# Tufts Health Unify

# 2016 Prior Authorization Medical Necessity Guidelines

**Effective: 01/2016 Updated: 11/2016** 



Tufts Health Plan P.O. Box 9194 Watertown, MA 02471-9194 Phone: **855-393-3154** 

Seven days a week, from 8 a.m. to 8 p.m. TuftsHealthUnify.org

# **ACTEMRA**

### **Products Affected**

• Actemra

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Rheumatoid Arthritis: The member must have a documented diagnosis of rheumatoid arthritis and a documented inadequate response or inability to tolerate at least one tumor necrosis factor antagonist: Cimzia (certolizumab), Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab), Simponi/Simponi Aria (golimumab). Polyarticular Juvenile Idiopathic Arthritis (PJIA) and Systemic Juvenile Idiopathic Arthritis (SJIA): The member must have a documented diagnosis of either disease and has a documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate OR BOTH corticosteroids (e.g., methylprednisolone, prednisolone, prednisone) AND NSAIDs (e.g. diclofenac, fenoprofen, ibuprofen, naproxen, etc.)
Age Restrictions	For PJIA and SJIA, the member must be over 2 years of age.
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **AFINITOR**

### **Products Affected**

• Afinitor

• Afinitor Disperz

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Advanced Renal Cell Carcinoma: Documented diagnosis of advanced renal cell carcinoma and the member has a demonstrated disease progression or intolerance following an appropriate trial with sunitinib (Sutent) or sorafenib (Nexavar). Advanced Hormone Receptor-Positive, HER2-Negative Breast Cancer (Advanced HR+ BC): Documented diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer, the member is postmenopausal, concurrently taking exemestane (Aromasin) and has a documented failure of letrozole (Femara) or anastrozole (Arimidex). Progressive Neuroendocrine Tumors: Documented diagnosis of progressive neuroendocrine tumors of pancreatic origin in adult patients with unresectable, locally advanced, or metastatic disease or a documented diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumor located in the gastrointestinal tract or lung. Renal Angiomyolipoma with Tuberous Sclerosis Complex: Documented presence of tuberous sclerosis and renal angiomyolipoma(s) greater than or equal to 3 cm in longest diameter. Subependymal Giant Cell Astrocytoma (SEGA): Documented diagnosis of subependymal giant cell astrocytoma associated with tuberous sclerosis and the member is not a candidate for surgical resection.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **ALECENSA**

### **Products Affected**

• Alecensa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) and has progressed on or are intolerant to crizotinib (Xalkori).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **AMPYRA**

# **Products Affected**

• Ampyra

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of Multiple Sclerosis and the member is receiving concurrent therapy with a disease modifying agent (e.g. Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Rebif, Tecfidera, or Tysabri) if indicated, and the member is ambulatory with a baseline timed 25 foot walk between 8 and 45 seconds.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a neurologist.
Coverage Duration	Initial authorization is for a period of 12 weeks. Subsequent authorization is for Life of Plan.
Other Criteria	Additional authorization may be provided if there is documented improvement in walking speed from pre-treatment baseline by at least 25%.

# **APTIOM**

### **Products Affected**

• Aptiom

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of partial-onset seizures and has had an insufficient response or intolerance to two (2) or more medications indicated for adjunct partial seizures (e.g. felbamate (Felbatol), Fycompa, gabapentin (Fanatrex, Gralise, Neurontin), lamotrigine (Lamictal, Lamictal XR, Lamictal ODT), Lyrica, levetiracetam (Keppra, Keppra XR), oxcarbazepine (Oxtellar XR, Trileptal), tiagabine (Gabitril), topiramate (Topamax, Trokendi XR), Potiga, Vimpat, and/or zonisamide (Zonegran)).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a neurologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **ARCALYST**

# **Products Affected**

• Arcalyst

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of a Cryopyrin-Associated Periodic Syndrome, Familial Cold Autoinflammatory Syndrome, or Muckle-Wells Syndrome.
Age Restrictions	The member must be 12 years of age or older.
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **AUBAGIO**

### **Products Affected**

• Aubagio

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have documented diagnosis of a relapsing form of multiple sclerosis (relapsing-remitting MS, progressive-relapsing MS, or secondary progressive MS with relapse) or the member has a documented failure, contraindication, or intolerance to fingolimod (Gilenya) or dimethyl fumurate (Tecfidera).
Age Restrictions	The member must be 18 years or age or older.
Prescriber Restrictions	The prescribing physician must be a neurologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **BENLYSTA**

# **Products Affected**

• Benlysta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Benlysta (belimumab) will not be approved as monotherapy, for members with severe active lupus nephritis or severe active central nervous system lupus, for members who are autoantibody negative or in combination with other biologics or intravenous cyclophosphamide.
Required Medical Information	The member must have a documented diagnosis of active, autoantibody positive (e.g. ANA, anti-ds-DNA, anti-Sm) systemic lupus erythematosus (SLE) and is concurrently taking standard therapy for SLE (e.g., corticosteroids, antimalarials, or immunosuppressives, alone or in combination).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a rheumatologist.
Coverage Duration	FDA-approved duration, balance of contract year or clinically appropriate duration
Other Criteria	None

# **BOSULIF**

### **Products Affected**

• Bosulif ORAL TABLET 100 MG, 500 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with a documented resistance or intolerance to prior therapy, including Gleevec (imatinib mesylate).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **BOTULINUM TOXINS**

### **Products Affected**

- Botox
- Dysport

• Xeomin

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Botulinum Toxins are excluded from coverage for cosmetic procedures.
Required Medical Information	Botox: Axillary hyperhidrosis: The member must have a diagnosis of severe primary axillary hyperhidrosis that is inadequately managed withtopical agents. Cervical dystonia: Diagnosis of cervical dystonia in adults to reduce the severity of associated abnormal head position and neck pain. Chronic migraine: Diagnosis of chronic migraine (at least 15 days per month with headache lasting 4 hours a day or longer). Overactive bladder: Diagnosis of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in adults who have an inadequate response to or who are intolerant to an anticholinergic medication. Strabismus and blepharospasm (associated with dystonia): Diagnosis of strabismus or blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders. Urinary incontinence: Diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition (eg, spinal cord injury [SCI], multiple sclerosis [MS]) in adults who have an inadequate response to or are intolerant of an anticholinergic medication. Diagnosis of lower limb spasticity to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis anterior, tibialis posterior, flexor hallucis longus, and flexor digitorum longus). Botox and Dysport: Diagnosis of upper limb spasticity in adults with need to decrease the severity of increased muscle tone in elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris), and finger flexors (flexor digitorum profundus and flexor digitorum sublimis). Dysport and Xeomin: Diagnosis of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain in toxin-naive and previously treated patients. Xeomin: Blepharospasm: Diagnosis of blepharospasm previously treated with Botox. Dysport: Diagnosis of pediatric lower limb spasticity.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Two (2) years
Other Criteria	None

# **BRIVIACT**

### **Products Affected**

• Briviact

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of partial-onset seizures and has had an insufficient response or intolerance to two (2) or more medications indicated for adjunct partial seizures (e.g. felbamate(Felbatol), Fycompa, gabapentin (Fanatrex, Gralise, Neurontin), lamotrigine (Lamictal, Lamictal XR, Lamictal ODT), Lyrica, levetiracetam (Keppra, Keppra XR), oxcarbazepine (Oxtellar XR, Trileptal), tiagabine (Gabitril), topiramate (Topamax, Trokendi XR), Potiga, Vimpat, and/or zonisamide (Zonegran)).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a neurologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **BUPRENORPHINE**

### **Products Affected**

• Buprenorphine HCl SUBLINGUAL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Buprenorphine will not be covered to treat pain.
Required Medical Information	The member must have a documented diagnosis of opioid dependence.
Age Restrictions	None
Prescriber Restrictions	The requesting physician must be certified to prescribe buprenorphine for opioid dependence and has been granted a special DEA waiver and prefix code (X DEA number), in accordance with DATA 2000.
Coverage Duration	Initial authorization is for 6 months. Subsequent authorization is for 1 (one) year.
Other Criteria	None

# **BUPRENORPHINE/NALOXONE**

### **Products Affected**

• Bunavail

Buprenorphine HCl-Naloxone HCl

• Suboxone

• Zubsolv

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Buprenorphine/naloxone preparations will not be covered to treat pain.
Required Medical Information	The member must have a physician-documented diagnosis of opioid dependence.
Age Restrictions	None
Prescriber Restrictions	The requesting physician must be certified to prescribe buprenorphine for opioid dependence and has been granted a special DEA waiver and prefix code (X DEA number), in accordance with DATA 2000.
Coverage Duration	Authorization is for one (1) year.
Other Criteria	None

# **CABOMETYX**

### **Products Affected**

• Cabometyx

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of advanced renal cell carcinoma (RCC) and documentation the member received prior anti-angiogenic therapy.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **CAPRELSA**

### **Products Affected**

• Caprelsa ORAL TABLET 100 MG, 300 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease.
Age Restrictions	None
Prescriber Restrictions	The prescriber must be an endocrinologist or oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **CARBAGLU**

### **Products Affected**

• Carbaglu

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of hyperammonemia due to Nacetylglutamate synthase (NAGS) deficiency.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **CELECOXIB**

### **Products Affected**

• Celecoxib

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Coverage may be authorized for members meeting one or more of the following clinical criteria: 1) 65 years of age or older. 2) Diagnosis of Rheumatoid Arthritis and 50 years of age or older. 3) Previous or active GI bleeding or hemorrhage. 4) History of GERD or peptic ulcer disease (PUD). 5)  Demonstrated lack of effectiveness in relief of symptoms or inability to tolerate at least two (2) prescription non-COX-2 inhibitor NSAIDs (e.g. diclofenac, fenoprofen, ibuprofen, naproxen, etc). 6) Inability to tolerate other agents in the NSAID class as evidenced by significant symptoms of GI intolerance (e.g., dyspepsia, gastritis, abdominal or stomach pain, heartburn). 7) Bleeding diathesis or other medical condition(s) that would constitute a significant predisposition to bleeding (e.g. coagulopathy, hemophilia, low platelet count, surgical procedure booked within 5 days of starting the COX-2 drug, etc.). 8) The member is currently taking any of the following medications: a) anticoagulants (e.g. Coumadin, Eliquis, enoxaparin, fondaparinux, Fragmin, heparin, Innohep, Lovenox, Pradaxa, Xarelto, warfarin) b) Methotrexate, azathioprine or other metabolites c) Oral corticosteroids (e.g. prednisone, dexamethasone, etc.) d) Proton pump inhibitors (PPIs) (e.g. lansoprazole, omeprazole, pantoprazole) e) H2 antagonists (e.g. cimetidine, famotidine, ranitidine) or misoprostol.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **CERDELGA**

# **Products Affected**

• Cerdelga

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of type 1 Gaucher Disease and documentation the member is a cytochrome P450 2D6 extensive metabolizer (EMs), intermediate metabolizer (IMs), or poor metabolizer (PMs) as detected by an FDA-cleared test.
Age Restrictions	The member must be 18 years of age or older.
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **CHOLBAM**

### **Products Affected**

• Cholbam

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Cholbam will not be approved for members with extrahepatic manifestations of bile acid synthesis disorders due to single enzyme defects (SEDs) or peroxisomal disorders (PDs), including Zellweger spectrum disorders.
Required Medical Information	The member must have a documented diagnosis of bile acid synthesis disorders due to single enzyme defects (SEDs). The member must have a documented diagnosis of peroxisomal disorders (PDs), including Zellweger spectrum disorders, who exhibit manifestations of hepatic disease, steatorrhea, or complications from decreased fat soluble vitamin absorption.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	FDA-approved duration, balance of contract year or clinically appropriate duration
Other Criteria	None

# **CIALIS**

### **Products Affected**

• Cialis

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Cialis is excluded from coverage for the treatment of Erectile Dysfunction.
Required Medical Information	The member must have a documented diagnosis of Benign Prostatic Hyperplasia (BPH) and has had a documented failure, adverse reaction, or contraindication to a 30-day trial of at least two (2) of the following medications: Alfuzosin, doxazosin, finasteride, tamsulosin, or terazosin.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **CIMZIA**

### **Products Affected**

• Cimzia

### • Cimzia Prefilled

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Crohn's Disease: The member must a documented diagnosis of Crohn's disease and an inadequate response to an appropriate trial with two (2) or more of the following agents: a) Corticosteroids (e.g., methylprednisolone, prednisolone, prednisone). b) 5-Aminosalicylates (e.g. Asacol, azulfidine, Colazal, Dipentum, Pentasa, Rowasa, sulfasalazine). c) 6-mercaptopurine (6-MP, Purinethol) or azathioprine. d) Methotrexate OR the member has demonstrated failure or intolerance to infliximab (Remicade). Psoriatic Arthritis: The member must have a documented diagnosis of psoriatic arthritis and has had an inadequate response or inability to take methotrexate or sulfasalazine at maximal doses for three (3) months. Rheumatoid Arthritis (RA): The member must have a documented diagnosis of rheumatoid arthritis and has documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate. Ankylosing Spondylitis: The member has a documented diagnosis of active ankylosing spondylitis.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **CINRYZE**

# **Products Affected**

• Cinryze

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of Hereditary Angioedema.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an immunologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **COMETRIQ**

### **Products Affected**

- Cometriq (100 mg Daily Dose)Cometriq (140 mg Daily Dose)
- Cometriq (60 mg Daily Dose)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of progressive, metastatic medullary thyroid cancer.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **CORLANOR**

### **Products Affected**

• Corlanor

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of symptomatic chronic heart failure with left ventricular ejection fraction 35% or less, who are in sinus rhythm with resting heart rate at least 70 beats per minute (bpm) and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a cardiologist
Coverage Duration	Life of Plan
Other Criteria	None

# **COSENTYX**

### **Products Affected**

• Cosentyx Sensoready Pen

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Plaque Psoriasis: The member must have a documented diagnosis of moderate-to-severe chronic plaque psoriasis and has failed to respond to, or has been unable to tolerate treatment with one (1) of the following medications: cyclosporine, methotrexate, or Soriatane (acitretin). Psoriatic Arthritis: The member must have a documented diagnosis of psoriatic arthritis and has had an inadequate response or inability to take methotrexate or sulfasalazine at maximal doses for three (3) months. Ankylosing Spondylitis: The member must have a documented diagnosis of active ankylosing spondylitis.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a dermatologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **COTELLIC**

### **Products Affected**

• Cotellic

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Cotellic is not indicated for treatment of patients with wild-type BRAF melanoma.
Required Medical Information	The member must have a documented diagnosis of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation and is being taken in combination with Zelboraf (vemurafenib).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **CRESTOR**

### **Products Affected**

• Crestor

### • Rosuvastatin Calcium

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Crestor and rosuvastatin 5 mg or 10 mg: The member requires moderate LDL lowering and has tried two (2) or more of the following drugs and could not tolerate treatment due to adverse effects or there was inadequate response to maximum tolerable doses: Either simvastatin 20 mg or higher OR pravastatin 40 mg or higher, AND atorvastatin 10 mg or higher. For Crestor and rosuvastatin 20 mg and 40 mg: The member requires high LDL lowering and has tried atorvastatin 40 mg or 80 mg and was unable to tolerate treatment due to adverse effects or there was inadequate response to maximum tolerable doses.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	2 years
Other Criteria	None

# **CYRAMZA**

# **Products Affected**

• Cyramza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Gastric Cancer: The member must have advanced or metastatic gastric or gastroesophageal junction adenocarcinoma with disease progression on or following fluoropyrimidine- or platinum-containing chemotherapy. Non-Small Cell Lung Cancer (NSCLC): The member must have a documented diagnosis of metastatic NSCLC with disease progression on or after platinum-based chemotherapy AND be using Cyramza in combination with docetaxel. Members with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy [tyrosine kinase (epidermal growth factor receptor [EGFR] or anaplastic lymphoma kinase [ALK]) inhibitor (e.g., afatinib, ceritinib, crizotinib, erlotinib, gefitinib)] for these aberrations, prior to receiving Cyramza. Colorectal Cancer: The member must have a documented diagnosis of metastatic colorectal cancer (mCRC) and has previously received, or provider indicates clinical inappropriateness to therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **DEXILANT**

### **Products Affected**

• Dexilant

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The prescribing physician must submit documentation that the member has tried and failed, or has a contraindication to omeprazole OR pantoprazole, AND lansoprazole OR rabeprazole.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Two (2) years
Other Criteria	None

# **DIFICID**

### **Products Affected**

• Dificid

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of Clostridium difficile infection with a treatment failure or inadequate response to metronidazole or vancomycin.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **ENBREL**

### **Products Affected**

• Enbrel Subcutaneous

• Enbrel SureClick

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Plaque Psoriasis: The member must have a documented diagnosis of moderate-to-severe chronic plaque psoriasis and has failed to respond to, or has been unable to tolerate treatment with one (1) of the following medications: cyclosporine, methotrexate, or Soriatane (acitretin). Rheumatoid Arthritis (RA) and Polyarticular Juvenile Idiopathic Arthritis (PJIA): The member must have a documented diagnosis of either disease and has a documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate. Psoriatic Arthritis: The member must have a documented diagnosis of psoriatic arthritis and has had an inadequate response or inability to take methotrexate or sulfasalazine at maximal doses for three (3) months. Rheumatoid Arthritis (RA): The member must have a documented diagnosis of rheumatoid arthritis and has documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate. Ankylosing Spondylitis: The member must have a documented diagnosis of active ankylosing spondylitis.
Age Restrictions	the member must be 2 years of age or older.
Prescriber Restrictions	The prescribing physician must be a dermatologist or rheumatologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **ENTRESTO**

### **Products Affected**

• Entresto

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Entresto will not be covered if the member is concomitantly taking an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB).
Required Medical Information	The member must have a documented diagnosis of chronic heart failure (NYHA Class II-IV) and reduced ejection fraction.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a cardiologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **ERIVEDGE**

### **Products Affected**

• Erivedge

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of metastatic basal cell carcinoma or locally advanced basal cell carcinoma that has recurred following surgery, or who are not candidates for surgery or radiation.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **ESBRIET**

### **Products Affected**

• Esbriet

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of idiopathic pulmonary fibrosis (IPF) and the member is not currently taking Ofev (nintedanib).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a pulmonologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **ESOMEPRAZOLE**

### **Products Affected**

• Esomeprazole Magnesium

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The prescribing physician must submit documentation that the member has tried and failed, or has a contraindication to omeprazole OR pantoprazole, AND lansoprazole OR rabeprazole.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Two (2) years
Other Criteria	None

### **EVZIO**

#### **Products Affected**

• Evzio

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Evzio will be approved for coverage if one of the following requirements are met: There is a Food and Drug Administration confirmed shortage of ALL preferred products for the emergency treatment of opioid overdose (naloxone vials and syringes, Narcan [naloxone] nasal spray) or the member or the member's caregiver(s) would be unable to utilize the alternative naloxone formulations (naloxone vials and syringes, Narcan [naloxone] nasal spray) due to significant visual, physical, or functional impairment.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

### **FABRAZYME**

#### **Products Affected**

• Fabrazyme

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have the definitive diagnosis of Fabry disease.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

### **FARYDAK**

#### **Products Affected**

• Farydak

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of multiple myeloma and has received at least 2 prior therapies including bortezomib (Velcade)and an immunomodulatory agent, and Farydak is being used in combination with Velcade and dexamethasone.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

### **FIRAZYR**

#### **Products Affected**

• Firazyr

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Firazyr (icatibant) will not be approved for members with acquired angioedema. Firazyr will not be approved for members concurrently taking an angiotensin converting enzyme (ACE) inhibitor.
Required Medical Information	The member must have a documented diagnosis of Hereditary Angioedema (HAE) with a history of at least one severe attack in the past 6 months. For HAE Types 1 & 2, the diagnosis must be confirmed by laboratory testing (e.g., low C4 level, reduced C1 esterase inhibitor level or function).
Age Restrictions	The member must be 18 years of age or older.
Prescriber Restrictions	The prescribing physician must be an allergist, hematologist or immunologist.
Coverage Duration	Life of Plan
Other Criteria	None

## **FORTEO**

#### **Products Affected**

• Forteo

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Coverage of Forteo will not be approved when used in combination with any of the other osteoporosis agents listed in the ""Required Medical Information"" section.
Required Medical Information	Coverage of Forteo may be authorized when the requesting physician has documented that the member is at high risk for fracture and has a T score less than or equal to -2.0 as evidenced via bone density scan or the requesting physician has documented that the member has had one or more osteoporotic fractures. For either condition previously listed, the member must also have had an inadequate response to, or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments: alendronate (Fosamax), calcitonin (Miacalcin), denosumab (Prolia), ibandronate (Boniva), raloxifene (Evista), risedronate (Actonel) or zoledronic acid (Reclast).
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Coverage of Forteo is limited to 24 months.
Other Criteria	None

# **FYCOMPA**

#### **Products Affected**

• Fycompa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of partial-onset seizures and has had an insufficient response or intolerance to two (2) or more medications indicated for adjunct partial seizures (e.g. Aptiom, felbamate (Felbatol), gabapentin (Fanatrex, Gralise, Neurontin), lamotrigine (Lamictal, Lamictal XR, Lamictal ODT), Lyrica, levetiracetam (Keppra, Keppra XR), oxcarbazepine (Oxtellar XR, Trileptal), tiagabine (Gabitril), topiramate (Topamax, Trokendi XR), Potiga, Vimpat, and/or zonisamide (Zonegran)). The member must have a documented diagnosis of primary generalized tonic-clonic seizures and has had an insufficient response or intolerance to two (2) or more medications indicated for primary generalized tonic-clonic seizures (e.g. valproate, lamotrigine, levetiracetam, phenytoin, felbamate, topiramate, and carbamazepine).
Age Restrictions	The member must be 12 years of age or older.
Prescriber Restrictions	The prescribing physician must be a neurologist.
Coverage Duration	Life of Plan
Other Criteria	None

## **GATTEX**

#### **Products Affected**

• Gattex

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of Short Bowel Syndrome (SBS) and a history of dependence on parenteral nutrition (PN)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

## **GAUCHER DISEASE TYPE 1 TREATMENTS**

#### **Products Affected**

- Cerezyme
- Elelyso

• Vpriv

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Coverage will not be approved for Type 2 or Type 3 Gaucher Disease.
Required Medical Information	The member must have a documented diagnosis of Type 1 Gaucher disease with at least a minimal level of disease severity.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

## **GILENYA**

#### **Products Affected**

• Gilenya

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of either relapsing remitting multiple sclerosis or secondary progressive multiple sclerosis or the member has a documented failure, contraindication, or intolerance to dimethyl fumurate (Tecfidera) or teriflunomide (Aubagio).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a neurologist.
Coverage Duration	Life of Plan
Other Criteria	None

### **GILOTRIF**

#### **Products Affected**

• Gilotrif

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	None
Required Medical Information	The member must have a documented diagnosis of metastatic non-small cell lung cancer and a documented epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or a documented diagnosis of metastatic, squamous non-small cell lung cancer (NSCLC) and documentation that the disease has progressed after platinum-based chemotherapy.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# GROWTH HORMONE REPLACEMENT THERAPY

- Egrifta
- Genotropin
- Genotropin MiniQuick
- Humatrope
- Norditropin FlexPro
- Nutropin AQ NuSpin 10
- Nutropin AQ NuSpin 20
- Nutropin AQ NuSpin 5

- Nutropin AQ Pen
- Omnitrope
- Saizen
- Saizen Click.Easy
- Serostim
- Zomacton
- Zorbtive

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Pediatric GHD, Initiation, member must be evaluated and treated by a pediatric endocrinologist, have not attained epiphyseal closure as determined by X-ray, have failed to respond to at least TWO standard GH stimulation test, have documented gender-specific delayed bone age, have the height at initiation of therapy at greater than 2 standard deviations below normal mean for age and sex. Member must have one of the following, Chronic Renal Insufficiency prior to transplantation, Turner Syndrome, Prader-Willi Syndrome, Intrauterine Growth Retardation or Noonan Syndrome. Pediatric GHD, continuation, documentation of the following is required, medical history as it relates to growth, including any test results and growth chart, continuing care plan and at least a doubling of the annualized pre-treatment growth rate after the first 6 months of therapy then an increase growth velocity of at least 3cm per year thereafter. Continuation of Therapy after Completion of Linear Growth, member will be re-evaluated after GH treatments have been stopped for at least 3 months to determine growth hormone status AND member must have failed to respond to at least one standard GH stimulation test. Acquired GHD, Member must have failed to respond to at least one standard GH stimulation test. AIDS Wasting Syndrome, documented diagnosis of AIDS AND a weight loss of at least 10% from baseline weight OR a BMI of less then 20 AND documentation that the member has had an adequate nutritional evaluation and has failed to respond adequately to a high calorie diet. Short Bowel Syndrome, a documented diagnosis of Short Bowel Syndrome from a gastroenterologist AND A documented dependence on IPN for nutritional support.
Age Restrictions	None
Prescriber Restrictions	None

PA Criteria	Criteria Details
Coverage Duration	Pediatric GHD, 6 months. Acquired GHD, 1 year. Short Bowel Syndrome, Zorbtive only, 28 days
Other Criteria	None

## **HARVONI**

#### **Products Affected**

• Harvoni

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D. All FDA-approved indications not otherwise excluded from Part D, chronic hepatitis C genotype 4, 5, or 6 infection.
<b>Exclusion Criteria</b>	None
Required Medical Information	Chronic hepatitis C infection confirmed by presence of HCV RNA in the serum prior to starting tx. For G1 infection, monotherapy: 1)Total 12 wks for tx-naive pts with or without cirrhosis. Tx for 8 wks can be considered in tx-naive pts without cirrhosis who have pre-tx HCV RNA below 6 million IU/mL, 2)For pts who failed prior tx with PEG-IFN and RBV with or without HCV PI: a) total 12 wks if no cirrhosis, b) total 24 wks for cirrhosis. For G4 infection, monotherapy: Total 12 wks for pts who are tx-naive or failed prior tx with PEG-IFN and RBV. For G5 infection, monotherapy: Total 12 wks for pts who are tx-naive or failed prior tx with PEG-IFN and RBV. For recurrent HCV infection post liver txp, monotherapy: Total 24 wks for tx-naive pts with G1 or 4 infection and documented anemia or RBV ineligibility. For G1 infection, tx with RBV: 1)Total 12 wks for pts with cirrhosis who failed prior tx with a SOF-containing regimen, 3)Total 24 wks for pts with cirrhosis who failed prior tx with a SOF-containing regimen. For decompensated cirrhosis (CTP class B or C), tx with RBV: 1)Total 12 wks for pts with G1 or 4 infection, 2)Total 24 wks for pts with G1 or 4 infection post liver txp. For recurrent HCV infection post liver txp, tx with RBV: Total 12 wks for pts with G1 or 4 infection post liver txp. For recurrent HCV infection post liver txp, tx with RBV: Total 12 wks for pts with G1 or 4 infection post liver txp. For recurrent HCV infection post liver txp, tx with RBV: Total 12 wks for pts with G1 or 4 infection, pt meets all of the following: 1)Pt meets the criteria for requested regimen above, 2)Will not receive tx with cobicistat given with tenofovir, 3)Will not receive tx with tipranavir.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a gastroenterologist, hepatologist, or an infectious disease specialist.
Coverage Duration	12-24 wks depending on baseline host/viral factors with reminder for 8 wk option when appropriate.

PA Criteria	Criteria Details
Other Criteria	Harvoni will not be used with other drugs containing sofosbuvir, including Sovaldi. Anemia defined as baseline hemoglobin below 10g/dL, RBV ineligibility defined as intolerance to RBV, pregnant female or male whose female partner is pregnant, hemoglobinopathy, or coadministration with didanosine. tx=treatment, G=genotype, pt=patient, PEG-IFN=peginterferon alfa, RBV=ribavirin, PI=protease inhibitor, SOF=sofosbuvir, CTP=Child Turcotte Pugh, txp=transplantation, ART=antiretroviral therapy.

## **HETLIOZ**

#### **Products Affected**

• Hetlioz

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Coverage will not be authorized for the diagnosis of insomnia.
Required Medical Information	The member must be completely blind AND has a physician-documented diagnosis of non-24-hour sleep-wake disorder (non-24).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a sleep specialist.
Coverage Duration	Initial authorization of Hetlioz (tasimelteon) is for four (4) months.
Other Criteria	Authorization for eight (8) additional months will require documentation of efficacy from the prescriber. Authorization for Life of Plan will require confirmation of continued efficacy beyond twelve (12) months.

## HRM ANTIPARKINSON AGENTS

#### **Products Affected**

• Benztropine Mesylate ORAL

• Trihexyphenidyl HCl

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member has had a physician-documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older.
Age Restrictions	The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication.
Prescriber Restrictions	None
Coverage Duration	Initial Approval: 1 year. Subsequent approval: Life of Plan.
Other Criteria	Non-HRM Alternatives include, but are not limited to: amantadine, carbidopa/levodopa, Tasmar

## HRM ESTROGEN-CONTAINING PRODUCTS

- Alora
- CombiPatch
- Duavee
- Enjuvia
- Estradiol
- Estropipate Femhrt Low Dose

- Fyavolv
- Menest
- Menostar
- Premarin ORAL
- Premphase
- Prempro

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	This criterion applies to estrogen-containing oral and topical patch products only, with or without progesterone.
Required Medical Information	The member has had a physician-documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older.
Age Restrictions	The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication.
Prescriber Restrictions	None
Coverage Duration	Initial Approval: 1 year. Subsequent approval: Life of Plan.
Other Criteria	Non-HRM Alternatives include, but are not limited to: alendronate, calcitonin, Forteo, ibandronate, Prolia, raloxifene, risedronate, zoledronic acid (osteoporosis), estradiol vaginal cream, vaginal tab, vaginal ring (menopausal/vaginal symptoms)

## HRM FIRST GENERATION ANTIPSYCHOTICS

#### **Products Affected**

• Thioridazine HCl

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member has had a physician-documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older.
Age Restrictions	The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication.
Prescriber Restrictions	None
Coverage Duration	Initial Approval: 1 year. Subsequent approval: Life of Plan.
Other Criteria	Non-HRM Alternatives include, but are not limited to: olanzapine, quetiapine, risperidone, ziprasidone (some may require STPA for approval)

## HRM HYDROXYZINE

#### **Products Affected**

• HydrOXYzine HCl ORAL

• HydrOXYzine Pamoate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member has had a physician-documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older.
Age Restrictions	The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication.
Prescriber Restrictions	None
Coverage Duration	Initial Approval: 1 year. Subsequent approval: Life of Plan.
Other Criteria	Non-HRM Alternatives include, but are not limited to: desloratadine, levocetirizine (pruritus), duloxetine, escitalopram, venlafaxine ER (anxiety), alprazolam, midazolam, temazepam (sedation)

# **HRM HYPNOTICS**

- Eszopiclone
- Zaleplon

- Zolpidem Tartrate Zolpidem Tartrate ER

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member has had a physician-documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older.
Age Restrictions	The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication.
Prescriber Restrictions	None
Coverage Duration	Initial Approval: 1 year. Subsequent approval: Life of Plan.
Other Criteria	Non-HRM Alternatives include, but are not limited to: Rozerem, Silenor, temazepam

### HRM MISCELLANEOUS

- Cyclobenzaprine HCl
- Cyproheptadine HCl
- Digoxin ORAL SOLUTION
- Digoxin ORAL TABLET 250 MCG
- Dihydroergotamine Mesylate
- Dipyridamole
- Disopyramide Phosphate
- Doxepin HCl ORAL

- GuanFACINE HCl ER
- Indomethacin
- Indomethacin ER
- Lanoxin ORAL TABLET 187.5 MCG, 250 MCG
- Megestrol Acetate
- NIFEdipine
- Norpace CR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member has had a physician-documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older.
Age Restrictions	The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication.
Prescriber Restrictions	None
Coverage Duration	Initial Approval: 1 year. Subsequent approval: Life of Plan.

PA Criteria	Criteria Details
Other Criteria	Non-HRM Alternatives include, but are not limited to: cyclobenzaprine (baclofen, tizanidine), cyproheptadine (levocetirizine, desloratadine), digoxin/Lanoxin 250 mcg (consider reducing dose to 0.125 mg daily or lower), dihydroergotamine (almotriptan, naratriptan, rizatriptan, sumatriptan), dipyridamole immediate-release (Aggrenox, anagrelide, clopidogrel,Brilinta, Effient), disopyramide (amiodarone, flecainide, mexiletine, propafenone, quinidine, sotalol), guanfacine extended-release (amphetamine salt combo, dexmethylphenidate, dextroamphetamine, methamphetamine, methylphenidate), indomethacin (celecoxib, ibuprofen, naproxen, tramadol), megestrol tablets (covered without authorization for advanced carcinoma of the breast or endometrium), megestrol oral suspension (dronabinol) nifedipine immediate-release (isosorbide dinitrate, isosorbide mononitriate, Nitro-BID), Norpace CR (acebutolol, flecainine, mexiletine, propafenone, quinidine, sotelol), reserpine (Hypertension: ACE-Inhibitor or angiotensin-receptor blocker. Psychoses: olanzapine, quetiapine, risperidone, ziprasidone (some may require STPA for approval))

## HRM NITROFURANTOIN

#### **Products Affected**

- Nitrofurantoin
- Nitrofurantoin Macrocrystal

• Nitrofurantoin Monohyd Macro

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member has had a physician-documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older.
Age Restrictions	The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication.
Prescriber Restrictions	None
Coverage Duration	Initial Approval: 1 year. Subsequent approval: Life of Plan.
Other Criteria	Non-HRM Alternatives include, but are not limited to: ciprofloxacin, levofloxacin, sulfamethoxazole/trimethoprim, trimethoprim

# HRM ORAL HYPOGLYCEMICS

- ChlorproPAMIDE
- GlyBURIDE

- GlyBURIDE MicronizedGlyBURIDE-MetFORMIN

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. None
<b>Exclusion Criteria</b>	None
Required Medical Information	The member has had a physician-documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older.
Age Restrictions	The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication.
Prescriber Restrictions	None
Coverage Duration	Initial Approval: 1 year. Subsequent approval: Life of Plan.
Other Criteria	Non-HRM Alternatives include, but are not limited to: glimepiride, glipizide, glipizide-metformin, tolazamide, tolbutamide

# HRM PHENOBARBITAL

#### **Products Affected**

• PHENobarbital

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member has had a physician-documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older.
Age Restrictions	The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication.
Prescriber Restrictions	None
Coverage Duration	Initial Approval: 1 year. Subsequent approval: Life of Plan.
Other Criteria	Non-HRM Alternatives include, but are not limited to: alprazolam, midazolam, temazepam (sedation), Cerebyx, lorazepam, midazolam (status epilepticus), carbamazepine, lamotrigine, levetiracetam, topiramate, valproate (seizures)

## HRM PROMETHAZINE

#### **Products Affected**

• Promethazine HCl ORAL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member has had a physician-documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older.
Age Restrictions	The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication.
Prescriber Restrictions	None
Coverage Duration	Initial Approval: 1 year. Subsequent approval: Life of Plan.
Other Criteria	Non-HRM Alternatives include, but are not limited to: budesonide nasal, desloratadine, fluticasone nasal, flunisolide nasal, levocetirizine, triamcinolone nasal (allergic rhinitis), Anzemet, Cesamet, Emend, meclizine, perphenazine, ondansetron, prochlorperazine, sancuso (emesis/motion sickness), alprazolam, midazolam, temazepam (sedation), desloratadine, levocetirizine (urticaria)

# HRM TRICYCLIC ANTIDEPRESSANTS

- Amitriptyline HCl
- ClomiPRAMINE HCl
- Imipramine HCl

- Imipramine Pamoate
- Surmontil
- Trimipramine Maleate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member has had a physician-documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older.
Age Restrictions	The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication.
Prescriber Restrictions	None
Coverage Duration	Initial Approval: 1 year. Subsequent approval: Life of Plan.
Other Criteria	Non-HRM Alternatives include, but are not limited to: citalopram, duloxetine, escitalopram, venlafaxine (depression), fluoxetine, fluvoxamine, paroxetine, sertraline (depression/OCD)

### **HUMIRA**

- Humira
- Humira Pediatric Crohns Start
- Humira Pen

- Humira Pen-Crohns Starter
- Humira Pen-Psoriasis Starter

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Crohn's Disease and Ulcerative Colitis (UC): The member must a documented diagnosis of either disease and an inadequate response to an appropriate trial with two (2) or more of the following agents: a) Corticosteroids (e.g., methylprednisolone, prednisolone, prednisone). b) 5-Aminosalicylates (e.g. Asacol, azulfidine, Colazal, Dipentum, Pentasa, Rowasa, sulfasalazine). c) 6-mercaptopurine (6-MP, Purinethol) or azathioprine. d) Methotrexate OR the member has demonstrated failure or intolerance to infliximab (Remicade). Plaque Psoriasis: The member must have a documented diagnosis of moderate-to-severe chronic plaque psoriasis and has failed to respond to, or has been unable to tolerate treatment with one (1) of the following medications: cyclosporine, methotrexate, or Soriatane (acitretin). Rheumatoid Arthritis (RA) and Polyarticular Juvenile Idiopathic Arthritis (PJIA): The member must have a documented diagnosis of either disease and has a documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate. Psoriatic Arthritis: The member must have a documented diagnosis of psoriatic arthritis and has had an inadequate response or inability to take methotrexate or sulfasalazine at maximal doses for three (3) months. Rheumatoid Arthritis (RA): The member must have a documented diagnosis of rheumatoid arthritis and has documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate. Ankylosing Spondylitis: The member must have a documented diagnosis of active ankylosing spondylitis. Hidradenitis Suppurativa: The member must have a documented diagnosis of moderate to severe hidradenitis suppurativa. Uveitis: The member must have a documented diagnosis of non-infectious intermediate, posterior, and panuveitis.
Age Restrictions	The member must be 2 years of age or older.
Prescriber Restrictions	The prescribing physician must be a dermatologist, gastroenterologist, ophthalmologist or rheumatologist.
Coverage Duration	Life of Plan
Other Criteria	None

## **IBRANCE**

#### **Products Affected**

• Ibrance

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must be a post-menopausal woman with a documented diagnosis of estrogen receptor (ER) - positive, human epidermal growth factor receptor-2 (HER-2) negative advanced metastatic breast cancer and Ibrance is being used in combination with letrozole OR the member must have a documented diagnosis of estrogen receptor positive, human epidermal growth factor receptor-2 negative advanced metastatic breast cancer with disease progression following endocrine therapy and documentation Ibrance (palbociclib) will be used in combination with fluvestrant.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **ICLUSIG**

#### **Products Affected**

• Iclusig

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Acute Lymphoblastic Leukemia: The member must have a documented diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL) for whom no other tyrosine kinase inhibitor therapy is indicated or who are T315I positive. Chronic Myeloid Leukemia: The member must have a documented diagnosis of chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) for whom no other tyrosine kinase inhibitor therapy is indicated or who are T315I positive.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

## **ILARIS**

#### **Products Affected**

• Ilaris

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Cryopyrin-Associated Periodic Syndromes: The member has a documented diagnosis of a Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS), or Muckle-Wells Syndrome (MWS). Systemic Juvenile Idiopathic Arthritis (SJIA): The member must have a documented diagnosis of systemic juvenile idiopathic arthritis and has a documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate OR BOTH corticosteroids (e.g., methylprednisolone, prednisolone, prednisone) AND NSAIDs (e.g. diclofenac, fenoprofen, ibuprofen, naproxen, etc.).
Age Restrictions	CAPS: The member must be 4 years of age or older. SJIA: The member must be 2 years of age or older.
Prescriber Restrictions	SJIA: The prescribing physician must be a rheumatologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **IMBRUVICA**

#### **Products Affected**

• Imbruvica

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of Chronic Lymphocytic Leukemia (CLL) or Mantle Cell Lymphoma (MCL) or the member has CLL with 17p deletion OR the member must have a documented diagnosis of Waldenstrom's macroglobulinemia.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

## **INCRELEX**

#### **Products Affected**

• Increlex

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Coverage of Increlex will not be authorized for conditions resulting in secondary forms of IGFD that include, but are not limited to: GH deficiency, malnutrition, hypothyroidism, or chronic steroid therapy.
Required Medical Information	The member must have a documented diagnosis of severe primary IGFD as defined by a height SD score less than or equal to -3.0, a basal IGF-1 SD score less than or equal to -3.0, normal or elevated GH level OR GH gene deletion and has developed neutralizing antibodies to GH. Radiographs documenting open epiphyses are required for members who are Tanner stage III or greater.
Age Restrictions	The member must be aged 2 to 18 years.
Prescriber Restrictions	The prescribing physician must be an endocrinologist.
Coverage Duration	Initial authorization is for 6 months. Subsequent authorization are annual.
Other Criteria	None

### **INLYTA**

#### **Products Affected**

• Inlyta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of advanced renal cell carcinoma and has failed a trial of at least one (1) first-line systemic therapy (e.g. Afinitor, Avastin, Nexavar, Sutent, Torisel, Votrient).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

## INTRAVENOUS IMMUNE GLOBULIN

- Bivigam
- Carimune NF
- Flebogamma DIF
- GamaSTAN S/D
- Gammagard

- Gammaked
- Gammaplex
- Gamunex-C
- Octagam
- Privigen

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Coverage not approved for progressive MS
Required Medical Information	Documented diagnosis one of the following, primary humoral immunodeficiency (Congenital agammaglobulinemia, Common variable immunodeficiency, Wiskott-Aldrich syndrome, X-linked agammaglobulinemia, or Severe combined immunodeficiency). Recurrent severe infection and documented severe deficiency or absence of IgG subclass. Clinically significant functional deficiency of humoral immunity as evidenced by documented failure to produce antibodies to specific antigens and a history of recurrent infections. Immune thrombocytopenic purpura (ITP) (Acute and Chronic refractory ITP). Chronic lymphocytic leukemia with associated hypogammaglobulinemia. Symptomatic human immunodeficiency virus (HIV) in patients less than 13 years of age, who are immunologically abnormal. Bone marrow transplantation. Solid organ transplantation. Kawasaki disease (mucocutaneous lymph node syndrome). Acute and chronic inflammatory Demyelinating polyradiculoneuropathy, Guillain-Barre syndrome, myasthenia gravis, Immune thrombocytopenic purpura in pregnancy, multifocal motor neuropathy (MMN) and dermatomyositis. Autoimmune mucocutaneous blistering diseases (Pemphigus vulgaris, Pemphigus foliaceus, Bullous pemphigoid, Mucous membrane pemphigoid (a.k.a., cicatrical pemphigoid), or Epidermolysis bullosa Acquisita). Scleromyxedema is covered for patients whose treatment with more traditional measures has failed. Humoral or vascular allograft rejection. Hemolytic anemia. Polymyositis and Dermatomyositis. Sensitized renal transplant recipients. Sepsis, Kidney disease, CMV infection, von Willebrand disorder, Uveitis, Toxic shock syndrome, RSV infection, HIV-associated thrombocytopenia, and treatment of post-transfusion Purpura, chronic inflammatory demyelinating polyneuropathy, Hepatitis A, Measles (Rubeola), Rubella, Varicella in immunosuppressed patients when varicella zoster immunoglobulin is not available.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	6 months upon initial approval

PA Criteria	Criteria Details
Other Criteria	None

### **IRESSA**

#### **Products Affected**

• Iressa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of metastatic non-small cell lung cancer (NSCLC) in tumors that have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **ITRACONAZOLE**

#### **Products Affected**

• Itraconazole

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member has must have a documented diagnosis of onychomycosis of the fingernails or toenails, or tinea capitis, and the requesting physician has documented that the member has had a treatment failure of, or is unable to tolerate, an adequate trial of terbinafine tablets or Lamisil oral granules, or the requesting physician has documented that the member has a case of one of the following fungal infections: Blastomycosis, Histoplasmosis, Cryptococcus neoformans, Aspergillosis or Tinea (pedis, corporis) resistant to aggressive topical therapy.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	This criteria applies to brand name Onmel

# **JAKAFI**

#### **Products Affected**

Jakafi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of intermediate or high-risk myelofibrosis. The member must have a documented diagnosis of polycythemia vera with an inadequate response to or intolerance to hydroxyurea.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Initial authorization is for 6 months. Subsequent authorization is for Life of Plan.
Other Criteria	Subsequent authorization requires documentation of spleen size reduction or symptomatic improvement.

### **JUXTAPID**

#### **Products Affected**

• Juxtapid

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a laboratory-confirmed documented diagnosis of homozygous familial hypercholesterolemia (HoFH) based on one of the following tests: a) LDLR DNA Sequence Analysis or LDLR Deletion/Duplication Analysis for large gene rearrangement testing - only if the Sequence Analysis is negative or APOB and PCSK9 testing if both of the above tests are negative but a strong clinical picture exists and the member is concurrently taking lipid-lowering medications or has a documented contraindication to lipid-lower medications.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **KADCYLA**

#### **Products Affected**

• Kadcyla

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of human epidermal growth factor receptor 2 (HER2)-positive, metastatic breast cancer and has previously received trastuzumab (Herceptin) and a taxane, separately or in combination. Patients should have either received prior therapy for metastatic disease or developed disease recurrence during or within 6 months of completing adjuvant therapy.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **KALYDECO**

#### **Products Affected**

• Kalydeco

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Kalydeco is not effective in patients with cystic fibrosis who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene and has not been studied in other populations of patients with cystic fibrosis.
Required Medical Information	Kalydeco is covered for members with a documented diagnosis of cystic fibrosis who have one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, R117H, S1251N, S1255P, S549N, or S549R. If the patient's genotype is unknown, a US Food and Drug Administration cleared cystic fibrosis mutation test should be used to detect the presence of a CFTR mutation followed by verification with bidirectional sequencing when recommended by the mutation test instructions for use.
Age Restrictions	Tablets: 6 years or older. Granules: 2-6 years of age.
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **KANUMA**

#### **Products Affected**

• Kanuma

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of Lysosomal Acid Lipase (LAL) deficiency and the diagnosis has been confirmed by a Dried Blood Spot (DBS) test, genetic testing or leucocyte testing.
Age Restrictions	None
Prescriber Restrictions	The prescriber must be a provider specializing in genetics and metabolism.
Coverage Duration	Life of Plan
Other Criteria	None

### **KEVEYIS**

#### **Products Affected**

• Keveyis

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

### **KINERET**

#### **Products Affected**

• Kineret

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Rheumatoid Arthritis (RA): The member must have a documented diagnosis of moderately to severely active rheumatoid arthritis and has documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate. Neonatal-Onset Multisystem Inflammatory Disease (NOMID): The member has a documented diagnosis of NOMID.
Age Restrictions	For RA, the member must be 18 years of age or older.
Prescriber Restrictions	The prescribing physician must be a rheumatologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **KORLYM**

#### **Products Affected**

• Korlym

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of hyperglycemia secondary to hypercortisolism in patients with endogenous Cushing syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **KUVAN**

#### **Products Affected**

• Kuvan

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Kuvan will not be covered unless used in conjunction with a phenylalanine-restricted diet.
Required Medical Information	The member must have a documented diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4-)responsive phenylketonuria (PKU).
Age Restrictions	None
Prescriber Restrictions	The prescribing physican must be a specialist in metabolic diseases.
Coverage Duration	Initial approval is for 8 weeks. Subsequent approval is for Life of Plan.
Other Criteria	Coverage may be authorized for continuing therapy if the member has demonstrated at least a 30% reduction in phenylalanine levels compared to baseline.

### **KYNAMRO**

#### **Products Affected**

• Kynamro

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a laboratory-confirmed documented diagnosis of homozygous familial hypercholesterolemia (HoFH) based on one of the following tests: a) LDLR DNA Sequence Analysis or LDLR Deletion/Duplication Analysis for large gene rearrangement testing - only if the Sequence Analysis is negative or APOB and PCSK9 testing if both of the above tests are negative but a strong clinical picture exists and the member is concurrently taking lipid-lowering medications or has a documented contraindication to lipid-lower medications.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

### **LENVIMA**

#### **Products Affected**

- Lenvima 10 MG Daily Dose
  Lenvima 14 MG Daily Dose
  Lenvima 18 MG Daily Dose

- Lenvima 20 MG Daily Dose

- Lenvima 24 MG Daily DoseLenvima 8 MG Daily DoseLenvima 8mg Daily Dose

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# LIDOCAINE TRANSDERMAL PATCHES

#### **Products Affected**

• Lidocaine EXTERNAL PATCH

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	For Postherpetic Neuralgia or Diabetic Neuropathy, the member must have had a failure, adverse reaction, or contraindication to gabapentin. Lidocaine transdermal patches may be approved for members who are not candidates for opioid or other oral pain management therapy.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	Coverage will be authorized for new members if their pain is currently well-controlled on lidocaine transdermal patches.

# **LONSURF**

#### **Products Affected**

• Lonsurf

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of metastatic colorectal cancer (mCRC) AND the member must have documentation they have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) biological therapy, and if rat sarcoma viral oncogene (RAS) wild-type, an anti-epidermal growth factor receptor (EGFR) therapy.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

### **LYNPARZA**

#### **Products Affected**

• Lynparza

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis deleterious or suspected deleterious germline BRCA mutated (as detected by an FDA-approved test) advanced ovarian cancer and provide documentation of failure of at least three prior lines of chemotherapy.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# MEDICATIONS FOR THE TREATMENT OF PULMONARY HYPERTENSION

#### **Products Affected**

- Adcirca
- Adempas
- Letairis
- Opsumit
- Orenitram
- Remodulin

- Revatio
- Sildenafil Citrate
- Tracleer
- Tyvaso
- Uptravi
- Ventavis

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a definitive diagnosis of pulmonary arterial hypertension (WHO group I: see below) as confirmed by right heart catheterization. World Health Organization (WHO) Classification of Pulmonary Hypertension - Group 1: a) Idiopathic PAH (primary pulmonary hypertension). b) Heritable PAH. c) Drug- and toxin-induced PAH. d) PAH associated with other diseases and conditions (APAH), such as: i) Connective tissue diseases ii) HIV infection iii) Portal hypertension iv) Congenital heart disease v) Schistosomiasis vi) Chronic hemolytic anemia. e) Persistent pulmonary hypertension of the newborn AND the pulmonary hypertension has progressed despite surgical treatment and/or maximal medical treatment of the underlying condition AND the medication used for treatment is consistent with its FDA approved functional class (see Other Criteria).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a cardiologist or pulmonologist.
Coverage Duration	Life of Plan
Other Criteria	Adcirca-NYHA Class II and III: Adempas-WHO Class II and III (Pulmonary Arterial Hypertension): Letairis-WHO Class II and III: Opsumit-WHO Class II and III: Orenitram-WHO Class II and III: Remodulin-NYHA Class II, III, and IV: sildenafil-NYHA Class II and III: Tracleer-NYHA Class II, III, and IV: Tyvaso-NYHA Class III: Uptravi - WHO Group I: Ventavis-NYHA Class III and IV

### **MEKINIST**

#### **Products Affected**

• Mekinist

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	If Mekinist (trametinib) is being used as a single agent it will not be approved for members who have received prior BRAF-inhibitor therapy.
Required Medical Information	The member must have a documented diagnosis of unresectable or metastatic melanoma with a BRAF V600E or BRAF V600K mutation as confirmed by an FDA-approved test for the detection of BRAF V600 mutations in tumor specimens.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# MODAFINIL AND NUVIGIL

#### **Products Affected**

- Armodafinil
- Modafinil

• Nuvigil

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Coverage will not be approved for generalized fatigue, jet lag, or sleep-deprivation not associated with a covered diagnosis.
Required Medical Information	The member must have a physician-documented diagnosis of Narcolepsy, Obstructive Sleep Apnea, or Shift-work sleep disorder.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **NATPARA**

#### **Products Affected**

• Natpara

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Natpara will not be approved for members who are well-controlled on calcium supplements and active forms of vitamin D alone, or for members with hypoparathyroidism caused by calcium-sensing receptor mutations or acute postsurgical hypoparathyroidism.
Required Medical Information	The member must have a documented diagnosis of hypocalcemia secondary to hypoparathyroidism and Natpara is being used as an adjunct to calcium and vitamin D supplementation. Before starting Natpara, the prescriber must confirm sufficient 25-hydroxyvitamin D stores and that serum calcium is above 7.5 mg/dL.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an endocrinologist.
Coverage Duration	Life of Plan
Other Criteria	None

### **NEXAVAR**

#### **Products Affected**

• NexAVAR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have one of the following: 1. Documented diagnosis of advanced Renal Cell Carcinoma (RCC). 2. Biopsy-proven, unresectable hepatocellular carcinoma (HCC). 3. Documented diagnosis of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.
Age Restrictions	The member must be 18 years of age or older.
Prescriber Restrictions	The prescribing physician must be a nephrologist, oncologist, or urologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **NINLARO**

#### **Products Affected**

• Ninlaro

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of multiple myeloma and Ninlaro is being used in combination with lenalidomide (Revlimid) and dexamethasone in patients who have received at least 1 prior therapy.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **NORTHERA**

#### **Products Affected**

• Northera

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of neurogenic orthostatic hypotension (NOH).
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **NUCALA**

#### **Products Affected**

• Nucala

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of severe asthma with an eosinophilic phenotype and documentation that underlying conditions or triggers for asthma or pulmonary disease are being maximally managed.
Age Restrictions	The member must be 12 years of age or older.
Prescriber Restrictions	The prescriber must be an asthma specialist (e.g., allergist, immunologist, pulmonologist).
Coverage Duration	Life of Plan
Other Criteria	None

# **NUEDEXTA**

#### **Products Affected**

• Nuedexta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of pseudobulbar affect (PBA).
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

### **NUPLAZID**

#### **Products Affected**

• Nuplazid

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of Parkinson disease and hallucinations and delusions associated with Parkinson disease psychosis.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a neurologist or psychiatrist or has documentation of a consultation with a neurologist or psychiatrist.
Coverage Duration	Life of Plan
Other Criteria	None

# **OCALIVA**

#### **Products Affected**

• Ocaliva

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Ocaliva will not be authorized for the treatment of non-alcoholic steatohepatitis.
Required Medical Information	The member must have a documented diagnosis of primary biliary cholangitis (PBC) in combination with ursodiol (ursodeoxycholic acid) in adults with an inadequate response to ursodiol, or as monotherapy in adults unable to tolerate ursodiol.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **ODOMZO**

#### **Products Affected**

• Odomzo

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of locally advanced basal cell carcinoma and one of the following: A) Documentation of disease recurrence following surgery or radiation therapy or B) Documentation that the member is not a candidate for surgery or radiation therapy.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

### **OFEV**

#### **Products Affected**

• Ofev

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of idiopathic pulmonary fibrosis (IPF) and the member is not currently taking Esbriet (pirfenidone).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a pulmonologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **ORENCIA**

#### **Products Affected**

- Orencia ClickJect
- Orencia Intravenous

• Orencia Subcutaneous

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Coverage of Orencia will not be approved if administered concomitantly with another tumor necrosis factor antagonist or Kineret (anakinra).
Required Medical Information	Rheumatoid Arthritis: The member must have a documented diagnosis of rheumatoid arthritis and a documented inadequate response or inability to tolerate at least one tumor necrosis factor antagonist: Cimzia (certolizumab), Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab), Simponi/Simponi Aria (golimumab). Juvenile Idiopathic Arthritis (JIA): The member must have a documented diagnosis of juvenile idiopathic arthritis and has a documented inadequate response or inability to tolerate Enbrel (etanercept) or Humira (adalimumab).
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

### **ORFADIN**

#### **Products Affected**

• Orfadin

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of genetic tyrosinemia Type-1 (hereditary tyrosinemia Type-1).
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

### **ORKAMBI**

#### **Products Affected**

• Orkambi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Orkambi will not be covered for individuals that are not homozygous for the F508del mutation.
Required Medical Information	The member must have a documented diagnosis of cystic fibrosis and have documentation from an FDA-approved CF mutation test that the member has the F508del mutation on both alleles of the CFTR gene.
Age Restrictions	The member must be 12 years of age or older.
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

### **OTEZLA**

#### **Products Affected**

• Otezla

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Psoriatic Arthritis: The member must have a documented diagnosis of psoriatic arthritis and has had an inadequate response or inability to tolerate methotrexate or sulfasalazine at maximal doses for three (3) months. Plaque Psoriasis: The member must have a documented diagnosis of moderate-to-severe chronic plaque psoriasis and has failed to respond to, or has been unable to tolerate treatment with one (1) of the following medications: cyclosporine, methotrexate, or Soriatane (acitretin).
Age Restrictions	The member must be 18 years of age or older.
Prescriber Restrictions	The prescribing physician must be a rheumatologist or dermatologist.
Coverage Duration	Life of Plan
Other Criteria	None

### **PERJETA**

#### **Products Affected**

• Perjeta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Metastatic Breast Cancer: The member must have a documented history of human epidermal growth factor receptor 2 (HER2)-positive metastatic breast cancer and has not received prior anti-HER2 therapy or chemotherapy for metastatic disease. Neoadjuvant Treatment of Breast Cancer: The member has a documented history of HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive).
Age Restrictions	The member must be 18 years of age or older.
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **POMALYST**

#### **Products Affected**

• Pomalyst

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of multiple myeloma and has received at least 2 prior therapies including lenalidomide (Revlimid) and bortezomib (Velcade), and has demonstrated disease progression on or within 60 days of completion of the last therapy.
Age Restrictions	The member must be 18 years of age or older.
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **POTIGA**

#### **Products Affected**

• Potiga

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of partial-onset seizures and has had an insufficient response or intolerance to two (2) or more medications indicated for adjunct partial seizures (e.g. Aptiom, felbamate (Felbatol), Fycompa, gabapentin (Fanatrex, Gralise, Neurontin), lamotrigine (Lamictal, Lamictal XR, Lamictal ODT), Lyrica, levetiracetam (Keppra, Keppra XR), oxcarbazepine (Oxtellar XR, Trileptal), tiagabine (Gabitril), topiramate (Topamax, Trokendi XR), Vimpat, and/or zonisamide (Zonegran)).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a neurologist.
Coverage Duration	Life of Plan
Other Criteria	None

# PROLIA AND XGEVA

### **Products Affected**

• Prolia

• Xgeva

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Coverage of Prolia (denosumab) for the treatment of osteoporosis in men and postmenopausal women may be authorized when the following criteria are met: The member is at high risk of fracture defined as a history of osteoporotic fracture or multiple risk factors for fracture and a T score less than or equal to -2.0 as evidenced via bone density scan or the member has had an inadequate response to, or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments [alendronate (Fosamax), calcitonin (Miacalcin), ibandronate (Boniva), raloxifene (Evista), risedronate (Actonel), zoledronic acid (Reclast)] or the member is a female at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer and is using Prolia (desosumab) as a treatment to increase bone mass. Coverage of Prolia may be authorized for men at high risk of fracture who are receiving androgen deprivation therapy for nonmetastatic prostate cancer. Coverage for Xgeva (denosumab) may be authorized for prevention of skeletal-related events in patients with bone metastases from solid tumors only or the member is being treated for unresectable giant cell tumor of bone (GCTB) or surgical resection of GCTB is likely to result in severe morbidity, or for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **PROMACTA**

### **Products Affected**

• Promacta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of Chronic Immune (idiopathic) Thrombocytopenic purpura (ITP) and have had an insufficient response or intolerance to corticosteroids, immunoglobulins, or splenectomy. Coverage may also be authorized for the treatment of thrombocytopenia in patients with chronic hepatitis C infection. Coverage may be authorized for the treatment of severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **RAVICTI**

### **Products Affected**

• Ravicti

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of a urea cycle disorder and the condition cannot be managed by dietary protein restriction and/or amino acid supplementation alone.
Age Restrictions	The member must be 2 years of age or older.
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **REMICADE**

### **Products Affected**

• Remicade

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Crohn's Disease, Pediatric Ulcerative Colitis, or Ulcerative Colitis (UC): The member must a documented diagnosis of one of the aforementioned diseases and an inadequate response to an appropriate trial with two (2) or more of the following agents: a) Corticosteroids (e.g., methylprednisolone, prednisolone, prednisone). b) 5-Aminosalicylates (e.g. Asacol, azulfidine, Colazal, Dipentum, Pentasa, Rowasa, sulfasalazine). c) 6-mercaptopurine (6-MP, Purinethol) or azathioprine. d) Methotrexate. Plaque Psoriasis: The member must have a documented diagnosis of severe chronic plaque psoriasis and has failed to respond to, or has been unable to tolerate treatment with one (1) of the following medications: cyclosporine, methotrexate, or Soriatane (acitretin). Psoriatic Arthritis: The member must have a documented diagnosis of psoriatic arthritis and has had an inadequate response or inability to take methotrexate or sulfasalazine at maximal doses for three (3) months. Rheumatoid Arthritis (RA): The member must have a documented diagnosis of rheumatoid arthritis and has documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate. Ankylosing Spondylitis: The member must have a documented diagnosis of active ankylosing spondylitis.
Age Restrictions	The member must be 18 years of age or older. For pediatric Crohn's Disease and Ulcerative Colitis, the member must 6 years of age or older.
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

### **REPATHA**

### **Products Affected**

- Repatha
- Repatha Pushtronex System

• Repatha SureClick

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Coverage may be authorized when ALL of the criteria are met: FOR ALL REQUESTS: INITIAL AUTHORIZATION: 1) Value and date of baseline LDL cholesterol. 2) Documented lipid-lowering treatments and responses. REAUTHORIZATION: 1) Pretreatment and current LDL cholesterol. INITIAL AUTHORIZATION: Clinical atherosclerotic CV disease (ASCVD): The member has a history of ASCVD or CV event (Provide documentation of the event/diagnosis. ASCVD is defined as a diagnosis of: Acute coronary syndromes, history of MI, angina, arterial revascularization procedure, stroke of atherosclerotic origin, transient ischemic attack, peripheral arterial disease of atherosclerotic origin OR ASCVD from CT angiogram or catheterization) AND current LDL-C level of greater than or equal to 70 mg/dL after treatment with a high-potency statin (See below), OR a contraindication/intolerance to statin therapy. Familial Hypercholesterolemia (FH): 1. Documented diagnosis by one of the following: a) Genetic test b) Meets Simon-Broome or WHO/Dutch Lipid Clinic Network Criteria. One of the previous AND one of the following: 1) Has concurrent ASCVD (See above) 2) Homozygous FH (HoFH): Current LDL-C level of greater than or equal to 100 mg/dL after treatment with a high-potency statin (See below) AND ezetimibe, OR a contraindication/intolerance to statin therapy AND is taking ezetimibe, OR a contraindication to BOTH statin therapy and ezetimibe. Heterozyous FH (HeFH): Current LDL-C level of greater than or equal to 100 mg/dL after treatment with a high-potency statin (See below), OR a contraindication/intolerance to statin
Age Restrictions	None
Prescriber Restrictions	The medication is being prescribed by or in consultation with a cardiologist, endocrinologist, lipidologist, or neurologist.
Coverage Duration	Initial: 6 months, Reauthorization: 12 months

PA Criteria	Criteria Details
Other Criteria	REAUTHORIZATION: Reauthorizations may be given in 12-month intervals, provided the following criteria are met: 1) The member has achieved or maintained a clinically significant LDL-C reduction. Include LDL-C value and date that LDL-C level was drawn. 2) The member is concurrently taking maximally-tolerated, high-potency statins unless otherwise contraindicated. Definitions: High-potency statin treatment: atorvastatin greater than or equal to 40 mg or rosuvastatin greater than or equal to 20 mg daily. Simon-Broome Diagnostic Criteria for definite FH: Total cholesterol greater than 290 mg/dL or LDL-C greater than 190 mg/dL and tendon xanthomas in the patient, first (parent, sibling or child) or second degree relative (grandparent, uncle or aunt). Dutch Lipid Clinical Network Criteria for definite FH: Total score greater than 8 points.

# **RESTASIS**

### **Products Affected**

• Restasis

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a definitive diagnosis of Chronic Dry Eye Syndrome, Keratoconjuctivitis Sicca (KCS), Keratitis Sicca, Xerophthalmia, or Sjogrens Syndrome, or is being treated for Ocular Graft vs. Host Disease or Corneal Transplant Rejection.
Age Restrictions	The member must be 16 years of age or older.
Prescriber Restrictions	The prescribing physician must be an ophthalmologist or optometrist.
Coverage Duration	Life of Plan
Other Criteria	None

# RETINOIDS FOR THE TOPICAL TREATMENT OF ACNE VULGARIS AND PSORIASIS

#### **Products Affected**

- Adapalene
- Atralin
- Avita
- Differin
- Fabior

- Retin-A
- Retin-A Micro
- Tazorac
- Tretinoin EXTERNAL
- Tretinoin Microsphere

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Coverage of topical acne products will not authorized for cosmetic purposes.
Required Medical Information	For all retinoids, the member must have a physician-documented diagnosis of acne vulgaris, comedones (white heads), or actinic keratosis. Tazorac may also be covered if the member has a physician-documented diagnosis of plaque psoriasis or documented diagnosis of skin cancer provided effective treatment with Tazorac is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature.
Age Restrictions	This criteria only applies to members age 26 or older. Authorization is not required for members 25 years of age or younger.
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

### **REVLIMID**

### **Products Affected**

• Revlimid

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Myelodysplastic Syndrome: The member must have a documented diagnosis of transfusion-dependent anemia due to myelodysplastic syndrome associated with the 5q-deletion cytogenetic abnormality. Multiple Myeloma: The member must have a documented diagnosis of multiple myeloma and Revlimid is being used in combination with dexamethasone. Mantle Cell Lymphoma: The member has a documented diagnosis of mantle cell lymphoma and the member's disease has relapsed or progressed after two prior therapies, one of which included Velcade (bortezomib).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a hematologist or oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

### **RITUXAN**

### **Products Affected**

• Rituxan

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Coverage for Rituxan may be authorized when used in combination with methotrexate for members with a diagnosis of active rheumatoid arthritis and have a documented inadequate response to an appropriate trial with at least one tumor necrosis factor (TNF) antagonist therapy, including Cimzia (certolizumab pegol), Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab) or Simponi/Simponi Aria (golimumab). Coverage may authorized for members with a documented diagnosis of Wegener's granulomatosis or microscopic polyangiitis, and the member is concurrently taking glucocorticoids (e.g., prednisone). Rituxan does not require prior authorization for members with a diagnosis of Non-Hodgkins Lymphoma or Chronic Lymphocytic Leukemia.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	Additional authorization for Wegener's granulomatosis or microscopic polyangiitis may be given if documentation of an objective measurable effect is provided indicating clinical improvement of condition. Subsequent authorizations may be given in 6-month intervals.

# **SIGNIFOR**

### **Products Affected**

• Signifor

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member has a documented diagnosis of Cushing's disease and pituitary surgery is not an option or has not been curative.
Age Restrictions	The member must be 18 years of age or older.
Prescriber Restrictions	The prescribing physician must be an endocrinologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **SIGNIFOR LAR**

### **Products Affected**

• Signifor LAR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of acromegaly and has had a failure of, or is unable to tolerate, a treatment regimen that includes octreotide (Sandostatin/ Sandostatin LAR Depot) OR lanreotide (Somatuline Depot), and the member is not a candidate for surgery and/or radiation, or has had an inadequate response to surgery and/or radiation.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an endocrinologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **SIMPONI**

### **Products Affected**

• Simponi Aria

• Simponi Subcutaneous

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Ankylosing Spondylitis: The member must have a documented diagnosis of active ankylosing spondylitis. Psoriatic Arthritis: The member must have a documented diagnosis of psoriatic arthritis and has had an inadequate response or inability to take methotrexate or sulfasalazine at maximal doses for three (3) months. Rheumatoid Arthritis (RA): The member must have a documented diagnosis of rheumatoid arthritis and has documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate. Ulcerative Colitis (UC): The member must a documented diagnosis of moderate to severely active ulcerative colitis and an inadequate response to an appropriate trial with two (2) or more of the following agents: a) Corticosteroids (e.g., methylprednisolone, prednisolone, prednisone). b) 5-Aminosalicylates (e.g. Asacol, azulfidine, Colazal, Dipentum, Pentasa, Rowasa, sulfasalazine). c) 6-mercaptopurine (6-MP, Purinethol) or azathioprine. d) Methotrexate OR the member has demonstrated failure or intolerance to infliximab (Remicade).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a dermatologist, gastroenterologist or rheumatologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **SIRTURO**

### **Products Affected**

• Sirturo

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) and Sirturo (bedaquiline) is being used in combination with at least three other drugs to which the patient's MDR-TB isolate has been shown to be susceptible in vitro. If in vitro testing results are unavailable, treatment may be initiated with Sirturo in combination with at least four other drugs to which the patient's MDR-TB isolate is likely to be susceptible.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **SOMAVERT**

### **Products Affected**

• Somavert

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of acromegaly and has had a failure of, or is unable to tolerate, a treatment regimen that includes octreotide, and the member is not a candidate for surgery and/or radiation, or has had an inadequate response to surgery and/or radiation.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an endocrinologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **SOVALDI**

### **Products Affected**

• Sovaldi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D, chronic hepatitis C genotype 5 or 6 infection.
<b>Exclusion Criteria</b>	None
Required Medical Information	Chronic hepatitis C infection confirmed by presence of HCV RNA in serum prior to 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 variants (eg, NS3 Q80K polymorphism) where applicable, liver transplantation status if applicable. For patients with genotype 1, 2, 3, or 4 infection and hepatocellular carcinoma awaiting liver transplantation: must meet MILAN criteria. Coverage conditions and specific durations of approval will be based on current AASLD treatment guidelines.
Age Restrictions	The member must be at 18 years of age or older.
Prescriber Restrictions	The prescribing physician must be a gastroenterologist, hepatologist, or an infectious disease specialist.
Coverage Duration	12 to 48 weeks depending on baseline host and viral factors.
Other Criteria	For HCV/HIV coinfection, patient meets criteria for requested regimen and will not receive treatment with tipranavir. For patients prescribed a treatment regimen that includes Olysio, no prior treatment failure with an HCV protease inhibitor (eg, telaprevir, simeprevir, boceprevir, paritaprevir) despite adequate dosing and duration of therapy. MILAN criteria defined as: 1) tumor size 5cm or less in diameter in pts with single hepatocellular carcinoma OR 3 tumor nodules or less, each 3cm or less in diameter in pts with multiple tumors, and 2) no extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor.

# **SPRYCEL**

### **Products Affected**

 Sprycel ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Chronic Myeloid (or Myelogenous) Leukemia (CML): The member must have a documented diagnosis of accelerated, or myeloid or lymphoid blast phase Ph+CML and documented resistance or intolerance to prior therapy, including Gleevec (imatinib mesylate). Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL): The member must have a documented diagnosis of Ph+ALL and documented resistance or intolerance to prior therapy, including Gleevec (imatinib mesylate). Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CP-CML): The member must have a documented diagnosis of Ph+ CP-CML.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an hematologist or oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **STELARA**

### **Products Affected**

• Stelara

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Plaque Psoriasis: The member must have a documented diagnosis of moderate-to-severe chronic plaque psoriasis and has failed to respond to, or has been unable to tolerate phototherapy and one (1) of the following medications: cyclosporine, methotrexate, or Soriatane (acitretin). Psoriatic Arthritis: The member must have a documented diagnosis of psoriatic arthritis and has had an inadequate response or inability to take methotrexate or sulfasalazine at maximal doses for three (3) months.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# **STIVARGA**

### **Products Affected**

• Stivarga

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of metastatic colorectal cancer and has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an antivascular endothelial growth factor (VEGF) therapy, and, if KRAS wild type, an antiepidermal growth factor receptor (EGFR) therapy. For advanced gastrointestinal stromal tumors (GIST), the member must have a documented diagnosis of GIST and documented prior failure, contraindication or intolerance to therapy with both imatinib mesylate (Gleevec) and sunitinib malate (Sutent).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **STRENSIQ**

### **Products Affected**

• Strensiq

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) confirmed with both biochemical and molecular genetic testing.
Age Restrictions	The member is/was 18 years of age or younger at age of onset.
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

# SUBLINGUAL ALLERGY IMMUNOTHERAPY

### **Products Affected**

• Grastek

• Oralair

• Ragwitek

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Grastek: The member must have documentation of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing within the last 2 years for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. Oralair: The member must have documentation of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the 5 grass species contained in this product in patients 10 to 65 years of age. Ragwitek: The member must have documentation of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing within the last 2 years for pollen-specific IgE antibodies for short ragweed pollen. For both all drugs, the member must also have failed, had an inadequate response, or is unable to tolerate treatment with two (2) or more agents in the following drug categories: leukotriene modifiers, oral antihistamines, intranasal antihistamines and/or intranasal corticosteroids.
Age Restrictions	Grastek age 5-65 years old, Oralair 10-65 years old, Ragwitek 18-65 years old. Not FDA-approved for members over 65 years of age.
Prescriber Restrictions	The prescribing physician must be or has consulted with an allergist or immunologist.
Coverage Duration	One year
Other Criteria	None

# **SUTENT**

### **Products Affected**

• Sutent

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Advanced Renal Cell Carcinoma: The member must have a documented diagnosis of advanced renal cell carcinoma. Gastrointestinal Stromal Tumor (GIST): The member must have a documented diagnosis of gastrointestinal stromal tumor and has a demonstrated disease progression or intolerance following an appropriate trial with Gleevec (imatinib mesylate). Progressive Neuroendocrine Tumors: The member must have a documented diagnosis of progressive neuroendocrine tumor located in the pancreas and the tumor cannot be removed by surgery or has spread to other parts of the body.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **SYLATRON**

### **Products Affected**

• Sylatron

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of melanoma with microscopic or gross nodal involvement and the melanoma has been completely excised with adequate surgical margins and complete lymphadenectomy must have occurred within 84 days.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a dermatologist or an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **SYLVANT**

### **Products Affected**

• Sylvant

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of multicentric Castleman disease and is HIV negative and human herpesvirus-8 (HHV-8) negative.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist or a hematologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **TAFINLAR**

### **Products Affected**

• Tafinlar

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Tafinlar is not indicated for the treatment of patients with wild-type BRAF melanoma.
Required Medical Information	The member must have a documented diagnosis of unresectable or metastatic melanoma with a BRAF V600E mutation (single agent therapy) or BRAF V600E or BRAF V600K mutation (in combination with Mekinist) and confirmed BRAF V600E or BRAF V600K mutation status using an FDA-approved test prior to treatment.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **TAGRISSO**

### **Products Affected**

• Tagrisso ORAL TABLET 40 MG, 80 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC) as detected by an FDA-approved test, and a documented failure, contraindication, or intolerance to prior tyrosine kinase inhibitor therapy (e.g., Gilotrif, Iressa, Tarceva).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

### **TALTZ**

### **Products Affected**

• Taltz

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of moderate-to-severe chronic plaque psoriasis and has failed to respond to, or has been unable to tolerate treatment with one (1) of the following medications: cyclosporine, methotrexate, or Soriatane (acitretin).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a dermatologist or rheumatologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **TASIGNA**

### **Products Affected**

• Tasigna

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Newly-diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML-CP): The member must have a documented diagnosis of Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Resistant or Intolerant Ph+ CML-CP and CML-AP: The member must have a documented diagnosis of Philadelphia chromosome positive chronic myelogenous leukemia in chronic phase or in accelerated phase and documented resistance or intolerance to prior therapy, including Gleevec (imatinib mesylate).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

### **TECFIDERA**

### **Products Affected**

• Tecfidera ORAL

• Tecfidera ORAL CAPSULE DELAYED RELEASE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a definitive diagnosis of a relapsing form of multiple sclerosis or the member has a documented failure, contraindication, or intolerance to at least ONE of the following multiple sclerosis immunomodulator agents: teflunomide (Aubagio) or fingolimod (Gilenya)
Age Restrictions	None
Prescriber Restrictions	The prescribing physician is a neurologist
Coverage Duration	Life of Plan
Other Criteria	None

# TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF)

#### **Products Affected**

- Abstral
- Actiq
- FentaNYL Citrate

- Fentora
- Lazanda
- Subsys

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	The Transmucosal Immediate-Release Fentanyl (TIRF) products will not be covered for any non-cancer pain indication.
Required Medical Information	The Transmucosal Immediate-Release Fentanyl (TIRF) products may be covered for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.
Age Restrictions	None.
Prescriber Restrictions	The prescribing physician must be an oncologist or a pain management specialist.
Coverage Duration	Life of Plan
Other Criteria	Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of morphine oral 60 mg daily or more, fentanyl transdermal 25 mcg/hour or more, oxycodone oral 30 mg daily or more, hydromorphone oral 8 mg daily or more, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking fentanyl sublingual.

### **TYKERB**

### **Products Affected**

• Tykerb

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	For HER2 overexpressing advanced or metastatic breast cancer, the member must have all of the following: 1. A documented diagnosis of HER2 overexpressing advanced or metastatic breast cancer. 2. The member has failed prior therapy with an anthracycline and a taxane chemotherapeutic agent. 3. The member has failed prior therapy with Herceptin (trastuzumab). 4. The member is concurrently treated with Xeloda (capecitabine). Hormone receptor positive metastatic breast cancer in post-menopausal women: The member must have a documented diagnosis of hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor and is concurrently being treated with an aromatase inhibitor (e.g. anastrozole, exemestane, or lotrozole).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

### **TYSABRI**

### **Products Affected**

• Tysabri

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Tysabri will not be approved when used in conjunction with other medications for the treatment of progressive multiple sclerosis (Betaseron, Avonex, Rebif or Copaxone) or when used in conjunction with other medications (corticosteroids, 5-aminosalicylates, 6-mercaptopurine and/or azathioprine, methotrexate or Humira)
Required Medical Information	Multiple Sclerosis: The member must have a documented diagnosis of relapsing multiple sclerosis and has a documented inadequate response or inability to tolerate an appropriate trial with at least one of the following agents: Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Lemtrada, Plegridy, Rebif, or Tecfidera. Crohn's Disease: The member must a documented diagnosis of Crohn's disease and both of the following: 1. An inadequate response to an appropriate trial with two (2) or more of the following agents: a) Corticosteroids (e.g., methylprednisolone, prednisolone, prednisone). b) 5-Aminosalicylates (e.g. Asacol, azulfidine, Colazal, Dipentum, Pentasa, Rowasa, sulfasalazine). c) 6-mercaptopurine (6-MP, Purinethol) or azathioprine. d) Methotrexate. 2. The member has demonstrated an inadequate response to an appropriate trial with at least one TNF-inhibitor and/or biologic indicated for Crohn's Disease.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a gastroenterologist or neurologist.
Coverage Duration	Intial authorization=6 months. Re-authorization may be given 12-month increments.
Other Criteria	None

# **VENCLEXTA**

### **Products Affected**

• Venclexta

• Venclexta Starting Pack

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of Chronic Lymphocytic Leukemia (CLL) with 17p deletion as detected by an FDA-approved test and has received at least 1 prior therapy.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	FDA-approved duration, balance of contract year or clinically appropriate duration
Other Criteria	None

### **VIMPAT**

### **Products Affected**

• Vimpat ORAL SOLUTION

• Vimpat ORAL TABLET

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of partial-onset seizures and has had an insufficient response or intolerance to at least one (1) other medication indicated for adjunct partial seizures (e.g. Aptiom, felbamate (Felbatol), Fycompa, gabapentin (Fanatrex, Gralise, Neurontin), lamotrigine (Lamictal, Lamictal XR, Lamictal ODT), Lyrica, levetiracetam (Keppra, Keppra XR), oxcarbazepine (Oxtellar XR, Trileptal), tiagabine (Gabitril), topiramate (Topamax, Trokendi XR), Potiga, and/or zonisamide (Zonegran)).
Age Restrictions	The member must be 17 years of age or older.
Prescriber Restrictions	The prescribing physician must be a neurologist.
Coverage Duration	Life of Plan
Other Criteria	None

### **VOTRIENT**

### **Products Affected**

• Votrient

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of advanced Renal Cell Carcinoma or Advanced Soft Tissue Sarcoma, and, for soft tissue sarcoma, the member must have received prior chemotherapy, including anthracycline treatment, or was unsuited for such therapy.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

### **XALKORI**

### **Products Affected**

• Xalkori

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by a Food and Drug Administration (FDA)-approved test or the member has documented ROS1-positive tumors.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

## **XELJANZ**

### **Products Affected**

• Xeljanz

• Xeljanz XR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of moderate to severely active Rheumatoid Arthritis and has a documented inadequate response at optimal doses or an inability to take methotrexate.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a rheumatologist.
Coverage Duration	Life of Plan
Other Criteria	None

## **XENAZINE**

### **Products Affected**

Tetrabenazine ORAL TABLET 12.5 MG, 25
 Xenazine ORAL TABLET 12.5 MG, 25 MG
 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of at least moderate chorea associated with Huntington's Disease and has demonstrated an inadequate response to OR is unable to tolerate an adequate trial with at least one of the following medications or classes of medication: Benzodiazepines, amantadine and/or Antipsychotics.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be a neurologist.
Coverage Duration	Life of Plan
Other Criteria	None

# XIFAXAN 550 MG

#### **Products Affected**

• Xifaxan ORAL TABLET 550 MG

PA Criteria	Criteria Details			
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.			
Exclusion Criteria	Coverage will not be authorized for treatment of diarrhea caused by pathogens other than E. coli, diarrhea complicated by fever or bloody stools, Irritable Bowe Syndrome, or prevention of traveler's diarrhea.			
Required Medical Information	Hepatic Encephalopathy: The member must have a documented diagnosis of hepatic encephalopathy and has had an inadequate response or has a contraindication to lactulose (Constulose, Duphalac, Enulose, Generlac). Inflammatory Bowel Disease (IBD): The member must have a documented diagnosis of IBD and has failed to respond to or has a contraindication to standard antibiotic treatment (e.g., ciprofloxacin, metronidazole). Irritable Bowel Disease with Diarrhea (IBS-D): The member must have a documented diagnosis of irritable bowel disease with diarrhea (IBS-D).			
Age Restrictions	For Hepatic Encephalopathy, the member must be 18 years of age or older.			
Prescriber Restrictions	None			
Coverage Duration	Life of Plan			
Other Criteria	Xifaxan 200 mg tablets do not require authorization.			

# **XOLAIR**

### **Products Affected**

• Xolair

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Coverage may be authorized when all of the following criteria are met: 1. The member has had a failure of a treatment regimen that included two (2) or more of the following: inhaled corticosteroids, oral corticosteroids, leukotriene modifiers or inhaled long-acting bronchodilators, or is unable to tolerate two (2) or more of these medications. 2. The member shows a definitive sensitivity on allergy testing to one or more perennial allergens. 3. The member has a pre-treatment serum IgE level equal to or greater then 30 IU/mL and less than or equal to 700 IU/mL. Chronic Idiopathic Urticaria (CIU): Coverage of Xolair may be authorized if the member has a definitive diagnosis of CIU for at least 6 weeks and the physician has documented that the member remains symptomatic despite H1 antihistamine treatment.
Age Restrictions	The member must 12 years of age or older.
Prescriber Restrictions	The precribing physician must be an allergist, immunologist or pulmonologist.
Coverage Duration	Life of Plan
Other Criteria	None

## **XTANDI**

### **Products Affected**

• Xtandi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of metastatic castration-resistant prostate cancer.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist or urologist.
Coverage Duration	Life of Plan
Other Criteria	None

## ZAVESCA

### **Products Affected**

• Zavesca

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	InformationThe member must have a documented diagnosis of mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy (e.g. Cerezyme) is not a therapeutic option (e.g. because of allergy, hypersensitivity, or poor venous access).
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Life of Plan
Other Criteria	None

## **ZELBORAF**

### **Products Affected**

• Zelboraf

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Zelboraf is not indicated for treatment of patients with wild-type BRAF melanoma.
Required Medical Information	The member must have a documented diagnosis of unresectable or metastatic melanoma that is BRAF V600E mutation-positive as detected by an FDA-approved test.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

## **ZOLINZA**

### **Products Affected**

• Zolinza

PA Criteria	Criteria Details				
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.				
<b>Exclusion Criteria</b>	None				
Required Medical Information	The member must have a documented diagnosis of advanced cutaneous T-cell lymphoma (Stage IIB and higher) and progressive, persistent or recurrent disease and documented current or prior treatment or treatment failure with at least one (1) systemic chemotherapeutic agents for cutaneous T-cell lymphoma.				
Age Restrictions	None				
Prescriber Restrictions	The prescribing physician must be an oncologist.				
Coverage Duration	Life of Plan				
Other Criteria	None				

## **ZYDELIG**

### **Products Affected**

• Zydelig

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	Chronic Lymphocytic Leukemia (CLL): The member must have a documented diagnosis of relapsed CLL and Zydelig will be given in combination with rituximab (Rituxan). Follicular B-cell non-Hodgkin lymphoma: The member must have a documented diagnosis of relapsed follicular B-cell non-Hodgkin lymphoma and the member must have documentation of at least 2 prior systemic therapies. Small Lymphocytic Lymphoma (SLL): The member must have a documented diagnosis of relapsed SLL and the member must have documentation of at least 2 prior systemic therapies.
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

# **ZYKADIA**

### **Products Affected**

• Zykadia

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	None
Required Medical Information	The member must have a documented diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic nonsmall cell lung cancer (NSCLC) and has had disease progression on or is intolerant to crizotinib (Xalkori).
Age Restrictions	None
Prescriber Restrictions	The prescribing physician must be an oncologist.
Coverage Duration	Life of Plan
Other Criteria	None

## **ZYTIGA**

### **Products Affected**

• Zytiga

PA Criteria	Criteria Details			
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.			
<b>Exclusion Criteria</b>	None			
Required Medical Information	The member must have a documented diagnosis of metastatic castration-resistant prostate cancer (CRPC) and Zytiga is being used in combination with prednisone.			
Age Restrictions	None			
Prescriber Restrictions	The prescribing physician must be an oncologist or urologist.			
Coverage Duration	Life of Plan			
Other Criteria	None			

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