greater than 200,000/mcL and less than or equal to 400,000/mcL and dosing will be adjusted to a platelet count sufficient to avoid clinically important bleeding.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Chronic liver disease: 1 month, ITP initial: 6 months, ITP reauthorization: Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DRIZALMA

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## Products Affected

- Drizalma Sprinkle

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The patient has tried duloxetine capsules OR 2) The patient is unable to take duloxetine capsules for any reason (e.g., difficulty swallowing capsules, requires nasogastric administration).
<b>Age Restrictions</b>	Generalized Anxiety Disorder - 7 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Cancer pain, chemotherapy-induced neuropathic pain
<b>Part B Prerequisite</b>	No

# DUPIXENT

## Products Affected

- Dupixent

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For atopic dermatitis (AD), initial therapy: 1) Patient has moderate-to-severe disease, 2) Patient has had an inadequate treatment response to either a topical corticosteroid or a topical calcineurin inhibitor, OR topical corticosteroids and topical calcineurin inhibitors are not advisable for the patient. For AD, continuation of therapy: the patient achieved or maintained positive clinical response. For moderate-to-severe asthma, initial therapy: Patient meets either of the following: 1) patient is oral corticosteroid dependent and asthma remains inadequately controlled despite current treatment with both of the following medications: a) high-dose inhaled corticosteroid and b) an additional controller (long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies, OR 2) patient has a baseline blood eosinophil count of at least 150 cells per microliter and their asthma remains inadequately controlled despite current treatment with both of the following medications: a) medium-to-high-dose inhaled corticosteroid and b) additional controller (long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For moderate-to-severe asthma, continuation of therapy: asthma control has improved on treatment with the requested drug. For chronic rhinosinusitis with nasal polyposis (CRSwNP): 1) the requested drug is used as add-on maintenance treatment, AND 2) the patient has experienced an inadequate treatment response to Xhance (fluticasone).
<b>Age Restrictions</b>	Atopic Dermatitis: 6 months of age or older, Asthma: 6 years of age or older, Chronic Rhinosinusitis with Nasal Polyposis and Prurigo Nodularis: 18 years of age or older, Eosinophilic Esophagitis: 12 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	AD, initial: 4 months, PN, initial: 6 months, All other: Plan Year

PA Criteria	Criteria Details
<b>Other Criteria</b>	For eosinophilic esophagitis (EoE), initial therapy: 1) diagnosis has been confirmed by esophageal biopsy, 2) patient weighs at least 40 kilograms, 3) patient experienced an inadequate treatment response, intolerance, or patient has a contraindication to a topical corticosteroid (e.g., fluticasone propionate or budesonide). For EoE, continuation of therapy: the patient achieved or maintained a positive clinical response. For prurigo nodularis (PN), initial therapy: Patient has had an inadequate treatment response to a topical corticosteroid OR topical corticosteroids are not advisable for the patient. For PN, continuation of therapy: The patient achieved or maintained a positive clinical response.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ELIGARD

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## Products Affected

- Eligard

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent androgen receptor positive salivary gland tumors
<b>Part B Prerequisite</b>	No

# EMGALITY

## Products Affected

- Emgality
- Emgality (300 MG Dose)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For the preventive treatment of migraine, initial: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants. For preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug, and the patient had a reduction in migraine days per month from baseline. For episodic cluster headache, initial: The patient experienced an inadequate treatment response, intolerance, or contraindication to a triptan 5-HT <sub>1</sub> receptor agonist. For episodic cluster headache, continuation: The patient received the requested drug for at least 3 weeks of treatment and had a reduction in weekly cluster headache attack frequency from baseline.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 3 months, Continuation: Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# EMSAM

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## Products Affected

- Emsam

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) Patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: a) serotonin and norepinephrine reuptake inhibitors (SNRIs), b) selective serotonin reuptake inhibitors (SSRIs), c) mirtazapine, d) bupropion OR 2) Patient is unable to swallow oral formulations.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ENBREL

## Products Affected

- Enbrel Mini
- Enbrel Subcutaneous Solution 25 MG/0.5ML
- Enbrel Subcutaneous Solution Prefilled Syringe
- Enbrel Subcutaneous Solution Reconstituted
- Enbrel SureClick Subcutaneous Solution Auto-Injector

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For moderately to severely active rheumatoid arthritis (new starts only): 1) Inadequate response, intolerance or contraindication to methotrexate (MTX) OR 2) Inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis (new starts only): 1) Inadequate response to a non-steroidal anti-inflammatory drug (NSAID) trial OR 2) Intolerance or contraindication to NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis AND 2) Patient meets any of the following: a) Patient has experienced an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, OR b) Pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, OR c) Patient has severe psoriasis that warrants a biologic as first-line therapy (i.e. at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). For hidradenitis suppurativa (new starts only): patient has severe, refractory disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Hidradenitis suppurativa

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

# ENDARI

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## Products Affected

- Endari

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	5 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# EPCLUSA

## Products Affected

- Epclusa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases (AASLD) treatment guidelines.
<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>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# EPIDIOLEX

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## Products Affected

- Epidiolex

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

# EPRONTIA

## Products Affected

- Eprontia

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For treatment of partial-onset seizures: 1)The patient has experienced an inadequate treatment response, intolerance, or contraindication to a generic anticonvulsant AND 2) the patient has experienced an inadequate treatment response, intolerance, or contraindication to any of the following: Aptiom, Vimpat, Xcopri, Spritam. For monotherapy treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response or intolerance to topiramate tablets or capsules, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response, intolerance, or contraindication to a generic anticonvulsant AND 2) If the patient is 4 years of age or older, the patient has experienced an inadequate treatment response, intolerance, or contraindication to Spritam or Vimpat. For the preventative treatment of migraines: 1) The patient has experienced an inadequate treatment response or intolerance to topiramate tablets or capsules, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules).
<b>Age Restrictions</b>	Epilepsy: 2 years of age or older, Migraine: 12 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ERGOTAMINE

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## Products Affected

- Ergotamine-Caffeine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coverage will be denied when used in conjunction with potent CYP3A4 inhibitors (e.g., ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin).
<b>Required Medical Information</b>	The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least ONE triptan 5-HT <sub>1</sub> agonist.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# ERIVEDGE

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## Products Affected

- Erivedge

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Adult medulloblastoma: patient has received chemotherapy previously AND has tumor(s) with mutations in the sonic hedgehog pathway
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Adult medulloblastoma
<b>Part B Prerequisite</b>	No

# ERLEADA

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## Products Affected

- Erleada

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ERLOTINIB

## Products Affected

- Erlotinib HCl

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For NSCLC (including brain metastases from NSCLC): 1) the disease is recurrent, advanced, or metastatic and 2) the patient has sensitizing EGFR mutation-positive disease. For pancreatic cancer: the disease is locally advanced, unresectable, recurrent, or metastatic.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent non-small cell lung cancer (NSCLC), recurrent chordoma, relapsed or stage IV renal cell carcinoma (RCC), brain metastases from non-small cell lung cancer (NSCLC), recurrent pancreatic cancer.
<b>Part B Prerequisite</b>	No

# ESBRIET

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## Products Affected

- Pirfenidone

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For idiopathic pulmonary fibrosis (Initial Review Only): 1) a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy reveals the usual interstitial pneumonia (UIP) pattern, OR 2) HRCT study of the chest reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported either by a lung biopsy or by a multidisciplinary discussion between at least a radiologist and pulmonologist who are experienced in idiopathic pulmonary fibrosis if a lung biopsy has not been conducted.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# EVEROLIMUS

## Products Affected

- Everolimus Oral Tablet 10 MG, 2.5 MG, 5 MG, 7.5 MG
- Everolimus Oral Tablet Soluble

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For breast cancer: 1) The disease is recurrent, advanced, or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, AND 2) The requested drug is prescribed in combination with exemestane, fulvestrant, or tamoxifen, AND 3) The requested drug is used for subsequent treatment. For renal cell carcinoma: The disease is relapsed, advanced, or stage IV. For subependymal giant cell astrocytoma (SEGA): The requested drug is given as adjuvant treatment. For gastrointestinal stromal tumor: The disease is recurrent, unresectable, or metastatic AND the patient failed an FDA-approved therapy (e.g., imatinib, sunitinib, regorafenib, ripretinib). For symptomatic or relapsed/refractory Erdheim-Chester Disease (ECD), symptomatic or relapsed/refractory Rosai-Dorfman Disease, and Langerhans Cell Histiocytosis (LCH): the patient must have a phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha (PIK3CA) mutation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Classic Hodgkin lymphoma, thymomas and thymic carcinomas, previously treated Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, soft tissue sarcoma (perivascular epithelioid cell tumors (PEComa) and lymphangioliomyomatosis subtypes), gastrointestinal stromal tumors, neuroendocrine tumors of the thymus, well differentiated grade 3 neuroendocrine tumors, thyroid carcinoma (papillary, Hurthle cell, and follicular), endometrial carcinoma, histiocytic neoplasms (Rosai-Dorfman Disease, Erdheim-Chester Disease, Langerhans Cell Histiocytosis)

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

# EXKIVITY

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## Products Affected

- Exkivity

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

# FABRAZYME

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## Products Affected

- Fabrazyme

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient meets ANY of the following: 1) Diagnosis of Fabry disease was confirmed by an enzyme assay demonstrating a deficiency of alpha-galactosidase enzyme activity or by genetic testing, OR 2) The patient is a symptomatic obligate female carrier.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# FANAPT

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## Products Affected

- Fanapt
- Fanapt Titration Pack

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For treatment of schizophrenia: 1) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine, risperidone, ziprasidone AND 2) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following brand products: Latuda, Rexulti, Secuado, Vraylar.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FASENRA

## Products Affected

- Fasenra
- Fasenra Pen

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For severe asthma: For initial therapy: 1) Either a) Patient has baseline blood eosinophil count of at least 150 cells per microliter OR b) Patient is dependent on systemic corticosteroids, and 2) Patient has a history of severe asthma despite current treatment with both of the following medications: a) inhaled corticosteroid and b) additional controller (long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose.
<b>Age Restrictions</b>	12 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FEBUXOSTAT

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## Products Affected

- Febuxostat

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For the chronic management of hyperuricemia in a patient with gout: 1) the patient has experienced an inadequate treatment response to a maximally titrated dose of allopurinol, OR 2) the patient has experienced an intolerance to allopurinol, OR 3) the patient has a contraindication that would prohibit a trial of allopurinol.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FENTANYL PATCH

## Products Affected

- FentaNYL Transdermal Patch 72 Hour 100 MCG/HR, 25 MCG/HR
- fentaNYL Transdermal Patch 72 Hour 12 MCG/HR, 50 MCG/HR, 75 MCG/HR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe enough to require daily, around-the-clock, long-term treatment in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FETZIMA

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## Products Affected

- Fetzima
- Fetzima Titration

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FINTEPLA

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## Products Affected

- Fintepla

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	2 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FLUCYTOSINE

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## Products Affected

- Flucytosine Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 weeks
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# FORM ALT PA SUCRALFATE

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## Products Affected

- Carafate Oral Suspension
- Sucralfate Oral Suspension

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient has experienced an intolerance to one other formulary product such as sucralfate tablets.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# FORTEO

## Products Affected

- Forteo Subcutaneous Solution Pen-Injector 600 MCG/2.4ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For postmenopausal osteoporosis: patient has ONE of the following (1 or 2): 1) a history of fragility fracture, OR 2) A pre-treatment T-score of less than or equal to -2.5 or pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment Fracture Risk Assessment Tool (FRAX) fracture probability AND patient has ANY of the following: a) indicators for higher fracture risk (e.g., advanced age, frailty, glucocorticoid therapy, very low T-scores, or increased fall risk), OR b) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy OR c) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. For primary or hypogonadal osteoporosis in men: patient has one of the following: 1) a history of osteoporotic vertebral or hip fracture, OR 2) pre-treatment T-score of less than or equal to -2.5, OR 3) pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment FRAX fracture probability. For glucocorticoid-induced osteoporosis: Patient has had an oral bisphosphonate trial of at least 1-year duration unless patient has a contraindication or intolerance to an oral bisphosphonate, AND patient meets ANY of the following: 1) patient has a history of fragility fracture, OR 2) a pre-treatment T-score of less than or equal to -2.5, OR 3) pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment FRAX fracture probability. Continuation of therapy: If the patient has received greater than or equal to 24 months of therapy with any parathyroid hormone analog: 1) The patient remains at or has returned to having a high risk for fracture, AND 2) The benefit of therapy with this prescribed medication outweighs the potential risks for this patient.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 24 months, Continuation: Plan Year

PA Criteria	Criteria Details
<b>Other Criteria</b>	Patient has high FRAX fracture probability if the 10 year probability is either greater than or equal to 20 percent for any major osteoporotic fracture or greater than or equal to 3 percent for hip fracture. If glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day, the estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture.
<b>Indications</b>	All FDA-approved 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 advanced renal cell carcinoma: the following criteria must be met: 1) The disease is relapsed or refractory, 2) The requested drug must be used after at least two prior systemic therapies, and 3) The patient has experienced disease progression or an intolerable adverse event with a trial of cabozantinib (Cabometyx).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FYCOMPA

## Products Affected

- Fycompa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For treatment of partial-onset seizures: 1) The patient experienced an inadequate treatment response, intolerance, or contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or contraindication to any of the following: Aptiom, Vimpat, Xcopri, Spritam. For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient experienced an inadequate treatment response, intolerance, or contraindication to a generic anticonvulsant AND 2) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following: Vimpat, Spritam.
<b>Age Restrictions</b>	Partial-onset seizures: 4 years of age or older. Primary generalized tonic-clonic seizures: 12 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# GATTEX

## Products Affected

- Gattex

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For short bowel syndrome (SBS) initial therapy: Adult patients were dependent on parenteral support for at least 12 months. For SBS continuation: Requirement for parenteral support has decreased from baseline while on therapy with the requested drug.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, gastrointestinal surgeon, or nutritional support specialist.
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# GAVRETO

## Products Affected

- Gavreto

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For non-small cell lung cancer, patient must meet all of the following: 1) The disease is recurrent, advanced, or metastatic, and 2) The tumor is rearranged during transfection (RET) fusion-positive or RET rearrangement-positive.
<b>Age Restrictions</b>	Non-small cell lung cancer: 18 years of age or older. Medullary thyroid cancer and thyroid cancer: 12 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent rearranged during transfection (RET) rearrangement-positive non-small cell lung cancer
<b>Part B Prerequisite</b>	No

# GILENYA

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## Products Affected

- Fingolimod HCl

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved 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>	For non-small cell lung cancer (NSCLC): Patient meets either of the following: 1) Patient has metastatic squamous NSCLC that progressed after platinum-based chemotherapy, OR 2) Patient has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# GLATIRAMER

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## Products Affected

- Glatiramer Acetate
- Glatopa

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# GRALISE

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## Products Affected

- Gralise Oral Tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Postherpetic neuralgia: The patient has experienced an inadequate treatment response or intolerance to gabapentin immediate-release.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# GROWTH HORMONE

## Products Affected

- Genotropin MiniQuick Subcutaneous Prefilled Syringe
- Genotropin Subcutaneous Cartridge

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Adult GHD: Pt meets any of the following: 1) failed 2 pre-tx GH stimulation tests, OR 2) pre-tx IGF-1 more than 2 SD below mean AND failed 1 pre-tx GH stimulation test. (Note: Stimulation tests include: a) insulin tolerance test [ITT] [peak GH less than or equal to 5 ng/ml], or b) Macrilen-stimulation test [peak GH level less than 2.8ng/ml], or c) glucagon-stimulation test [GST] [peak GH level less than or equal to 3 ng/ml] for pt with a body mass index [BMI] 25-30 kg/m2 and high pretest probability of GHD [e.g., acquired structural abnormalities] or BMI less than 25 kg/m2, or d) GST [peak GH level less than or equal to 1 ng/ml] in pt with BMI 25-30 kg/m2 and low pretest probability of GHD or BMI greater than 30 kg/m2), OR 3) organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with 3 or more pituitary hormone deficiencies AND pre-tx IGF-1 more than 2 SD below mean, OR 4) genetic or structural hypothalamic-pituitary defects, OR 5) childhood-onset GHD with congenital (genetic or structural) abnormality of the hypothalamus/pituitary/CNS. Renewal for pediatric GHD, TS, SGA, and adult GHD: Patient is experiencing improvement.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HAEGARDA

## Products Affected

- Haegarda

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For hereditary angioedema: The requested drug is being used for the prevention of acute angioedema attacks. Patient has hereditary angioedema (HAE) with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR patient has hereditary angioedema with normal C1 inhibitor confirmed by laboratory testing. For patients with HAE with normal C1 inhibitor, EITHER 1) Patient tested positive for an F12, angiotensin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation OR 2) Patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month.
<b>Age Restrictions</b>	6 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HARVONI

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## Products Affected

- Harvoni

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases (AASLD) treatment guidelines.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria applied consistent w/ current AASLD-IDSA guidance. Reminder for 8wk option if appropriate.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HERCEPTIN

## Products Affected

- Herceptin Intravenous Solution Reconstituted  
150 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Neoadjuvant therapy for breast cancer: 6 months, Other: Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent or advanced unresectable HER2-positive breast cancer, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer in combination with pertuzumab, tucatinib, or lapatinib, HER2-positive recurrent salivary gland tumor.
<b>Part B Prerequisite</b>	No

# HERCEPTIN HYLECTA

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## Products Affected

- Herceptin Hylecta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Neoadjuvant therapy for breast cancer: 6 months, Other: Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent or advanced unresectable HER2-positive breast cancer.
Part B Prerequisite	No



# HERZUMA

## Products Affected

- Herzuma

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Neoadjuvant therapy for breast cancer: 6 months, Other: Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent or advanced unresectable HER2-positive breast cancer, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer in combination with pertuzumab, tucatinib, or lapatinib, HER2-positive recurrent salivary gland tumor.
<b>Part B Prerequisite</b>	No

# HETLIOZ

## Products Affected

- Tasimelteon

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For Non-24-Hour Sleep-Wake Disorder: 1) for initial therapy and continuation of therapy: a) diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas) and b) unable to perceive light in either eye, AND 2) if currently on therapy with the requested drug, patient must meet at least one of the following: a) increased total nighttime sleep or b) decreased daytime nap duration. For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS): 1) for initial therapy and continuation therapy, the patient has a confirmed diagnosis of SMS AND 2) if currently on therapy with the requested drug, the patient experiences improvement in the quality of sleep since starting therapy.
<b>Age Restrictions</b>	Non-24: 18 years of age or older. SMS: 16 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with sleep disorder specialist or neurologist
<b>Coverage Duration</b>	Initiation: 6 Months, Renewal: Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HRM-ANTICONVULSANTS

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## Products Affected

- PHENobarbital Oral Elixir
- PHENobarbital Oral Tablet
- PHENobarbital Sodium Injection

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Epilepsy
<b>Part B Prerequisite</b>	No

# HRM-ANTIPARKINSON

## Products Affected

- Benztropine Mesylate Oral
- Trihexyphenidyl HCl

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. EPS (extrapyramidal symptoms): 1) The patient has not tried the non-HRM alternative drug amantadine AND 2) The patient has a contraindication to the non-HRM alternative drug amantadine OR 3) The patient has tried the non-HRM alternative drug amantadine AND 4) The patient experienced an inadequate treatment response OR intolerance to the non-HRM alternative drug amantadine.</p> <p>Parkinson's: 1) The patient has tried two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole. AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HRM-CYPROHEPTADINE

## Products Affected

- Cyproheptadine HCl Oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Pruritus, spasticity due to spinal cord injury
<b>Part B Prerequisite</b>	No

# HRM-DIPYRIDAMOLE

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## Products Affected

- Dipyridamole Oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HRM-GUANFACINE ER

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## Products Affected

- guanFACINE HCl ER

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HRM-GUANFACINE IR

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## Products Affected

- guanFACINE HCl Oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# HRM-HYDROXYZINE

## Products Affected

- hydroXYzine HCl Oral Syrup
- hydroXYzine HCl Oral Tablet
- hydroXYzine Pamoate Oral Capsule 25 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release OR 3) The patient has not tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 4) The patient has acute anxiety. For all indications: 1) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. AND 2) If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, cyclobenzaprine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

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

# HRM-HYDROXYZINE INJ

## Products Affected

- HydrOXYzine HCl Intramuscular

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For alcohol withdrawal syndrome: 1) The patient has not tried one of the following alternative drugs: clorazepate or lorazepam AND 2) The patient has a contraindication to one of the following alternative drugs: clorazepate or lorazepam OR 3) The patient has tried one of the following alternative drugs: clorazepate or lorazepam AND 4) The patient experienced an inadequate treatment response OR intolerance to one of the following alternative drugs: clorazepate or lorazepam. For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release OR 3) The patient has not tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 4) The patient has acute anxiety.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

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

# HRM-HYPNOTICS

## Products Affected

- Zolpidem Tartrate Oral Tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For insomnia: 1) The patient meets one of the following: a) the patient has a contraindication to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) OR b) The non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) has been tried AND the patient experienced an inadequate treatment response OR intolerance to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) AND 2) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient AND 3) If the patient is using two or more additional central nervous system (CNS) active medications (e.g., lorazepam, quetiapine, sertraline, clonazepam, escitalopram, alprazolam) with the requested drug, the prescriber has determined that taking multiple central nervous system (CNS) active medications is medically necessary for the patient [Note: Use of multiple central nervous system (CNS) active medications in older adults is associated with an increased risk of falls.].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) APPLIES TO GREATER THAN CUMULATIVE 90 DAYS OF THERAPY PER YEAR.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

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

# HRM-PROMETHAZINE

## Products Affected

- Promethazine HCl Injection
- Promethazine HCl Oral Syrup
- Promethazine HCl Oral Tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HRM-SCOPOLAMINE

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## Products Affected

- Scopolamine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Excessive salivation
<b>Part B Prerequisite</b>	No



# HRM-SKELETAL MUSCLE RELAXANTS

## Products Affected

- Cyclobenzaprine HCl Oral Tablet 10 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. AND 2) If the patient is using one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, hydroxyzine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HUMIRA

## Products Affected

- Humira Pediatric Crohns Start Subcutaneous Prefilled Syringe Kit 80 MG/0.8ML, 80 MG/0.8ML & 40MG/0.4ML
- Humira Pen Subcutaneous Pen-Injector Kit
- Humira Pen-CD/UC/HS Starter
- Humira Pen-Pediatric UC Start
- Humira Pen-Ps/UV/Adol HS Start Subcutaneous Pen-Injector Kit 40 MG/0.8ML
- Humira Pen-Psor/Uveit Starter
- Humira Subcutaneous Prefilled Syringe Kit 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For moderately to severely active rheumatoid arthritis (new starts only): 1) Inadequate response, intolerance or contraindication to methotrexate (MTX) OR 2) Inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and axial spondyloarthritis (new starts only): 1) Inadequate response to a non-steroidal anti-inflammatory drug (NSAID) trial OR 2) Intolerance or contraindication to NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) Patient meets any of the following: a) Patient has experienced an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, OR b) Pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, OR c) Patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected). For moderately to severely active Crohn's disease (new starts only): 1) Inadequate response to at least one conventional therapy (e.g., corticosteroids), OR 2) Intolerance or contraindication to conventional therapy. For moderately to severely active ulcerative colitis (new starts only): 1) Inadequate response to at least one conventional therapy (e.g., corticosteroids), OR 2) Intolerance or contraindication to conventional therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Axial spondyloarthritis, Behcet's syndrome
<b>Part B Prerequisite</b>	No

# IBRANCE

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## Products Affected

- Ibrance

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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Unresectable well-differentiated/dedifferentiated liposarcoma of the retroperitoneum, recurrent hormone receptor-positive human epidermal growth factor receptor 2 (HER2)-negative breast cancer
<b>Part B Prerequisite</b>	No

# ICATIBANT

## Products Affected

- Icatibant Acetate Subcutaneous Solution Prefilled Syringe
- Sajazir Subcutaneous Solution Prefilled Syringe

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For hereditary angioedema (HAE): The requested drug is being used for the treatment of acute angioedema attacks. Patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR patient has HAE with normal C1 inhibitor confirmed by laboratory testing. For patients with HAE with normal C1 inhibitor, EITHER 1) Patient tested positive for an F12, angiotensin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation OR 2) Patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ICLUSIG

## Products Affected

- Iclusig

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For chronic myeloid leukemia (CML) or acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For CML, including patients who have received a hematopoietic stem cell transplant: 1) patient has accelerated or blast phase CML and no other kinase inhibitor is indicated, OR 2) patient has chronic phase CML and has experienced resistance or intolerance to at least 2 prior kinase inhibitors AND at least one of those was imatinib or dasatinib, OR 3) patient is positive for the T315I mutation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Myeloid and/or lymphoid neoplasms with eosinophilia and FGFR1 or ABL1 rearrangement in the chronic phase or blast phase
<b>Part B Prerequisite</b>	No

# IDHIFA

## Products Affected

- IDHIFA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation: 1) patient is 60 years of age or older with newly-diagnosed AML and meets one of the following: a) patient is not a candidate for intensive induction therapy, or b) patient declines intensive induction chemotherapy, OR 2) patient is 60 years of age or older and the requested drug will be used as post-induction therapy following response to induction therapy with the requested drug OR 3) patient has relapsed or refractory AML.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Newly-diagnosed acute myeloid leukemia
<b>Part B Prerequisite</b>	No

# IMATINIB

## Products Affected

- Imatinib Mesylate

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), including patients who have received a hematopoietic stem cell transplant: diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For CML: patient did not fail (excluding failure due to intolerance) prior therapy with a tyrosine kinase inhibitor. For melanoma: c-Kit mutation is positive.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Desmoid tumors, pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT), recurrent chordoma, melanoma, Kaposi sarcoma, chronic myelomonocytic leukemia, chronic graft versus host disease (cGVHD), T-cell acute lymphoblastic leukemia with ABL-class translocation, aggressive systemic mastocytosis for well-differentiated systemic mastocytosis (WDSM) or when eosinophilia is present with FIP1L1-PDGFRB fusion gene, myeloid and/or lymphoid neoplasms with eosinophilia and ABL1, FIP1L1-PDGFRB, or PDGFRB rearrangement in the chronic phase or blast phase
<b>Part B Prerequisite</b>	No



# IMBRUVICA

## Products Affected

- Imbruvica

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For mantle cell lymphoma: 1) the requested drug will be used as second-line or subsequent therapy, OR 2) the requested drug will be used in combination with rituximab as pretreatment to induction therapy with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen, OR 3) the requested drug will be used as aggressive induction therapy. For marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, and splenic marginal zone lymphoma): the requested drug will be used as second-line or subsequent therapy. For hairy cell leukemia: the requested drug will be used as a single agent for disease progression. For primary CNS lymphoma: 1) the disease is relapsed or refractory OR 2) the requested drug is used for induction therapy as a single agent. For diffuse large B-cell lymphoma and high-grade B-cell lymphoma: the requested drug will be used as second-line or subsequent therapy. For AIDS-related B-cell lymphoma: the requested drug will be used as a single agent and as second-line or subsequent therapy for relapsed disease. For post-transplant lymphoproliferative disorders: the requested drug will be used in patients who have received prior chemoimmunotherapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	Hairy cell leukemia, lymphoplasmacytic lymphoma, primary central nervous system (CNS) lymphoma, AIDS-related B-cell lymphoma, diffuse large B-cell lymphoma, post-transplant lymphoproliferative disorders, high-grade B-cell lymphoma, mantle cell lymphoma, marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, splenic marginal zone lymphoma)
<b>Part B Prerequisite</b>	No

# INCRELEX

## Products Affected

- Increlex

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pediatric patients with closed epiphyses
<b>Required Medical Information</b>	For growth failure due to severe primary insulin-like growth factor-1 (IGF-1) deficiency or growth hormone (GH) gene deletion in patients who have developed neutralizing antibodies to GH, patient meets all of the following prior to beginning therapy with the requested drug (new starts only): 1) height 3 or more standard deviations (SD) below the mean for children of the same age and gender AND 2) basal IGF-1 level 3 or more SD below the mean for children of the same age and gender AND 3) provocative growth hormone test showing a normal or elevated growth hormone level. For growth failure due to severe primary IGF-1 deficiency or GH gene deletion in patients who have developed neutralizing antibodies to GH, continuation of therapy: patient is experiencing improvement.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# INGREZZA

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## Products Affected

- Ingrezza

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# INLYTA

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## Products Affected

- Inlyta

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For renal cell carcinoma: The disease is advanced, relapsed, or stage IV.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Thyroid carcinoma (papillary, Hurthle cell, or follicular)
<b>Part B Prerequisite</b>	No

# INQOVI

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## Products Affected

- Inqovi

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# INREBIC

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## Products Affected

- Inrebic

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement: the disease is in chronic or blast phase.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and janus kinase 2 (JAK2) rearrangement, accelerated phase myelofibrosis, blast phase myelofibrosis/acute myeloid leukemia
<b>Part B Prerequisite</b>	No

# IR BEFORE ER

## Products Affected

- Hysingla ER
- Methadone HCl Intensol
- Methadone HCl Oral Solution
- Methadone HCl Oral Tablet
- Morphine Sulfate ER Oral Tablet Extended Release

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe enough to require daily, around-the-clock, long-term treatment in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# IRESSA

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## Products Affected

- Gefitinib
- Iressa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For non-small cell lung cancer (NSCLC): 1) disease must be metastatic, advanced, or recurrent AND 2) patient must have a sensitizing EGFR mutation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Sensitizing epidermal growth factor receptor (EGFR) mutation-positive recurrent non-small cell lung cancer (NSCLC).
<b>Part B Prerequisite</b>	No

# ISOTRETINOIN

## Products Affected

- Accutane 40 MG
- Amnesteem • Zenatane
- Claravis
- ISOTretinoin Oral Capsule 10 MG, 20 MG, 30 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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Refractory acne vulgaris, severe refractory rosacea, neuroblastoma, cutaneous T-cell lymphoma (CTCL) (e.g., mycosis fungoides, Sezary syndrome), high risk for developing skin cancer (squamous cell cancers), transient acantholytic dermatosis (Grover's Disease), keratosis follicularis (Darier Disease), lamellar ichthyosis, pityriasis rubra pilaris.
<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>	The requested drug will be used orally. For the treatment of onychomycosis due to dermatophytes ( <i>Tinea unguium</i> ), the diagnosis has been confirmed by a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Disseminated/CNS histoplasmosis, Histoplasmosis/Coccidioidomycosis/CGD ppx: 12 mths. Others: 6 mths
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Coccidioidomycosis, Coccidioidomycosis prophylaxis in HIV infection, Cryptococcosis, Microsporidiosis, Talaromycosis (formerly Penicilliosis), Histoplasmosis prophylaxis in HIV infection, Invasive fungal infection prophylaxis in liver transplant, chronic granulomatous disease (CGD), and hematologic malignancy, Sporotrichosis, Pityriasis versicolor, Tinea versicolor, Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis.
<b>Part B Prerequisite</b>	No

# IVERMECTIN TAB

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## Products Affected

- Ivermectin Oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The requested drug is not being prescribed for the prevention or treatment of coronavirus disease 2019 (COVID-19).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Ascariasis, Cutaneous larva migrans, Mansonelliasis, Scabies, Gnathostomiasis, Pediculosis
<b>Part B Prerequisite</b>	No

# IVIG

## Products Affected

- Bivigam GM/100ML, 20 GM/200ML, 5 GM/50ML
- Flebogamma DIF Intravenous Solution 10 GM/100ML, 10 GM/200ML, 2.5 GM/50ML, 20 GM/200ML, 20 GM/400ML, 5 GM/100ML, 5 GM/50ML
- Gammagard
- Gammagard S/D Less IgA
- Gammaked Injection Solution 1 GM/10ML, 10 GM/100ML, 20 GM/200ML, 5 GM/50ML
- Gammaplex Intravenous Solution 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 20 GM/400ML, 5 GM/100ML, 5 GM/50ML
- Gamunex-C
- Octagam
- Panzyga
- Privigen

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For B-cell chronic lymphocytic leukemia (CLL): 1) serum IgG less than 500 mg/dL OR 2) a history of recurrent bacterial infections. For bone marrow transplant/hematopoietic stem cell transplant (BMT/HSCT): 1) IVIG is requested within the first 100 days post-transplant OR 2) serum IgG less than 400 mg/dL. For pediatric human immunodeficiency virus (HIV) infection: 1) serum IgG less than 400 mg/dL OR 2) history of recurrent bacterial infections. For dermatomyositis and polymyositis: 1) at least one standard first-line treatment (corticosteroid or immunosuppressant) has been tried but was unsuccessful or not tolerated OR 2) patient is unable to receive standard therapy because of a contraindication or other clinical reason. For pure red cell aplasia (PRCA): PRCA is secondary to parvovirus B19 infection.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# JAKAFI

## Products Affected

- Jakafi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For polycythemia vera: patient had an inadequate response or intolerance to interferon therapy or hydroxyurea. For acute lymphoblastic leukemia: patient has a cytokine receptor-like factor 2 (CRLF2) mutation or a mutation associated with activation of the Janus kinase/signal transducers and activators of transcription (JAK/STAT) pathway. For CMML-2: the requested drug is used in combination with a hypomethylating agent. For BCR-ABL negative aCML: the requested drug is used as a single agent or in combination with a hypomethylating agent. For essential thrombocythemia: patient had an inadequate response or loss of response to hydroxyurea, interferon therapy, or anagrelide. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement: the disease is in chronic or blast phase.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Lower-risk myelofibrosis, accelerated phase myelofibrosis, blast phase myelofibrosis/acute myeloid leukemia, acute lymphoblastic leukemia (ALL), chronic myelomonocytic leukemia (CMML)-2, BCR-ABL negative atypical chronic myeloid leukemia (aCML), essential thrombocythemia, and myeloid, lymphoid or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement
<b>Part B Prerequisite</b>	No

# JAYPIRCA

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## Products Affected

- Jaypirca

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# KALYDECO

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## Products Affected

- Kalydeco Oral Packet 13.4 MG, 25 MG, 50 MG, 75 MG
- Kalydeco Oral Tablet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For cystic fibrosis (CF): The requested medication will not be used in combination with other medications containing ivacaftor.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# KANJINTI

## Products Affected

- Kanjinti

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Neoadjuvant therapy for breast cancer: 6 months, Other: Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent or advanced unresectable HER2-positive breast cancer, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer in combination with pertuzumab, tucatinib, or lapatinib, HER2-positive recurrent salivary gland tumor.
<b>Part B Prerequisite</b>	No

# KETOCONAZOLE

## Products Affected

- Ketoconazole Oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute or chronic liver disease. Concurrent use with drugs that are contraindicated with ketoconazole tablets: dofetilide, quinidine, pimozone, cisapride, methadone, disopyramide, dronedarone, ranolazine, ergot alkaloids, irinotecan, lurasidone, oral midazolam, alprazolam, triazolam, felodipine, nisoldipine, tolvaptan, eplerenone, lovastatin, simvastatin, or colchicine.
<b>Required Medical Information</b>	The potential benefits outweigh the risks of treatment with oral ketoconazole. For systemic fungal infections, the patient has any of the following diagnoses: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis. For Cushing's syndrome: the requested drug is being prescribed for a patient who cannot tolerate surgery or where surgery has not been curative.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Cushing's syndrome
<b>Part B Prerequisite</b>	No

# KEVZARA

## Products Affected

- Kevzara

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For moderately to severely active rheumatoid arthritis (new starts only): 1) Inadequate response, intolerance or contraindication to methotrexate (MTX) OR 2) Inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For polymyalgia rheumatica (PMR) (new starts only): 1) The patient has experienced an inadequate treatment response to corticosteroids OR 2) The patient has experienced a disease flare while attempting to taper corticosteroids.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# KEYTRUDA

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## Products Affected

- Keytruda Intravenous Solution

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

# KISQALI

## Products Affected

- Kisqali (200 MG Dose)
- Kisqali (400 MG Dose)
- Kisqali (600 MG Dose)
- Kisqali Femara (200 MG Dose)
- Kisqali Femara (400 MG Dose)
- Kisqali Femara (600 MG Dose)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer, in combination with an aromatase inhibitor, or fulvestrant.
<b>Part B Prerequisite</b>	No

# KORLYM

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## Products Affected

- Korlym

<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>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved 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>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LAPATINIB

## Products Affected

- Lapatinib Ditosylate

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For breast cancer, the patient meets all the following: a) the disease is recurrent, advanced, or metastatic (including brain metastases), b) the disease is human epidermal growth factor receptor 2 (HER2)-positive, c) the requested drug will be used in combination with any of the following: 1) aromatase inhibitor, 2) capecitabine, OR 3) trastuzumab.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Brain metastases from human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent HER2-positive breast cancer, recurrent epidermal growth factor receptor (EGFR)-positive chordoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer in combination with trastuzumab.
<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>	For differentiated thyroid cancer (follicular, papillary, or Hurthle cell): disease is not amenable to radioactive iodine therapy and unresectable, locally recurrent, persistent, or metastatic. For hepatocellular carcinoma: disease is unresectable or inoperable, local, metastatic or with extensive liver tumor burden. For renal cell carcinoma, the disease is advanced, relapsed, or stage IV. For endometrial carcinoma, the patient meets ALL of the following: 1) The disease is advanced, recurrent, or metastatic, 2) The patient experienced disease progression following prior systemic therapy, AND 3) The patient is not a candidate for curative surgery or radiation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Medullary thyroid carcinoma, recurrent endometrial carcinoma, thymic carcinoma
<b>Part B Prerequisite</b>	No

# LEUPROLIDE

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## Products Affected

- Leuprolide Acetate Injection

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Use in combination with growth hormone for children with growth failure and advancing puberty, recurrent androgen receptor positive salivary gland tumors
<b>Part B Prerequisite</b>	No

# LIDOCAINE PATCHES

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## Products Affected

- Lidocaine External Patch 5 %

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Pain associated with diabetic neuropathy, pain associated with cancer-related neuropathy (including treatment-related neuropathy [e.g., neuropathy associated with radiation treatment or chemotherapy]).
<b>Part B Prerequisite</b>	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>	For colorectal cancer: The disease is advanced or metastatic. For gastric or gastroesophageal junction adenocarcinoma, all of the following criteria must be met: 1) The disease is unresectable locally advanced, recurrent, or metastatic, and 2) The patient has been previously treated with at least two prior lines of chemotherapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LORBRENA

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## Products Affected

- Lorbrena

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For recurrent, advanced, or metastatic non-small cell lung cancer: 1) Disease is anaplastic lymphoma kinase (ALK)-positive OR 2) Disease is positive for repressor of silencing (ROS)-1 rearrangement and the requested drug is being used following disease progression on crizotinib, entrectinib, or ceritinib.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Anaplastic lymphoma kinase (ALK)-positive recurrent non-small cell lung cancer (NSCLC), repressor of silencing (ROS)-1 rearrangement-positive recurrent, advanced, or metastatic NSCLC.
<b>Part B Prerequisite</b>	No

# LUMAKRAS

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## Products Affected

- Lumakras

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LUMIZYME

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## Products Affected

- Lumizyme

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of Pompe disease was confirmed by an enzyme assay demonstrating a deficiency of acid alpha-glucosidase (GAA) enzyme activity or by genetic testing.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LUPRON PED

## Products Affected

- Lupron Depot-Ped (1-Month)
- Lupron Depot-Ped (3-Month)
- Lupron Depot-Ped (6-Month)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For central precocious puberty (CPP), patients not currently receiving therapy must meet all of the following criteria: 1) Diagnosis of CPP was confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test OR a pubertal level of a third generation luteinizing hormone (LH) assay, 2) Assessment of bone age versus chronological age supports the diagnosis of CPP, and 3) The onset of secondary sexual characteristics occurred prior to 8 years of age for female patients OR prior to 9 years of age for male patients.
<b>Age Restrictions</b>	CPP: Patient must be less than 12 years old if female and less than 13 years old if male.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# LUPRON-ENDOMETRIOSIS

## Products Affected

- Lupron Depot (1-Month) Intramuscular Kit 3.75 MG
- Lupron Depot (3-Month) Intramuscular Kit 11.25 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For uterine fibroids, patient must meet one of the following: 1) Diagnosis of anemia (e.g., hematocrit less than or equal to 30 percent and/or hemoglobin less than or equal to 10g/dL), OR 2) the requested medication will be used prior to surgery for uterine fibroids. For breast cancer, the requested drug is used for hormone receptor (HR)-positive disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Fibroids: 3 months (mo), max 6 mo total. Endometriosis: 6 mo, max 12 mo total. Others: Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Breast cancer, epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
<b>Part B Prerequisite</b>	No

# LYNPARZA

## Products Affected

- Lynparza Oral Tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For recurrent or metastatic breast cancer: the disease is BRCA 1/2-germline mutated. For prostate cancer: 1) The patient has a BRCA mutation and the requested drug will be used in combination with abiraterone and either prednisone or prednisolone OR 2) The patient has progressed on prior treatment with an androgen receptor-directed therapy. For epithelial ovarian, fallopian tube, or primary peritoneal cancer: The requested drug is used for maintenance therapy for stage II-IV or recurrent disease who are in complete or partial response to chemotherapy. For uterine leiomyosarcoma: 1) the requested drug is used as second-line therapy AND 2) the patient has BRCA-altered disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent HER2-negative, BRCA 1/2-germline mutated breast cancer, recurrent or metastatic HER2-positive, BRCA 1/2-germline mutated breast cancer, uterine leiomyosarcoma.
<b>Part B Prerequisite</b>	No

# LYRICA CR

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## Products Affected

- Lyrica CR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to gabapentin.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LYTGOBI

## Products Affected

- Lytgobi (12 MG Daily Dose)
- Lytgobi (16 MG Daily Dose)
- Lytgobi (20 MG Daily Dose)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For cholangiocarcinoma: 1) patient has a diagnosis of unresectable, locally advanced or metastatic cholangiocarcinoma, 2) patient has received a previous treatment, AND 3) patient disease has a fibroblast growth factor receptor 2 (FGFR2) gene fusion or other rearrangement.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Extrahepatic cholangiocarcinoma
<b>Part B Prerequisite</b>	No

# MAVYRET

## Products Affected

- Mavyret

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh [CTP] class B or C).
<b>Required Medical Information</b>	For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [CTP class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases (AASLD) treatment guidelines.
<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>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# MEGESTROL

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## Products Affected

- Megestrol Acetate Oral Suspension 625 MG/5ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient has experienced an inadequate treatment response or intolerance to megestrol 40 mg/mL oral suspension.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Cancer-related cachexia in adults
<b>Part B Prerequisite</b>	No

# MEKINIST

## Products Affected

- Mekinist

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For adjuvant treatment of melanoma,: 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), and 2) The requested drug will be used in combination with dabrafenib. For unresectable or metastatic melanoma: 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), and 2) The requested drug will be used as a single agent or in combination with dabrafenib. For brain metastases from melanoma, central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma), non-small cell lung cancer, solid tumors, and anaplastic thyroid cancer: 1) The tumor is positive for a BRAF V600E mutation, and 2) The requested drug will be used in combination with dabrafenib. For uveal melanoma, the requested drug will be used as a single agent. For low grade serous ovarian cancer and ovarian borderline epithelial tumors (low malignant potential) with invasive implants: The requested drug will be used to treat persistent or recurrent disease. For gallbladder cancer, intrahepatic cholangiocarcinoma, and extrahepatic cholangiocarcinoma: 1) The tumor is positive for a BRAF V600E mutation, 2) the disease is unresectable or metastatic, and 3) The requested drug will be used in combination with dabrafenib.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	Brain metastases from melanoma, uveal melanoma, central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma), low grade serous ovarian cancer, ovarian borderline epithelial tumors (low malignant potential) with invasive implants, Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai-Dorfman disease, gallbladder cancer, intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma
<b>Part B Prerequisite</b>	No



# MEKTOVI

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## Products Affected

- Mektovi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For cutaneous melanoma: The patient must meet all of the following criteria: 1) Tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), 2) The requested drug will be used in combination with encorafenib, and 3) The requested drug will be used for either of the following: a) unresectable or metastatic disease, or b) adjuvant systemic therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Adjuvant systemic therapy for cutaneous melanoma
<b>Part B Prerequisite</b>	No

# MEMANTINE

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## Products Affected

- Memantine HCl ER
- Memantine HCl Oral Solution 2 MG/ML
- Memantine HCl Oral Tablet 10 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This edit only applies to patients less than 30 years of age.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# METHYLPHENIDATE

## Products Affected

- Metadate ER Oral Tablet Extended Release 20 MG
- Methylphenidate HCl ER Oral Tablet Extended Release
- Methylphenidate HCl Oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The patient has a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) OR 2) The patient has a diagnosis of narcolepsy confirmed by a sleep study OR 3) The requested drug is being prescribed for the treatment of cancer-related fatigue after other causes of fatigue have been ruled out.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# MIGLUSTAT

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## Products Affected

- Miglustat

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For type 1 Gaucher disease (GD1): The diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# MODAFINIL

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## Products Affected

- Modafinil

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The patient has a diagnosis of narcolepsy and the diagnosis is confirmed by sleep lab evaluation OR 2) The patient has a diagnosis of Shift Work Disorder (SWD) OR 3) The patient has a diagnosis of obstructive sleep apnea (OSA) and the diagnosis is confirmed by polysomnography
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# MONJUVI

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## Products Affected

- Monjuvi

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# MVASI

## Products Affected

- Mvasi

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>	Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Breast cancer, central nervous system (CNS) tumor types: adult low-grade (WHO Grade I or II) glioma, adult intracranial and spinal ependymoma, anaplastic gliomas, adult medulloblastoma, primary central nervous system lymphoma, meningiomas, limited and extensive brain metastases, and metastatic spine tumors, malignant pleural mesothelioma, ovarian cancer/fallopian tube cancer/primary peritoneal cancer types: carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, mucinous carcinoma, grade 1 endometrioid carcinoma, low-grade serous carcinoma, ovarian borderline epithelial tumors (low malignant potential) with invasive implants, and malignant sex cord-stromal tumors, soft tissue sarcoma types: angiosarcoma and solitary fibrous tumor/hemangiopericytoma, uterine neoplasms, endometrial carcinoma, vulvar squamous cell carcinoma, and ophthalmic-related disorders: diabetic macular edema, neovascular (wet) age-related macular degeneration including polypoidal choroidopathy and retinal angiomatous proliferation subtypes, macular edema following retinal vein occlusion, proliferative diabetic retinopathy, choroidal neovascularization, neovascular glaucoma and retinopathy of prematurity, hepatocellular carcinoma, small bowel adenocarcinoma.

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



# NAGLAZYME

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## Products Affected

- Naglazyme

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of Mucopolysaccharidosis VI (Maroteaux-Lamy syndrome) was confirmed by an enzyme assay demonstrating a deficiency of N-acetylgalactosamine 4-sulfatase (arylsulfatase B) enzyme activity or by genetic testing.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# NATPARA

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## Products Affected

- Natpara

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Acute postsurgical hypoparathyroidism (within 6 months of surgery) and expected recovery from hypoparathyroidism.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# NERLYNX

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## Products Affected

- Nerlynx

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer, brain metastases from HER2-positive breast cancer.
<b>Part B Prerequisite</b>	No

# NEXAVAR

## Products Affected

- NexAVAR
- SORafenib Tosylate

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For acute myeloid leukemia: the disease is FMS-like tyrosine kinase 3-internal tandem duplication (FLT3-ITD) mutation-positive AND either of the following is met (1 OR 2): 1) the requested drug will be used as maintenance therapy after hematopoietic stem cell transplant, OR 2) the requested drug is used in combination with azacitidine or decitabine for low-intensity treatment induction or post-induction therapy AND either a) the patient has a physiologic age of 60 years of age or older or b) the disease is relapsed/refractory. For thyroid carcinoma: histology is follicular, papillary, Hurthle cell or medullary. For gastrointestinal stromal tumor (GIST): the disease is unresectable, recurrent, or metastatic AND the patient has failed on an FDA-approved therapy (e.g., imatinib, sunitinib, regorafenib, ripretinib). For renal cell carcinoma: the patient meets ALL of the following: 1) The disease is advanced, AND 2) The patient has experienced disease progression or an intolerable adverse event with a trial of cabozantinib or axitinib. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia: 1) The disease has a FLT3 rearrangement AND 2) The disease is in chronic or blast phase.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	Acute myeloid leukemia, soft tissue sarcoma (angiosarcoma, desmoid tumors/aggressive fibromatosis, and solitary fibrous tumor subtypes), gastrointestinal stromal tumor, medullary thyroid carcinoma, osteosarcoma, recurrent chordoma, epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia
<b>Part B Prerequisite</b>	No

# NINLARO

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## Products Affected

- Ninlaro

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Relapsed/refractory systemic light chain amyloidosis, Waldenstrom macroglobulinemia, lymphoplasmacytic lymphoma
<b>Part B Prerequisite</b>	No

# NITISINONE

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## Products Affected

- Nitisinone

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For hereditary tyrosinemia type 1 (HT-1): Diagnosis of HT-1 is confirmed by one of the following: 1) biochemical testing (e.g., detection of succinylacetone in urine) or 2) DNA testing (mutation analysis).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# NORTHERA

## Products Affected

- Droxidopa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For neurogenic orthostatic hypotension (nOH): Prior to initial therapy, patient has a persistent, consistent decrease in systolic blood pressure of at least 20 mmHg OR decrease in diastolic blood pressure of at least 10 mmHg within 3 minutes of standing or head-up tilt test. For continuation of therapy for nOH, patient must experience a sustained reduction in symptoms of nOH (i.e., decrease in dizziness, lightheadedness, or feeling faint). For both initial and continuation of therapy for nOH, the requested drug will be used for patients with neurogenic orthostatic hypotension associated with one of the following diagnoses: 1) primary autonomic failure due to Parkinson's disease, multiple system atrophy, or pure autonomic failure, OR 2) dopamine beta-hydroxylase deficiency, OR 3) non-diabetic autonomic neuropathy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# NOXAFIL SUSP

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## Products Affected

- Noxafil Oral Suspension
- Posaconazole Oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The requested drug will be used orally. For treatment of oropharyngeal candidiasis: patient has experienced an inadequate treatment response, intolerance, or has a contraindication to fluconazole.
<b>Age Restrictions</b>	13 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Oropharyngeal candidiasis: 1 month. All other indications: 6 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# NUBEQA

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## Products Affected

- Nubeqa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# NUEDEXTA

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## Products Affected

- Nuedexta

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# NUPLAZID

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## Products Affected

- Nuplazid Oral Capsule
- Nuplazid Oral Tablet 10 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For hallucinations and delusions associated with Parkinson's disease psychosis, the diagnosis of Parkinson's disease must be made prior to the onset of psychotic symptoms.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# NURTEC

## Products Affected

- Nurtec

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Acute migraine treatment: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to one triptan 5-HT <sub>1</sub> receptor agonist . Preventive treatment of migraine, initial: The patient meets either of the following: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants. Preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug, and the patient had a reduction in migraine days per month from baseline.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Preventive treatment of migraine - initial: 3 months, All other indications: Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# OCREVUS

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## Products Affected

- Ocrevus

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# OCTREOTIDE

## 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>	For acromegaly (initial): 1) patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, and 2) patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly continuation of therapy: patient's IGF-1 level has decreased or normalized since initiation of therapy. For tumor control of thymomas and thymic carcinomas, the requested drug will be used for any of the following: 1) locally advanced or metastatic disease, 2) postoperatively following tumor resection.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Tumor control of thymomas and thymic carcinomas.
<b>Part B Prerequisite</b>	No

# ODOMZO

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## Products Affected

- Odomzo

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# OFEV

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## Products Affected

- Ofev

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# OGIVRI

## Products Affected

- Ogivri

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Neoadjuvant therapy for breast cancer: 6 months, Other: Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent or advanced unresectable HER2-positive breast cancer, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer in combination with pertuzumab, tucatinib, or lapatinib, HER2-positive recurrent salivary gland tumor.
<b>Part B Prerequisite</b>	No

# OMNIPOD

## Products Affected

- Omnipod 5 G6 Intro (Gen 5)
- Omnipod 5 G6 Pod (Gen 5)
- Omnipod Classic PDM (Gen 3)
- Omnipod Classic Pods (Gen 3)
- Omnipod DASH Intro (Gen 4)
- Omnipod DASH Pods (Gen 4)
- Omnipod Go

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: 1) The patient has diabetes requiring insulin management with multiple daily injections AND 2) The patient is self-testing glucose levels 4 or more times per day OR the patient is using a continuous glucose monitor AND 3) The patient has experienced any of the following with the current diabetes regimen: inadequate glycemic control, recurrent hypoglycemia, wide fluctuations in blood glucose, dawn phenomenon with persistent severe early morning hyperglycemia, severe glycemic excursions. Continuation: the patient has stable or improved glycemic control.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ONTRUZANT

## Products Affected

- Ontruzant

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Neoadjuvant therapy for breast cancer: 6 months, Other: Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent or advanced unresectable HER2-positive breast cancer, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer in combination with pertuzumab, tucatinib, or lapatinib, HER2-positive recurrent salivary gland tumor.
<b>Part B Prerequisite</b>	No

# ONUREG

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## Products Affected

- Onureg

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# OPSUMIT

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## Products Affected

- Opsumit

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): Diagnosis was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ORAL-INTRANASAL FENTANYL

## Products Affected

- FentaNYL Citrate Buccal Lozenge On A Handle

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The requested drug is indicated for the treatment of breakthrough CANCER-related pain only. The requested drug is being prescribed for the management of breakthrough pain in a CANCER patient with underlying CANCER pain AND 2) The International Classification of Diseases (ICD) diagnosis code provided supports the CANCER-RELATED diagnosis. [Note: For drug coverage approval, ICD diagnosis code provided MUST support the CANCER-RELATED diagnosis.] AND 3) The patient is currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying CANCER pain AND 4) The requested drug is intended only for use in opioid tolerant patients. The patient can safely take the requested dose based on their current opioid use history. [Note: Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 60 mg of oral hydrocodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, or an equianalgesic dose of another opioid medication daily for one week or longer.].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ORGOVYX

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## Products Affected

- Orgovyx

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# ORKAMBI

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## Products Affected

- Orkambi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For cystic fibrosis (CF): The requested medication will not be used in combination with other medications containing ivacaftor.
<b>Age Restrictions</b>	1 year of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ORSERDU

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## Products Affected

- Orserdu

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

# OTEZLA

## Products Affected

- Otezla

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For plaque psoriasis (new starts only): Patient meets either of the following: 1) Inadequate treatment response or intolerance to ANY of the following: a) a topical therapy (e.g., topical corticosteroids, calcineurin inhibitors, vitamin D analogs), b) phototherapy (e.g., UVB, PUVA), or c) pharmacologic treatment with methotrexate, cyclosporine, or acitretin, OR 2) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# OZEMPIC

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## Products Affected

- Ozempic (0.25 or 0.5 MG/DOSE)
- Ozempic (1 MG/DOSE) Subcutaneous Solution  
Pen-Injector 4 MG/3ML
- Ozempic (2 MG/DOSE)

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PANRETIN

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## Products Affected

- Panretin

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Topical treatment of cutaneous lesions in patients with non-AIDS-related Kaposi sarcoma
<b>Part B Prerequisite</b>	No

# PEGASYS

## Products Affected

- Pegasys Subcutaneous Solution 180 MCG/ML
- Pegasys Subcutaneous Solution Prefilled Syringe

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For chronic hepatitis C: Hepatitis C virus (HCV) confirmed by presence of hepatitis C virus HCV RNA in serum prior to starting treatment and the planned treatment regimen.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	HCV: 12-48wks. Criteria applied consistent w/current AASLD/IDSA guidance. HBV: 48wks. Other: Plan Yr
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower-risk myelofibrosis), systemic mastocytosis, adult T-cell leukemia/lymphoma, mycosis fungoides/sezary syndrome, primary cutaneous CD30+ T-cell lymphoproliferative disorders, hairy cell leukemia, Erdheim-Chester disease.
<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>	For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FGFR1 rearrangement: the disease is in chronic or blast phase.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PHENYL BUTYRATE

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## 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>	For urea cycle disorders (UCD): Diagnosis of UCD was confirmed by enzymatic, biochemical or genetic testing.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved 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>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Neoadjuvant therapy for breast cancer: 6 months. Other: Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer
<b>Part B Prerequisite</b>	No

# PHYTONADIONE TABLETS

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## Products Affected

- Phytonadione Tablet 5 MG Oral

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved 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>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated breast cancer in combination with fulvestrant.
<b>Part B Prerequisite</b>	No

# POMALYST

## Products Affected

- Pomalyst

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For multiple myeloma: The patient has previously received at least two prior therapies for multiple myeloma, including an immunomodulatory agent AND a proteasome inhibitor. For Kaposi sarcoma, patient meets one of the following: 1) patient has acquired immunodeficiency syndrome (AIDS), or 2) patient is negative for human immunodeficiency virus (HIV).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Relapsed/refractory systemic light chain amyloidosis, primary central nervous system (CNS) lymphoma, POEMS syndrome.
<b>Part B Prerequisite</b>	No

# POSACONAZOLE

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## Products Affected

- Posaconazole Oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The requested drug will be used orally. For prophylaxis of invasive Aspergillus and Candida infections: patient weighs greater than 40 kilograms.
<b>Age Restrictions</b>	Treatment of Invasive Aspergillosis: 13 years of age or older, Prophylaxis of Invasive Aspergillus and Candida Infections: 2 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PRALUENT

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## Products Affected

- Praluent Subcutaneous Solution Auto-Injector

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PREVYMIS

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## Products Affected

- Prevymis Oral

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For prophylaxis of cytomegalovirus (CMV) infection or disease in hematopoietic stem cell transplant (HSCT): 1) the patient is CMV-seropositive, AND 2) the patient is a recipient of an allogeneic HSCT. For prophylaxis of CMV disease in kidney transplant: 1) the patient is CMV-seronegative, AND 2) the patient is a high risk recipient of kidney transplant.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	7 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PRILOSEC POWDER

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## Products Affected

- PriLOSEC Oral Packet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient is unable to take oral solid dosage forms for any reason (e.g., difficulty swallowing tablets or capsules, requires administration via feeding tube).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Treatment and prevention of nonsteroidal anti-inflammatory drug-induced gastrointestinal ulcer, esophageal strictures, dyspepsia, maintenance treatment of duodenal ulcers
<b>Part B Prerequisite</b>	No



# PROCRIT

## Products Affected

- Procrit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients receiving chemotherapy with curative intent. Patients with myeloid cancer.
<b>Required Medical Information</b>	Requirements regarding hemoglobin (Hgb) values exclude values due to a recent transfusion. For initial approval: 1) for all uses except anemia due to chemotherapy or myelodysplastic syndrome (MDS): patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%), AND 2) for all uses except surgery: pretreatment (no erythropoietin treatment in previous month) Hgb is less than 10 g/dL (less than 9 g/dL for anemia in congestive heart failure), AND 3) for MDS: pretreatment serum erythropoietin level is 500 international units/L or less. For reauthorizations (patient received erythropoietin treatment in previous month) in all uses except surgery: 1) patient has received at least 12 weeks of erythropoietin therapy, AND 2) patient responded to erythropoietin therapy, AND 3) current Hgb is less than 12 g/dL, AND 4) for all uses except anemia due to chemotherapy or MDS: patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	16 weeks
<b>Other Criteria</b>	Coverage includes use in anemia in patients whose religious beliefs forbid blood transfusions. Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual (e.g., used for treatment of anemia for a patient with chronic renal failure who is undergoing dialysis, or furnished from physician's supply incident to a physician service).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	Anemia due to myelodysplastic syndromes (MDS), anemia in congestive heart failure (CHF), anemia in rheumatoid arthritis (RA), anemia due to hepatitis C treatment (ribavirin in combination with either interferon alfa or peginterferon alfa)
<b>Part B Prerequisite</b>	No

# PROMACTA

## Products Affected

- Promacta

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For chronic or persistent immune thrombocytopenia (ITP): 1) For new starts: a) Patient (pt) has had an inadequate response or is intolerant to a prior therapy such as corticosteroids or immunoglobulins, b) Untransfused platelet (plt) count at any point prior to the initiation of the requested medication is less than 30,000/mcL OR 30,000-50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes pt to trauma) AND c) For chronic ITP only: pt has had an inadequate response or intolerance to avatrombopag. 2) For continuation of therapy, plt count response to the requested drug: a) Current plt count is less than or equal to 200,000/mcL OR b) Current plt count is greater than 200,000/mcL to less than or equal to 400,000/mcL and dosing will be adjusted to a plt count sufficient to avoid clinically important bleeding. For thrombocytopenia associated with chronic hepatitis C: 1) For new starts: the requested drug is used for initiation and maintenance of interferon-based therapy. 2) For continuation of therapy: pt is receiving interferon-based therapy. For severe aplastic anemia (AA): 1) For new starts: a) Pt will use the requested drug with standard immunosuppressive therapy for first line treatment OR b) the pt had an insufficient response to immunosuppressive therapy. 2) For continuation of therapy : 1) Current plt count is 50,000-200,000/mcL OR 2) Current plt count is less than 50,000/mcL and pt has not received appropriately titrated therapy for at least 16 weeks, OR 3) Current plt count is less than 50,000/mcL and pt is transfusion-independent, OR 4) Current plt count is greater than 200,000/mcL to less than or equal to 400,000/mcL and dosing will be adjusted to achieve and maintain an appropriate target plt count.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	HCV: 6mo, ITP/AA initial: 6mo, ITP reauth: Plan Year, AA reauth: APR-Plan Year, IPR-16 wks
<b>Other Criteria</b>	APR: adequate platelet response (greater than 50,000/mcL), IPR: inadequate platelet response (less than 50,000/mcL).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PULMOZYME

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## Products Affected

- Pulmozyme Inhalation Solution 2.5 MG/2.5ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For cystic fibrosis: Diagnosis of cystic fibrosis was confirmed by appropriate diagnostic or genetic testing.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# QINLOCK

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## Products Affected

- Qinlock

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# QUETIAPINE XR

## Products Affected

- QUETiapine Fumarate ER

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

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



# QUININE SULFATE

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## Products Affected

- QuiNINE Sulfate Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 month
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Babesiosis, uncomplicated Plasmodium vivax malaria.
Part B Prerequisite	No

# REGRANEX

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## Products Affected

- Regranex

<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>	20 weeks
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# RELISTOR INJ

## Products Affected

- Relistor Subcutaneous Solution

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For the treatment of opioid-induced constipation in a patient with chronic non-cancer pain, including chronic pain related to prior cancer or its treatment who does not require frequent (e.g., weekly) opioid dosage escalation: 1) the patient is unable to tolerate oral medications OR 2) the patient meets one of the following criteria A) experienced an inadequate treatment response or intolerance to an oral drug indicated for opioid-induced constipation in a patient with chronic non-cancer pain (e.g., Movantik) OR B) the patient has a contraindication that would prohibit a trial of an oral drug indicated for opioid-induced constipation in a patient with chronic non-cancer pain (e.g., Movantik).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	4 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# REMICADE

## Products Affected

- inFLIXimab
- Remicade

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For moderately to severely active Crohn's disease (new starts only): 1) Pt has fistulizing disease, OR 2) Inadequate response to at least one conventional therapy (e.g., corticosteroids), OR 3) Intolerance or contraindication (CI) to conventional therapy. For moderately to severely active ulcerative colitis (new starts only): 1) Inadequate response to at least one conventional therapy (e.g., corticosteroids) OR 2) Intolerance or CI to conventional therapy. For moderately to severely active rheumatoid arthritis (new starts only): 1) Pt meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) or leflunomide OR b) intolerance or CI to MTX AND leflunomide AND 2) Pt meets ANY of the following: a) inadequate response, intolerance or CI to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis (new starts only): Inadequate response to a non-steroidal anti-inflammatory drug (NSAID) trial OR intolerance or CI to NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at time of diagnosis, AND 2) Pt meets ANY of the following: a) pt has experienced inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with MTX, cyclosporine, or acitretin, OR b) pharmacologic treatment with MTX, cyclosporine, or acitretin is contraindicated, OR c) pt has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year

PA Criteria	Criteria Details
<b>Other Criteria</b>	For hidradenitis suppurativa (new starts only): Pt has severe, refractory disease. For uveitis (new starts only): Inadequate response or intolerance or has a CI to a trial of immunosuppressive therapy for uveitis. For FDA-approved indications and off-label uses that overlap: The patient had an intolerable adverse event to Renflexis and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Behcet's syndrome, granulomatosis with polyangiitis (Wegener's granulomatosis), hidradenitis suppurativa, juvenile idiopathic arthritis, pyoderma gangrenosum, sarcoidosis, Takayasu's arteritis, uveitis.
<b>Part B Prerequisite</b>	No

# RENFLEXIS

## Products Affected

- Renflexis

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For moderately to severely active Crohn's disease (new starts only): 1) Pt has fistulizing disease, OR 2) Inadequate response to at least one conventional therapy (e.g., corticosteroids), OR 3) Intolerance or contraindication (CI) to conventional therapy. For moderately to severely active ulcerative colitis (new starts only): 1) Inadequate response to at least one conventional therapy (e.g., corticosteroids) OR 2) Intolerance or CI to conventional therapy. For moderately to severely active rheumatoid arthritis (new starts only): 1) Pt meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) or leflunomide OR b) intolerance or CI to MTX AND leflunomide AND 2) pt meets ANY of the following: a) inadequate response, intolerance or CI to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis (new starts only): Inadequate response to a non-steroidal anti-inflammatory drug (NSAID) trial OR intolerance or CI to NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at time of diagnosis, AND 2) Pt meets ANY of the following: a) pt has experienced inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with MTX, cyclosporine, or acitretin, OR b) pharmacologic treatment with MTX, cyclosporine, or acitretin is contraindicated, OR c) pt has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year

PA Criteria	Criteria Details
<b>Other Criteria</b>	For hidradenitis suppurativa (new starts only): pt has severe, refractory disease. For uveitis (new starts only): Inadequate response or intolerance or has a CI to a trial of immunosuppressive therapy for uveitis.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Behcet's syndrome, granulomatosis with polyangiitis (Wegener's granulomatosis), hidradenitis suppurativa, juvenile idiopathic arthritis, pyoderma gangrenosum, sarcoidosis, Takayasu's arteritis, uveitis
<b>Part B Prerequisite</b>	No

# RETEVMO

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## Products Affected

- Retevmo

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For non-small cell lung cancer, patient must meet all of the following: 1) The disease is recurrent, advanced or metastatic, and 2) Tumor is RET fusion-positive or RET rearrangement-positive.
<b>Age Restrictions</b>	Non-small cell lung cancer: 18 years of age or older. Medullary thyroid cancer and thyroid cancer: 12 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent rearranged during transfection (RET)-rearrangement positive non-small cell lung cancer, Langerhans Cell Histiocytosis with a RET gene fusion, symptomatic or relapsed/refractory Erdheim-Chester Disease with a RET gene fusion, symptomatic or relapsed/refractory Rosai-Dorfman Disease with a RET gene fusion.
<b>Part B Prerequisite</b>	No



# REVLIMID

## Products Affected

- Lenalidomide
- Revlimid

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

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

# REZLIDHIA

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## Products Affected

- Rezlidhia

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved 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>	12 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# RINVOQ

## Products Affected

- Rinvoq

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For moderately to severely active rheumatoid arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance or has a contraindication to methotrexate (MTX) AND at least one tumor necrosis factor (TNF) inhibitor (e.g., Enbrel [etanercept], Humira [adalimumab]). For active psoriatic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance or has a contraindication to at least one TNF inhibitor (e.g., Enbrel [etanercept], Humira [adalimumab]). For moderately to severely active ulcerative colitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., Humira [adalimumab]). For moderately to severely active Crohn's disease (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least on TNF inhibitor (e.g., Humira [adalimumab]). For atopic dermatitis, continuation of therapy: the patient achieved or maintained positive clinical response. For active ankylosing spondylitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., Enbrel [etanercept], Humira [adalimumab]). For non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor.
<b>Age Restrictions</b>	Atopic dermatitis: 12 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Atopic dermatitis (initial): 4 months, All others: Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

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

# ROZLYTREK

## Products Affected

- Rozlytrek

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For all neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, the disease is without a known acquired resistance mutation. For ROS1-positive non-small cell lung cancer, the patient has recurrent, advanced, or metastatic disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent ROS1-positive non-small cell lung cancer (NSCLC), Non-metastatic neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, first-line treatment of NTRK gene fusion-positive solid tumors.
<b>Part B Prerequisite</b>	No

# RUBRACA

## Products Affected

- Rubraca

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For metastatic castration-resistant prostate cancer with a deleterious breast cancer susceptibility gene (BRCA) mutation (germline and/or somatic): 1) patient has been treated with androgen receptor-directed therapy, 2) patient has been treated with a taxane-based chemotherapy or the patient is not fit for chemotherapy, 3) the requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. For maintenance treatment of BRCA mutated epithelial ovarian, fallopian tube, primary peritoneal cancer: 1) the patient has advanced (stage II-IV) disease and is in complete or partial response to primary therapy or 2) the patient has recurrent disease and is in complete or partial response to platinum-based chemotherapy. For uterine leiomyosarcoma: 1) the requested drug is used as second-line therapy AND 2) the patient has BRCA-altered disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Uterine leiomyosarcoma, advanced (stage II-IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer
<b>Part B Prerequisite</b>	No



# RYBELSUS

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## Products Affected

- Rybelsus

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

# RYDAPT

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## Products Affected

- Rydapt

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For acute myeloid leukemia (AML): AML is FLT3 mutation-positive. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FGFR1 or FLT3 rearrangements: the disease is in chronic or blast phase.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Relapsed or refractory acute myeloid leukemia (AML), myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FGFR1 or FLT3 rearrangements, post-induction therapy for AML, re-induction in residual disease for AML
<b>Part B Prerequisite</b>	No

# SAPROPTERIN

## 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 phenylketonuria (PKU): For patients who have not yet received a therapeutic trial of the requested drug, the patient's pretreatment, including before dietary management, phenylalanine level is greater than 6 mg/dL (360 micromol/L). For patients who completed a therapeutic trial of the requested drug, the patient must have experienced improvement (e.g., reduction in blood phenylalanine levels, improvement in neuropsychiatric symptoms).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 2 months. All others: Plan Year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SAVELLA

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## Products Affected

- Savella
- Savella Titration Pack

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to duloxetine or pregabalin.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SCSEMBLIX

## Products Affected

- Scemblix

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For chronic myeloid leukemia (CML) in the chronic phase: 1) the diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene AND the patient meets either of the following: A) the patient has previously been treated with 2 or more tyrosine kinase inhibitors (TKIs) AND at least one of those was imatinib or dasatinib, OR B) the patient is positive for the T315I mutation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SIGNIFOR

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## Products Affected

- Signifor

<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>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SILDENAFIL

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## Products Affected

- Sildenafil Citrate Oral Tablet 20 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): Diagnosis was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) If the request is for an adult, pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SIRTURO

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## Products Affected

- Sirturo

<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>	Prescribed by or in consultation with an infectious disease specialist.
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# SKYRIZI

## Products Affected

- Skyrizi
- Skyrizi Pen

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient meets any of the following: a) patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, or b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, or c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). For moderately to severely active Crohn's disease (new starts only): 1) Inadequate response to at least one conventional therapy (e.g., corticosteroids), OR 2) Intolerance or contraindication to conventional therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SKYRIZI-CD

## Products Affected

- Skyrizi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient meets any of the following: a) patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, or b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, or c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). For moderately to severely active Crohn's disease (new starts only): 1) Inadequate response to at least one conventional therapy (e.g., corticosteroids), OR 2) Intolerance or contraindication to conventional therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SOMATULINE DEPOT

## Products Affected

- Somatuline Depot Subcutaneous Solution 120 MG/0.5ML, 60 MG/0.2ML, 90 MG/0.3ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For acromegaly (initial): 1) patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, and 2) patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly continuation of therapy: patient's IGF-1 level has decreased or normalized since initiation of therapy. For tumor control of neuroendocrine tumors (NETs) of the thymus or lung: patient has locoregional unresectable disease and/or distant metastatic disease. For tumor control of well-differentiated grade 3 unresectable locally advanced or metastatic NETs (not of gastroenteropancreatic origin): patient has favorable biology (e.g., relatively low Ki-67 [less than 55%] and somatostatin receptor [SSR] positive imaging). For tumor control of pheochromocytomas or paragangliomas: 1) patient has symptomatic locally unresectable disease with SSR positive imaging or 2) patient has distant metastases that are secreting tumors.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Tumor control of neuroendocrine tumors (NETs) of the lung, thymus or unresected primary gastrinoma, well-differentiated grade 3 neuroendocrine tumors not of gastroenteropancreatic origin, pheochromocytoma/paraganglioma.
<b>Part B Prerequisite</b>	No

# SOMAVERT

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## Products Affected

- Somavert

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For acromegaly (initial): 1) patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, and 2) patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly (continuation of therapy): patient's IGF-1 level has decreased or normalized since initiation of therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SPRYCEL

## Products Affected

- Sprycel

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For chronic myeloid leukemia (CML), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia (Ph) chromosome or BCR-ABL gene, and 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I/A, F317L/V/I/C, and V299L. For acute lymphoblastic leukemia (ALL), the patient has a diagnosis of one of the following: 1) Philadelphia chromosome positive ALL, including patients who have received a hematopoietic stem cell transplant: diagnosis that has been confirmed by detection of the Ph chromosome or BCR-ABL gene, and if patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I/A, F317L/V/I/C, and V299L, OR 2) Ph-like B-ALL with ABL-class kinase fusion, OR 3) relapsed or refractory T-cell ALL with ABL-class translocation. For GIST, 1) the disease has progressed on imatinib in patients with PDGFRA D842V mutation, OR 2) the patient has failed at least 2 FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib)
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Gastrointestinal stromal tumor (GIST), metastatic chondrosarcoma, recurrent chordoma, T-cell acute lymphoblastic leukemia (ALL), and Philadelphia (Ph)-like B-ALL, myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase

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

# STELARA

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## Products Affected

- Stelara Intravenous
- Stelara Subcutaneous Solution 45 MG/0.5ML
- Stelara Subcutaneous Solution Prefilled Syringe

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For moderate to severe plaque psoriasis (new starts): At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved 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>	For gastrointestinal stromal tumors: The disease is progressive, locally advanced, unresectable, or metastatic.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Progressive gastrointestinal stromal tumors (GIST), osteosarcoma, glioblastoma, angiosarcoma, retroperitoneal/intra-abdominal soft tissue sarcoma, rhabdomyosarcoma, and soft tissue sarcomas of the extremities, body wall, head and neck, advanced colorectal cancer.
<b>Part B Prerequisite</b>	No



# SUTENT

## Products Affected

- SUNItinib Malate

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For renal cell carcinoma (RCC): 1) The disease is relapsed, advanced, or stage IV OR 2) the requested drug is being used as adjuvant treatment for patients that are at high risk of recurrent RCC following nephrectomy. For gastrointestinal stromal tumor (GIST): the disease is unresectable, recurrent, or metastatic AND the patient has failed on an FDA-approved therapy (e.g., imatinib, sunitinib, regorafenib, ripretinib). For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia: 1) The disease has a FLT3 rearrangement AND 2) The disease is in chronic or blast phase.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Thyroid carcinoma (follicular, medullary, papillary, and Hurthle cell), soft tissue sarcoma (angiosarcoma, solitary fibrous tumor, and alveolar soft part sarcoma subtypes), recurrent chordoma, thymic carcinoma, lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia
<b>Part B Prerequisite</b>	No

# SYMDEKO

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## Products Affected

- Symdeko

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For cystic fibrosis: The requested medication will not be used in combination with other medications containing ivacaftor.
<b>Age Restrictions</b>	6 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SYMPAZAN

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## Products Affected

- Sympazan

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	2 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# SYNRIBO

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## Products Affected

- Synribo

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TABRECTA

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## Products Affected

- Tabrecta

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For recurrent, advanced, or metastatic NSCLC: Tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent non-small cell lung cancer (NSCLC).
<b>Part B Prerequisite</b>	No

# TADALAFIL (PAH)

## Products Affected

- Adcirca
- Alyq
- Tadalafil (PAH)
- Tadliq

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): Diagnosis was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TAFINLAR

## Products Affected

- Tafinlar

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For brain metastases from melanoma, adjuvant treatment of melanoma, and central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma): 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), and 2) The requested drug will be used in combination with trametinib. For unresectable or metastatic melanoma: 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), and 2) The requested drug will be used as a single agent or in combination with trametinib. For non-small cell lung cancer: 1) The tumor is positive for a BRAF V600E mutation, and 2) The requested drug will be used as a single agent or in combination with trametinib. For thyroid carcinoma with papillary, follicular, or Hurthle histology: The tumor is positive for BRAF activating mutation (e.g., V600E or V600K). For Langerhans Cell Histiocytosis and Erdheim-Chester Disease: The disease is positive for a BRAF V600E mutation. For gallbladder cancer, extrahepatic cholangiocarcinoma, and intrahepatic cholangiocarcinoma: 1) The disease is positive for a BRAF V600E mutation and 2) The disease is unresectable or metastatic and 3) The requested drug will be used in combination with trametinib. For solid tumors: ) The tumor is positive for a BRAF V600E mutation, and 2) The requested drug will be used in combination with trametinib.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
<b>Off Label Uses</b>	Brain metastases from melanoma, thyroid carcinoma (papillary carcinoma, follicular carcinoma, and Hurthle cell carcinoma), central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma), gallbladder cancer, extrahepatic cholangiocarcinoma, intrahepatic cholangiocarcinoma, Langerhans cell histiocytosis, Erdheim-Chester disease
<b>Part B Prerequisite</b>	No



# TAGRISO

## Products Affected

- Tagrisso

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For NSCLC, the requested drug is used in any of the following settings: 1) The patient meets both of the following: a) patient has metastatic, advanced, or recurrent NSCLC (including brain and/or leptomeningeal metastases from NSCLC) and b) patient has a sensitizing EGFR mutation OR 2) The patient meets both of the following: a) request is for adjuvant treatment of NSCLC following tumor resection and b) patient has EGFR mutation-positive disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Sensitizing epidermal growth factor receptor (EGFR) mutation-positive recurrent non-small cell lung cancer (NSCLC), brain metastases from sensitizing EGFR mutation-positive NSCLC, leptomeningeal metastases from EGFR mutation-positive NSCLC.
<b>Part B Prerequisite</b>	No

# TALTZ

## Products Affected

- Taltz

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab). For active ankylosing spondylitis (new starts only): the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active psoriatic arthritis (PsA) (new starts only): the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active non-radiographic axial spondyloarthritis (new starts only): Patient meets any of the following: 1) has had an inadequate response to a non-steroidal anti-inflammatory drug (NSAID) trial or 2) has an intolerance or contraindication to NSAIDs.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

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

# TALZENNA

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## Products Affected

- Talzenna

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent germline breast cancer susceptibility gene (BRCA)-mutated breast cancer
<b>Part B Prerequisite</b>	No

# TARGRETIN TOPICAL

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## Products Affected

- Bexarotene

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Stage 2 or higher mycosis fungoides/Sezary syndrome, chronic or smoldering adult T-cell leukemia/lymphoma, primary cutaneous marginal zone lymphoma, primary cutaneous follicle center lymphoma.
<b>Part B Prerequisite</b>	No

# TASIGNA

## Products Affected

- Tasigna

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For chronic myeloid leukemia (CML) or acute lymphoblastic leukemia (ALL), diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For CML, including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: patient has experienced resistance or intolerance to imatinib or dasatinib. If patient experienced resistance to an alternative tyrosine kinase inhibitor for CML, patient is negative for T315I, Y253H, E255K/V, and F359V/C/I mutations. For GIST, patient must have progressed on imatinib, sunitinib, and regorafenib.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), gastrointestinal stromal tumor (GIST), myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase.
<b>Part B Prerequisite</b>	No

# TAZAROTENE

## Products Affected

- Tazarotene External Cream
- Tazorac External Cream 0.05 %

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For plaque psoriasis: 1)The requested drug is being prescribed to treat less than or equal to 20 percent of the patient's body surface area (BSA) AND 2) the patient experienced an inadequate treatment response or intolerance to at least one topical corticosteroid OR has a contraindication that would prohibit a trial of topical corticosteroids.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved 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>	
<b>Age Restrictions</b>	Epithelioid sarcoma: 16 years of age or older, Follicular lymphoma: 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# TECENTRIQ

## Products Affected

- Tecentriq

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For urothelial carcinoma, patient meets one of the following criteria: 1) Patient is ineligible for cisplatin therapy and tumors express PD-L1 (defined as PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5 percent of the tumor area) OR 2) Patient is ineligible for any platinum containing chemotherapy. For non-small cell lung cancer (NSCLC): 1) the patient has recurrent, advanced or metastatic disease AND the requested drug will be used as any of the following: a) first-line treatment of tumors with high PD-L1 expression (defined as PD-L1 stained greater than or equal to 50 percent of tumor cells or PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 10 percent of the tumor area) and no EGFR or ALK genomic tumor aberrations, b) used in combination with carboplatin, paclitaxel, and bevacizumab, or in combination with carboplatin and albumin-bound paclitaxel for nonsquamous NSCLC, or c) the requested drug will be used as subsequent therapy or continuation maintenance therapy, OR 2) the patient has stage II to IIIA disease AND the requested drug will be used as adjuvant treatment following resection and platinum-based chemotherapy for tumors with PD-L1 expression on greater than or equal to 1 percent of tumor cells. For hepatocellular carcinoma, the requested drug will be used as initial treatment in combination with bevacizumab.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	Recurrent non-small cell lung cancer, single agent maintenance for extensive small cell lung cancer following combination treatment with etoposide and carboplatin, urothelial carcinoma.
<b>Part B Prerequisite</b>	No

# TECFIDERA

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## Products Affected

- Tecfidera Oral Capsule Delayed Release
- Tecfidera Oral Capsule Delayed Release Therapy Pack

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

# TEMAZEPAM

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## Products Affected

- Temazepam Oral Capsule 15 MG, 30 MG, 7.5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For short-term treatment of insomnia: 1) The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 65 years of age or older.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TEPMETKO

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## Products Affected

- Tepmetko

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For recurrent, advanced, or metastatic NSCLC: Tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent non-small cell lung cancer (NSCLC).
<b>Part B Prerequisite</b>	No

# TERIPARATIDE

## Products Affected

- Teriparatide (Recombinant)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For postmenopausal osteoporosis: patient has ONE of the following (1 or 2): 1) a history of fragility fracture, OR 2) A pre-treatment T-score of less than or equal to -2.5 or pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment Fracture Risk Assessment Tool (FRAX) fracture probability AND patient has ANY of the following: a) indicators for higher fracture risk (e.g., advanced age, frailty, glucocorticoid therapy, very low T-scores, or increased fall risk), OR b) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy OR c) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. For primary or hypogonadal osteoporosis in men: patient has one of the following: 1) a history of osteoporotic vertebral or hip fracture, OR 2) pre-treatment T-score of less than or equal to -2.5, OR 3) pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment FRAX fracture probability. For glucocorticoid-induced osteoporosis: Patient has had an oral bisphosphonate trial of at least 1-year duration unless patient has a contraindication or intolerance to an oral bisphosphonate, AND patient meets ANY of the following: 1) patient has a history of fragility fracture, OR 2) a pre-treatment T-score of less than or equal to -2.5, OR 3) pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment FRAX fracture probability. Continuation of therapy: If the patient has received greater than or equal to 24 months of therapy with any parathyroid hormone analog: 1) The patient remains at or has returned to having a high risk for fracture, AND 2) The benefit of therapy with this prescribed medication outweighs the potential risks for this patient.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 24 months, Continuation: Plan Year

PA Criteria	Criteria Details
<b>Other Criteria</b>	Patient has high FRAX fracture probability if the 10 year probability is either greater than or equal to 20 percent for any major osteoporotic fracture or greater than or equal to 3 percent for hip fracture. If glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day, the estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TETRABENAZINE

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## Products Affected

- Tetrabenazine

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For treatment of chorea associated with Huntington's disease: The patient must have a prior inadequate response or intolerable adverse event with deutetrabenazine therapy. For treatment of tardive dyskinesia: The patient must have a prior inadequate response or intolerable adverse event with deutetrabenazine or valbenazine therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Tic disorders, tardive dyskinesia, hemiballismus, chorea not associated with Huntington's disease.
<b>Part B Prerequisite</b>	No



# TETRACYCLINE

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## Products Affected

- Tetracycline HCl Oral

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient will use the requested drug orally.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# THALOMID

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## Products Affected

- Thalomid

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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Myelofibrosis-related anemia, AIDS-related aphthous stomatitis, Kaposi sarcoma, chronic graft-versus-host disease, Crohn's disease, multicentric Castleman's disease., Rosai-Dorfman disease, Langerhans cell histiocytosis
<b>Part B Prerequisite</b>	No

# TIBSOVO

## Products Affected

- Tibsovo

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient has disease with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation. For acute myeloid leukemia (AML): 1) patient has newly-diagnosed AML and meets one of the following: a) 75 years of age or older, b) patient has comorbidities that preclude use of intensive induction chemotherapy, or c) patient is 60 years of age or older and declines intensive induction chemotherapy, OR 2) patient is 60 years of age or older and the requested drug will be used as post-induction therapy following response to induction therapy with the requested drug, OR 3) patient has relapsed or refractory AML. For locally advanced, unresectable, or metastatic cholangiocarcinoma: the requested drug will be used as subsequent treatment for progression on or after systemic treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Conventional (grades 1-3) or dedifferentiated chondrosarcoma. Newly-diagnosed acute myeloid leukemia (AML) if 60-74 years of age and without comorbidities.
<b>Part B Prerequisite</b>	No

# TOBRAMYCIN

## Products Affected

- Tobramycin Inhalation Nebulization Solution 300 MG/5ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For cystic fibrosis and non-cystic fibrosis bronchiectasis, the patient must meet one of the following: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) the patient has a history of Pseudomonas aeruginosa infection or colonization in the airways.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Non-cystic fibrosis bronchiectasis
<b>Part B Prerequisite</b>	No

# TOPICAL LIDOCAINE

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## Products Affected

- Glydo External Prefilled Syringe
- Lidocaine External Ointment 5 %
- Lidocaine HCl External Solution
- Lidocaine-Prilocaine External Cream

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The requested drug is being used for topical anesthesia, AND 2) If the requested drug will be used as part of a compounded product, then all the active ingredients in the compounded product are Food and Drug Administration (FDA) approved for topical use.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TOPICAL TESTOSTERONES

## Products Affected

- Testosterone Transdermal Gel 12.5 MG/ACT (1%), 20.25 MG/ACT (1.62%), 25 MG/2.5GM (1%), 50 MG/5GM (1%)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Primary or hypogonadotropic hypogonadism: 1) Request is for continuation of testosterone therapy and the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with age-related hypogonadism (also referred to as late-onset hypogonadism) have not been established.] OR 2) Request is not for continuation of testosterone therapy and the patient has at least two confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values [Note: Safety and efficacy of testosterone products in patients with age-related hypogonadism (also referred to as late-onset hypogonadism) have not been established.]. Gender dysphoria: The patient is able to make an informed decision to engage in hormone therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Gender Dysphoria
<b>Part B Prerequisite</b>	No

# TOPICAL TRETINOIN

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## Products Affected

- Tretinoin External Cream
- Tretinoin External Gel 0.01 %, 0.025 %

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TRAZIMERA

## Products Affected

- Trazimera

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>	Neoadjuvant therapy for breast cancer: 6 months. Other: Plan Year.
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent or advanced unresectable HER2-positive breast cancer, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer in combination with pertuzumab, tucatinib, or lapatinib, HER2-positive recurrent salivary gland tumor.
<b>Part B Prerequisite</b>	No



# TREPROSTINIL INJ

## Products Affected

- Treprostinil

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For pulmonary arterial hypertension (World Health Organization [WHO] Group 1), the diagnosis was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TRIENTINE

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## Products Affected

- Trientine HCl Oral Capsule 250 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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TRIKAFTA

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## Products Affected

- Trikafta

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For cystic fibrosis: The requested medication will not be used in combination with other medications containing ivacaftor.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TRULICITY

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## Products Affected

- Trulicity

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	10 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TRUSELTIQ

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## Products Affected

- Truseltiq (100MG Daily Dose)
- Truseltiq (125MG Daily Dose)
- Truseltiq (50MG Daily Dose)
- Truseltiq (75MG Daily Dose)

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

# TRUXIMA

## Products Affected

- Truxima

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For moderately to severely active rheumatoid arthritis (new starts only): 1) patient meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) OR b) patient has intolerance or contraindication to MTX, AND 2) patient meets ANY of the following: a) inadequate response, intolerance, or contraindication to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. Hematologic malignancies must be CD20-positive. For multiple sclerosis: 1) patient has a diagnosis of relapsing remitting multiple sclerosis and 2) patient has had an inadequate response to two or more disease-modifying drugs indicated for multiple sclerosis despite adequate duration of treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Immune checkpoint inhibitor-related toxicities: 3 months, All other: Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
<b>Off Label Uses</b>	<p>Non-Hodgkin's lymphoma subtypes [small lymphocytic lymphoma (SLL), mantle cell lymphoma, marginal zone lymphomas (nodal, splenic, gastric mucosa-associated lymphoid tissue [MALT], nongastric MALT), Burkitt lymphoma, primary cutaneous B-cell lymphoma, high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma), high-grade B-cell lymphoma not otherwise specified, histological transformation from follicular lymphoma to diffuse large B-cell lymphoma, histological transformation from nodal marginal zone lymphoma to diffuse large B-cell lymphoma, Castleman's disease, acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma, hairy cell leukemia, post-transplant lymphoproliferative disorder (PTLD), B-cell lymphoblastic lymphoma], refractory immune or idiopathic thrombocytopenic purpura (ITP), autoimmune hemolytic anemia, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, chronic graft-versus-host disease (GVHD), Sjogren syndrome, thrombotic thrombocytopenic purpura, refractory myasthenia gravis, Hodgkin's lymphoma (nodular lymphocyte-predominant), primary central nervous system (CNS) lymphoma, leptomeningeal metastases from lymphomas, acute lymphoblastic leukemia, prevention of Epstein-Barr virus (EBV)-related PTLD, multiple sclerosis, immune checkpoint inhibitor-related toxicities, pemphigus vulgaris, pediatric aggressive mature B-cell lymphomas, and Rosai-Dorfman disease, and pediatric mature B-cell acute leukemia.</p>
<b>Part B Prerequisite</b>	No

# TUKYSA

## Products Affected

- Tukysa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For colorectal cancer (including appendiceal adenocarcinoma): 1) the patient has advanced, unresectable, or metastatic disease AND 2) the patient has human epidermal growth factor receptor 2 (HER2)-positive disease AND 3) the patient has RAS wild-type disease AND 4) the requested drug will be used in combination with trastuzumab and 5) the patient has not previously been treated with a HER2 inhibitor.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer
<b>Part B Prerequisite</b>	No



# TURALIO

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## Products Affected

- Turalio

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For Langerhans Cell Histiocytosis: 1) disease has colony stimulating factor 1 receptor (CSF1R) mutation. For Erdheim-Chester Disease and Rosai-Dorfman Disease: 1) disease has CSF1R mutation AND patient has any of the following: a) symptomatic disease OR b) relapsed/refractory disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Langerhans Cell Histiocytosis, Erdheim-Chester Disease, Rosai-Dorfman Disease
<b>Part B Prerequisite</b>	No

# TYMLOS

## Products Affected

- Tymlos

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For postmenopausal osteoporosis: patient has ONE of the following: 1) a history of fragility fracture, OR 2) a pre-treatment T-score of less than or equal to -2.5 or pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment Fracture Risk Assessment Tool (FRAX) fracture probability AND patient has ANY of the following: a) indicators for higher fracture risk (e.g., advanced age, frailty, glucocorticoid therapy, very low T-scores, or increased fall risk), OR b) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy, OR c) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. For osteoporosis in men: patient has ONE of the following: 1) a history of osteoporotic vertebral or hip fracture, OR 2) a pre-tx T-score of less than or equal to -2.5 or pre-tx T-score greater than -2.5 and less than -1 with a high pre-tx FRAX fracture probability AND patient has ANY of the following: a) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy, OR b) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	24 months lifetime total for parathyroid hormone analogs
<b>Other Criteria</b>	Patient has high Fracture Risk Assessment Tool (FRAX) fracture probability if the 10 year probability is either greater than or equal to 20 percent for any major osteoporotic fracture or greater than or equal to 3 percent for hip fracture. If glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day, the estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture.
<b>Indications</b>	All FDA-approved Indications.

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

# UCERIS

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## Products Affected

- Budesonide ER Oral Tablet Extended Release 24 Hour

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one 5-aminosalicylic acid (5-ASA) therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	2 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VALCHLOR

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## Products Affected

- Valchlor

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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Chronic or smoldering adult T-cell leukemia/lymphoma, Stage 2 or higher mycosis fungoides/Sezary syndrome, primary cutaneous marginal zone lymphoma, primary cutaneous follicle center lymphoma, lymphomatoid papulosis, unifocal Langerhans cell histiocytosis (LCH) with isolated skin disease.
<b>Part B Prerequisite</b>	No

# VANFLYTA

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## Products Affected

- Vanflyta

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VELCADE

## Products Affected

- Bortezomib Injection Solution Reconstituted 1 MG, 2.5 MG
- Bortezomib Injection Solution Reconstituted 3.5 MG
- Bortezomib Intravenous Solution Reconstituted

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>	Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Systemic light chain amyloidosis, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, multicentric Castleman's disease, adult T-cell leukemia/lymphoma, acute lymphoblastic leukemia, Kaposi's sarcoma, Hodgkin lymphoma, POEMS syndrome
<b>Part B Prerequisite</b>	No

# VENCLEXTA

## Products Affected

- Venclexta
- Venclexta Starting Pack

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For acute myeloid leukemia (AML): 1) patient is 60 years of age or older OR 2) patient is less than 60 years of age with unfavorable risk genetics and TP53-mutation OR 3) patient has comorbidities that preclude use of intensive induction chemotherapy OR 4) patient has relapsed or refractory disease. For blastic plasmacytoid dendritic cell neoplasm (BPDCN): 1) patient has systemic disease being treated with palliative intent OR 2) patient has relapsed or refractory disease. For multiple myeloma: 1) the disease is relapsed or progressive AND 2) the requested drug will be used in combination with dexamethasone AND 3) patient has t(11:14) translocation. For Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma: 1) patient has previously treated disease that did not respond to primary therapy OR 2) patient has progressive or relapsed disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Mantle cell lymphoma, blastic plasmacytoid dendritic cell neoplasm (BPDCN), multiple myeloma, relapsed or refractory acute myeloid leukemia (AML), Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, relapsed or refractory systemic light chain amyloidosis with translocation t(11:14)
<b>Part B Prerequisite</b>	No



# VENTAVIS

## Products Affected

- Ventavis

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For pulmonary arterial hypertension (World Health Organization [WHO] Group 1), the diagnosis was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VERSACLOZ

## Products Affected

- Versacloz

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For the treatment of a severely ill patient with schizophrenia who failed to respond adequately to standard antipsychotic treatment (i.e., treatment-resistant schizophrenia): 1) the patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: A) aripiprazole, B) asenapine, C) olanzapine, D) quetiapine, E) risperidone, F) ziprasidone AND 2) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following brand products: A) Latuda, B) Rexulti, C) Secuado, D) Vraylar.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VERZENIO

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## Products Affected

- Verzenio

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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer in combination with fulvestrant or an aromatase inhibitor, or as a single agent if progression on prior endocrine therapy and prior chemotherapy in the metastatic setting.
<b>Part B Prerequisite</b>	No

# V-GO

## Products Affected

- V-Go 20 Kit 20 UNIT/24HR
- V-Go 30 Kit 30 UNIT/24HR
- V-Go 40 Kit 40 UNIT/24HR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: 1) The patient has diabetes requiring insulin management with multiple daily injections AND 2) The patient is self-testing glucose levels 4 or more times per day OR the patient is using a continuous glucose monitor AND 3) The patient has experienced any of the following with the current diabetes regimen: inadequate glycemic control, recurrent hypoglycemia, wide fluctuations in blood glucose, dawn phenomenon with persistent severe early morning hyperglycemia, severe glycemic excursions. Continuation: the patient has stable or improved glycemic control.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VICTOZA

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## Products Affected

- Victoza Subcutaneous Solution Pen-Injector

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VIGABATRIN

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## Products Affected

- Vigabatrin
- Vigadrone

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For complex partial seizures (CPS): patient has experienced an inadequate treatment response to at least two antiepileptic drugs for CPS.
<b>Age Restrictions</b>	Infantile Spasms: 1 month to 2 years of age. CPS: 2 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VITRAKVI

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## Products Affected

- Vitrakvi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For all neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, the disease is without a known acquired resistance mutation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Non-metastatic neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, first-line treatment of NTRK gene fusion-positive solid tumors.
<b>Part B Prerequisite</b>	No

# VIZIMPRO

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## Products Affected

- Vizimpro

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced or metastatic, and 2) the patient has sensitizing EGFR mutation-positive disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent non-small cell lung cancer (NSCLC).
<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>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VORICONAZOLE

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## Products Affected

- Voriconazole Intravenous
- Voriconazole Oral

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The patient will use the requested drug orally or intravenously.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VOSEVI

## Products Affected

- Vosevi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh class B or C)
<b>Required Medical Information</b>	For hepatitis C: Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases (AASLD) treatment guidelines.
<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>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VOTRIENT

## Products Affected

- Votrient

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For renal cell carcinoma: The disease is advanced, relapsed, or stage IV. For gastrointestinal stromal tumor (GIST): the disease is unresectable, recurrent, or metastatic AND the patient has failed on an FDA-approved therapy (e.g., imatinib, sunitinib, regorafenib, ripretinib). For soft tissue sarcoma (STS): The patient does not have an adipocytic soft tissue sarcoma. For uterine sarcoma: The disease is recurrent or metastatic.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Thyroid carcinoma (follicular, papillary, Hurthle cell, or medullary), uterine sarcoma, chondrosarcoma, gastrointestinal stromal tumor.
<b>Part B Prerequisite</b>	No

# VUMERITY

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## Products Affected

- Vumerity

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VYVANSE

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## Products Affected

- Lisdexamfetamine Dimesylate
- Vyvanse

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The patient has a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) OR 2) The requested drug is being prescribed for the treatment of moderate to severe binge eating disorder (BED) in an adult.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# WELIREG

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## Products Affected

- Welireg

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XALKORI

## Products Affected

- Xalkori

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For NSCLC, the requested drug is used in any of the following settings: 1) the patient has recurrent, advanced or metastatic ALK-positive NSCLC, 2) the patient has recurrent, advanced or metastatic ROS-1 positive NSCLC, or 3) the patient has NSCLC with high-level MET amplification or MET exon 14 skipping mutation. For IMT, the disease is ALK-positive. For ALCL, the disease is relapsed or refractory and ALK-positive.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent non-small cell lung cancer (NSCLC), NSCLC with high-level MET amplification or MET exon 14 skipping mutation, symptomatic or relapsed/refractory anaplastic lymphoma kinase (ALK)-fusion positive Erdheim-Chester Disease, symptomatic or relapsed/refractory (ALK)-fusion positive Rosai-Dorfman Disease, (ALK)-fusion positive Langerhans Cell Histiocytosis.
<b>Part B Prerequisite</b>	No



# XELJANZ

## Products Affected

- Xeljanz
- Xeljanz XR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance or has a contraindication to methotrexate (MTX) AND at least one tumor necrosis factor (TNF) inhibitor (e.g., Enbrel [etanercept], Humira [adalimumab]). For active psoriatic arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., Enbrel [etanercept], Humira [adalimumab]) AND 2) the requested drug is used in combination with a nonbiologic DMARD. For active ankylosing spondylitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., Enbrel [etanercept], Humira [adalimumab]). For moderately to severely active ulcerative colitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., Humira [adalimumab]). For active polyarticular course juvenile idiopathic arthritis (pcJIA) (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., Enbrel [etanercept], Humira [adalimumab]).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

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

# XERMELO

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## Products Affected

- Xermelo

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XGEVA

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## Products Affected

- Xgeva

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For hypercalcemia of malignancy: condition is refractory to intravenous (IV) bisphosphonate therapy or there is a clinical reason to avoid IV bisphosphonate therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XHANCE

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## Products Affected

- Xhance

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient has experienced an inadequate treatment response to generic fluticasone nasal spray.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XIFAXAN

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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>	For irritable bowel syndrome with diarrhea (IBS-D): 1) The patient has not previously received treatment with the requested drug OR 2) The patient has previously received treatment with the requested drug AND a) the patient is experiencing a recurrence of symptoms AND b) the patient has not already received an initial 14-day course of treatment and two additional 14-day courses of treatment with the requested drug.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Reduction in risk of overt HE recurrence: 6 Months, IBS-D: 14 Days
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XOLAIR

## Products Affected

- Xolair

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For allergic asthma initial therapy: 1) Patient has positive skin test (or blood test) to at least 1 perennial aeroallergen, 2) Patient has baseline IgE level greater than or equal to 30 IU/mL, and 3) Patient has inadequate asthma control despite current treatment with both of the following medications: a) Inhaled corticosteroid, and b) Additional controller (long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For allergic asthma continuation therapy only: Patient's asthma control has improved on treatment with the requested drug since initiation of therapy. For chronic idiopathic urticaria (CIU) initial therapy: 1) Patient has been evaluated for other causes of urticaria, including bradykinin-related angioedema and IL-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis), and 2) Patient has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks. For CIU continuation therapy: Patient has experienced a response (e.g., improved symptoms) since initiation of therapy. For nasal polyps: 1) the requested drug is used as add-on maintenance treatment, AND 2) the patient has experienced an inadequate treatment response to Xhance (fluticasone).
<b>Age Restrictions</b>	For CIU: 12 years of age or older. For allergic asthma: 6 years of age or older. For nasal polyps: 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	CIU initial: 6 months. All others: Plan Year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

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



# XOSPATA

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## Products Affected

- Xospata

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement: the disease is in chronic or blast phase.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement
<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>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XTANDI

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## Products Affected

- Xtandi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XYREM

## Products Affected

- Sodium Oxybate
- Xyrem

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The diagnosis has been confirmed by sleep lab evaluation. EDS: 1)The patient experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate) OR has a contraindication that would prohibit a trial of central nervous system (CNS) stimulant drugs (e.g., amphetamine, dextroamphetamine, or methylphenidate) [Note: Coverage of amphetamines may require prior authorization.] AND 2) If the patient is 18 years of age or older, the patient experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) wakefulness promoting drug (e.g., armodafinil) OR has a contraindication that would prohibit a trial of central nervous system (CNS) wakefulness promoting drugs (e.g., armodafinil) [Note: coverage of armodafinil may require prior authorization.].
<b>Age Restrictions</b>	7 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a sleep disorder specialist or neurologist.
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	If the request is for a continuation of therapy, then the patient experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ZARXIO

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## Products Affected

- Zarxio

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Use of the requested product within 24 hours prior to or following chemotherapy.
<b>Required Medical Information</b>	For prophylaxis or treatment of myelosuppressive chemotherapy-induced febrile neutropenia (FN) patient must meet both of the following: 1) Patient has a solid tumor or non-myeloid cancer, and 2) Patient has received, is currently receiving, or will be receiving treatment with myelosuppressive anti-cancer therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Neutropenia in myelodysplastic syndromes (MDS), agranulocytosis, neutropenia in aplastic anemia, human immunodeficiency virus (HIV)-related neutropenia, neutropenia related to renal transplant.
<b>Part B Prerequisite</b>	No

# ZEJULA

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## Products Affected

- Zejula

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For uterine leiomyosarcoma: 1) the requested drug is used as second-line therapy AND 2) the patient has BRCA-altered disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	In combination with bevacizumab for persistent or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer for platinum-sensitive disease, uterine leiomyosarcoma
<b>Part B Prerequisite</b>	No

# ZELBORAF

## Products Affected

- Zelboraf

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For adjuvant treatment of melanoma, and central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma): 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K) and 2) The requested drug will be used in combination with cobimetinib. For unresectable or metastatic melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K) and 2) the requested drug will be used as a single agent, or in combination with cobimetinib (with or without atezolizumab). For Erdheim-Chester Disease and Langerhans Cell Histiocytosis: Tumor is positive for BRAF V600 mutation. For non-small cell lung cancer: 1) Tumor is positive for the BRAF V600E mutation, and 2) The patient has recurrent, advanced, or metastatic disease. For thyroid carcinoma: 1) Tumor is positive for BRAF mutation, and 2) Patient has radioiodine refractory follicular, Hurthle cell, or papillary thyroid carcinoma. For hairy cell leukemia: The requested drug will be used for subsequent therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Non-small cell lung cancer, hairy cell leukemia, thyroid carcinoma (i.e., papillary carcinoma, follicular carcinoma, and Hurthle cell carcinoma), central nervous system cancer (i.e., glioma, meningioma, astrocytoma), adjuvant systemic therapy for cutaneous melanoma, Langerhans cell histiocytosis.
<b>Part B Prerequisite</b>	No

# ZIEXTENZO

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## Products Affected

- Ziextenzo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Use of the requested product less than 24 hours before or after chemotherapy.
<b>Required Medical Information</b>	For prophylaxis of myelosuppressive chemotherapy-induced febrile neutropenia: the patient must meet both of the following: 1) Patient has a solid tumor or non-myeloid cancer, and 2) Patient is currently receiving or will be receiving treatment with myelosuppressive anti-cancer therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Stem cell transplantation-related indications
<b>Part B Prerequisite</b>	No



# ZIRABEV

## Products Affected

- Zirabev

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>	Plan Year
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Breast cancer, central nervous system (CNS) tumor types: adult low-grade (WHO Grade I or II) glioma, adult intracranial and spinal ependymoma, anaplastic gliomas, adult medulloblastoma, primary central nervous system lymphoma, meningiomas, limited and extensive brain metastases, and metastatic spine tumors, malignant pleural mesothelioma, ovarian cancer/fallopian tube cancer/primary peritoneal cancer types: carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, mucinous carcinoma, grade 1 endometrioid carcinoma, low-grade serous carcinoma, ovarian borderline epithelial tumors (low malignant potential) with invasive implants, and malignant sex cord-stromal tumors, soft tissue sarcoma types: angiosarcoma and solitary fibrous tumor/hemangiopericytoma, uterine neoplasms, endometrial carcinoma, vulvar squamous cell carcinoma, and ophthalmic-related disorders: diabetic macular edema, neovascular (wet) age-related macular degeneration including polypoidal choroidopathy and retinal angiomatous proliferation subtypes, macular edema following retinal vein occlusion, proliferative diabetic retinopathy, choroidal neovascularization, neovascular glaucoma and retinopathy of prematurity, hepatocellular carcinoma, small bowel adenocarcinoma.

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

# ZOLINZA

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## Products Affected

- Zolanza

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Mycosis fungoides, Sezary syndrome.
<b>Part B Prerequisite</b>	No

# ZONISADE

## Products Affected

- Zonisade

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For adjunctive treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom, Xcopri, Spritam OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules).
<b>Age Restrictions</b>	16 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ZTALMY

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## Products Affected

- Ztalmy

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	2 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ZYDELIG

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## Products Affected

- Zydelig

<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>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Refractory chronic lymphocytic leukemia (CLL), relapsed or refractory small lymphocytic lymphoma (SLL).
<b>Part B Prerequisite</b>	No

# ZYKADIA

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## Products Affected

- Zykadia Oral Tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For NSCLC: the patient has recurrent, advanced, or metastatic ALK-positive or ROS1-positive disease. For inflammatory myofibroblastic tumor: the disease is ALK-positive. For brain metastases from NSCLC: the patient has ALK-positive NSCLC.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Recurrent ALK-positive non-small cell lung cancer (NSCLC), recurrent, advanced, or metastatic ROS1-positive NSCLC, inflammatory myofibroblastic tumor (IMT), brain metastases from NSCLC.
<b>Part B Prerequisite</b>	No

# ZYPREXA RELPREVV

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## Products Affected

- ZyPREXA Relprevv

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Tolerability with oral olanzapine has been established.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No