

Turquoise Care

#### Prior Authorization Criteria Document for Presbyterian Turquoise Care

#### **General Information and Definitions:**

- Inclusion of a drug on this list does not mean that it will be covered.
- Prior Authorization (PA) You or your doctor must get permission or an OK from
  Presbyterian Turquoise Care before you fill your drug. If you don't get permission,
  Presbyterian Turquoise Care may not pay for the drug. You or your doctor can ask for
  permission by fax, phone, email or regular mail.
- Step Therapy (ST) You must first try certain drugs to treat a health problem before a different drug will be covered for the same health problem. For example, if Drug A and Drug B both treat your health problem, we may not cover Drug B unless you try Drug A first. If Drug A does not work for you, the plan may then cover Drug B.

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#### **Step Therapy Criteria**

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### **Prior Authorization Criteria**

# Abilify Discmelt (aripiprazole orally disintegrating tablet)(Cent Care)

#### **Products Affected**

ARIPiprazole Oral Tablet Dispersible

PA Criteria	Criteria Details
Covered Uses	1. Schizophrenia Spectrum Disorder (including schizoaffective disorder or schizophreniform disorder), 2. Bipolar I Disorder, 3. Major Depressive Disorder, 4. Autistic Disorder, 5. Tourette's Syndrome.
Exclusion Criteria	N/A
Required Medical Information	1. Schizophrenia Spectrum Disorder (including schizoaffective disorder or schizophreniform disorder): The patient must have a documented intolerance, side effects or lack of efficacy to at least two (2) other formulary atypical antipsychotics. Medication trials that fail due to lack of efficacy must be attempted at a maximal approved dose for a minimum of 4 weeks if no response, and a minimum of 12 weeks if partial response. OR The patient has a current diagnosis of Metabolic Syndrome, Pre-Metabolic Syndrome, or Diabetes Mellitus and has failed ziprasidone or there is clinical documentation why ziprasidone is not clinically appropriate. 2. Bipolar I Disorder: The patient must have a documented intolerance, side effects or lack of efficacy to at least two (2) formulary alternatives which could include preferred atypical antipsychotics (olanzapine, quetiapine, risperidone, or ziprasidone) and/or another formulary mood stabilizing medication (e.g. lithium, divalproex, or lamotrigine). 3. Major Depressive Disorder: Abilify must be used as adjunctive or add on treatment, not as monotherapy. AND The patient must have a documented trial and failure of at least three (3) other formulary antidepressants at a maximum tolerated dose for a minimum of 4 weeks. OR Patient must have a documented trial and failure of at least two (2) antidepressants and one (1) adjunctive agent at maximum tolerated doses for a minimum of 4 weeks. 4. Autistic Disorder: The patient must have a documented intolerance, side effects, or lack of

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PA Criteria	Criteria Details
	efficacy to risperidone, or documentation that risperidone is not clinically appropriate. 5. Treatment of tics associated with Tourette's Syndrome. 6. All other off-label indications: Use of atypical antipsychotics must be supported by a medical compendium and the patient must have a documented intolerance, side effects or lack of efficacy to at least two (2) formulary atypical antipsychotics.
Age Restrictions	N/A
Prescriber Restrictions	Must be initiated by a certified behavioral health provider (e.g. psychiatrist, CNP with psychiatry certification).
Coverage Duration	Up to 1 year
Other Criteria	The patient must be unable to swallow tablets and is not currently taking other oral non-dissolving tablets or capsules OR The patient has a significant history of cheeking despite monitored supervision. Quantity Limits: Tablets = 30 tablets for 30 days

### Abilify Maintena (aripiprazole)(Cent Care)

#### **Products Affected**

- Abilify Maintena Intramuscular Prefilled Syringe
- Abilify Maintena Intramuscular Suspension Reconstituted ER

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. 1. Schizophrenia 2. Bipolar Disorder
Exclusion Criteria	N/A
Required Medical Information	1. Schizophrenia: a. Trial and failure of three atypical antipsychotics for a minimum of 4 weeks (non-responders) or 12 weeks (partial responders) - e.g., aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, first-generation antipsychotics, AND a documented trial and failure of Aristada AND Invega Sustenna or Invega Trinza, OR member has a current diagnosis of metabolic syndrome, pre-metabolic syndrome, or diabetes mellitus and has failed aripiprazole AND ziprasidone, unless there is a documented contraindication or intolerance. 2. Bipolar: a. Trial and failure of three alternatives from the following: i. lamotrigine, ii. lithium, iii. carbamazepine, iv. valproic acid, v. Atypical Antipsychotics (e.g., aripiprazole, lurasidone, quetiapine).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a Behavior Health Practitioner
Coverage Duration	Up to one (1) year
Other Criteria	Preferred Specialty Pharmacy Dispensing Required. Code: J0401. 1mg = 1 billable unit

## Actemra (tocilizumab)(Cent Care)

#### **Products Affected**

• Actemra ACTPen

• Actemra Subcutaneous

PA Criteria	Criteria Details
<b>Covered Uses</b>	1) Juvenile Idiopathic Arthritis (JIA) 2) Rheumatoid Arthritis (RA) - Moderate to Severe 3) Giant Cell Arteritis
Exclusion Criteria	
Required Medical Information	1. JIA: a. Prescribed by or in consultation with a rheumatologist. b. An adequate trial (3 months or more) of one of the following DMARDs: i. Leflunomide ii. Methotrexateiii. Sulfasalazine c.Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents (e.g., Amjevita, Enbrel,Orencia). 2.RA a. Prescribed by or in consultation with a rheumatologist. b. Documented presence of moderate to severe rheumatoid arthritis (RA). Moderate to severe RA defined as: DAS-28 greater than 3.2 or CDAI greater than 10.1. c. An adequate trial (3 months or more) of one of the following DMARDs: i. Hydroxychloroquine ii.Leflunomide iii. Methotrexate iv. Sulfasalazine d. Trial and failure, unless contraindicated or not tolerated, of Kevzara AND one of the following: Amjevita, Enbrel, Orencia, Rinvoq). 3. Giant Cell Arteritis (adult patients) a.Prescribed by or in consultation with a rheumatologist or cardiologist b. Have developed, or are at high risk for, adverse effects of prednisone. c. Have had an adequate trial of methotrexate or cyclophosphamide.
Age Restrictions	
Prescriber Restrictions	JIA and RA: Must be prescribed by or in consultation with a rheumatologist. Giant Cell Arteritis: Must be prescribed by or in consultation with a rheumatologist or cardiologist.
Coverage Duration	Initial Approval: 6 months. Continuation: 1 year
Other Criteria	For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy, 2. The appropriate Disease Specific Criteria has been met. 3. Use of a Specialty Pharmacy is required. 4. Continuation: Documentation of clinical benefit is required.

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# Advair Diskus (fluticasone/salmeterol) (Cent Care)

#### **Products Affected**

- Fluticasone-Salmeterol Inhalation Aerosol
   Powder Breath Activated 100-50
   MCG/ACT, 250-50 MCG/ACT, 500-50
   MCG/ACT
- Wixela Inhub Inhalation Aerosol Powder Breath Activated 100-50 MCG/ACT, 250-50 MCG/ACT, 500-50 MCG/ACT

PA Criteria	Criteria Details
Covered Uses	1. Documented trial and failure of either mometasone/formoterol MDI (Dulera)* or budesonide/formoterol MDI (Symbicort)* within the past 150days.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication and previous therapies attempted including dose, duration, and results(s) are required.
Age Restrictions	
Prescriber Restrictions	N/A
Coverage Duration	Up to one year.
Other Criteria	Quantity Limit: One Diskus for 30 days.

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## Albenza (albendazole)

#### **Products Affected**

• Albendazole Oral

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documentation showing that all formulary alternatives have been trialed for the requested diagnosis AND the dose is within the recommended dosing for the diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	N/A
Other Criteria	

## Ambien CR (zolpidem)(Cent Care)

#### **Products Affected**

• Zolpidem Tartrate ER

PA Criteria	Criteria Details
<b>Covered Uses</b>	Insomnia
Exclusion Criteria	N/A
Required Medical Information	Patient must have a documented treatment failure of all of the following: Zolpidem oral tablets, A formulary benzodiazepine used for the treatment of insomnia AND Trazodone
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Quantity Limit: 30 tablets per 30 days

## **Amicar Solution (aminocaproic acid)**

#### **Products Affected**

• Aminocaproic Acid Oral Solution

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documents must show patient is unable to swallow tablets and are not currently taking other oral non-dissolving tablets or capsules
Age Restrictions	Maximum: 12 years of age
Prescriber Restrictions	
Coverage Duration	up to 1 year
Other Criteria	

### Amjevita (adalimumab-atto) 40 mg/0.8 mL Prefilled Autoinjector

#### **Products Affected**

- Amjevita Subcutaneous Solution Auto-Injector
- Amjevita Subcutaneous Solution Prefilled
   Amjevita-Ped 15kg to <30kg</li>
- Syringe 40 MG/0.4ML
- Amjevita-Ped 10kg to <15kg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. 1. Ankylosing Spondylitis (AS) 2. Psoriatic Arthritis (PsA) 3. Juvenile Idiopathic Arthritis (JIA) 4. Rheumatoid Arthritis (RA) 5. Crohn's Disease 6. Ulcerative Colitis 7. Plaque Arthritis (PsO) 8. Hidradenitis Suppurativa (HS) 9. Uveitis. Amjevita is the preferred adalimumab product for all FDA approved indications.
Exclusion Criteria	
Required Medical Information	1. AS: a. Prescribed by or in consultation with a rheumatologist. b. The patient has a documented trial and failure with a non-steroidal anti-inflammatory drug (NSAID) or such treatment is contraindicated or not tolerated. c. Patients with peripheral arthritis must have a documented trial and failure with sulfasalazine or such treatment is contraindicated or not tolerated. d. Patients with axial disease and a trial and failure of, or a contraindication to, NSAIDs can be started on Amjevita without a trial of sulfasalazine. 2. PsA: a. Prescribed by or in consultation with a dermatologist or rheumatologist. b. An adequate trial (3 months or more) of one of the following DMARDs: i. Cyclosporine ii. Leflunomide iii. Methotrexate iv. Sulfasalazine 3. JIA: a. Prescribed by or in consultation with a rheumatologist. b. At least 2 years of age weighing at least 10 kg. c. An adequate trial (3 months or more) of one of the following DMARDs: i. Leflunomide ii. Methotrexate iii. Sulfasalazine 4. RA: a. Prescribed by or in consultation with a rheumatologist. b. Documented presence of moderate to severe rheumatoid arthritis (RA). Moderate to severe RA is defined as: DAS-28 more than 3.2 or CDAI more than 10.1. c. An adequate trial (3 months or more) of one of the following other DMARDs: i. Hydroxychloroquine ii. Leflunomide iii. Methotrexate iv. Sulfasalazine 5. CD: a. Prescribed by or in consultation with a gastroenterologist. b. At least 6 years of age weighing at least 40 kg. c. For induction and maintaining clinical remission in patients with moderately to severely active Crohn's Disease in patients with an inadequate response or intolerance to conventional therapy: i. Corticosteroids (e.g., prednisone,

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PA Criteria	Criteria Details
	prednisolone, dexamethasone, budesonide). ii. Methotrexate iii. Thiopurines (azathioprine, mercaptopurine).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to 1 year
Other Criteria	6. UC: a. Prescribed by or in consultation with a gastroenterologist. b. The patient must have an adequate trial (3 months or more) or intolerance to ONE of the following: i. 5-Aminosalicylates (balsalazide, mesalamine, sulfasalazine) ii. Cyclosporine iii.Steroids iv. Thiopurines (azathioprine, 6-MP). 7. PsO a. Prescribed by or in consultation with a dermatologist. b. The patient must have more than 3% of their body surface area (BSA) affected by PsO c.The disease is severe as defined by a total PASI of 5 or more and/or a DLQI) of more than 5. d. The patient has failed to adequately respond to or is intolerant to a 3-month trial of a topical agents (topical corticosteroid, topical calcineurin inhibitor, topical vitamin D analog, etc.). 8. HS: Hurley Stage III or refractory Hurley Stage II HS and a trial of an antibiotic (topical 1% clindamycin, doxycycline) or hormonal therapy (finasteride). 9. UV: a. Prescribed by or in consultation with an ophthalmologist or rheumatologist. b. Documented diagnosis of noninfectious intermediate posterior and panueveitis in adult patients and meets the following: i. trial and failure, unless contraindicated or not tolerated, of conventional therapy, such as ophthalmic or systemic corticosteroids AND immunosuppressive drugs (e.g., azathioprine, cyclosporine, methotrexate, or tacrolimus). For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy, 2. The appropriate Disease Specific Criteria has been met. 5. Use of a Specialty Pharmacy is required.

# Androderm (testosterone transdermal patch)(Cent Care)

#### **Products Affected**

• Androderm Transdermal Patch 24 Hour

PA Criteria	Criteria Details
Covered Uses	1. Primary hypogonadism in men (congenital or acquired). 2. Hypogonadotropic hypogonadism (congenital or acquired). 3. As a continuous therapy for gender dysphoria/gender identity disorder
Exclusion Criteria	Exclusions: 1. Due to a lack of controlled evaluations in women and the potential for virilizing effects, testosterone products will not be approved for use in women who do not meet criterion for gender dysphoria/gender identity disorder. 2. Testosterone replacement will not be covered for the treatment of sexual dysfunction.
Required Medical Information	1. Primary hypogonadism in men (congenital or acquired). Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter?s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals AND Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with an elevated LH and FSH. 2. Hypogonadotropic hypogonadism (congenital or acquired). Idiopathic gonadotropin or LHRH deficiency or pituitary hypothalamic injury from tumors, trauma, or radiation AND Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with a low or low-normal LH and FSH (If your patient has low LH and FSH levels, please follow-up on these low levels or consider a referral to an endocrinology provider). 3. As a continuous therapy for gender dysphoria/gender identity disorder when all of the following are met: a. The patient?s insurance benefit includes coverage for the treatment of gender dysphoria/gender identity disorder. b. The patient meets DSM 5 criteria for diagnosis of Persistent Gender Dysphoria documented by a qualified licensed mental health professional experienced in the field, i. If significant medical or mental health concerns are present, there must be documentation that they are well controlled. c. One of the following: i. Member has lived as their chosen or reassigned gender full-time for 12 months or more, ii. Treatment plan documents that the patient will live as their reassigned gender full-time for a minimum of 12 months while concurrently receiving continuous hormone therapy, iii. Patient has completed gender transition and requires continued hormone therapy to maintain physical characteristics more congruent with their gender identity.

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PA Criteria	Criteria Details
Age Restrictions	18 years or greater
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Must have a documented trial and failure of testosterone gel 1 % (generic for Androgel 1%). Quantity Limits: Androderm 2mg = 60 patches per 30 days, Androderm 4mg = 30 patches per 30 days.

### AndroGel 1% (testosterone topical gel)(Cent Care)

#### **Products Affected**

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

MG/5GM (1%)

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Primary hypogonadism in men (congenital or acquired). 2. Hypogonadotropic hypogonadism (congenital or acquired). 3. As a continuous therapy for gender dysphoria/gender identity disorder
Exclusion Criteria	Exclusions: 1. Due to a lack of controlled evaluations in women and the potential for virilizing effects, testosterone products will not be approved for use in women who do not meet criterion for gender dysphoria/gender identity disorder. 2. Testosterone replacement will not be covered for the treatment of sexual dysfunction.
Required Medical Information	1. Primary hypogonadism in men (congenital or acquired). Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals AND Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with an elevated LH and FSH. 2. Hypogonadotropic hypogonadism (congenital or acquired). Idiopathic gonadotropin or LHRH deficiency or pituitary hypothalamic injury from tumors, trauma, or radiation AND Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with a low or low-normal LH and FSH (If your patient has low LH and FSH levels, please follow-up on these low levels or consider a referral to an endocrinology provider). 3. As a continuous therapy for gender dysphoria/gender identity disorder when all of the following are met: a. The patient's insurance benefit includes coverage for the treatment of gender dysphoria/gender identity disorder. b. The patient meets DSM 5 criteria for diagnosis of Persistent Gender Dysphoria documented by a qualified licensed mental health professional experienced in the field, i. If significant medical or mental health concerns are present, there must be documentation that they are well controlled. c. One of the following: i. Member has lived as their chosen or reassigned gender full-time for 12 months or more, ii. Treatment plan documents that the patient will live as their reassigned gender full-time for a minimum of 12 months while concurrently receiving continuous hormone therapy, iii. Patient has completed gender transition and requires continued hormone therapy to maintain physical characteristics more congruent with their gender identity.
Age Restrictions	18 years or greater

PA Criteria	Criteria Details
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	2.5gm packets: 75gm (30 packets) for 30 days (1 packet per day), 5gm packets: 300gm (60 packets) for 30 days (2 packets per day), Pump: 300gm for 30 days (8 actuations per day).

### **Anzemet (dolasetron) Tablets(Cent Care)**

#### **Products Affected**

• Anzemet Oral

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Nausea and vomiting associated with moderately emetogenic cancer chemotherapy
Exclusion Criteria	N/A
Required Medical Information	Patient has a documented treatment failure with antiemetic regimens that include generic ondansetron or generic granisetron. Treatment failure is defined as an allergy, intolerable side effects, significant drug-drug interactions, or lack of complete response.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Quantity Limit: 3 tablets per 30 days

### Aranesp (darbepoetin alfa)(Cent Care)

#### **Products Affected**

• Aranesp (Albumin Free) Injection Solution 100 MCG/ML, 25 MCG/ML, 300 MCG/ML, 40 MCG/ML, 60 MCG/ML

PA Criteria	Criteria Details
Covered Uses	1. Treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis, 2. For the treatment of anemia in patients with nonmyeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy, 3. Anemia due to HCV Treatment
Exclusion Criteria	The use of Aranesp is considered experimental, investigational, and unproven for any indication not listed above, including but not limited to the following: a. Aplastic anemia, b. B-12 and folate deficiency anemias, c. Iron deficiency anemia, d. Post-hemorrhagic anemia
Required Medical Information	1. Treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis. a. The maximum dose for the first 4 weeks of treatment is 9 mcg/kg. b. Hemoglobin must be <11g/dl. 2. For the treatment of anemia in patients with nonmyeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy. a. The maximum dose for the first 4 weeks of treatment is 9 mcg/kg. b. Hemoglobin must be <11g/dl. 3. Anemia due to HCV Treatment: a. Recent (within 2-3 weeks) hemoglobin <10g/dl AND b. Persists for at least 2 weeks after ribavirin dose reduction (may be reduced in 200mg incremental reductions or one-time reduction to 600mg/day) OR Patient is receiving peginterferon/ribavirin alone with documented evidence that the patient is post-liver transplantation or HIV/HCV co-infected.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Up to 6 months
Other Criteria	Code: J0881. 1mcg (0.001mg) = 1 billable unit

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### Aricept ODT (donepezil orally disintegrating) Criteria

#### **Products Affected**

• Donepezil HCl Oral Tablet Dispersible

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documentation that the patient is unable to take or swallow oral medication, should not be on other tablets or capsules
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Arixtra (fondaparinux)(Cent Care)

#### **Products Affected**

• Fondaparinux Sodium

PA Criteria	Criteria Details
Covered Uses	1. Patient will be undergoing total knee replacement, total hip replacement, hip fracture repair, pulmonary embolism treatment or deep venous thrombosis treatment, 2. The patient has an allergy or HIT with documented antiplatelet antibody to unfractionated heparin (UFH).
Exclusion Criteria	Contraindications: 1. Patients with creatinine clearance < 30 ml/min, 2. Patient with weight <50 kg (deep vein thrombosis prophylaxis) Evidence of active bleeding, 3. Bacterial endocarditis, 4. Thrombocytopenia with a positive test for antiplatelet antibody to fondaparinux, 5. Hypersensitivity to fondaparinux, 6. Epidural/spinal anesthesia
Required Medical Information	Chart notes documenting: 1. Patient will be undergoing total knee replacement, total hip replacement, hip fracture repair, pulmonary embolism treatment or deep venous thrombosis treatment AND The patient has an allergy or Heparin Induced Thrombocytopenia (HIT) with documented antiplatelet antibody to low molecular weight heparin (LMWH), OR 2. The patient has an allergy or HIT with documented antiplatelet antibody to unfractionated heparin (UFH).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 time
Other Criteria	Fondaparinux 2.5 mg SQ daily, initiated 6 hours postoperatively for thromboprophylaxis. Fondaparinux weight adjusted dosing for thromboembolism treatment; 5.0 mg, 7.5 mg, 10 mg for body weights of

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### Astagraf XL (tacrolimus extended release)

### **Products Affected**

• Astagraf XL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Patient has tried and failed tacrolimus immediate release capsules despite good adherence (tacrolimus levels must be submitted showing poor control) and pharmacy claims show regular fills
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to 1 Year
Other Criteria	

## Auryxia (ferric citrate)

### **Products Affected**

• Auryxia

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1) Diagnosis of hyperphosphatemia (serum phosphate greater than 5.5mg/dL)2) Adequate trial of TWO of the following:calcium acetate, Phoslyra, or sevelamer(Renvela or Renagel)AND 3) Adequate trial of lanthanum carbonate (Fosrenol)OR1) Diagnosis of iron deficiency anemia associated with chronic kidney disease not ondialysis AND has had an inadequate response or intolerance to oral iron supplements
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to one (1) Year
Other Criteria	

### Austedo (deutetrabenazine)(COMM, EXC, CentCare)

#### **Products Affected**

Austedo

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Chorea associated with Huntington disease: 2. Tardive Dyskinesia. Disease specific criteria must be met.
Exclusion Criteria	N/A
Required Medical Information	Documentation of the following: 1.The patient does not have untreated or inadequately treated depression. 2.The patient is not actively suicidal.3.The patient does not have hepatic impairment. 4.The patient is not taking monoamine oxidase inhibitors (MAOIs) or reserpine. 5.The appropriate Disease Specific Criteria below have been met. a. Chorea associated with Huntington disease i. The medication is being prescribed by or in consultation with a neurologist. ii. The patient is ambulatory. iii. Documentation of a baseline total maximal chorea score from the Unified Huntington Disease Rating Scale (UHDRS) must be provided. iv. The member has a documented trial and failure, or intolerance to, or a medical reason for avoiding the use of tetrabenazine and one of the following: amantadine or riluzole. b. Tardive Dyskinesia i. The medication is prescribed by or in consultation with a neurologist or psychiatrist. ii. The patient has documented diagnosis of tardive dyskinesia. iii. Trial and failure of amantadine. iv. At least 60 days of stable (drug and dose) exposure to a first generation antipsychotic, second generation antipsychotic, or certain dopamine receptor-blocking drugs used in the treatment of nausea and gastroparesis (e.g., prochlorperazine, promethazine, metoclopramide). v. Documentation of a baseline Abnormal Involuntary Movement Scale (AIMS) must be provided.
Age Restrictions	Approved for use in adults only.
Prescriber Restrictions	Must be prescribed by a neurologist or in consultation with a neurologist.
Coverage Duration	Initial approval: 6 months. Renewal: One year.
Other Criteria	Continuation of Therapy: 1.For all indications: Documentation showing the patient continues to be monitored for depression, suicidal ideation, and hepatic impairment. 2.Chorea associated with Huntington disease: Documented improvement in the total maximal chorea score from the

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PA Criteria	Criteria Details
	UHDRS compared to baseline. 3. Tardive Dyskinesia: Documented improvement in AIMS compared to baseline. Specialty Pharmacy Required. Quantity Limits: - 6mg and 9mg - 90 tablets for 30 days- 12mg - 120 tablets for 30 days.

### Avsola (infliximab-axxq)

### **Products Affected**

Avsola

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Ankylosing Spondylitis (AS), 2. Psoriatic Arthritis (PsA), 3. Rheumatoid Arthritis (RA), 4. Crohn's Disease (CD) - Moderate to Severe, 5. Plaque Psoriasis (PsO), 6. Ulcerative Colitis (Adult and Pediatric)
Exclusion Criteria	
Required Medical Information	1. AS - a. Documented trial and failure of a non-steroidal anti-inflammatory drug (NSAID) or such treatment is contraindicated or not tolerated, b. Patients with peripheral arthritis must have a documented trial and failure with sulfasalazine unless contraindicated or not tolerated, c. Patients with axial disease and who have tried and failed, or a contraindication or intolerance, an NSAID can be started on Avsola without a trial of sulfasalazine. 2. PsA - Adequate trial (3 months or more) of one of the following DMARDs: cyclosporine, leflunomide, methotrexate, sulfasalazine. 3. RA - a. Documented presence of moderate to severe RA as defined by a DAS28 greater than 3.2 or CDAI greater than 10.1, b. Ha received at least 3 months of current and continuous (at a minimum quarterly) follow-up, c. Adequate trial (3 months or more) of one of the following DMARDs: azathioprine, gold salt, hydroxychloroquine, leflunomide, methotrexate, minocycline, sulfasalazine. 4. CD - a. Inadequate response or intolerance to one of the following conventional therapies: corticosteroids, immunomodulatory drugs (e.g. AZA, mercaptopurine, MTX), antibiotics (e.g., metronidazole, quinolones). 5. PsO - a. BSA involvement of greater than 10 percent or 5 percent if it affects hands, feet, face, or genitals, b. Psoriasis Area Severity Index greater than or equal to 10 or a Dermatology Life Quality Index greater than 10. c. Trial/failure with phototherapy or photochemotherpay unless contraindicated, not tolerated, or unavailable, or trial/failure with MTX. 6. UC - a. Trial/failure to one of the following: 5-aminosalicylates, cyclosporine, corticosteroids, thiopurines.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by or in consultation with a rheumatologist, dermatologist, or gastroenterologist.
Coverage	One year

MPC032453 Effective: 01/01/2025

PA Criteria	Criteria Details
Duration	
Other Criteria	The patient must have had A current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test prior to initiation of therapy.

### Azedra (iobenguane I 131)

### **Products Affected**

• Azedra Dosimetric

Azedra Therapeutic

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documents show iobenguane scan positive unresectable, locally advanced or metastatic pheochromocytoma or paraganglipma (PPGL) AND Member falls into one of the categories: 1)unresectable progressive PPGL, 2)symptoms from the disease that cannot be controlled by local methods (e.g., resection, radiation therapy, nonsurgical ablative therapy), 3)tumors that are not rapidly progressing.
Age Restrictions	at least 12 years old
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	For patients with rapidly progressive tumors of bone-predominant extensive disease, chemotherapy is a preferred option even if iobenguane scan positive.

### **Baraclude** (entecavir)

### **Products Affected**

• Entecavir

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Drug will not be approved if: 1) Immune-tolerant chronic hepatitis B(CHB), 2)Inactive chronic hepatitis B, 3)Children 2 to 18 years old with persistently normal ALT, regardless of HBV DNA levels 4) There is insufficient evidence to support the use of entecavir in pregnant women
Required Medical Information	1) Immune-active CHB AND one of the following: a) ALT more than 2 times upper limit of normal, b) significant histological disease (significant inflammation or fibrosis on biopsy)and HBV DNA greater than 2000IU/mL if HBeAG negative or greater than 2000IU/mL if HBeAG positive c) cirrhosis and HBV DNA greater than 2000IU/mL d)high risk factors (more than 40 years old, family history of liver cancer, previous treatment or extra-hepatic symptoms), 2)Immune-tolerant CHB and more than 40 years old, HBV DNA at least 1,000,000IU/mL 3)compensated cirrhosis 4)HBs-AG positive and decompensated cirrhosis 5)2 to 18 years old with elevated ALT and HBV DNA greater than 1,000,000IU/mL
Age Restrictions	at least 2 years old
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Continuation: 1) HBeAg-positive adults without cirrhosis who seroconvert to anti-HBe(continue for at least 12 months of persistently normal ALT and undetectable serum HBV DNA levels) 2) HBeAg or HBsAG positive with cirrhosis 3) HBeAg-negative immune-active CHB

### Belsomra (suvorexant) (COMM, EXC, Cent Care)

### **Products Affected**

• Belsomra

PA Criteria	Criteria Details
Covered Uses	Insomnia. The patient must have a documented treatment failure of all of the following: a. Zolpidem oral tablets. b. A formulary benzodiazepine. c. Trazodone.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Up to one year.
Other Criteria	Quantity Limit: 30 tablets for 30 days.

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### Benlysta (belimumab)(Cent Care)

### **Products Affected**

• Benlysta

PA Criteria	Criteria Details
Covered Uses	1. Active, autoantibody positive (e.g. ANA, anti-ds-DNA, anti-Sm) systemic lupus erythematosus (SLE)2. Lupus Nephritis
Exclusion Criteria	Exclusions (will not be approved in the following instances): 1. As monotherapy, 2. For patients with active central nervous system lupus, 3. For patients who are autoantibody negative, 4. In combination with other biologics (other B-cell targeted therapy) and/or intravenous cyclophosphamide or if the member is currently receiving high dose prednisone? 100mg/day.
Required Medical Information	1. Documented diagnosis of active, autoantibody positive (e.g. ANA, antids-DNA, anti-Sm) systemic lupus erythematosus (SLE), 2. The member is concurrently taking and is compliant with standard therapy for SLE (e.g. corticosteroids, antimalarials, or immunosuppressives [alone or in combination]). 3. The member is concurrently taking and iscompliant with standard therapy for Lupus Nephritis (e.g. corticosteroids, antimalarials, or immunosuppressives (alone or in combination).
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by rheumatologist
Coverage Duration	Initial Approval: 6 months. Continuation: 1 year
Other Criteria	Reauthorization Criteria: Documentation must be submitted demonstrating a clinical benefit has been established and maintained compared to baseline. Code: J0490. 10mg = 1 billable unit

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### Berinert (C1 esterase inhibitor, human)(Cent Care)

#### **Products Affected**

Berinert

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diagnosis of hereditary angioedema (HAE)
Exclusion Criteria	Use of Berinert for the treatment of HAE with normal C1 inhibitor (Type III) will be reviewed on a case by case basis.
Required Medical Information	Chart notes documenting: 1. The diagnosis of hereditary angioedema (HAE) has been clinically established by, or in consultation with, an allergist or immunologist. 2. Diagnosis of HAE is documented based on evidence of low C4 level AND one of the following: a. A low C1 inhibitor (C1-INH) antigenic level OR b. A normal C1-INH antigenic level and a low C1-INH functional level, 3. The member is not concurrently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy, 4. The member must be experiencing at least one symptom of a moderate or severe attack (i.e. swelling of the face, throat, or abdomen).
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by or in consultation with an allergist or immunologist.
Coverage Duration	6 months
Other Criteria	Continuation of Therapy Criteria: Medical records documenting frequency of acute HAE attacks and the patient?s response to therapy must be provided. If the patient is experiencing more than one acute HAE attack per month, medical records documenting use of a long-term prophylactic therapy (LTP) or the clinical rational for avoiding LTP must be provided. Preferred Specialty Pharmacy Dispensing Required. Code: J0597. 10 units = 1 billable unit.

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### **Bosulif (bosutinib)**

### **Products Affected**

• Bosulif Oral Capsule 100 MG

• Bosulif Oral Tablet

PA Criteria	Criteria Details
<b>Covered Uses</b>	1.Philadelphia chromosome positive chronic myeloid leukemia in chronic phase, accelerated phase, or blast phase2.Philadelphia chromosome positive acute lymphoblastic leukemia
Exclusion Criteria	
Required Medical Information	Indications for Approval: 1.Philadelphia chromosome positive chronic myeloid leukemia in chronic phase, accelerated phase, or blast phase?Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec) AND dasatinib (Sprycel) or nilotinib (Tasigna).2.Philadelphia chromosome positive acute lymphoblastic leukemia ?Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec) AND dasatinib (Sprycel) or nilotinib (Tasigna).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Continuation Criteria: All of the following must be met:1.Documentation that the patient does not have evidence of disease progression must be submitted.2.Documentation that the patient does not have unacceptable toxicity from therapy must be submitted.

# Botox (onabotulinumtoxinA)(COMM, EXC, Cent Care)

### **Products Affected**

• Botox

PA Criteria	Criteria Details
Covered Uses	1. Blepharospasm (doses of 100 units or less), 2. Cervical Dystonia (doses of 300 units or less), 3. Cerebral Palsy (doses of 400 units or less), 4. Facial Nerve Disorder/Hemi-facial Spasm (doses of 100 units or less), 5. Severe Palmar Hyperhidrosis (doses of 100 units or less) 6. Severe Primary Axillary Hyperhidrosis (doses of 100 units or less) 7. Laryngeal Dystonia (doses of 100 units or less) 8. Limb Dystonia (doses of 100 units or less) 9. Chronic Migraine Prophylaxis (total dose of 155 units or less) 10. Spasmodic Torticollis (doses of 300 units or less) 11. Spasticity resulting from an acquired or congenital brain disorder (doses of 400 units or less) 12. Strabismus (doses of 100 units or less) 13. Urinary incontinence treatment due to detrusor overactivity (doses of 200 units or less) associated with a neurologic condition (e.g. spinal cord injury, MS) 14. Overactive bladder (OAB) (doses of 100 units or less) with symptoms of urinary incontinence, urgency and frequency in adults who have had an inadequate response to or are intolerant of an anticholinergic medication. 15. Upper and lower limb spasticity for individuals over the age of 2 years. (maximum total doses: Adult: up to 400 units, pediatric upper limb spasticity: 200 units, pediatric lower limb spasticity: 300 units).
Exclusion Criteria	For migraine prophylaxis: Botox will not be approved if calcitonin generelated peptide receptors (CGRP) has been used in the last 4 (four) months
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required. Documentation requirements for specific diagnoses are as follows: 1. Severe Palmar Hyperhidrosis (doses of 100 units or less) that meets following criteria: Documented trials and failures of drying agents such as topical aluminum chloride (DrySol, Xerac AC, and Hypercare) 2. Severe Primary Axillary Hyperhidrosis (doses of 100 units or less) that meets the following criteria: Documented trials and failures of anticholinergics and drying agents such as topical aluminum chloride (DrySol, Xerac AC, and Hypercare) 3. Chronic Migraine Prophylaxis (total dose of 155 units or less) that meets the following criteria: a. 15 days per month or more with headache lasting 4 hours a day or longer, b. Documented trials and failures of at least 2(two) prophylactic therapies for at least 60(sixty) days each, c. Must be prescribed by, or in

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PA Criteria	Criteria Details
	consultation with a neurologist. 4. Urinary incontinence treatment due to detrusor overactivity (doses of 200 units or less) associated with a neurologic condition (e.g. spinal cord injury, MS) a. Age greater than or equal to 18 years: who have had an inadequate response to or are intolerant of two anticholinergic medications used for urinary incontinence such as oxybutynin and tolterodine. b. Age less than 18 years: (check package for minimum age): who have had an inadequate response to or are intolerant of one anticholinergic medications used for urinary incontinence such as oxybutynin 5. Overactive bladder (OAB) (doses of 100 units or less) with symptoms of urinary incontinence, urgency and frequency in adults who have had an inadequate response to or are intolerant of an anticholinergic medication.
Age Restrictions	N/A
Prescriber Restrictions	Botox must be prescribed by, or in consultation with a neurologist.
Coverage Duration	One year.
Other Criteria	Code: J0585. 1 unit = 1 billable unit.

## **Brilinta** (ticagrelor)

### **Products Affected**

• Brilinta

PA Criteria	Criteria Details
<b>Covered Uses</b>	1)Diagnosis of Acute Coronary Syndrome 2) reduce the risk of a first myocardial infarction (MI) or stroke in patients with coronary artery disease (CAD) at high risk for such events.
Exclusion Criteria	
Required Medical Information	Patient must have a documented diagnosis of Acute ischemic stroke or high risk transient ischemic attack (TIA), Acute Coronary Syndrome OR All of the following are met i. Over 50 years of age ii. History of PCI or CABG, OR angiographic evidence of at least 50% lumen stenosis of at least 1 coronary artery iii. Diagnosis of diabetes mellitus type 2
Age Restrictions	
Prescriber Restrictions	Therapy must be initiated by a cardiologist
Coverage Duration	For acute ischemic stroke or high risk TIA- 30 days only, all other diagnoses: up to 1 year
Other Criteria	Quantity Limit: 60 tablets for 30 days

## Briumvi (ublituximab-xiiy)

### **Products Affected**

• Briumvi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Must meet all of the following: Documented diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. Trial and failure, unless contraindicated or not tolerated, to one generic disease modifying therapy (DMT), such as dimethyl fumarate, fingolimod.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	Initial: six (6) months. Renewal: one (1) year.
Other Criteria	

## Cabenua (cabotegravir / rilpirivine)

### **Products Affected**

• Cabenuva

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Initial (All of the following must be met): 1. Patient has no prior virologic failures or baseline resistance to either cabotegravir or rilpivirine. 2. Patient is currently on a stable antiretroviral regimen. 3. Documentation showing viral suppression (HIV-1 RNA less than 50 copies/mL) for at least 3 months prior to initiation of Cabenuva. 4. Provider attestation that patient understands the risks of missed doses AND has the ability to adhere to the required monthly or every 2 months injection appointments.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	Renewal criteria: Documentation that patient has maintained viral suppression (HIV-1 RNA less than 50 copies/mL) AND patient has been adherent to injection appointments with no missed doses.

### Cabometyx (cabozantinib)

### **Products Affected**

• Cabometyx

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. First-line therapy for the treatment of renal cell carcinoma. 2. Subsequent therapy for the treatment of advanced renal cell carcinoma.
Exclusion Criteria	
Required Medical Information	Indications for Approval: 1.First-line therapy for the treatment of renal cell carcinoma.i.Documentation that the patient belongs to the poor- or intermediate risk group must be provided.2.Subsequent therapy for the treatment of advanced renal cell carcinoma.i.Documentation of previous therapies tried must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

### **CAPLYTA** (lumateperone)

### **Products Affected**

• Caplyta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1. Schizophrenia: a. Trial and failure of three atypical antipsychotics for a minimum of 4 weeks (non-responders) or 12 weeks (partial responders) - e.g., aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, first-generation antipsychotics, OR member has a current diagnosis of metabolic syndrome, pre-metabolic syndrome, or diabetes mellitus and has failed aripiprazole AND ziprasidone, unless there is a documented contraindication or intolerance. 3. Bipolar: a. Monotherapy: Trial and failure of three alternatives from the following: i. lamotrigine, ii. lithium, iii. carbamazepine, iv. valproic acid, v. Atypical Antipsychotics (e.g., aripiprazole, lurasidone, quetiapine). b. adjunct therapy: will be used with either lithium or valproic acid.
Age Restrictions	at least 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with a Behavior Health Practitioner
Coverage Duration	Up to One (1) year
Other Criteria	

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### Cayston (aztreonam) (Comm/CenCare/EXC)

### **Products Affected**

• Cayston

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications.
Exclusion Criteria	N/A
Required Medical Information	1. The patient must have cystic fibrosis. 2. The patient must have Pseudomonas aeruginosa in the lungs. 3. The patient must 7 years of age or older. 4. The FEV1 must be between 25% - 75% predicted.
Age Restrictions	Age 7 and up.
Prescriber Restrictions	N/A
Coverage Duration	6 months.
Other Criteria	Continuation of Therapy: Documentation of improved FEV1 is required. Must have a decrease in the sputum density of P. aeruginosa. Specialty Pharmacy distribution required.

### Cellcept (mycophenolate mofetil) Suspension

### **Products Affected**

Mycophenolate Mofetil Oral Suspension
 Reconstituted

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	The patient must be 12 years of age or younger OR the patient must be unable to take or swallow tablets and are not currently taking other oral non-dissolving tablets or capsules
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Cimzia (certolizumab pegol)

#### **Products Affected**

- Cimzia
- Cimzia (2 Syringe)
- Cimzia Prefilled Subcutaneous Kit
- Cimzia Starter Kit
- Cimzia-Starter

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. 1.Ankylosing spondylitis, Active (AS) 2. Crohn's disease, moderate to severe (CD) 3. Plaque psoriasis (psoriatic vulgaris), moderate to severe (PsO) 4. Psoriatic arthritis, Active (PsA)5. Rheumatoid arthritis, moderate to severe (RA) 6. Non-radiographic Axial Spondyloarthritis (NR-AXSPA)
Exclusion Criteria	
Required Medical Information	1. AS, Active: a. The drug is being prescribed by or in consultation with a rheumatologist. b. The patient has a documented trial and failure with a non-steroidal anti-inflammatory drug (NSAID) or such treatment is contraindicated or not tolerated. c. Patients with peripheral arthritis must have a documented trial and failure with sulfasalazine or such treatment is contraindicated or not tolerated. d. Patients with axial disease, and a trial and failure of, or a contraindication to, NSAIDs can be started on Cimzia without a trial of sulfasalazine. e. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents used to treat this indication (e.g., Amjevita, Enbrel, Rinvoq, Taltz). 2. CD, Moderate to Severe: a. The drug is being prescribed by or in consultation with a gastroenterologist. b. For induction and maintaining clinical remission in patients with moderately to severely active Crohn's Disease in patients with an inadequate response or intolerance to conventional therapy: i. Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide). ii. Methotrexate iii. Thiopurines (azathioprine, mercaptopurine) iv. Trial and failure, unless contraindicated or not tolerated, of Amjevita and Skyrizi. 3.PsO, Chronic, Moderate to Severe: a. The drug is being prescribed by or in consultation with a dermatologist. b. The patient must have more than 3% of their body surface area (BSA) affected by PsO. c. The disease is severe as defined by a total PASI of at least 5 and/or a DLQI score more than 5. d. The patient has failed to adequately respond to or is intolerant to a 3-month trial of a topical agent (topical corticosteroid, topical calcineurin inhibitor, topical vitamin D analog, etc.). e. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents (e.g., Amjevita, Enbrel, Orencia, Rinvoq, Skrizi, Taltz).

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	1.AS and NR-AXSPA - prescribed by or in consultation with a rheumatologist 2. CD- prescribed by or in consultation with a gastroenterologist 3. PsO- prescribed by or in consultation with a dermatologist 4. PsA- prescribed by or in consultation with a dermatologist or rheumatologist 5. RA- prescribed by or in consultation with a rheumatologist
Coverage Duration	Approval length: Up to one (1) Year
Other Criteria	4. PsA, Active: a. The drug is being prescribed by or in consultation with a dermatologist or rheumatologist. b. An adequate trial (3 months or more) of one of the following DMARDs: 1. Cyclosporine 2. Leflunomide 3. Methotrexate 4. Sulfasalazine c. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents (e.g., Amjevita, Enbrel, Orencia, Rinvoq, Skyrizi, Taltz). 5. RA, moderate to severe: a. The drug is being prescribed by or in consultation with a rheumatologist. b. Documented presence of moderate to severe rheumatoid arthritis (RA). Moderate to severe RA is defined as DAS-28 more than 3.2 or CDAI more than 10.1. c.An adequate trial (3 months or more) of one of the following DMARDs: 1. Hydroxychloroquine 2. Leflunomide 3. Methotrexate 4. Sulfasalazine d. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents (e.g., Amjevita, Enbrel, Kevzara, Orencia, Rinvoq). 6. NR-AXSPA: 1. Trial and failure of NSAID. 2. Trial and failure of Rinvoq and Taltz.For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy, 2. The appropriate Disease Specific Criteria has been met. 3. Use of a Specialty Pharmacy is required. Continuation Criteria: Documentation of positive response with Cimzia treatment

### Cinryze (C1 esterase inhibitor, human)(Cent Care)

#### **Products Affected**

• Cinryze

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diagnosis of hereditary angioedema (HAE)
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting: 1. The diagnosis of hereditary angioedema (HAE) has been clinically established by, or in consultation with, an allergist or immunologist, 2. Diagnosis of HAE is documented based on evidence of low C4 level AND one of the following: a. A low C1 inhibitor (C1-INH) antigenic level OR b. A normal C1-INH antigenic level and a low C1-INH functional level, 3. The member has a history of more than one moderate to severe attack per month (i.e. swelling of the face, throat, or abdomen), 4. Baseline frequency of HAE attacks must be documented, 5. The member is not concurrently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy, 6. The member has had an insufficient response, contraindication, or intolerance to attenuated androgens (i.e. danazol).
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by or in consultation with an allergist or immunologist.
Coverage Duration	6 months
Other Criteria	Continuation of Therapy Criteria: Medical records documenting a decrease of at least 50% in the frequency of attacks and significant improvement in severity and duration of attacks must be provided. Preferred Specialty Pharmacy Dispensing Required. Code: J2598. 10 units = 1 billable unit.

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### **Codeine and Tramadol Medications in Children**

#### **Products Affected**

- Acetaminophen-Codeine
- Acetaminophen-Codeine #2
- Acetaminophen-Codeine #3
- Acetaminophen-Codeine #4
- Butalbital-APAP-Caff-Cod Oral Capsule
- 50-325-40-30 MG
- Butalbital-ASA-Caff-Codeine
- Codeine Sulfate Oral Tablet 30 MG, 60 MG
- traMADol HCl Oral Tablet 50 MG

PA Criteria	Criteria Details
Covered Uses	(1) Patient must be greater than 12 years of age. Codeine and tramadol containing medications will not be covered for any indication in patients under 12 years of age. (2) For patients aged 12 to 18 years documentation must be provided confirming that patient does not have any of the following medical conditions: obesity, obstructive sleep apnea, severe lung disease. (3) Tramadol will not be covered for the treatment of postoperative pain management of tonsillectomy and/or adenoidectomy.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Not covered for patients under 12 years of age. Prior authorization required for patients 12 to 18 years of age.
Prescriber Restrictions	
Coverage Duration	Up to 3 months.
Other Criteria	

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### **Continuous Glucose Monitors (CGM) and Supplies**

#### **Products Affected**

- Dexcom G6 Receiver
- Dexcom G6 Sensor
- Dexcom G6 Transmitter
- Dexcom G7 Receiver
- Dexcom G7 Sensor

- Guardian 4 Glucose Sensor
- Guardian 4 Transmitter
- Guardian Link 3 Transmitter
- Guardian Sensor (3)
- Guardian Sensor 3

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diabetes Mellitus type 1 OR 2
Exclusion Criteria	Patient is pregnant (Freestyle 14 Day and Dexcom 6 only) or critically ill.
Required Medical Information	1) The beneficiary is insulin-treated with multiple (three or more) daily injections of insulin or on a compatible insulin pump. 2) Patient has inadequate glycemic control (A1c 7% or higher) despite intensive diabetes management including multiple adjustments in self-monitoring and insulin administration, OR, patient has a history of inadequate glycemic control (despite compliance) of recurrent (2 or more events within a 30-day period), severe hypoglycemic events (e.g., BG less than 70 mg/dL) despite appropriate modifications in insulin therapy and member compliance. 3) All patients must be capable of using devices safely (either by themselves or with a caregiver. 4) Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1,2, and 3) above are met 5) Patient is not concurrently using Diabetic Test Strips for routine blood glucose monitoring. Member will be allowed a sufficient quantity for the purposes of calibration and/or other scenarios described at the end of this policy. Preferred Products: 1) Freestyle Libre 2) For Freestyle 14 Day, must be 18 years of age or older.3) For Freestlye Libre 2 and Freestyle Libre 3, must be 4 years of age and older. 4) DexCom will only be covered for: a. Pediatric patients aged 2 to 4. b.Patients established on a compatible insulin pump. c. Have a documented medical or other reason why Freestyle Libre® cannot be used. 5) Guardian 3: a. Patient has been established on a Medtronic insulin pump.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) Year
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PA Criteria	Criteria Details
Other Criteria	Continuation Criteria: Treating practitioner must submit documentation that an in-person visit with the beneficiary has occurred every six months or more frequently to assess adherence to their CGM regimen and diabetes treatment plan.

### Cosentyx (sekinumab)

#### **Products Affected**

- Cosentyx
- Cosentyx (300 MG Dose)
- Cosentyx Sensoready (300 MG)
- Cosentyx Sensoready Pen Subcutaneous Solution Auto-Injector 150 MG/ML
- Cosentyx UnoReady

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. 1. Ankylosing Spondylitis, Active (AS), 2. Plaque Psoriasis (PsO), 3. Psoriatic Arthritis, Active (PsA), 4, Hidradenitis Suppurativa (HS).
Exclusion Criteria	
Required Medical Information	1. Ankylosing spondylitis, Active: a. The drug is being prescribed by or in consultation with a rheumatologist. b. The patient has a documented trial and failure with a non-steroidal anti-inflammatory drug (NSAID) or such treatment is contraindicated or not tolerated. c. Patients with peripheral arthritis must have a documented trial and failure with sulfasalazine or such treatment is contraindicated or not tolerated. d. Patients with axial disease and a trial and failure of, or a contraindication to, NSAIDs can be started on Cosentyx without a trial of sulfasalazine. e. Trial and failure, unless contraindicated or not tolerated, to TWO of the following preferred agents: Taltz, AND Amjevita OR Enbrel OR Rinvoq. 2. Plaque psoriasis (psoriasis vulgaris), moderate to severe: a. The drug is being prescribed by or in consultation with a dermatologist. b. The patient must have more than 3% of their body surface area (BSA) affected by plaque psoriasis. c. The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) more than 5 and/or a Dermatology Life Quality Index (DLQI) more than 5. d. The patient has failed to adequately respond to or is intolerant to a 3-month trial of a topical agents (topical corticosteroid, topical calcineurin inhibitor, topical vitamin D analog, etc.). e. Trial and failure, unless contraindicated or not tolerated, of TWO of the following preferred agents: Taltz, AND Amjevita OR Enbrel OR Skyrizi. 3. Psoriatic arthritis, Active: a. The drug is being prescribed by or in consultation with a dermatologist or rheumatologist b. An adequate trial (3 months or more) of one of the following DMARDs: i.Cyclosporine ii. Leflunomide iii. Methotrexate iv. Sulfasalazine c. Trial and failure, unless contraindicated or not tolerated, to TWO of the following preferred agents: Taltz, AND Amjevita OR Enbrel OR Orencia OR Rinvoq OR Skyrizi.
Age Restrictions	

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PA Criteria	Criteria Details
Prescriber Restrictions	1.AS- prescribed by or in consultation with a rheumatologist 2. PsO-prescribed by or in consultation with a dermatologist 3. PsA- prescribed by or in consultation with a dermatologist or rheumatologist
Coverage Duration	Initial: 6 months, Continuation: Up to 1 year
Other Criteria	4. HS: a. Hurley Stage III or refractory Hurley Stage II HS and a trial of an antibiotic (topical 1% clindamycin, doxycycline) or hormonal therapy (finasteride). b. Trial an failure, unless contraindicated or not tolerated, of Amjevita. For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy, 2. The appropriate Disease Specific Criteria has been met. 3. Use of a Specialty Pharmacy is required. Continuation Criteria: Documentation of positive response with Cosentyx treatment. Quantity Limits: Initial month 5mL per 35 days, Maintenance: 2mL per 56 days

### **Crinone (progesterone gel) (Cent Care)**

### **Products Affected**

• Crinone Vaginal Gel 8 %

PA Criteria	Criteria Details
Covered Uses	To reduce the risk of spontaneous preterm birth in pregnant women with a short cervix (less than or equal to 20mm before 24 weeks) on ultrasound examination in the current pregnancy and no history of preterm birth.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting a cervical length of less than or equal to 20mm prior to 24 weeks and no history of preterm birth.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Through 36 weeks gestation.
Other Criteria	

### Crysvita (burosumab-twza) Criteria

### **Products Affected**

• Crysvita

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.  1)Familial x-linked hypophosphatemic vitamin D refractory rickets  2)diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) Associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized
Exclusion Criteria	
Required Medical Information	(1) Diagnosis of XLH confirmed by one of the following:- Genetic testing OR Elevated FGF23 level greater than 30 pg/mL (2) Documented baseline serum phosphorus level that is below the normal range for age. (3) Patient has a reduced tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR). (4) Presence of clinical signs and symptoms of the disease (e.g. rickets, growth retardation, musculoskeletal pain, bone fractures). (5) Patient is not receiving oral phosphate or active vitamin D analogs. (6) Patient does not have severe renal impairment (eGFR less than 30 mL/min/1.73 m2) (7) Requested dose is recommended per the U.S. FDA approved labeling.
Age Restrictions	For XLH at least 6 months of age, for tumor induced osteomalacia at least 2 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist experienced in the treatment of metabolic bone disorders (i.e., endocrinologist or nephrologist).
Coverage Duration	Initial Length of Approval: 6 months, Renewal Length of Approval: 1 year
Other Criteria	Continuation of Therapy Criteria: (1) Patient has experienced normalization of serum phosphate while on therapy. (2) Patient has experienced a positive clinical response to Crysvita evidenced by increased serum phosphorus levels, a reduction in serum total alkaline phosphatase activity, improvement in symptoms (e.g., increased height velocity, reduction of generalized bone pain) and/or improvement in radiographic imaging of Rickets/osteomalacia. (3) Requested dose is recommended per the U.S. FDA approved labeling. Quantity limits: Pediatric patients: up to 3 vials of 30mg per two(2) weeks, Adults: Up to 3

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PA Criteria	Criteria Details
	vials of 30mg per 4 weeks

### **Daliresp** (roflumilast)(Cent Care)

### **Products Affected**

• Roflumilast Oral Tablet 500 MCG

PA Criteria	Criteria Details
<b>Covered Uses</b>	Treatment of Severe COPD (GOLD stage III or worse)
Exclusion Criteria	N/A
Required Medical Information	1. Patient must be 18 years of age or older, 2. Patient must have a diagnosis of severe COPD with chronic bronchitis (GOLD Stage III or worse) and documentation of continued exacerbations in the last 6 months, 3. Severe COPD is defined by the GOLD guidelines as FEV1 < 50% predicted, 4. Patient must be currently receiving two standard treatments for severe COPD (i.e. long-acting B-agonist, long-acting anticholinergic, and short-acting anticholinergic).
Age Restrictions	18 years or greater
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Quantity Limit: 30 tablets per 30 days

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## Dayvigo (lemborexant)

### **Products Affected**

• DayVigo

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Patient must have a documented treatment failure of all the following: Zolpidem oral tablets, A formulary benzodiazepine used for the treatment of insomnia AND Trazodone
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Delatestryl (testosterone enanthate injection)(Cent Care)

#### **Products Affected**

• Testosterone Enanthate Intramuscular Solution

	T
PA Criteria	Criteria Details
Covered Uses	1. Primary hypogonadism in men (congenital or acquired). 2. Hypogonadotropic hypogonadism (congenital or acquired). 3. As a continuous therapy for gender dysphoria/gender identity disorder
Exclusion Criteria	Exclusions: 1. Due to a lack of controlled evaluations in women and the potential for virilizing effects, testosterone products will not be approved for use in women who do not meet criterion for gender dysphoria/gender identity disorder. 2. Testosterone replacement will not be covered for the treatment of sexual dysfunction.
Required Medical Information	1. Primary hypogonadism in men (congenital or acquired). Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter?s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals AND Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with an elevated LH and FSH. 2. Hypogonadotropic hypogonadism (congenital or acquired). Idiopathic gonadotropin or LHRH deficiency or pituitary hypothalamic injury from tumors, trauma, or radiation AND Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with a low or low-normal LH and FSH (If your patient has low LH and FSH levels, please follow-up on these low levels or consider a referral to an endocrinology provider). 3. As a continuous therapy for gender dysphoria/gender identity disorder when all of the following are met:  a. The patient?s insurance benefit includes coverage for the treatment of gender dysphoria/gender identity disorder. b. The patient meets DSM 5 criteria for diagnosis of Persistent Gender Dysphoria documented by a qualified licensed mental health professional experienced in the field, i. If significant medical or mental health concerns are present, there must be documentation that they are well controlled. c. One of the following: i. Member has lived as their chosen or reassigned gender full-time for 12 months or more, ii. Treatment plan documents that the patient will live as their reassigned gender full-time for a minimum of 12 months while concurrently receiving continuous hormone therapy, iii. Patient has completed gender transition and requires continued hormone therapy to maintain physical characteristics more congruent with their gender

PA Criteria	Criteria Details
	identity.
Age Restrictions	18 years or greater
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	100mg Code: J3120. 100mg = 1 billable unit, 200mg Code: J3130. 200mg = 1 billable unit

### **Depen (penicillamine)**

#### **Products Affected**

• penicillAMINE Oral Tablet

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	The appropriate disease specific criteria below must be met:(1) Member has a documented diagnosis of Wilson's Disease(2) Member has a documented diagnosis of cystinuria and ALL of the following are met: (a) Member has tried and failed conservative therapy including: high fluid intake, sodium and protein restriction, urinary alkalinization. (b) The member must have had an adequate trial and failure of (3 months or more)or contraindication or intolerance to use of tiopronin (Thiola).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Wilson's Disease: 1 year, Cystinuria: 6 months
Other Criteria	Cystinuria continuation of therapy criteria: Documentation of benefit must be submitted (i.e. decrease in stone formation).

## **Depo-Testosterone** (testosterone cypionate injection)(Cent Care)

#### **Products Affected**

• Testosterone Cypionate Intramuscular

Solution 100 MG/ML, 200 MG/ML

PA Criteria	Criteria Details
Covered Uses	1. Primary hypogonadism in men (congenital or acquired). 2. Hypogonadotropic hypogonadism (congenital or acquired). 3. As a continuous therapy for gender dysphoria/gender identity disorder
Exclusion Criteria	Exclusions: 1. Due to a lack of controlled evaluations in women and the potential for virilizing effects, testosterone products will not be approved for use in women who do not meet criterion for gender dysphoria/gender identity disorder. 2. Testosterone replacement will not be covered for the treatment of sexual dysfunction.
Required Medical Information	1. Primary hypogonadism in men (congenital or acquired). Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter?s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals AND Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with an elevated LH and FSH. 2. Hypogonadotropic hypogonadism (congenital or acquired). Idiopathic gonadotropin or LHRH deficiency or pituitary hypothalamic injury from tumors, trauma, or radiation AND Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with a low or low-normal LH and FSH (If your patient has low LH and FSH levels, please follow-up on these low levels or consider a referral to an endocrinology provider). 3. As a continuous therapy for gender dysphoria/gender identity disorder when all of the following are met:  a. The patient?s insurance benefit includes coverage for the treatment of gender dysphoria/gender identity disorder. b. The patient meets DSM 5 criteria for diagnosis of Persistent Gender Dysphoria documented by a qualified licensed mental health professional experienced in the field, i. If significant medical or mental health concerns are present, there must be documentation that they are well controlled. c. One of the following: i. Member has lived as their chosen or reassigned gender full-time for 12 months or more, ii. Treatment plan documents that the patient will live as their reassigned gender full-time for a minimum of 12 months while concurrently receiving continuous hormone therapy, iii. Patient has completed gender transition and requires continued hormone therapy to maintain physical characteristics more congruent with their gender

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PA Criteria	Criteria Details
	identity.
Age Restrictions	18 years or greater
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	100mg Code: J1070. 100mg = 1 billable unit, 200mg Code: J1080. 200mg = 1 billable unit

## Descovy (emtricitabine-tenofovir alafenamide) COMM/EXCH/MCAID

#### **Products Affected**

• Descovy

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Treatment of HIV-1 2. Pre-exposure Prophylaxis (PrEP)
Exclusion Criteria	
Required Medical Information	1. Treatment of HIV-1: a. Will be prescribed in combination with other antiretroviral agents. b. Member weighs at least 14 kg. c. If member is treatment naïve and weighs 17 kg or more, emtricitabine-tenofovir disoproxil fumarate (generic for Truvada) must be used, unless contraindicated or not toleratedOR- d.Submission of medical records documenting a diagnosis of osteoporosis as defined by a BMD T-score - 2.5 or less based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-score], or medical records documenting a diagnosis of osteopenia as defined by a BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) with evidence of progressive bone loss on serial DEXA scan. 2. PrEP: a. Recent negative HIV-1 test. b. Request is for 200 mg/25 mg strength. c. Medical records documenting emtricitabine-tenofovir disoproxil fumarate (generic for Truvada) is contraindicated or not tolerated. d. Estimated glomerular filtration rate less than 60 mL/min OR- e.e.Submission of medical records documenting a diagnosis of osteoporosis as defined by a BMD T-score -2.5 or less based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-score], or medical records documenting a diagnosis of osteopenia as defined by a BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) with evidence of progressive bone loss on serial DEXA scan.
Age Restrictions	
Prescriber	

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PA Criteria	Criteria Details
Restrictions	
Coverage Duration	One (1) year
Other Criteria	

### Dificid (fidaxomicin)(Cent Care)

#### **Products Affected**

• Dificid Oral Suspension Reconstituted

PA Criteria	Criteria Details
<b>Covered Uses</b>	Treatment of Clostridium difficile-associated diarrhea (CDAD)
Exclusion Criteria	N/A
Required Medical Information	A diagnosis of Clostridium difficile-associated diarrhea AND A documented trial and failure of oral vancomycin in a tapered and/or pulsed regimen.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 time
Other Criteria	Quantity Limit: 136mL for 30 days.

### **Dolophine** (methadone tablets)(Cent Care)

#### **Products Affected**

- Methadone HCl Oral Solution
- Methadone HCl Oral Tablet

PA Criteria	Criteria Details
<b>Covered Uses</b>	Treatment of Pain
Exclusion Criteria	Methadone is excluded from coverage for use in drug treatment programs
Required Medical Information	Chart notes documenting medical indication
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Quantity Limit: 180 tablets for 30 days.

### **Dupixent (dupilumab)**

#### **Products Affected**

• Dupixent

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. 1. Atopic Dermatitis (AD) 2. Asthma 3. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) 4. Eosinophilic Esophagitis (EoE) 5. Prurigo Nodularis (PN)
Exclusion Criteria	
Required Medical Information	1. AD: a. diagnosis of moderate to severe atopic dermatitis, b. 6 months of age and older, c. trial and failure, contraindication, or intolerance to each of the following: i. medium to high potency topical steroid (e.g., mometasone, fluocinolone, fluocinonide), ii. topical calcineurin inhibitor, d. Investigator Global Assessment (IGA) greater than or equal to 3, e. Eczema Area and Severity Index (EASI) score greater than or equal to 16, f. minimum body surface area involvement of greater than or equal to 10%. 2. Asthma: a. diagnosis of moderate to severe asthma defined as prebronchodilator FEV1 less than or equal to 80%, b. 6 years of age and older, c. Meets one of the following: i. Daily dependence on oral corticosteroids in addition to the regular use of an inhaled corticosteroid plus an additional controller and history of one or more asthma exacerbations in the past 12 months that required treatment with systemic corticosteroids, or emergency visit or hospitalization for treatment. ii. Blood eosinophils of 150 cells/mcL or more. 3. CRSwNP: a. 18 years of age and older, b. to be used as add-on maintenance treatment for individuals with i. nasal polyps detected by direct examination, endoscopy, or sinus CT scan and ii. significant rhinosinusitis such as nasal obstruction rhinorrhea, or reduction or loss of smell as documented by the prescriber, c. Bilateral Nasal Polyp Score (NPS) of at least 5, and NPS of at least 2 in each nostril, d. documented inadequate response to nasal corticosteroids, e. patient has received treatment with systemic corticosteroids within the past two years (or has a contraindication) or has had prior surgery for nasal polyps. 4. EoE: a. 1 year of age or older. b. trial/failure of a proton pump inhibitor or topical glucocorticoid steroid, greater than or equal to 15 intraepithelial eosinophils per high-power field (eos/hpf).
Age Restrictions	

PA Criteria	Criteria Details
Prescriber Restrictions	Must be prescribed by or in consultation with an allergist, immunologist, dermatologist, pulmonologist, orolaryngologist, gastroenterologist.
Coverage Duration	Up to one (1) year
Other Criteria	5. Prurigo Nodularis: a. Worst Itch-Numeric Rating Scale (WI-NRS) greater than or equal to 7 and 20 or more nodular lesions. b. Inadequate response, intolerance, or contraindication to a high potency topical steroid (e.g., betamethasone, fluocinonide, triamcinolone). For renewal: AD: Documentation of positive clinical response and will not be used in combination with another biologic medication. Asthma: Documented clinical response demonstrated by reduction in frequency of exacerbations, decreased utilization of rescue medications, increase in FEV1 from pretreatment baseline, reduction in oral corticosteroid requirements, and Dupixent will not be used with another biologic medication. CRSwNP: Documented clinical response, patient will continue to receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids, and patient will not use Dupixent with another biologic medication. EoE: positive clinical response as demonstrated by a decrease in eos/hpf and improvement in baseline Dysphagia Symptom Questionnaire (DSQ) score. PN: positive clinical response to treatment.

# **Dysport** (abobotulinumtoxin A) (COMM/EXCH/Cent Care)

#### **Products Affected**

• Dysport

PA Criteria	Criteria Details
Covered Uses	1. Cervical Dystonia. 2. Upper limb spasticity in the following muscle groups:: biceps brachii, brachialis, brachioradialis, flexor carpi radialis or ulnaris, flexor digitorum profundus or superficialis, pronator teres in accordance with approved dosages listed in prescribing information for each muscle group. 3. Lower limb spasticity in the following muscle groups: flexor digitorum longus, flexor halucis longus, gastrocnemius medial head or gastrocnemius lateral head, soleus, tibialis posterior in accordance with approved dosages listed in prescribing information for each muscle group. 4. Pediatric lower limb spasticity (ages 2 and older) in accordance with approved dosage listed in the prescribing information.
Exclusion Criteria	The use of Dysport for improving the appearance of glabellar lines will not be approved as this is a cosmetic use and a benefit exclusion.
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Up to one year.
Other Criteria	Code: J05865 units = 1 billable unit

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### **Edecrin (ethacryinic acid)/ COMM/EXC/Cent Care**

#### **Products Affected**

• Ethacrynic Acid Oral

PA Criteria	Criteria Details
<b>Covered Uses</b>	The patient must have a documented sulfa allergy OR the patient must have failed a 30-day trial of bumetanide, furosemide, or toresemide.
Exclusion Criteria	N/A
Required Medical Information	Documentation of contraindications to formulary alternatives and/or previous therapeutic trials.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Up to one year.
Other Criteria	N/A

### **Effient (prasugrel)(Cent Care)**

#### **Products Affected**

• Prasugrel HCl

PA Criteria	Criteria Details
<b>Covered Uses</b>	Patient must have acute coronary syndrome (ACS) and will be managed with percutaneous coronary intervention (PCI) as follows: 1. Patients with unstable angina or NSTEMI OR 2. Patients with STEMI when managed with primary or delayed PCI
Exclusion Criteria	N/A
Required Medical Information	1. Chart notes documenting medical indication, 2. Patient must be less than 75 year of age unless high risk, 4. Patient must weigh more than 60 kg AND one of the following must be met: a. Documented allergy to clopidogrel (Plavix?), such as a rash OR b. Documented treatment failure with clopidogrel (Plavix?) OR c. Patient is considered to be high risk. Examples include: i. Patient is a diabetic, ii. Complex PCI patient with multiple overlapping stents and/or bifurcation stenting, iii. Patient has documented severe renal impairment.
Age Restrictions	Must be less than 75 years of age
Prescriber Restrictions	Must be prescribed by cardiologist
Coverage Duration	up to 1 year
Other Criteria	Quantity Limit: 30 tablets per 30 days

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### Elmiron (pentosan)(Cent Care)

#### **Products Affected**

• Elmiron

PA Criteria	Criteria Details
<b>Covered Uses</b>	Treatment of interstitial cystitis pain
Exclusion Criteria	N/A
Required Medical Information	1. Must have documented diagnosis of interstitial cystitis AND 2. Documentation of a minimum 30-day trial and failure of or intolerance to amitriptyline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Continuation of Therapy: Documentation of improvement in pain. Quantity Limit: 90 tablets per 30 days.

### **Emend (aprepitant) Capsules(Cent Care)**

#### **Products Affected**

• Aprepitant Oral Capsule

PA Criteria	Criteria Details
<b>Covered Uses</b>	Prevention of chemotherapy induced nausea and vomiting (CINV)
Exclusion Criteria	N/A
Required Medical Information	1. The patient must be receiving Emend in combination with a 5-HT3 antagonist and dexamethasone. 2. Must meet one of the following: a) The patient is being treated with a cancer chemotherapy regimen which has high emetogenic potential. b) The patient is being treated with a cancer chemotherapy regimen which includes an anthracycline and cyclophosphamide in combination. c) The patient is receiving a cancer chemotherapy regimen which has moderate emetogenic potential and has failed antiemetic therapy with a 5-HT3 antagonist in combination with dexamethasone.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Quantity Limit: 40mg - 1 capsule for a prescription fill, 80mg - 3 capsules for a prescription fill, 125mg - 1 capsule for a prescription fill, 80/125mg pack - 1 package (contains 3 capsules) for a prescription fill.

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### **Emend Oral Suspension (aprepitant) Comm/HIX/CC**

#### **Products Affected**

• Emend Oral Suspension Reconstituted

PA Criteria	Criteria Details
<b>Covered Uses</b>	Prevention of chemotherapy induced nausea and vomiting (CINV)
Exclusion Criteria	N/A
Required Medical Information	1. The patient must be 12 years of age or younger or the patient must be unable to take or swallow Emend capsules. 2. The patient must be receiving Emend in combination with a 5-HT3 antagonist and dexamethasone. 3. Must meet one of the following: a). The patient is being treated with a cancer chemotherapy regimen which has high emetogenic potential. b)The patient is being treated with a cancer chemotherapy regimen which includes an anthracycline and cyclophosphamide in combination. c) The patient is receiving a cancer chemotherapy regimen which has moderate emetogenic potential and has failed antiemetic therapy with a 5-HT3 antagonist in combination with dexamethasone.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Six (6) months.
Other Criteria	Quantity Limit: Six (6) kits for 28 days.

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### Emsam Patch (selegiline patch)(Cent Care)

#### **Products Affected**

• Emsam

PA Criteria	Criteria Details
<b>Covered Uses</b>	Treatment of major depressive disorder
Exclusion Criteria	N/A
Required Medical Information	1. Patient must have documented diagnosis of major depressive disorder AND the patient is symptomatic despite treatment with maximum dose of: a. Two different SSRIs (citalopram, fluoxetine, sertraline, paroxetine) AND b. One SNRI (venlafaxine) AND c. One miscellaneous antidepressant (bupropion, mirtazapine)
Age Restrictions	18 years or greater
Prescriber Restrictions	Must be prescribed by a psychiatrist
Coverage Duration	1 year
Other Criteria	Quantity Limit: 30 patches per 30 days

### Enbrel (etanercept)(COMM, EXC, Cent Care)

#### **Products Affected**

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

Enbrei Subcutaneous Solution Prefilled	
PA Criteria	Criteria Details
Covered Uses	1. Rheumatoid arthritis (RA), 2. Polyarticular juvenile idiopathic arthritis (JIA), 3. Ankylosing spondylitis (AS), 4. Psoriatic arthritis (PsA), 5. Plaque psoriasis (PsO)
Exclusion Criteria	N/A
Required Medical Information	1. AS: a. Prescribed by or in consultation with a rheumatologist. b. The patient has a documented trial and failure with a non-steroidal antiinflammatory drug (NSAID) or such treatment is contraindicated or not tolerated. c. Patients with peripheral arthritis must have a documented trial and failure with sulfasalazine or such treatment is contraindicated or not tolerated. d. Patients with axial disease and a trial and failure of, or a contraindication to, NSAIDs can be started on Enbrel without a trial of sulfasalazine. 2. JIA: a. Prescribed by or in consultation with a rheumatologist. b. An adequate trial (3 months or more) of one of the following other DMARDs:i. Leflunomide ii. Methotrexate iii. Sulfasalazine 3. PsO: a. The drug is being prescribed by or in consultation with a dermatologist. b. The patient must have greater than 3% of their body surface area (BSA) affected by plaque psoriasis. c. The disease is severe as defined by a total PASI of at least 5 and/or a DLQI more than 5. d. The patient has failed to adequately respond to or is intolerant to a 3-month trial of a topical agent (topical corticosteroid, topical calcineurin inhibitor, topical vitamin D analogs, etc.). 4. PsA: a. The drug is being prescribed by or in consultation with a dermatologist or rheumatologist. b. An adequate trial (3 months or more) of one of the following DMARDs: i. Cyclosporine ii. Leflunomide iii. Methotrexate iv. Sulfasalazine. 5. RA: a. The drug is being prescribed by or in consultation with a rheumatologist. b. Documented presence of moderate to severe rheumatoid arthritis (RA). Moderate to severe RA is defined as DAS-28 greater than 3.2 or CDAI greater than 10.1. c. An adequate trial (3 months or more) of one of the following DMARDs: i. Hydroxychloroquine ii. Leflunomide iii. Methotrexate iv. Sulfasalazine
Age Restrictions	N/A

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PA Criteria	Criteria Details
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy, 2 2. The appropriate Disease Specific Criteria has been met. 4. Use of a Specialty Pharmacy is required. 5. Continuation criteria: documents showing clinical benefit to treatment.

### Entresto (sacubitril-valsartan) (Comm/HIX/CC

#### **Products Affected**

Entresto

PA Criteria	Criteria Details
Covered Uses	A documented diagnosis of NYHA Class II-IV heart failure with a LVEF equal to or less than 40%.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting all of the following are required: 1. The medication is being initiated by a cardiologist or in consultation with a cardiologist. 2. Pediatric and adult patients at least one year of age. 3. The patient has a documented diagnosis of NYHA Class II-III heart failure with a LVEF less than or equal to 40%. 4. The patient is receiving guideline directed therapy with a beta-blocker or has a documented intolerance or contraindication to this medication. 5. The patient does not have any of the following: - History of angioedema related to an ACEI or ARB Need for continued therapy with an ACEI, ARB alone, or direct renin inhibitor (e.g., aliskerin) - Symptomatic hypotension - Severe renal impairment (eGFR less than 30 mL/min/1.73 m2) - Severe hepatic impairment (Child-Turcotte-Pugh class C) - Serum potassium greater than 5.2 mEq/LContinuation Criteria: 1. Dose has been titrated to a dose of 97 mg/103 mg twice daily, or to a maximum dose as tolerated in adult and pediatric patients weighing at least 50 kg, 72 mg/78 mg in pediatric patients weighing at least 40 kg and less than 50 kg, or 3.1 mg/kg in pediatric patients weighing less than 40 kg. 2. Patient has a positive clinical response to therapy.
Age Restrictions	Pediatric and adult patients at least one year of age.
Prescriber Restrictions	Prescribed by a cardiologist or in consultation with a cardiologist.
Coverage Duration	One year.
Other Criteria	Quantity limit of 60 tablets for 30 days.

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### Entyvio (vedolizumab)

#### **Products Affected**

• Entyvio Intravenous

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. 1. Crohn's disease, moderate to severe (CD) 2. Ulcerative Colitis (UC), moderate to severe
Exclusion Criteria	
Required Medical Information	2)CD- Inadequate response to at least ONE of the following: corticosteroids, methotrexate (MTX), thiopurines, or antibiotics AND ONE of the preferred products for this indication 2) UC- The patient must have an adequate trial (3 months or more) or intolerance to at least ONE of the following: Thiopurines (azathioprine, 6-MP),5-Aminosalicylates (balsalazide, mesalamine, sulfasalazine), cyclosporine, steroids AND TWO of the preferred products for this indication
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	Initial approval length: 4 months. Continuation approval length: 12 months
Other Criteria	For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy, 2. The appropriate Disease Specific Criteria has been met. 3. Use of a Specialty Pharmacy is required. 4. Continuation Criteria: a. Documentation of positive clinical response to Entyvio. Discontinue use if no evidence of efficacy by week 14

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### **Ethyol (amifostine)(Cent Care)**

#### **Products Affected**

• Ethyol

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications: 1. Reduction of renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer. 2. Reduction of the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancers when the radiation port includes a substantial portion of the parotid glands.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

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### Euflexxa (sodium hyaluronate 1%)(Cent Care)

#### **Products Affected**

• Euflexxa Intra-Articular Solution Prefilled Syringe

PA Criteria	Criteria Details
<b>Covered Uses</b>	Osteoarthritis (OA) of the knee
Exclusion Criteria	Not covered for OA of joints other than knee joints
Required Medical Information	Indications for initial approval (all must be met). Chart notes documenting: 1. Clinical diagnosis of osteoarthritis of the knee supported by radiographic evidence of osteophytes in the knee joint, sclerosis in bone adjacent to the knee or joint space narrowing OR Documented symptomatic arthritis of the knee according to the American College of Rheumatology clinical and laboratory criteria which requires knee pain and at least five (5) of the following: a. Age older than 50 years, b. Bony enlargement on exam, c. Bony tenderness on exam, d. Crepitus on exam on exam, d. No palpable warmth on exam, e. Morning stiffness that improves within 30 minutes of activity, f. Erythrocyte sedimentation rate less than 40mm/hour, g. Rheumatoid factor less than 1:40, h. Synovial fluid analysis: clear viscous, white blood cell count less than 2,000 microliters (2.00 x 109/L), 2. The pain cannot be attributed to other forms of joint disease (e.g. acute knee injuries, rheumatoid arthritis, patellafemoral syndrome, chondromalacia of the knee), 3. The pain interferes with functional activities. 4. Documented lack of sufficient improvement in pain or function following a three month trial of at least two of the following: a. Non-pharmacological interventions (e.g. exercise, weight loss, physical therapy), b. Non-narcotic analgesics (e.g. acetaminophen, topical capsaicin, tramadol), c. Non-steroidal anti-inflammatory drugs (NSAIDs), d. Intra-articular corticosteroids, 5. Bilateral injections may be allowed if both knees meet the criteria for coverage.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	One series of 3 injections.
Other Criteria	Criteria for Continuation of Therapy (all of the following must be met): 1. Documentation of a significant reduction in pain and improvement in function as a result of the previous injections must be provided. 2. Pain

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PA Criteria	Criteria Details
	has recurred. 3. At least 6 months have passed since the prior series of injections. Quantity Limit: One series of injections. Preferred Specialty Pharmacy Dispensing Required. Code: J7323. 1 injection = billable unit

### **Exelon (rivastigmine) Patch**

#### **Products Affected**

• Rivastigmine Tartrate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documented trial and failure of formulary preferred cholinesterase inhibitors, donepezil and galantamine
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	up to one (1) year
Other Criteria	

### Fanapt (iloperidone)

#### **Products Affected**

• Fanapt

Fanapt Titration Pack

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Schizophrenia 2. Bipolar Disorder
Exclusion Criteria	
Required Medical Information	1. Schizophrenia: a. Trial and failure of three atypical antipsychotics for a minimum of 4 weeks (non-responders) or 12 weeks (partial responders) - e.g., aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, first-generation antipsychotics, unless there is a documented contraindication or intolerance. 2. Bipolar: a. Trial and failure of three alternatives from the following: i. lamotrigine, ii. lithium, iii. carbamazepine, iv. valproic acid, v. Atypical Antipsychotics (e.g., aripiprazole, lurasidone, quetiapine).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to one (1) year
Other Criteria	

### Farxiga (dapagliflozin)

#### **Products Affected**

• Farxiga

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1. Diabetes Mellitus Type II with Established Cardiovascular Disease (CAD, prior MI, or stroke) (all must be met): a. Member is on concomitant antidiabetic (which includes a maximized dose of metformin, unless contraindicated or not tolerated) and antiatherosclerotic therapy. b. If the request is for treatment of DMII alone, a documented intolerance to Steglatro must be submitted and that the member has been on a maximized dose of metformin for at least 3 months, unless contraindicated or not tolerated. c.eGFR is greater than or equal 45 mL/min/1.73 m2. 2. Heart Failure (all must be met): a. Ejection fraction of 40% or less, or ejection fraction greater than 40% AND evidence of structural heart disease. b. Suboptimal response to beta blocker therapy, an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB), an angiotensin receptor-neprilysin inhibitor (ARNI), and an aldosterone antagonist. c. Member is not on dialysis. 3. Chronic Kidney Disease at Risk of Progression (all must be met): a. Member has albuminuria with urine albumin creatinine ratio (UACR) greater than 200 mg/g. b. eGFR is greater than or equal to 25 mL/min/1.73 m2 and less than 75 mL/min/1.73 m2. c. Will be used in combination with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) unless contraindicated or not tolerated.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months. Continuation: 1 year
Other Criteria	Continuation criteria: Documented clinical response to therapy.Quantity Limit: 30 tablets for 30 days.Approved by the P&T Committee on 04/20/2022.

### Fazaclo (clozapine ODT)(Cent Care)

#### **Products Affected**

- CloZAPine Oral Tablet Dispersible 100 MG, 25 MG
- cloZAPine Oral Tablet Dispersible 12.5 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications
Exclusion Criteria	N/A
Required Medical Information	The patient is unable to take or swallow oral medication (They should not be on other oral medications) OR The patient is cheeking the medication (cheeking is considered not swallowing the medication then spitting it out when the caregiver is not looking).
Age Restrictions	N/A
Prescriber Restrictions	Must be initiated by a psychiatrist or in consultation with a psychiatrist for all indications.
Coverage Duration	1 year
Other Criteria	Quantity Limits: 12.5mg tablets ? 60 tablets per 30 days, 25mg tablets ? 180 tablets per 30 days, 100mg tablets ? 270 tablets for 30 days

### Feraheme (ferumoxytol)(Cent Care)

#### **Products Affected**

• Feraheme

Ferumoxytol

PA Criteria	Criteria Details
Covered Uses	1.For the treatment of chemotherapy-induced iron deficiency anemia*.  2.For the treatment of iron deficiency anemia* in chronic kidney disease patients undergoing chronic hemodialysis. 3.For the treatment of documented iron deficiency anemia* in a patient who has a documented disorder of the gastrointestinal tract of which symptoms may be aggravated by oral iron therapy. Example: Inflammatory bowel disease.  4.For the treatment of a documented iron deficiency anemia* in a patient who has had a documented severe intolerance or treatment failure to an oral iron product after an adequate trial and after attempts have been made to identify and treat the underlying cause(s) of the deficiency.
Exclusion Criteria	N/A
Required Medical Information	Iron Deficiency Anemia defined as (without chronic kidney disease or acute or chronic inflammatory conditions): • Ferritin less than 30 ng/mL, OR • TSAT less than 20%, OR • Absence of stainable iron in bone marrow. Iron Deficiency Anemia defined as (with chronic kidney disease or acute or chronic inflammatory conditions): • Ferritin less than 100 ng/mL, OR • TSAT less than 20% (if serum ferritin 100-200 ng/mL, TSAT less than 20% is required to confirm iron deficiency).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 time
Other Criteria	Compendial Uses: Non-FDA approved uses for the injectable iron products that are considered to be "medically-accepted indications" based on the drug information sources that CMS has recognized to be authoritative compendia will be considered for approval for treatment if the diagnosis, dosing, frequency, and length of therapy are supported by, and are consistent with published medical literature. Continuation of treatment or retreatment with an injectable iron product for compendial uses will only be approved if medically necessary, if clinical improvement has been demonstrated, and if supported by published medical literature.

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## Ferrlecit (sodium ferric gluconate complex)(Cent Care)

#### **Products Affected**

Ferrlecit

• Na Ferric Gluc Cplx in Sucrose

PA Criteria	Criteria Details
Covered Uses	1.For the treatment of chemotherapy-induced iron deficiency anemia*.  2.For the treatment of iron deficiency anemia* in chronic kidney disease patients undergoing chronic hemodialysis. 3.For the treatment of documented iron deficiency anemia* in a patient who has a documented disorder of the gastrointestinal tract of which symptoms may be aggravated by oral iron therapy. Example: Inflammatory bowel disease.  4.For the treatment of a documented iron deficiency anemia* in a patient who has had a documented severe intolerance or treatment failure to an oral iron product after an adequate trial and after attempts have been made to identify and treat the underlying cause(s) of the deficiency.
Exclusion Criteria	N/A
Required Medical Information	Iron Deficiency Anemia defined as (without chronic kidney disease or acute or chronic inflammatory conditions): • Ferritin less than 30 ng/mL, OR • TSAT less than 20%, OR • Absence of stainable iron in bone marrow. Iron Deficiency Anemia defined as (with chronic kidney disease or acute or chronic inflammatory conditions): • Ferritin less than 100 ng/mL, OR • TSAT less than 20% (if serum ferritin 100-200 ng/mL, TSAT less than 20% is required to confirm iron deficiency).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 time
Other Criteria	Compendial Uses: Non-FDA approved uses for the injectable iron products that are considered to be "medically-accepted indications" based on the drug information sources that CMS has recognized to be authoritative compendia will be considered for approval for treatment if the diagnosis, dosing, frequency, and length of therapy are supported by, and are consistent with published medical literature. Continuation of treatment or retreatment with an injectable iron product for compendial

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PA Criteria	Criteria Details
	uses will only be approved if medically necessary, if clinical improvement has been demonstrated, and if supported by published medical literature.

### Firazyr (icatibant)(Cent Care)

#### **Products Affected**

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diagnosis of hereditary angioedema (HAE)
Exclusion Criteria	Use of Berinert, Firazyr, or Kalbitor for the treatment of HAE with normal C1 inhibitor (Type III) will be reviewed on a case by case basis.
Required Medical Information	Chart notes documenting: 1. The diagnosis of hereditary angioedema (HAE) has been clinically established by, or in consultation with, an allergist or immunologist. 2. Diagnosis of HAE is documented based on evidence of low C4 level AND one of the following: a. A low C1 inhibitor (C1-INH) antigenic level OR b. A normal C1-INH antigenic level and a low C1-INH functional level, 3. The member is not concurrently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy, 4. The member must be experiencing at least one symptom of a moderate or severe attack (i.e. swelling of the face, throat, or abdomen).
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by or in consultation with an allergist or immunologist.
Coverage Duration	6 months
Other Criteria	Continuation of Therapy Criteria: Medical records documenting frequency of acute HAE attacks and the patient?s response to therapy must be provided. If the patient is experiencing more than one acute HAE attack per month, medical records documenting use of a long-term prophylactic therapy (LTP) or the clinical rational for avoiding LTP must be provided. Preferred Specialty Pharmacy Dispensing Required.

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### Firdapse (amifampridine)

#### **Products Affected**

• Firdapse

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1.Documentation of clinical symptoms suggestive of Lambert-Eaton myasthenic syndrome (LEMS) such as:a. proximal weakness affecting legs, difficulty standingb. eyes: dry eyes, delayed pupil reaction to light, ptosis, diplopiac. face: eyelid elevationd. throat: difficulty swallowing, difficulty chewing2. Documentation of confirmatory diagnostic test results including:a. Repetitive Nerve Stimulation (RNS) testing showing reproducible post-exercise increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared with pre-exercise baseline value or a similar increment on high-frequency repetitive nerve stimulation without exercise ORb. Positive anti-P/Q type voltage-gated calcium channel antibody test3. Documentation of a trial and failure of pyridostigmine
Age Restrictions	At least 6 years of age
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 3 months, Continuation: 6 months
Other Criteria	Continuation Criteria: Documentation of clinical improvement in symptoms

### Forteo (teriparatide)(Cent Care)

#### **Products Affected**

• Teriparatide Subcutaneous Solution Pen- Injector 600 MCG/2.4ML

PA Criteria	Criteria Details
Covered Uses	1. Treatment of Postmenopausal Women with Osteoporosis at High Risk for Fracture, 2. Increase of Bone Mass in Men with Primary or Hypogonadal Osteoporosis at High Risk for Fracture 3. Treatment of Men and Women with Glucocorticoid-Induced Osteoporosis at High Risk for Fracture
Exclusion Criteria	N/A
Required Medical Information	1. Bone Mineral Density (BMD) T-score -3.5 or less based on BMD measurements from lumbar spine, femoral neck, total hip, and/or one-third radius (wrist) -OR- 2.Bone mineral density (BMD) T-score between -2.5 and -3.5 in the lumbar spine, femoral neck, total hip, and/or one-third radius (wrist) -AND- a. History of one of the following: i. Vertebral compression fracture ii. Fracture of the hip iii. Fracture of the distal radius iv. Fracture of the pelvis v. Fracture of the proximal humerus -OR- 3. BMD T-score between -1.0 and -2.5 and one of the following FRAX 10-year fracture probabilities: i. Major osteoporotic fracture at 20% or more ii. Hip fracture at 3% or more -OR- 4. History of failure, contraindication, or intolerance to an intravenous bisphosphonate AND Prolia. 5.Inadequate response to, or is unable to tolerate, Tymlos (abaloparatide). Length of Approval: 1 year. Please note parathyroid hormone (PTH) analogs should not be used for more than 2 years. Cumulative use of PTH analogs for greater than 2 years will not be approved.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Preferred Specialty Pharmacy Dispensing Required.

### Fortesta (testosterone topical gel)(Cent Care)

#### **Products Affected**

• Testosterone Transdermal Gel 10

MG/ACT (2%)

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Primary hypogonadism in men (congenital or acquired). 2. Hypogonadotropic hypogonadism (congenital or acquired). 3. As a continuous therapy for gender dysphoria/gender identity disorder
Exclusion Criteria	Exclusions: 1. Due to a lack of controlled evaluations in women and the potential for virilizing effects, testosterone products will not be approved for use in women who do not meet criterion for gender dysphoria/gender identity disorder. 2. Testosterone replacement will not be covered for the treatment of sexual dysfunction.
Required Medical Information	1. Primary hypogonadism in men (congenital or acquired). Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter?s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals AND Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with an elevated LH and FSH. 2. Hypogonadotropic hypogonadism (congenital or acquired). Idiopathic gonadotropin or LHRH deficiency or pituitary hypothalamic injury from tumors, trauma, or radiation AND Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with a low or low-normal LH and FSH (If your patient has low LH and FSH levels, please follow-up on these low levels or consider a referral to an endocrinology provider). 3. As a continuous therapy for gender dysphoria/gender identity disorder when all of the following are met: a. The patient?s insurance benefit includes coverage for the treatment of gender dysphoria/gender identity disorder. b. The patient meets DSM 5 criteria for diagnosis of Persistent Gender Dysphoria documented by a qualified licensed mental health professional experienced in the field, i. If significant medical or mental health concerns are present, there must be documentation that they are well controlled. c. One of the following: i. Member has lived as their chosen or reassigned gender full-time for 12 months or more, ii. Treatment plan documents that the patient will live as their reassigned gender full-time for a minimum of 12 months while concurrently receiving continuous hormone therapy, iii. Patient has completed gender transition and requires continued hormone therapy to maintain physical characteristics more congruent with their gender identity.
Age Restrictions	18 years or greater

MPC032453 Effective: 01/01/2025

PA Criteria	Criteria Details
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Must have a documented trial and failure of testosterone gel 1% (generic for AndroGel 1%). Quantity Limit: two (2) canisters (120 g) for 30 days.

### Forenol (lanthanum carbonate)

#### **Products Affected**

• Lanthanum Carbonate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1) Documents showing hyperphosphatemia (serum phosphate greater than 5.5mg/dL) 2) Adequate trial of TWO for the following: calcium acetate, Phoslyra, or sevelamer (Renvela or Renagel)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to one (1) Year
Other Criteria	

### Fragmin (dalteparin)(Cent Care)

#### **Products Affected**

- Fragmin Subcutaneous Solution 10000 UNIT/ML, 12500 UNIT/0.5ML, 15000 UNIT/0.6ML, 18000 UNT/0.72ML, 2500 UNIT/0.2ML, 5000 UNIT/0.2ML, 7500
- UNIT/0.3ML, 95000 UNIT/3.8MLFragmin Subcutaneous Solution Prefilled Syringe

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications
Exclusion Criteria	N/A
Required Medical Information	1. Approved for FDA labeled indications only AND 2. The patient must have a documented trial and failure of, or clinical reason for avoidance of enoxaparin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	up to 6 months
Other Criteria	Quantity Limit: 30ml for 30 days.

# **Gamifant** (emapalumab-lzsg)

#### **Products Affected**

• Gamifant Intravenous Solution 10

MG/2ML, 50 MG/10ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Primary hemophagocytic lymphohistiocytosis (HLH)
Exclusion Criteria	
Required Medical Information	1. Primary HLH based on a molecular diagnosis or family history consistent with primary HLH or 5 out of the 8 criteria fulfilled:A. Fever B. Splenomegaly C. Cytopenias affecting 2 of 3 lineages in the peripheral blood: hemoglobin less than 9, platelets less than 100x10^9/L, neutrophils less than 1 x 10^9/LD. Hypertriglyceridemia (fasting triglycerides greater than 3mmol/L or at least 265 mg/dL) and/or hypofibrinogenemia(at least 1.5 g/L)E. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancyF. Low or absent NK-cell activityG. Ferritin at least 500 mcg/L,H. Soluble CD25 at least 2400 U/mL2. Evidence of active disease as assessed by treating physician3. Refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy based on one of the following criteria:A. Having not responded or not achieved a satisfactory responseB.Having not maintained a satisfactory response to conventional HLH therapyC. Intolerance to conventional HLH treatments4. Patients does not have active infections caused by mycobacteria and Histoplasma Capsulatum5. Gamifant will be administered concomitantly with dexamethasone
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial approval: 2 months, Continuation: 3 months
Other Criteria	Continuation of therapy Criteria: Documentation of clinical improvement in symptoms

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# Gel-One (cross-linked hyaluronate) Comm/HIX/CC

#### **Products Affected**

• Durolane Intra-Articular

PA Criteria	Criteria Details
<b>Covered Uses</b>	Osteoarthritis (OA) of the knee
Exclusion Criteria	Not covered for OA of joints other than knee joints.
Required Medical Information	Indications for initial approval (all must be met). Chart notes documenting: 1. Clinical diagnosis of osteoarthritis of the knee supported by radiographic evidence of osteophytes in the knee joint, sclerosis in bone adjacent to the knee or joint space narrowing OR Documented symptomatic arthritis of the knee according to the American College of Rheumatology clinical and laboratory criteria which requires knee pain and at least five (5) of the following: a. Age older than 50 years, b. Bony enlargement on exam, c. Bony tenderness on exam, d. Crepitus on exam on exam, d. No palpable warmth on exam, e. Morning stiffness that improves within 30 minutes of activity, f. Erythrocyte sedimentation rate less than 40mm/hour, g. Rheumatoid factor less than 1:40, h. Synovial fluid analysis: clear viscous, white blood cell count less than 2,000 microliters (2.00 x 109/L), 2. The pain cannot be attributed to other forms of joint disease (e.g. acute knee injuries, rheumatoid arthritis, patellafemoral syndrome, chondromalacia of the knee), 3. The pain interferes with functional activities. 4. Documented lack of sufficient improvement in pain or function following a three month trial of at least two of the following: a. Non-pharmacological interventions (e.g. exercise, weight loss, physical therapy), b. Non-narcotic analgesics (e.g. acetaminophen, topical capsaicin, tramadol), c. Non-steroidal anti-inflammatory drugs (NSAIDs), d. Intra-articular corticosteroids, 5. Bilateral injections may be allowed if both knees meet the criteria for coverage.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	See Other Criteria section for coverage duration details.
Other Criteria	Criteria for Continuation of Therapy (all of the following must be met): 1. Documentation of a significant reduction in pain and improvement in function as a result of the previous injections must be provided. 2. Pain

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PA Criteria	Criteria Details
	has recurred. 3. At least 6 months have passed since the last injection. Quantity Limit: One dose to knee. Preferred Specialty Pharmacy Dispensing required. Code: J7326. 30mg (one dose) = billable unit.

# Gender Affirming Medical Treatment (GNRH Analogs and Cross-Sex Hormones)

#### **Products Affected**

- Eligard
- Lupron Depot-Ped (1-Month)

• Lupron Depot-Ped (3-Month)

#### **PA** Criteria

#### Criteria Details

#### **Covered Uses**

1. Treatment with GNRH Analogs (e.g., Lupron, Lupron Depot) as an initial or continuous therapy for gender affirming treatment in children and adolescents (less than 18 years of age). All of the following must be met: a. The patient's benefit includes coverage of gender affirming therapy. b. For initiation, one letter of assessment from a healthcare professional who has competencies in the assessment of transgender and gender diverse people is required. The letter shall address all of the following: i. Member has the capacity to make a fully informed decision and to consent to treatment. ii. Medical provider attests that the adolescent has been informed of the potential irreversible effect and side effects of treatment, including potential loss of fertility and options to preserve fertility. iii. Mental health and physical conditions that could negatively impact the outcome of gender affirming intervention have been assessed, with risks and benefits discussed. iv. If medical or mental health concerns are present, they are reasonably well controlled. v. Adolescent has given informed consent and the parents, caretakers, or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process. c. The drug must be initiated by a pediatric endocrinologist or a medical provider experienced in child or adolescent gender affirming treatment. d. The treating provider has confirmed that puberty has started in the adolescent (at least Tanner stage 2). 2. Masculinizing or feminizing gender affirming treatment as initial or continuous therapy in children and adolescents (less than 18 years of age). All of the following must be met: a. The patient's benefit includes coverage of gender affirming therapy. b. Member is at least 16 years of age (with medical director review, exceptions may be considered on a case by case basis). c. For initiation of gender affirming hormonal treatment, one letter of assessment from a healthcare professional who has competencies in the assessment of transgender and gender diverse people is required. The letter shall address all of the following: i. Member has the capacity to make a fully informed decision and to consent for treatment. ii. Medical provider attests that the adolescent has been informed of the potential irreversible effects and side effects, including the potential loss of fertility and options to preserve fertility). iii. All mental health and physical conditions that could negatively impact the outcome of gender affirming intervention have been assessed, with risks and

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PA Criteria	Criteria Details
	benefits discussed. iv. If medical or mental health concerns are present, they must be reasonably well controlled. v. The adolescent has given informed consent and the parents, caretakers, or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process. d. Gender marker is not necessary for initial approval and refills for continuation.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to 12 months
Other Criteria	Masculinizing or Feminizing Gender Affirming Hormone Treatment for Initial or Continuous Therapy in Adults (18 years of age and older). All of the following must apply: a. The patient's insurance benefit includes coverage of gender affirming therapy. b. For initiation, one letter from a healthcare professional who has competencies in the assessment of transgender and gender diverse people is required. The letter shall address all of the following: i. Medical provider attests that the member has been informed of the potential irreversible effects and side effects of treatment, including potential loss of fertility and options to preserve fertility. ii. All mental health and physical conditions that could negatively impact the outcome of gender affirming intervention have been assessed, with risks and benefits discussed. iii. If medical or mental health concerns are present, they must be reasonably well controlled. c. Gender marker (male, female, or other) is not necessary for initial approval and refills for continuation of therapyOR- d. Patient has completed gender transition and requires continued hormone treatment for gender affirming maintenance. e. Exclusions: i. Due to a lack of controlled evaluations in females and the potential for virilizing effects, testosterone products will not be approved for use in females requesting virilizing medications for purposes other than transgender related affirmation therapy. ii.Testosterone replacement will not be covered for the treatment of sexual dysfunction.

# **Gleevec (Imatinib)(Cent Care)**

#### **Products Affected**

• Imatinib Mesylate

PA Criteria	Criteria Details
Covered Uses	1. Acute lymphoblastic leukemia: Adults with relapsed or refractory Philadelphia chromosome?positive (Ph+) acute lymphoblastic leukemia (ALL), 2. Acute lymphoblastic leukemia: Pediatric patients with newly diagnosed Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL) in combination with chemotherapy, 3. Aggressive systemic mastocytosis: Adults with aggressive systemic mastocytosis without the D816V c-Kit mutation or with c-Kit mutational status unknown, 4. Chronic myeloid leukemia: a. Newly diagnosed adults and children with Ph+ chronic myeloid leukemia (CML) in chronic phase, b. Patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon alpha therapy, c. Children with Ph+ chronic phase CML whose disease has recurred after stem cell transplant or who are resistant to interferon alpha therapy, 5. Dermatofibrosarcoma protuberans (DFSP): Adults with unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans, 6. GI stromal tumors: a. Patients with KIT (CD117)?positive unresectable and/or metastatic malignant GI stromal tumors (GIST), b. Adjuvant treatment of patients following complete gross resection of KIT (CD117)?positive GIST, 7. Hypereosinophilic syndrome and/or chronic eosinophilic leukemia: Adults with hypereosinophilic syndrome and/or chronic eosinophilic leukemia who have the FIP1L1-platelet?derived growth factor receptor (PDGFR)? fusion kinase (mutational analysis or fluorescent in situ hybridization [FISH] demonstration of CHIC2 allele deletion) and for patients with hypereosinophilic syndrome and/or chronic eosinophilic leukemia who are FIP1L1-PDGFR? fusion kinase negative or unknown, 8. Myelodysplastic/Myeloproliferative diseases: Adults with myelodysplastic/myeloproliferative diseases associated with PDGFR gene rearrangements
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A

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PA Criteria	Criteria Details
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Preferred Specialty Pharmacy Dispensing Required.

### **Granulocyte-Colony Stimulating Factors**

#### **Products Affected**

- Fulphila
- Neulasta Onpro
- Udenyca

- Udenyca Onbody
- Zarxio
- Ziextenzo

PA Criteria	Criteria Details
Covered Uses	1. Cancer patients receiving myelosuppressive therapy. 2. Patients with acute myeloid leukemia receiving induction or consolidation chemotherapy. 3. Cancer patients receiving bone marrow transplant. 4. Patients undergoing peripheral blood progenitor cell collection and therapy. 5. Patients with severe chronic neutropenia (cyclic or idiopathic) that meets the following criteria: Documentation that the patient is symptomatic with at least three clinically significant infections treated with antibiotics or one life-threatening infection treated with IV antibiotic therapy during the previous 12 months. AND one of the following: a. Documented diagnosis of severe chronic neutropenia (idiopathic) with an ANC of less than 500/mm3 on three separate occasions over the previous 6 months. OR b. Documented diagnosis of severe chronic neutropenia (cyclic) with five consecutive days per cycle with an ANC less than 500/mm3 for each of 3 regularly spaced cycles over a 6-month period. 6. Patients with severe chronic neutropenia (congenital) that have a documented diagnosis of congenital neutropenia.
Exclusion Criteria	
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required. Compendial Uses: Non-FDA approved uses are considered to be "medically-accepted indications" based on the drug information sources that CMS has recognized to be authoritative compendia will be considered for approval for treatment if the diagnosis, dosing, frequency, and length of therapy are supported by, and are consistent with published medical literature. Continuation of treatment or retreatment for a compendial use will only be approved if medically necessary, if clinical improvement has been demonstrated, and if supported by published medical literature.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	Up to 1 Year
Other Criteria	Exceptions: Other medical conditions or exceptions to the above conditions of coverage will be considered through the Prior Authorization process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed. Preferred Specialty Pharmacy Dispensing Required.

# Haegarda (C1 esterase inhibitor-human)

#### **Products Affected**

• Haegarda

PA Criteria	Criteria Details
Covered Uses	Hereditary angioedema (HAE) type 1 or 2
Exclusion Criteria	Will not be approved in combination with other prophylactic treatments. Younger than 12 years old.
Required Medical Information	Documentation of the following: 1) diagnosis was made by an allergist or immunologist 2)At least 12 years old or pregnant 3)Recurrent episodes angioedema (without hives), laryngeal edema, abdominal pain and vomiting AND Family history AND age of onset was before thirty (30) years of age AND low C4 levels AND one of the following: a. low C1 inhibitor antigenic level (C1-INH) b. normal C1-INH and low C1-INH fuctional level 4) History of at least one moderate/severe attack per month 5) Baseline HAE attacks 6) Not taking an angiotensin converting enzyme inhibitor or estrogen replacement therapy 7) at least two (2) on demand treated episodes per month or limited emergency services 8) Has tried and failed tranexamic acid or danazol or there is a medical reason for not using this 9)Documented trial and failure of Takhzyro
Age Restrictions	At least 12 years of age
Prescriber Restrictions	
Coverage Duration	Initial: 4 weeks, Continuation: 6 months
Other Criteria	Continuation Criteria: 1) Medical records showing a decrease of at least 50% in frequency of attacks and significant improvement in severity and duration of attacks 2)If the patient is experiencing more than one acute HAE attack per month, medical records documenting use of a long-term prophylactic therapy (LTP) or the clinical rational for avoiding LTP must be provided. Preferred Specialty Pharmacy Dispensing Required.

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# **Hepatitis C Treatment Criteria(Cent Care)**

#### **Products Affected**

• Ribavirin Oral Tablet 200 MG

PA Criteria	Criteria Details
Covered Uses	Treatment of Chronic Hepatitis C Infection. Note: Preferred formulary medications must be utilized before consideration of non-formulary agents and all medications are subject to formulary quantity limits and approved dosages.
Exclusion Criteria	N/A
Required Medical Information	1. Patient must be diagnosed with Chronic Hepatitis C Infections including laboratory documentation of genotype and subtype. 2. Patient must currently have detectable HCV RNA levels 3. Child -Pugh Score 4. Chart notes documenting presence or absence of ascites and encephalopathy. 5. Additional required lab results (within the past 3 months): a. Aspartate transaminase (AST, including upper and lower limit), b. Alanine Transaminase (ALT), c. Platelet Count, d. Bilirubin, e. Albumin, f. INR within 6 months of request (only patients with cirrhosis) g. Absolute Neutrophil Count (ANC), h. Hemoglobin (Hgb), Serum Creatinine (SCr).
Age Restrictions	3 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	Length of approval will be dependent on multiple factors and must be recommended in either the medic
Other Criteria	1. Treatment history: If treatment experienced, provide regimen received including duration of therapy. If regimen was not completed, include reason for discontinuation. The response to therapy: 1) Responder: i. Relapse, ii Reinfection, 2) Non-responder: i Null responder (HCV RNA levels declined less than 2 log10 IU/ml by week 12), ii Partial responders (greater than 2 log10 IU/ml response whose virus remained detectable by week 24), 2. Hepatitis A and B screening including HBsAg, anti-HBs, anti-HBc, HAV Ab3 (labs required). Hep B tests drawn within the past 3 months not required unless patient is at current risk. Specialty pharmacy required.

### Humulin u-500 (insulin human regular)

#### **Products Affected**

- HumuLIN R U-500 (CONCENTRATED) Subcutaneous Solution Pen-Injector
- HumuLIN R U-500 KwikPen

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documentation showing that the patient has had adequate trials of preferred insulin products AND that the patient is using a total of more than 200 units of insulin units per day from basal and bolus insulins
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to One (1) year
Other Criteria	

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# **Hylenex (hyaluronidase Human)**

#### **Products Affected**

• Hylenex

PA Criteria	Criteria Details
<b>Covered Uses</b>	Dispersion/absorption enhancement of injected drugs (extravasation management)
Exclusion Criteria	
Required Medical Information	Documents must show that this drug is being used as part of a chemotherapy regimen to treat extravasation of appropriate agents
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to six (6) months
Other Criteria	

# **Iclusig (panatinib)**

#### **Products Affected**

• Iclusig

PA Criteria	Criteria Details
<b>Covered Uses</b>	1.Philadelphia chromosome positive chronic myeloid leukemia in chronic phase, accelerated phase, or blast phase.2.Philadelphia chromosome positive acute lymphoblastic leukemia
Exclusion Criteria	
Required Medical Information	Indications for Approval:1.Philadelphia chromosome positive chronic myeloid leukemia in chronic phase, accelerated phase, or blast phase.?Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec) AND dasatinib (Sprycel) or nilotinib (Tasigna).OR?Results of mutational testing are positive for T315I2.Philadelphia chromosome positive acute lymphoblastic leukemia ?Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec) AND dasatinib (Sprycel) or nilotinib (Tasigna).OR?Results of mutational testing are positive for T315I
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Continuation Criteria: All of the following must be met:1.Documentation that the patient does not have evidence of disease progression must be submitted.2.Documentation that the patient does not have unacceptable toxicity from therapy must be submitted.

### Imbruvica (ibrutinib)

#### **Products Affected**

• Imbruvica Oral Tablet 140 MG, 280 MG, 420 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1.Chronic graft versus host disease (cGVHD): Patient must have a documented trial and failure of prednisone and a calcinuerin inhibitor 2.For all non-FDA indications, there must be a category 1 or 2 recommendation in the National Comprehensive Cancer Network (NCCN) or a Class I or II recommendation in the Thompson Micromedex DrugDex compendium.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

# Imfinzi (durvalumab)

#### **Products Affected**

• Imfinzi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Indications for Approval: 1.Unresectable Stage III non-small cell lung cancer that has not progressed following concurrent platinum-based chemotherapy and radiation therapy.2.Locally advanced or metastatic urothelial carcinoma in patients who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapyANDPatient has a documented medical reason for avoiding use of Keytruda (pembrolizumab)*.*Keytruda requires a prior authorization for coverage.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 Months
Other Criteria	

# **Increlex** (mecasermin)(Cent Care)

#### **Products Affected**

• Increlex

PA Criteria	Criteria Details
Covered Uses	Growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.
Exclusion Criteria	N/A
Required Medical Information	1. Severe Primary IGFD is defined by all of the following: a. Height standard deviation score? -3.0, b. Basal IGF-1 standard deviation score? -3.0, c. Normal or elevated growth hormone (GH). 2. Severe Primary IGFD includes patients with mutations in the GH receptor (GHR), post-GHR signaling pathway, and IGF-1 gene defects; they are not GH deficient.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	up to 1 year
Other Criteria	Preferred Specialty Pharmacy Dispensing Required.

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# INFeD (iron dextran)(Cent Care)

#### **Products Affected**

Infed

PA Criteria	Criteria Details
Covered Uses	1.For the treatment of chemotherapy-induced iron deficiency anemia*.  2.For the treatment of iron deficiency anemia* in chronic kidney disease patients undergoing chronic hemodialysis. 3.For the treatment of documented iron deficiency anemia* in a patient who has a documented disorder of the gastrointestinal tract of which symptoms may be aggravated by oral iron therapy. Example: Inflammatory bowel disease.  4.For the treatment of a documented iron deficiency anemia* in a patient who has had a documented severe intolerance or treatment failure to an oral iron product after an adequate trial and after attempts have been made to identify and treat the underlying cause(s) of the deficiency.
Exclusion Criteria	N/A
Required Medical Information	Iron Deficiency Anemia defined as (without chronic kidney disease or acute or chronic inflammatory conditions): • Ferritin less than 30 ng/mL, OR • TSAT less than 20%, OR • Absence of stainable iron in bone marrow. Iron Deficiency Anemia defined as (with chronic kidney disease or acute or chronic inflammatory conditions): • Ferritin less than 100 ng/mL, OR • TSAT less than 20% (if serum ferritin 100-200 ng/mL, TSAT less than 20% is required to confirm iron deficiency).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 time
Other Criteria	Compendial Uses: Non-FDA approved uses for the injectable iron products that are considered to be "medically-accepted indications" based on the drug information sources that CMS has recognized to be authoritative compendia will be considered for approval for treatment if the diagnosis, dosing, frequency, and length of therapy are supported by, and are consistent with published medical literature. Continuation of treatment or retreatment with an injectable iron product for compendial uses will only be approved if medically necessary, if clinical improvement has been demonstrated, and if supported by published medical literature.

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PA Criteria	Criteria Details
	Code: J1750. 50mg = 1 billable unit.

# Injectafer (ferric carboxymaltose)(Cent Care)

#### **Products Affected**

• Injectafer

PA Criteria	Criteria Details
Covered Uses	1.For the treatment of chemotherapy-induced iron deficiency anemia*.  2.For the treatment of iron deficiency anemia* in chronic kidney disease patients undergoing chronic hemodialysis. 3.For the treatment of documented iron deficiency anemia* in a patient who has a documented disorder of the gastrointestinal tract of which symptoms may be aggravated by oral iron therapy. Example: Inflammatory bowel disease.  4.For the treatment of a documented iron deficiency anemia* in a patient who has had a documented severe intolerance or treatment failure to an oral iron product after an adequate trial and after attempts have been made to identify and treat the underlying cause(s) of the deficiency.
Exclusion Criteria	N/A
Required Medical Information	Iron Deficiency Anemia defined as (without chronic kidney disease or acute or chronic inflammatory conditions): • Ferritin less than 30 ng/mL, OR • TSAT less than 20%, OR • Absence of stainable iron in bone marrow. Iron Deficiency Anemia defined as (with chronic kidney disease, acute/chronic inflammatory conditions, or heart failure - left ventricular ejection fraction less than 45%): • Ferritin less than 100 ng/mL, OR • TSAT less than 20% (if serum ferritin 100-200 ng/mL, TSAT less than 20% is required to confirm iron deficiency).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 time
Other Criteria	Compendial Uses: Non-FDA approved uses for the injectable iron products that are considered to be "medically-accepted indications" based on the drug information sources that CMS has recognized to be authoritative compendia will be considered for approval for treatment if the diagnosis, dosing, frequency, and length of therapy are supported by, and are consistent with published medical literature. Continuation of treatment or retreatment with an injectable iron product for compendial uses will only be approved if medically necessary, if clinical improvement

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PA Criteria	Criteria Details
	has been demonstrated, and if supported by published medical literature.

### IVIG (Immune Globulin (human), IV)(COMM, EXC)

#### **Products Affected**

• Flebogamma DIF

Gamunex-C

PA Criteria	Criteria Details
Covered Uses	Note: Preferred products are Flebogamma and Gamunex-C. Use for the following indications will be considered for approval for treatment with IVIG when supported by current treatment guidelines, and standard interventions, treatments, and/or therapy have failed or are contraindicated. Dosing, frequency, and length of therapy must be supported by, and consistent with published medical literature. Diagnosis of one of the following: a. Children with acquired immunodeficiency syndrome (AIDS) b. bone marrow and organ transplant recipients (except corneal) who are at risk for cytomegalovirus (CMV) and pneumonia due to immunosuppressant agents, c. post bone marrow transplant, d. adults with human immunodeficiency virus (HIV) who are immunosuppressed in association with AIDS or AIDS-related complex (ARC) e. infection, prevention in: HIV-infected patients, patients with primary defective antibody synthesis, hypogammaglobulinemia and/or recurrent bacterial infections, with B-cell chronic lymphocytic leukemia, f. Kawasaki syndrome, g. Primary immunodeficiencies including congenital agammaglobulinemia, hypogammaglobulinemia, common variable immunodeficiency, X-linked immunodeficiency, severe combined immunodeficiency, Wiskott-Aldrich syndrome, h. idiopathic or immune thrombocytopenia purpura (ITP).
Exclusion Criteria	The use of intravenous and/or subcutaneous immunoglobulin is considered experimental, investigational, and unproven for any indication not listed above, including but not limited to the following: acquired Factor VIII inhibition, acquired von Willebrand's Syndrome, acute lymphoblastic leukemia, acute renal failure, adrenoleukodystrophy, Amyotrophic Lateral Sclerosis (ALS or Lou Gehrig disease), antiphospholipid ab syndrome, aplastic anemia, asthma and inflammatory chest disease, Behcet's Syndrome, burns, chronic (primary or secondary) progressive multiple sclerosis, chronic fatigue syndrome, congenital heart block, cystic fibrosis, demyelinating optic neuritis, diabetes mellitus, Diamond-Blackfan anemia, endotoxemia, epilepsy, euthyroid ophthalmopathy, Factor VIII inhibitors, acquired, hemolytic transfusion reaction (except post-transfusion purpura), Hemolytic Uremic syndrome, Hemophagocytic syndrome, inclusion-body myositis, membranous nephropathy, motor neuron syndromes, multiple myeloma (except multiple myeloma with stable plateau phase disease who are at high risk of recurrent infections - see Off-Label Indications above), myelopathy,

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PA Criteria	Criteria Details
	HTLV-1 associated, neonatal hemolytic disease, nephrotic syndrome, non-immune thrombocytopenia, paraproteinemic neuropathy, post-infectious sequelae, progressive lumbosacral plexopathy, recent-onset dilated cardiomyopathy, recurrent otitis media, recurrent, spontaneous fetal loss with previous pregnancies, refractory rheumatoid arthritis, adult and juvenile, thrombotic thrombocytopenic purpura, uveitis. EXCEPTIONS: Exceptions to these conditions of coverage are considered through the Prior Authorization process. Clinical, peer reviewed, published evidence will be required for any diagnosis not otherwise listed.
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Up to 1 year
Other Criteria	IVIG may be considered medically necessary when standard interventions/therapy has failed, become intolerable, or are contraindicated for any of the following off-label indications: 1. Acute inflammatory demyelinating polyneuropathy in patients with one or more of the following: rapid deterioration with acute symptoms for less than 2 weeks, rapidly deteriorating ability to ambulate, unable to ambulate for 10 meters, or deteriorating PFTs. 2. Autoimmune hemolytic anemia not responsive to corticosteroids. 3. Autoimmune neutropenia not responsive to other modalities. 4. Chronic inflammatory demyelinating polyneuropathy used alone or following therapeutic plasma exchange to prolong its effect. 5. Hyperimmunoglobulin E syndrome. 6. Infection prophylaxis and/or treatment adjunct in high-risk, preterm, low-birth-weight neonates. 7. Refractory inflammatory myopathies for corticosteroid-resistant patients. 8. Lambert-Eaton myasthenic syndrome not controlled by anticholinesterases and diaminopyridine. 9. Malignancies of various types, especially leukemic illnesses that are vulnerable to recurrent infections due to an immunosuppressed system, including multiple myeloma with stable plateau phase disease and a high risk of recurrent infections. 10. Multifocal motor neuropathy in patients with anti-GM1 antibodies and conduction who are not responsive to conventional therapy (i.e. corticosteroids or immunosuppressants). 11. Multiple Sclerosis (severe manifestations of RRMS only) when patient is not responsive to other therapy. 12. Myasthenia gravis with one of the

PA Criteria	Criteria Details
	following: acute severe decompensation not responsive to other treatments, myasthenia crisis in patients with contraindications to plasma exchange, or chronic debilitating disease not responsive to cholinesterase inhibitors, steroids, or azathioprine. 13. Severe neonatal alloimune thrombocytopenia not responsive to other interventions. 14. Severe post transfusion purpura. 15. Pure red cell aplasia with documented parovirus B19 infection and with severe, refractory anemia. 16. Prior to solid organ transplant for treatment of patients at high risk of anti-body mediated rejection, including highly sensitized patients, and those receiving an ABO incompatible organ. 17. Treatment of antibody mediated rejections following a solid organ transplant. 18. Stiff Person Syndrom when anti-GAD antibody is present and other therapy has failed (i.e., benzodiazepines, baclofen, phenytoin, clonidine, tizanidine). 19. Systemic Lupus Erythromatosus in patients with severe active illness not responsive to other interventions. 20. Toxic Shock Syndrome or Toxic Necrotizing Fasciitis due to streptococcal or staphylococcal organisms and one of the following: infection is refractory to several hours of aggressive therapy OR an undrainable focus is present OR the patient has persistent oliguria with pulmonary edema. 21. Vasculitis Syndrome in patients with severe active illnesses not responsive to other interventions.

# Jakafi (ruxolitinib)

#### **Products Affected**

Jakafi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	For graft-versus-host-disease (GVHD)- if patient has received more than one (1) allogenic hematopoietic stem cell transplantation (allo-HSCT) OR there is evidence of relapsed primary disease or have been treated for relapse after the allo-HSCT was performed
Required Medical Information	For oncology diagnoses: there must be a Category 1 or 2 recommendation in the National Comprehensive Cancer Network (NCCN) compendium or there must be a Class I or II recommendation in the Thomson Micromedex DrugDex compendium. Preferred formulary drugs must be used before consideration of non-preferred agents. For graft-versus host disease (GVHD): If this drug is being used to treat GVHD, you must have grade two (2) to four (4) GVHD that has progressed or has not changed after treatment with steroids. You must have also tried two (2) of the following: cyclosporine, tacrolimus, sirolimus, or mycophenolate mofetil
Age Restrictions	minimum 12 years old
Prescriber Restrictions	
Coverage Duration	up to six (6) months
Other Criteria	

# **Kalbitor** (ecallantide)(Cent Care)

#### **Products Affected**

• Kalbitor

PA Criteria	Criteria Details
Covered Uses	1. Diagnosis of HAE is documented based on evidence of low C4 level AND one of the following: a. A low C1 inhibitor (C1-INH) antigenic level. OR b. A normal C1-INH antigenic level and a low C1-INH functional level. 2. The member is not concurrently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy. 3. The member must be experiencing at least one symptom of a moderate or severe attack (i.e. swelling of the face, throat, or abdomen).
Exclusion Criteria	Use of Berinert, Firazyr, or Kalbitor for the treatment of HAE with normal C1 inhibitor (Type III) will be reviewed on a case by case basis.
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	Diagnosis of hereditary angioedema (HAE) has been clinically established by, or in consultation with, an allergist or immunologist
Coverage Duration	6 months
Other Criteria	Continuation of Therapy Criteria: Medical records documenting frequency of acute HAE attacks and the patient?s response to therapy must be provided. If the patient is experiencing more than one acute HAE attack per month, medical records documenting use of a long-term prophylactic therapy (LTP) or the clinical rational for avoiding LTP must be provided. Code: J1290. 1mg = billable unit.

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# Kalydeco (ivacaftor)

#### **Products Affected**

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Indications for Approval: All of the following must be met:1.Documentation that patient has a diagnosis of cystic fibrosis 2.Patient is not homozygous for the F508del mutation in the CFTR gene and has one of the CFTR gene mutations as indicated in the FDA label.  3. Documentation of all of the following: i. Pretreatment ppFEV1 (within the past 30 days). For patients 6 years of age or younger, submission of appropriate baseline pulmonary monitoring/testing is required ii.Patient has had two negative respiratory cultures for any of the following: Burkholderia cenocepacia, Burkholderia dolasa, or Mycobacterium abseccus in the past 12 months iii.Baseline ALT, AST, and bilirubin that are less than three times upper limit of normal. ALT and AST should be assessed every 3 months during the first year of treatment, and annually thereafter iv.Baseline ophthalmic exam for pediatric patients v.No dual therapy with another CFTR potentiator is planned.
Age Restrictions	Patient is within FDA approved ages
Prescriber Restrictions	
Coverage Duration	Initial Approval: 6 months Reauthorization: 1 Year
Other Criteria	Continuation Criteria: All of the following must be met: 1. Patients response to therapy is documented (e.g. stable or improvement of ppFEV1 from baseline, weight gain, decreased exacerbations, etc.). 2. Patient has had two negative respiratory cultures for any of the following: Burkholderia cenocepacia, Burkholderia dolasa, or Mycobacterium abseccus in the past 12 months. 3. Documentation of annual testing of ALT, AST, and bilirubin levels after the first year of therapy. 4. No dual therapy with another CFTR potentiator is planned.

# **Kevzara** (sarilumab)

#### **Products Affected**

Kevzara

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. 1. Rheumatoid Arthritis, Moderate to Severe (RA). 2. Polymyalgia Rheumatica (PMR). 3. Pediatric Juvenile Arthritis (pJIA)
Exclusion Criteria	
Required Medical Information	RA: 1. Documented presence of moderate to severe rheumatoid arthritis (RA). Moderate to severe RA is defined as DAS-28 greater than 3.2 or CDAI greater than 10.1. 2. An adequate trial (3 months or more) of one of the following DMARDs: a. Hydroxychloroquine b. Leflunomide c. Methotrexate d. Sulfasalazine. PMR: Inadequate response to corticosteroid therapy. 2. At least one episode of unequivocal PMR flare while attempting to taper corticosteroids. pJIA: a. Prescribed by or in consultation with a rheumatologist. b. An adequate trial (3 months or more) of one of the following DMARDs: i. Leflunomide ii. Methotrexate iii. Sulfasalazine, AND trial and failure of TWO preferred agents used to treat the same indication: Amjevita, Enbrel, Humira, Rinvoq, Xeljanz. c. Member weighs at least 63 kg.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist
Coverage Duration	Up to 1 year
Other Criteria	For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy, 2. Use of a Specialty Pharmacy is required. CONTINUATION CRITERIA: Documentation of positive response to treatment with Kevzara. Quantity Limit: 2.28 mL per 28 days

### Kuvan (sapropterin dihydrochloride) Criteria

#### **Products Affected**

• Sapropterin Dihydrochloride Oral Packet • Sapropterin Dihydrochloride Oral Tablet

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diagnosis of phenylketonuria
Exclusion Criteria	
Required Medical Information	(1)Tetrahydrobiopterin (BH4) deficiency has been ruled out.(2) Patient has a baseline phenylalanine level at least 600 micromol/L.(3) Patient has failed a phenylalanine-restricted diet alone despite strict compliance.(4)The patient is seeing a dietician that specializes in phenylketonuria/metabolic disease.
Age Restrictions	
Prescriber Restrictions	Metabolic disease specialist
Coverage Duration	Initial Length of Approval: 1 month, Continuation: Up to 1 year (dependent on response)
Other Criteria	Continuation of Therapy Criteria: (1) The prescribing physician is a metabolic disease specialist. (2) Documentation that patient is following a phenylalanine restricted diet. (3) Laboratory reassessment is conducted after an initial one month trial. a. Patients responding to therapy (at least 30% reduction in blood phenylalanine levels from baseline) and have maintained phenylalanine levels below baseline levels will be approved for an additional 1 year of therapy. b. Patients on the 20 mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline by at least 30% after 1 month are considered non-responders, and further treatment with Kuvan will not be authorized. c. Patients on the 10 mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline by at least 30% after 1 month of therapy should increase to 20 mg/kg/day. These patients are approved for another 1 month trial at the higher dose. Quantity will be limited to an amount sufficient to allow for up to the FDA approved maximum recommended dosage.

# LAMICTAL XR (lamotrigine)

#### **Products Affected**

• lamoTRIgine ER

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documents showing trial and failure of at least two (2) anti-seizure drugs in the previous 120 days
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to one (1) Year
Other Criteria	

# Liquid drugs

#### **Products Affected**

- Enalapril Maleate Oral Solution
- Xatmep

Qbrelis

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	The patient is unable to take or swallow oral medications and should be on other oral tablets or capsules
Age Restrictions	Criteria applies to patients greater than 12 years of age
Prescriber Restrictions	
Coverage Duration	up to one (1) year
Other Criteria	

# LOKELMA (sodium zirconium cyclosilicate)

#### **Products Affected**

• Lokelma

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded
Exclusion Criteria	
Required Medical Information	Documents showing the following is required- 1.) Baseline potassium 5.1 to less than 6.5mmol/liter at two screenings 2.) Patient is adhering to a low-potassium diet 3.) Medications known to cause hyperkalemia has been discontinued or reduced to the lowest effective dose 4.) Adequate trial of diuretics (loop or thiazides) or there are medical reasons for avoiding them (a) Adequate trial is defined as at least 4 weeks of a stable dose (b) Loop diuretics are recommended if GFR is less than 40 ml/min/1.73m2 5.) Patient must have tried Veltassa (patiromer) or have a medical reason why it cannot be used
Age Restrictions	at least 18 years old
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

### Lovenox (enoxaparin) Quantity

#### **Products Affected**

 Enoxaparin Sodium Injection Solution 300 MG/3ML Prefilled Syringe

Enoxaparin Sodium Subcutaneous

• Enoxaparin Sodium Injection Solution

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Prior authorization only applies to quantities exceeding 30 syringes in a 90 day period
Exclusion Criteria	
Required Medical Information	Indications for Approval:One of the following must be met:1. The patient has an active cancer diagnosis.2. The patient is currently pregnant and has a condition associated with a high risk of developing thrombosis (e.g., personal or family history of venous thromboembolism, current deep vein thromboembolism or pulmonary embolism, factor V Leiden mutation, mechanical prosthetic heart valve, atrial fibrillation, antiphospholipid antibody syndrome). Pregnancy must be confirmed by positive lab results or imaging.3. Other indications - medical records must be submitted documenting a medical reason for avoiding the use of formulary agents and the requested duration of therapy must be supported in by the medical compendia.
Age Restrictions	N/A
Prescriber Restrictions	
Coverage Duration	See below
Other Criteria	Active Cancer diagnosis: 6 months, Pregnancy: Up to 6 weeks after delivery Date, other indications: up to 6 months

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# Lybalvi (MCAID)

#### **Products Affected**

• Lybalvi

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Schizophrenia 2. Bipolar Disorder
Exclusion Criteria	
Required Medical Information	1. Schizophrenia: a. Trial and failure of three atypical antipsychotics for a minimum of 4 weeks (non-responders) or 12 weeks (partial responders) - e.g., aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, first-generation antipsychotics, OR member has a current diagnosis of metabolic syndrome, pre-metabolic syndrome, or diabetes mellitus and has failed aripiprazole AND ziprasidone, unless there is a documented contraindication or intolerance. 3. Bipolar: a. Monotherapy: Trial and failure of three alternatives from the following: i. lamotrigine, ii. lithium, iii. carbamazepine, iv. valproic acid, v. Atypical Antipsychotics (e.g., aripiprazole, lurasidone, quetiapine). b. adjunct therapy: will be used with either lithium or valproic acid.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a Behavior Health Practitioner
Coverage Duration	Up to one (1) year
Other Criteria	

### MAVENCLAD (cladiribine)

#### **Products Affected**

- Mavenclad (10 Tabs)
- Mavenclad (4 Tabs)
- Mavenclad (5 Tabs)
- Mavenclad (6 Tabs)

- Mavenclad (7 Tabs)
- Mavenclad (8 Tabs)
- Mavenclad (9 Tabs)

Wiavenciau (0 1 aus)	
PA Criteria	Criteria Details
<b>Covered Uses</b>	Relapsing forms of multiple sclerosis, including relapsing-remitting and active secondary progressive disease.
Exclusion Criteria	1. The patient has not already received two years of therapy with Mavenclad 2. Mavenclad cannot be used in conjunction with any other therapies for treatment of multiple sclerosis (MS)
Required Medical Information	Documentation of the following: a. An Expanded Disability Status Scale (EDSS) score of greater than or equal to 3 (moderate-to-advanced disability) b. History of relapsing, remitting MS with current SPMS defined as non-relapse related MS disease progression. c. Active disease defined by one of the following: i. Documented progression in the EDSS 2 years prior to treatment with Mavenclad ii. Relapses in the 2 years prior to treatment with Mavenclad iii. Gadolinium-enhancing lesions on T1-weighted images and new or newly enlarged non-enhancing lesions on T2-weighted monthly brain magnetic resonance imaging (MRI) scans 5. Not using Mavenclad in conjunction with any other therapies for treatment of multiple sclerosis. 6. Documentation of an inadequate response to the covered alternatives used to treat the same indication. 7. No current malignancy, HIV infection, or active chronic infection, such as hepatits, TB. 8. The patient has not already received two years of therapy with Mavenclad.
Age Restrictions	Over 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the treatment of MS (e.g.neurologist)
Coverage Duration	Up to six (6) months
Other Criteria	Specialty Pharmacy Required.

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### MAYZENT (SIPONIMOD)

#### **Products Affected**

• Mayzent

Mayzent Starter Pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Exclusion Criteria	
Required Medical Information	Documentation of the following: a. An Expanded Disability Status Scale (EDSS) score of greater than or equal to 3 (moderate-to-advanced disability) b. History of relapsing, remitting MS with current SPMS defined as non-relapse related MS disease progression. c. Active disease defined by one of the following: i. Documented progression in the EDSS 2 years prior to treatment with siponimod ii. Relapses in the 2 years prior to treatment with siponimod iii. Gadolinium-enhancing lesions on T1-weighted images and new or newly enlarged non-enhancing lesions on T2-weighted monthly brain magnetic resonance imaging (MRI) scans 4. Not using Mayzent in conjunction with any other therapies for treatment of multiple sclerosis. 5. Has not, in the last six months, experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure. 6. No presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless has a functioning pacemaker. 7. The following baseline information must be submitted: a. Varicella zoster vaccination or confirmed auto-antibody varicella zoster virus antibody status. Patients who are negative mush be vaccinated.b. CYP2C9 genotype determination (alters dose) i. If genotype is CYP2C9*1/*3 or *2/*3, dose is reduced. ii. If genotype is CYP2C9*3/*3, Mayzent is contraindicated. c. Recent CBC and LFTs (within one month prior to initiating therapy) d. Ophthalmic evaluation
Age Restrictions	Over 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the treatment of MS (e.g., neurologist).
Coverage Duration	Up to six (6) months

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PA Criteria	Criteria Details
Other Criteria	Specialty Pharmacy Required. Quantity Limit: 0.25 mg tablet: 120 for 30 days, 2 mg: 30 tabs per 30 days.

### **Megace ES (megestrol)(Cent Care)**

#### **Products Affected**

• Megestrol Acetate Oral Suspension 625 MG/5ML

PA Criteria	Criteria Details
Covered Uses	The patient must have a documented failure, or contraindication to megestrol suspension. AND The patient has a diagnosis of cancer-related cachexia. OR The patient has a diagnosis of AIDS Wasting Syndrome.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A

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# Migraine

#### **Products Affected**

• Aimovig

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Chronic Migraine 2. Episodic Migraine
Exclusion Criteria	
Required Medical Information	1. Chronic Migraine: a. 15 or more migraine-like or tension-type headache days per month, and has experienced for more than 3 months. b. 3 month trial of at least two prophylactic medications from at least two of the following categories: i. Anticonvulsants (e.g. divalproex, valproate, topiramate) ii. Beta-blockers (e.g. metoprolol, propranolol, timolol) iii. Antidepressants (e.g. amitriptyline, venlafaxine) iv. Candesartan. c. Member has been evaluated for and does not have medication overuse headache. d. The patient has a documented trial and failure of two Botox (onabotulinumtoxinA) injections (minimum 6 months of treatment). 2. Episodic Migraine: a. The patient has 4 to 14 migraine days per month. b. The patient has been evaluated for and does not have medication overuse headache. c. 3 month trial of at least two prophylactic medications from at least two of the following categories: i. Anticonvulsants (e.g. divalproex, valproate, topiramate) ii. Beta-blockers (e.g. metoprolol, propranolol, timolol) iii. Antidepressants (e.g. amitriptyline, venlafaxine). iv. Candesartan. d. An oral CGRP for preventive treatment MAY be considered after documentation has been provided that the member has failed a three month treatment of Aimovig.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or headache specialist.
Coverage Duration	Initial: 3 months. Continuation: Up to 12 months
Other Criteria	Continuation Criteria (all must met): (1) Documentation that member has experienced a reduction of 2 or more migraine days per month, (2) Member has not received a Botox injection while on Aimovig and will not be initiating Botox for headache prophylaxis while using Aimovig.

### Mounjaro (tirzepatide)

#### **Products Affected**

• Mounjaro

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. To be used an an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).
Exclusion Criteria	
Required Medical Information	Indications for approval (all must be met ):1. Diagnosis of type 2 diabetes mellitus (T2DM).2. Uncontrolled T2DM as evidenced by an HgbA1c of 7% or greater that has been measured within the past 90 days.3. a. The member has failed metformin, either as monotherapy or as combination therapy, unless contraindicated or not tolerated. b. The member has tried and failed at least a 90-day course of either a sodium-glucose cotransporter 2 (SGLT2) inhibitor (e.g., Steglatro, Farxiga) or a dipeptidyl peptidase-4 (DPP-4) inhibitor (e.g., alogliptin), unless contraindicated or not tolerated.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

### Mulpleta (lusutrombopag)

#### **Products Affected**

• Mulpleta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Low risk procedures such as paracentesis, routine endoscopy, or central line placement
Required Medical Information	Documents must show that 1) procedure date is within 8(eight) to 14 (fourteen) days from request date 2)Baseline platelets are less than 50x10^9/L 3) the procedure carries and intermediate to high risk of bleeding (i.e. spinal surgery, cardiac surgery, large polypectomy, liver biopsy)
Age Restrictions	at least 18 years old
Prescriber Restrictions	gastroenterologist, hematologist, or hepatologist
Coverage Duration	7 days (one course only)
Other Criteria	

### Multaq (dronedarone)(Cent Care)

#### **Products Affected**

• Multaq

PA Criteria	Criteria Details
Covered Uses	Patient has one of the following indications: 1. Atrial Fibrillation, 2. Paroxysmal Atrial Fibrillation, 3. Atrial Flutter AND Must meet all of the following criteria: a. Must not have NYHA Class IV heart failure or NYHA Class II-III heart failure with a recent decompensation. b. A documented trial and failure of: i. Two generic antiarrhythmics such as flecainide, sotalol, or propafenone. OR ii. Amiodarone with unacceptable side effects.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Quantity Limit: 60 tablets for 30 days.

### NAYZILAM (midazolam)

#### **Products Affected**

• Nayzilam

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded
Exclusion Criteria	
Required Medical Information	Diagnosis of acute intermittent seizures.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to one (1) Year
Other Criteria	Quantity Limit: 10 delivery systems per 30 days

### **Neurokinin 1 receptor Antagonist**

#### **Products Affected**

• Cinvanti

PA Criteria	Criteria Details
<b>Covered Uses</b>	1) Chemotherapy-induced nausea and vomiting, Due to highly emetogenic chemotherapy 2) Chemotherapy-induced nausea and vomiting, Due to Moderately emetogenic chemotherapy
Exclusion Criteria	
Required Medical Information	Indications for Approval:1. The patient must be receiving drug in combination with a 5-HT3 antagonist and dexamethasone AND 2. Must meet one of the following criteria: a) The patient is being treated with a cancer chemotherapy regimen which has high emetogenic potential. b) The patient is being treated with a cancer chemotherapy regimen which has moderate emetogenic potential and has failed anti-emetic therapy with a 5-HT3 antagonist in combination with dexamethasone
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

### **Non-Preferred anti-DEPRESSANTS**

#### **Products Affected**

- Fetzima
- Fetzima Titration
- Marplan
- Nefazodone HCl

- Protriptyline HCl
- Trimipramine Maleate Oral
- Trintellix

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documentation must show a diagnosis of depression and an adequate trial of each of the following: 1) a selective serotonin reuptake inhibitor (SSRI), 2) a selective norepinephrine reuptake inhibitor (SNRI), and 3) bupropion or mirtazapine
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) year
Other Criteria	An adequate trial is defined as taking the drug for at least four (4) weeks at a therapeutic dose. Therapeutic failure is defined as no improvement in symptoms or intolerable side effects to the medication.

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### **Non-Preferred Injectable Anti-Psychotics**

#### **Products Affected**

• Perseris

• ZyPREXA Relprevv

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documentation showing that a trial and failure of Aristada AND either Invega Sustenna or Invega Trinza or medical reasons for avoiding them
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	up to one (1) year
Other Criteria	

# Nuedexta (dextroamphetamine/quinidine) (COMM, EXC, Cent Care)

#### **Products Affected**

• Nuedexta

PA Criteria	Criteria Details
<b>Covered Uses</b>	Documented diagnosis for the treatment of pseudobulbar affect secondary to a neurological disease or injury (e.g. Multiple Sclerosis, Parkinsons, stroke, traumatic brain injury).
Exclusion Criteria	N/A
Required Medical Information	Medical records including the following: Indications for Approval (all of the following must be met): 1. Documented diagnosis for the treatment of pseudobulbar affect secondary to a neurological disease or injury (e.g. Multiple Sclerosis, Parkinsons, stroke, traumatic brain injury). 2. Must be prescribed by or in consultation with a neurologist. 3. Member must have a documented baseline score greater than or equal to 13 on the Center for Neurologic Study - Lability Scale (CNS-LS). 4. Documents showing the number of daily episodes must be submitted. Continuation of Treatment Criteria (all of the following must be met): 1. Documentation showing the CNS-LS score has decreased and the decrease is maintained. 2. Documented decrease in the number of daily episodes.
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by or in consultation with a neurologist.
Coverage Duration	Initial Approval - one month. Continuation of therapy - 6 months.
Other Criteria	Quantity Limit: 60 tablets for 30 days.

### **Nutritional Supplementation(Cent Care)**

#### **Products Affected**

• Boost

PA Criteria	Criteria Details
Covered Uses	1. For patients who must be tube fed oral nutritional supplements and products, requests should be submitted directly to Presbyterian Health Plan?s enteral nutrition provider. 2. Oral nutritional support: a. On the basis of a specific medical indication for a patient who has a defined need for which nutritional support is considered therapeutic, and for which regular food, blenderized food, or commercially available retail consumer nutritional supplements would not meet his or her medical needs. A current dietary or nutritional consult will be required for evaluation. b. When medically necessary due to inborn errors of metabolism. A current dietary or nutritional consult will be required for evaluation. c. When medically necessary to correct or ameliorate physical illnesses or conditions in a patient under 21 years of age. A current dietary or nutritional consult will be required for evaluation. Examples of medical necessity: i. Diagnosis or clinical condition that relates to the need for restoration of a pathological loss of tissue and attempts at regular food intake have failed to increase the protein and caloric absorption. ii. Conditions related to swallowing disorders, malabsorption syndromes, and/or chronic conditions with persistent weight loss, or debilitated skin integrity contribution or poor healing of tissues, i.e. decubitus ulcers, etc.
Exclusion Criteria	Exclusions: 1. Coverage does not include commercially available food alternatives, such as low or sodium-free foods, low or fat-free foods, low or cholesterol-free foods, low or sugar-free foods, low or high calorie foods for weight loss or weight gain, or alternative foods due to food allergies or intolerance. 2. Enteral nutrition for non-tube fed patients or patients who DO NOT have inborn errors of metabolism or other medical conditions under the age of 5 years is not a covered benefit. Patients under 5 years old should be referred to Women, Infants, and Children (WIC) Food and Nutrition Services.
Required Medical Information	Chart notes documenting medical indication and planned course of therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A

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PA Criteria	Criteria Details
Coverage Duration	up to 1 year
Other Criteria	N/A

### Nuvigil (armodafinil)

#### **Products Affected**

• Armodafinil

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Narcolepsy 2. Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS)3. Shift Work Sleep Disorder (SWSD) 4. Multiple Sclerosis Related Fatigue
Exclusion Criteria	
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required. Diagnosis specific requirements also apply. 1. Narcolepsy - The patient must have a treatment failure, inability to tolerate, or other medical contraindication (including but not limited to: cardiovascular disease) to one or more formulary alternative medications. 2. OSAHS - Documentation that the member has been on CPAP for at least two months and is using it four or more hours a night is required. 3. SWSD - A letter from the employer is required stating the member is working a variable, alternating, or third shift. 4. Multiple Sclerosis Related Fatigue
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by a sleep specialist or neurologist.
Coverage Duration	Up to one year.
Other Criteria	Quantity Limit: 30 tablets per 30 days

### Ocrevus (ocrelizumab) (COMM, HIX, Cent Care)

#### **Products Affected**

Ocrevus

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Documented trial and failure of Briumvi for relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Primary progressive MS: documented diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by a neurologist.
Coverage Duration	Up to one year.
Other Criteria	Specialty pharmacy required.

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# Ofev (nintedanib)

#### **Products Affected**

Ofev

PA Criteria	Criteria Details
<b>Covered Uses</b>	Interstitial pulmonary fibrosis (IPF) or Interstitial lung disease (ILD)
Exclusion Criteria	Will not be approved in combination with Esbriet (pirfenidone)
Required Medical Information	(1)Patient has a baseline FVC at least 50%, (2)For IPF: diagnosis is confirmed by one of the following: a)Finding on high-resolution computed tomography indicates usual interstitial pneumonia (UIP) b)A surgical lung biopsy demonstrates UIP c)Exclusions from other known causes of interstitial lung disease must be documented (i.e. occupational or environmental exposure, drug toxicity, or connective tissue disease)(3)For ILD with a progressive phenotype: a) greater than 10% fibrotic features on computed tomography, b)presented with clinical signs of progression, c)FVC at least 45% predicted, d)DLCO 30-79% of predicted, e)Progression on standard management,(4) The patient is a nonsmoker or has been abstinent from smoking for at least 6 weeks
Age Restrictions	at least forty (40) years of age
Prescriber Restrictions	Prescribed by or in consultation with a Pulmonologist
Coverage Duration	1 year
Other Criteria	Continuation Criteria 1. Predicted FVC has not declined by 10% or more OR more than 200mL decrease 2. Patient continues to be smoke free

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### **Omnipod Dash**

#### **Products Affected**

- Omnipod 5 DexG7G6 Intro Gen 5
- Omnipod 5 DexG7G6 Pods Gen 5
- Omnipod Classic Pods (Gen 3)
- Omnipod DASH Intro (Gen 4)
- Omnipod DASH Pods (Gen 4)

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diabetes Mellitus Type 1 or 2
Exclusion Criteria	
Required Medical Information	1.The patient is currently using Blood Glucose Monitor (BGM) AND is testing four or more times per day or using a Continuous Glucose Monitor (CGM) on a regular basis.2. The beneficiary is insulin-treated with three or more injections of insulin daily3. The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary based on BGM or CGM testing results.4. Within six (6) months prior to ordering the insulin pump, the treating practitioner has an in-person visit or tele-visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-4) above are met
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	1 year for pods
Other Criteria	Continuation of Therapy Criteria:1. Treating practitioner must submit documentation that an in-person visit or tele-visit with the beneficiary has occurred every six months or more frequently2. Beneficiary is responding positively to therapyQuantity limit: 10 pods per monthFor requests exceeding this quantity, documents and clinical rationale must be provided

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### **Omnitrope** (somatropin)

#### **Products Affected**

• Omnitrope Subcutaneous Solution

Reconstituted

PA Criteria	Criteria Details
Covered Uses	Indications for approval in CHILDREN (up to age 18): All the following must be met. 1.) Documented growth hormone deficiency that meets the following criteria: a) Patient must be evaluated by a pediatric endocrinologist b)Epiphyses are not closed. TWO of the following must be met: A. Subnormal response (10ng/ml or less) to at least two GH provocative stimulation tests or subnormal response to one GH provocative stimulation test and IGF1 and IGFBP-3 more than 2 SD below the mean for age and gender. i) For patients with documented panhypopituitarism or a history of cranial radiation no simulation tests required. ii) In a neonate with hypoglycemia, but not metabolic disorder, a peak GH level less than 20 ng/ml is usually diagnostic of GHD. B. Baseline height 2.25 SD or more below mean (or below the 3rd percentile) for age or gender. C. Growth failure defined as I. Two to Four Years: height velocity (HV) less than 5.5cm per year II. Four to Six years: HV less than 5cm per year III. Six years to puberty: for BOYS-less than 4cm per year, for GIRLS-less than 4.5cm per year D. Documentation of bone age 2 SD or more below the normal for chronological age. Note: Provocative stimulation tests include arginine, clonidine, glucagon, insulin, and levodopa. 2. TURNER SYNDROME IN FEMALES. a. Diagnosis of Turner Syndrome confirmed by appropriate genetic testing. b. Patient has a growth rate below 7 cm per year if less than 3 years of age, and below 4 cm per year if greater than 3 years of age. d. Bone age less than 14 years. e. Documentation if epiphyses are not closed. 3. CHRONIC RENAL INSUFFICIENCY a) Documented clinical diagnosis of chronic renal insufficiency. b) Patient has a growth rate less than 7 cm per year if less than 3 years of age. c) Existing metabolic derangements (such as acidosis, secondary hyperparathyroidism, malnutrition) have been corrected. d) Documentation if epiphyses are not closed. e) Patient is not post renal transplant. 4. SMALL FOR GESTATIONAL AGE a. Documented birth weight of less than 2,500 g at a

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PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	ADULTS: All the following must be met. 1. Adult onset GHD - Multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma. a. Patient has 2 or more of the following pituitary hormone deficiencies: thyroid stimulating hormone deficiency, adrenocorticotropin hormone deficiency, gonadotropin deficiency, and arginine vasopressin (aka vasopressin or antidiuretic hormone (ADH)) deficiency. b. Low serum IGF-I. c. Patient must exhibit clinical features of adult GHD including increased body fat, decreased muscle mass, poor exercise performance, decreased bone density, and cardiovascular risk factors (high LDL, low HDL). d. Documentation of baseline information (IGF-I levels, lipids, bone density, cardiovascular factors, body composition, exercise capacity) provided with each request.2. Childhood onset GHD - Adults who were GH deficient as children or adolescents. a. Patient has subnormal response to at least 2 provocative stimulation tests (5 ng/ml or less) following a GH washout period (1-3 months). b. Patient must exhibit clinical features of adult GHD including increased body fat, decreased muscle mass, poor exercise performance, decreased bone density, and cardiovascular risk factors. c. Documentation of baseline information (IGF-I levels, lipids, bone density, cardiovascular factors, body composition, exercise capacity) provided with each request.
Age Restrictions	N/A
Prescriber Restrictions	Evaluation by an endocrinologist
Coverage Duration	up to 1 year
Other Criteria	Continuation of Therapy Criteria and Approval Length for Children: 1. Epiphyses must not be closed. 2. First year of therapy: HV must double the pretreatment rate. 3. After first year of therapy: HV must be 2.5 cm/yr or more. Continuation of Therapy Criteria and Approval Length for Adults: Authorization for all the above indications will be for 1 year, after which documentation will be required to support therapy benefit. Compendial Uses: Non-FDA approved uses for the growth hormone products that are considered to be "medically-accepted indications" based on the drug information sources that CMS has recognized to be authoritative compendia will be considered for approval for treatment with if the diagnosis, dosing, frequency, and length of therapy are supported by, and are consistent with published medical literature. Continuation of

PA Criteria	Criteria Details
	treatment or retreatment with a growth hormone product for a compendial use will only be approved if medically necessary, if clinical improvement has been demonstrated, and if supported by published medical literature. Exceptions: Any other medical conditions or exceptions to the above conditions of coverage for a growth hormone product will be considered through the Pharmacy Exception process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed. Preferred Specialty Pharmacy Dispensing Required. Note: Vials only will be covered on Medicaid plans.

### **Oncology**

#### **Products Affected**

- Adcetris
- Alecensa
- Alimta
- Aliqopa
- Alunbrig
- Ayvakit
- Balversa
- Bavencio
- Beleodag
- Besponsa
- Bexarotene Oral
- Blenrep
- Blincyto
- Braftovi Oral Capsule 75 MG
- Brukinsa
- Calquence
- Campath
- Caprelsa
- Cometriq (60 MG Daily Dose)
- Copiktra
- Cyramza
- Darzalex
- Darzalex Faspro
- Daurismo
- Emcyt
- Empliciti
- Enhertu
- Erbitux
- Erivedge
- Erleada
- Erlotinib HCl
- Erwinaze Injection
- Everolimus
- Evomela
- Fareston
- Farydak
- Gazyva
- Gefitinib
- Gilotrif
- Hycamtin Oral
- Ibrance Oral Tablet
- Inlyta

- Inqovi
- Jaypirca
- Jelmyto
- Kadcyla
- Keytruda Intravenous Solution
- Kisqali (200 MG Dose)
- Kisqali (400 MG Dose)
- Kisqali (600 MG Dose)
- Kisqali Femara (200 MG Dose)
- Kisqali Femara (400 MG Dose)
- Kisqali Femara (600 MG Dose)
- Krazati
- Kyprolis
- Lapatinib Ditosylate
- Lenalidomide
- Lenvima (10 MG Daily Dose)
- Lenvima (12 MG Daily Dose)
- Lenvima (14 MG Daily Dose)
- Lenvima (18 MG Daily Dose)
- Lenvima (20 MG Daily Dose)
- Lenvima (24 MG Daily Dose)
- Lenvima (4 MG Daily Dose)
- Lenvima (8 MG Daily Dose)
- Leukeran
- Libtayo
- Lonsurf
- Lorbrena
- Lumakras Oral Tablet 120 MG, 320 MG
- Lumoxiti
- Lynparza Oral Tablet
- Marqibo
- Matulane
- Mekinist Oral Tablet
- Mektovi
- Monjuvi
- Myleran
- Mylotarg Intravenous Solution
  - Reconstituted 4.5 MG
- Nerlynx
- Nubeqa
- Odomzo
- Oncaspar Injection

- Opdivo
- Orserdu
- Padcev
- PAZOPanib HCl
- Pemazyre
- Perjeta
- Pigray (200 MG Daily Dose)
- Piqray (250 MG Daily Dose)
- Piqray (300 MG Daily Dose)
- Polivy
- Pomalyst
- Poteligeo
- Provenge Intravenous Suspension
- Qinlock
- Retevmo Oral Capsule
- romiDEPsin Intravenous Solution
- Rozlytrek Oral Capsule
- Rubraca
- Rybrevant
- Sarclisa
- SORAfenib Tosylate
- Stivarga
- SUNItinib Malate
- Tabloid
- Tabrecta
- Tafinlar Oral Capsule
- Tagrisso
- Talzenna
- Tazverik
- Tecentriq

- Temozolomide
- Thalomid
- Tibsovo
- Trelstar Mixject
- Trodelvy
- Tukysa
- Ukoniq
- Unituxin
- Venclexta
- Venclexta Starting Pack
- Verzenio
- Vizimpro
- Xalkori Oral Capsule
- Xospata
- Xpovio (100 MG Once Weekly)
- Xpovio (40 MG Once Weekly)
- Xpovio (40 MG Twice Weekly)
- Xpovio (60 MG Once Weekly)
- Xpovio (60 MG Twice Weekly)
- Xpovio (80 MG Once Weekly)
- Xpovio (80 MG Twice Weekly)
- Yervoy
- Zaltrap
- Zejula
- Zelboraf
- Zepzelca
- Zirabev
- Zolinza
- Zydelig
- Rydapt

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. There must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium. a. If two or more regimens/agents carry the same NCCN recommendation, rationale must be submitted that includes a review of the evidence blocks. 2. There must be a Class I or Class II recommendation in the Thomson Micromedex DrugDex Compendium.
Exclusion Criteria	
Required Medical Information	

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	up to 6 months
Other Criteria	Note: Preferred formulary medications must be utilized before consideration of non-formulary agents and all medications are subject to formulary quantity limits and approved dosages.
<b>Covered Uses</b>	There must be a Category 1 or 2 recommendation in the National Comprehensive Cancer Network (NCCN) compendium or there must be a Class I or II recommendation in the Thomson Micromedex DrugDex compendium.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	up to 6 months
Other Criteria	Preferred formulary medications must be utilized before consideration of non-formulary agents and all medications are subject to formulary quantity limits and approved dosages.

### **Oncology**

#### **Products Affected**

- Adcetris
- Alecensa
- Alimta
- Aliqopa
- Alunbrig
- Ayvakit
- Balversa
- Bavencio
- Beleodag
- Besponsa
- Bexarotene Oral
- Blenrep
- Blincyto
- Braftovi Oral Capsule 75 MG
- Brukinsa
- Calquence
- Campath
- Caprelsa
- Cometriq (60 MG Daily Dose)
- Copiktra
- Cyramza
- Darzalex
- Darzalex Faspro
- Daurismo
- Emcyt
- Empliciti
- Enhertu
- Erbitux
- Erivedge
- Erleada
- Erlotinib HCl
- Erwinaze Injection
- Everolimus
- Evomela
- Fareston
- Farydak
- Gazyva
- Gefitinib
- Gilotrif
- Hycamtin Oral
- Ibrance Oral Tablet
- Inlyta

- Inqovi
- Jaypirca
- Jelmyto
- Kadcyla
- Keytruda Intravenous Solution
- Kisqali (200 MG Dose)
- Kisqali (400 MG Dose)
- Kisqali (600 MG Dose)
- Kisqali Femara (200 MG Dose)
- Kisqali Femara (400 MG Dose)
- Kisqali Femara (600 MG Dose)
- Krazati
- Kyprolis
- Lapatinib Ditosylate
- Lenalidomide
- Lenvima (10 MG Daily Dose)
- Lenvima (12 MG Daily Dose)
- Lenvima (14 MG Daily Dose)
- Lenvima (18 MG Daily Dose)
- Lenvima (20 MG Daily Dose)
- Lenvima (24 MG Daily Dose)
- Lenvima (4 MG Daily Dose)
- Lenvima (8 MG Daily Dose)
- Leukeran
- Libtayo
- Lonsurf
- Lorbrena
- Lumakras Oral Tablet 120 MG, 320 MG
- Lumoxiti
- Lynparza Oral Tablet
- Marqibo
- Matulane
- Mekinist Oral Tablet
- Mektovi
- Monjuvi
- Myleran
- Mylotarg Intravenous Solution
  - Reconstituted 4.5 MG
- Nerlynx
- Nubeqa
- Odomzo
- Oncaspar Injection

- Opdivo
- Orserdu
- Padcev
- PAZOPanib HCl
- Pemazyre
- Perjeta
- Pigray (200 MG Daily Dose)
- Piqray (250 MG Daily Dose)
- Piqray (300 MG Daily Dose)
- Polivy
- Pomalyst
- Poteligeo
- Provenge Intravenous Suspension
- Qinlock
- Retevmo Oral Capsule
- romiDEPsin Intravenous Solution
- Rozlytrek Oral Capsule
- Rubraca
- Rybrevant
- Sarclisa
- SORAfenib Tosylate
- Stivarga
- SUNItinib Malate
- Tabloid
- Tabrecta
- Tafinlar Oral Capsule
- Tagrisso
- Talzenna
- Tazverik
- Tecentriq

- Temozolomide
- Thalomid
- Tibsovo
- Trelstar Mixject
- Trodelvy
- Tukysa
- Ukoniq
- Unituxin
- Venclexta
- Venclexta Starting Pack
- Verzenio
- Vizimpro
- Xalkori Oral Capsule
- Xospata
- Xpovio (100 MG Once Weekly)
- Xpovio (40 MG Once Weekly)
- Xpovio (40 MG Twice Weekly)
- Xpovio (60 MG Once Weekly)
- Xpovio (60 MG Twice Weekly)
- Xpovio (80 MG Once Weekly)
- Xpovio (80 MG Twice Weekly)
- Yervoy
- Zaltrap
- Zejula
- Zelboraf
- Zepzelca
- Zirabev
- Zolinza
- Zydelig
- Rydapt

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. There must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium. a. If two or more regimens/agents carry the same NCCN recommendation, rationale must be submitted that includes a review of the evidence blocks. 2. There must be a Class I or Class II recommendation in the Thomson Micromedex DrugDex Compendium.
Exclusion Criteria	
Required Medical Information	

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	up to 6 months
Other Criteria	Note: Preferred formulary medications must be utilized before consideration of non-formulary agents and all medications are subject to formulary quantity limits and approved dosages.
<b>Covered Uses</b>	There must be a Category 1 or 2 recommendation in the National Comprehensive Cancer Network (NCCN) compendium or there must be a Class I or II recommendation in the Thomson Micromedex DrugDex compendium.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	up to 6 months
Other Criteria	Preferred formulary medications must be utilized before consideration of non-formulary agents and all medications are subject to formulary quantity limits and approved dosages.

### **Ongentys (opicapone)**

#### **Products Affected**

• Ongentys Oral Capsule 50 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's disease
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Specialty Pharmacy required

### Onpattro (patisiran)

#### **Products Affected**

• Onpattro

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	1)Cannot be currently taking diflunisal, tafamidis, doxycycline or tauroursodeoxycholic acid 2)Contraindication for members with severe renal impairment, end-stage renal disease, moderate or severe hepatic impairment, or prior liver transplant
Required Medical Information	1)Documentation showing pathogenic transthyretin (TTR) mutation (e.g., V30M).2) Documentation of one of the following:a) Baseline polyneuropathy disability (PND) score 3B or lessb) Baseline FAP Stage 1 or 23) Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction)4) Dose must be within accordance with U.S. Food and Drug administration prescribing information
Age Restrictions	at least 18 (eighteen) years old
Prescriber Restrictions	
Coverage Duration	1 Year
Other Criteria	Continuation Criteria: All of the following must be met: 1. Documentation of one of the following: a) Patient continues to have PND score 3B or less b) Patient continues to have a FAB Stage 1 or 22. Documentation that the member has experienced a positive clinical response to Onpattro3. Member is not currently taking diflunisal, tafamidis, doxycycline or tauroursodeoxycholic acid.

# Orap (pimozide)

#### **Products Affected**

• Pimozide

PA Criteria	Criteria Details
<b>Covered Uses</b>	1) Tourette Disorder 2) Delusional Infestation
Exclusion Criteria	
Required Medical Information	Documented trial and failure of at least two (2) preferred formulary antipsychotic medications used to treat the specified indication
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) Year
Other Criteria	

### Orencia (abatacept)(CentCare)

#### **Products Affected**

- Orencia ClickJect
- Orencia Subcutaneous Solution Prefilled

PA Criteria	Criteria Details
Covered Uses	1.Adult Psoriatic Arthritis (PsA) 2. Juvenile Idiopathic Arthritis (JIA) 3. Rheumatoid arthritis (RA)
Exclusion Criteria	
Required Medical Information	Chart notes documenting medical indication and appropriate Disease Specific Criteria below has been met: 1.) PsA - Three months or more trial of ONE of the following: cyclosporine, leflunomide (LEF), methotrexate (MTX), SSZ 2.) JIA - The patient must have 3 months trial of one of the following: Leflunomide, Methotrexate, Sulfasalazine. 3.) RA - DAS-28 greater than 3.2 or CDAI greater than 10.1 AND the patient must have 3 months trial of at least ONE of the following: Hydroxychloroquine, Leflunomide, Methotrexate, Sulfasalazine.
Age Restrictions	
Prescriber Restrictions	1.PsA- prescribed by or in consultation with a dermatologist or rheumatologist 2. JIA and RA- prescribed by or in consultation with a rheumatologist
Coverage Duration	Up to 12 months
Other Criteria	For all indications the patient must have: Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy. Subcutaneous Administration for Adult RA: a. After a single intravenous infusion as a loading dose, a 125mg subcutaneous injection should be given within 24 hours, followed by 125mg subcutaneously once a week. b. Patients who are unable to receive an infusion may initiate weekly injections of subcutaneous Orencia without an intravenous loading dose. c. Patients transitioning from Orencia intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. Preferred Specialty Pharmacy Dispensing Required. Continuation Criteria: Documented positive response with Orencia treatment Code: J0129. 10mg = 1 billable unit.

Syringe

### $ORIAHNN\ (elagolix/estradiol/norethindrone)$

#### **Products Affected**

Oriahnn

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1) Documented heavy menstrual bleeding due to uterine fibroids, 2) Trial and therapeutic failure of any two of the following drugs: a.hormonal contraceptives (oral or intrauterine), b. GnRH analogs, c. tranexamic acid
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	INITIAL: 6 months, CONTINUATION: 1 year up to a total of 24 months of treatment
Other Criteria	CONTINUATION CRITERIA: Documented benefit from treatment AND patient has not been treated for more than 24 months with Oriahnn

# Orilissa (elagolix)

#### **Products Affected**

• Orilissa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy, Osteoporosis, Severe hepatic impairment, Concomitant use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine and gemfibrozil)
Required Medical Information	Documents showing trial and failure of at least two of the following:a. Nonsteroidal anti-inflammatory medicationb. Hormonal contraceptivec. GnRH agonist
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 3 months, Continuation: 150mg: 1 Year, 200mg: 3 months
Other Criteria	Continuation of therapy Criteria:1. Documentation that patient has decrease in endometriosis related pain.2. Documented decrease in analgesic medications used.*NOTE*A maximum of 24 months of therapy with Orilissa 150 mg will be authorized and a maximum of 6 months of therapy with Orilissa 200 mg will be authorized.

### Orkambi (lumacaftor-ivacaftor)

#### **Products Affected**

• Orkambi Oral Tablet

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Indications for Approval:All of the following must be met:1.Documentation that patient has a diagnosis of cystic fibrosis.2.Patient is at least 6 years of age.3.Patient is homozygous for the F508del mutation in the CFTR gene.4.Documentation of all of the following:i.Pretreatment ppFEV1 (within the past 30 days). ii.Patient has had two negative respiratory cultures for any of the following: Burkholderia cenocepacia, Burkholderia dolasa, or Mycobacterium abseccus in the past 12 months.iii.Baseline ALT, AST, and bilirubin that are less than three times upper limit of normal. ALT and AST should be assessed every 3 months during the first year of treatment, and annually thereafter.iv.Baseline ophthalmic exam for pediatric patients.v.No dual therapy with another CFTR potentiator is planned.
Age Restrictions	At least 6 years old
Prescriber Restrictions	
Coverage Duration	Initial Approval: 6 months. Reauthorization: 1 Year
Other Criteria	Continuation Criteria: All of the following must be met: 1. Patients response to therapy is documented (e.g. stable or improvement of ppFEV1 from baseline, weight gain, decreased exacerbations, etc.). 2. Patient has had two negative respiratory cultures for any of the following: Burkholderia cenocepacia, Burkholderia dolasa, or Mycobacterium abseccus in the past 12 months. 3. Documentation of annual testing of ALT, AST, and bilirubin levels after the first year of therapy. 4. No dual therapy with another CFTR potentiator is planned.

### Otezla (apremilast)

#### **Products Affected**

• Otezla Oral Tablet 30 MG

& 30 MG

• Otezla Oral Tablet Therapy Pack 10 & 20

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. 1.Behcet's Syndrome 2. Plaque psoriasis (psoriasis vulgaris) (PsO) 3. Psoriatic arthritis, Active (PsA)
Exclusion Criteria	
Required Medical Information	1. Behcet's Syndrome: a. Must be prescribed by or in consultation with a rheumatologist or ophthalmologists. b. The patient has inadequate response to or is intolerant to a minimum 3-months trial to one of the following: i. Azathioprine ii. Colchicine iii. Cyclosporine iv. Cyclophosphamide v. High dose glucocorticoids vi. Mesalamine vii. Mycophenolate mofetil ix Tumor Necrosis Factor (TNF) blocker, e.g., Humira (for Behcet's related uveitis) 2. Psoriatic Arthritis (PsA): a. Must be prescribed by or in consultation with a rheumatologist or dermatologist. b. An adequate trial (3 months or more) of one of the following DMARDs: i.Cyclosporine ii. Leflunomide iii. Methotrexate iv. Sulfasalazine v.Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents used to treat this indication (e.g., Amjevita, Enbrel, Orencia, Rinvoq, Skyrizi, Taltz). 3. Plaque Psoriasis (psoriasis vulgaris): a. Must be prescribed by or in consultation with a dermatologist. b. The patient has failed to adequately respond to or is intolerant to a 3-month trial of a topical agent (topical corticosteroid, topical calcineurin inhibitor, topical vitamin D analogs, etc.). c. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents used to treat this indication (e.g., Amjevita, Enbrel, Skyrizi, Taltz).
Age Restrictions	
Prescriber Restrictions	1. Behcet's Syndrome-prescribed by or in consultation with a rheumatologist or ophthalmologist 2. PsO- prescribed by or in consultation with a dermatologist 3. PsA- prescribed by or in consultation with a dermatologist or rheumatologist
Coverage Duration	Up to 12 months
Other Criteria	For all diagnoses: 1.The appropriate Disease Specific Criteria has been met. 2. Use of a Specialty Pharmacy is required. Continuation Criteria:

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PA Criteria	Criteria Details
	Documentation of positive response with Otezla treatment

### Palynziq (pegvaliase-pqpz) Criteria

### **Products Affected**

• Palynziq

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diagnosis of phenylketonuria
Exclusion Criteria	
Required Medical Information	(1)Member has a baseline phenylalanine level of 600 micromol/L or higher(2) Member has failed an adequate trial of Kuvan (sapropterin) in conjunction with a phenylalanine-restricted diet despite strict compliance.(3) The patient is seeing a dietician that specializes in phenylketonuria/metabolic disease.(4) An epinephrine auto-injector has been prescribed to the patient
Age Restrictions	
Prescriber Restrictions	Metabolic disease specialist
Coverage Duration	See Below
Other Criteria	Continuation Criteria: 1.Palynziq is prescribed by a metabolic disease specialist.2.Patient has continued on a phenylalanine restricted diet.3.Patient is seeing a dietician that specializes in phenylketonuria/metabolic disease.4.An epinephrine auto-injector has been prescribed to the patient.5.Laboratory documentation of current phenylalanine levels is required and one of the following will apply:a)Patients responding to therapy (at least 20% reduction in blood phenylalanine levels from baseline) and have maintained phenylalanine levels below baseline levels will be approved for an additional 1 year of therapy.b)Patients receiving a 20 mg/day dose for 24 weeks of therapy whose blood phenylalanine levels have not decreased from baseline by at least 20% should increase to 40 mg/day. These patients will be approved for an additional 16 weeks of therapy at the higher dose.c)Patients receiving 40 mg/day dose for 16 weeks of therapy whose blood phenylalanine levels have not decreased from baseline by at least 20% are considered non-responders and further treatment with Palynziq will not be authorizedQUANTITY LIMITS: 2.5 mg/0.5 mL syringe: 6 syringes per 35 days (length of approval 5 weeks)-10 mg/0.5 mL syringe: 14 syringes per 28 days (length of approval 4 weeks)-20 mg/mL syringe: 28 syringes

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PA Criteria	Criteria Details
	per 28 days (initial length of approval 24 weeks). Note: Up to 56 syringes per 28 days (40 mg per day) will be authorized for patients who have not achieved a response with 20 mg once daily continuous treatment for at least 24 weeks. Initial length of approval at the 40 mg once daily dose will be for 16 weeks.

### Paxil (paroxetine) oral suspension

### **Products Affected**

• PARoxetine HCl Oral Suspension

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Indications for approval:Documentation that the patient is unable to swallow oral tablets or capsules ANDThe patient is not currently taking other medications in an oral tablet or capsule form.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Approval Length: Up to 1 year
Other Criteria	

### **PCSK9 Inhibitors**

### **Products Affected**

• Repatha

- Repatha SureClick
- Repatha Pushtronex System

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. 1. Atherosclerotic Cardiovascular Disease (ASCVD) as confirmed by one of the following: a. Acute coronary syndromes. b. History of myocardial infarction. c. Stable or unstable angina. d. Coronary or other arterial revascularization. e. Stroke. f. Transient ischemic attack. g. Peripheral arterial disease presumed to be of atherosclerotic origin. 2. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by Dutch Lipid Clinic diagnostic criteria score greater than or equal to 9 (i.e. definite FH). 3. Homozygous Familial Hypercholesterolemia (HoFH): a. Genetic analysis (note that evolocumab is not covered for members with two LDL receptor negative alleles), or b. An untreated LDL level over 500mg/dl, and the presence of xanthomas before the age of 10, or evidence of heterozygous familial hypercholesterolemia in both parents.
Exclusion Criteria	Will not be approved when used in combination with another proprotein convertase subtilsin/kexin type 9 (PCSK9) inhibitor.
Required Medical Information	1. Submission of medical records (e.g. chart notes, laboratory values) documenting ONE of the following: a. Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy and will continue to receive a high-intensity statin at maximally tolerated dose. OR b. Both of the following: i. Patient is unable to tolerate* high-intensity statins. ii. Patient has been receiving at least 12 consecutive weeks of moderate-intensity statin therapy and will continue to receive a moderate-intensity statin at maximally tolerated dose. c. Both of the following: i. Patient is unable to tolerate* moderate- and high-intensity statins. ii. Patient has been receiving at least 12 consecutive weeks of low-intensity statin therapy and will continue to receive a low-intensity statin at maximally tolerated dose. d. Patient is unable to tolerate* low-, moderate-, and high-intensity statins, AND i. Has undergone a trial of a statin re-challenge with another low intensity statin with documented reappearance of muscle symptoms, or ii.Has a labeled contraindication to all statins as documented in medical records, or iii. Has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times the upper limit of normal (ULN). 2. Submission of medical records one of the following: a. If the patient is within 25% of goal LDL-C, patient must have received at least 12 consecutive weeks of ezetimibe therapy as adjunct to maximally tolerated statin therapy and will continue

PA Criteria	Criteria Details
	to receive ezetimibe. b. Patient has a history of failure, contraindication, or intolerance to ezetimibe. 3. Submission of medical records documenting the following within the past 30 days: LDL-C equal to or greater than 70mg/dl, or less than 50% LDL-C reduction from baseline while on maximally tolerated lipid lowering regimen. 4. Medication is used as adjunct to a low-fat diet and exercise.
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by, or in consultation with one of the following: a. Cardiologist b. Endocrinologist c. Lipid specialist
Coverage Duration	Initial approval 3 months. Continuation 6 months.
Other Criteria	Trial and failure of the preferred formulary drug (Repatha) is required before consideration of non-formulary drugs in this class. All drugs are subject to formulary quantity limits and approved dosages. *Statin Intolerance for the purpose of this criteria is defined as intolerable and persistent (i.e. more than 2 weeks) symptoms: 1) Myalgia (muscle symptoms without CK elevations), or 2) Myositis (muscle symptoms with CK elevations greater than 10 times upper limit of normal [ULN])Table 1.HIGH-INTENSITY statin atorvastatin 40-80 mg, Crestor (rosuvastatin) 20-40 mg MODERATE-INTENSITY statin atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than 20 mg, pravastatin more than 40 mg, lovastatin 40 mg, fluvastatin XL 80 mg, fluvastatin 40 mg twice daily, or pitavastatin greater than 2 mg LOW-INTENSITY statin simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, pitavastatin 1 mg Criteria for continuation of therapy:1.Submission of medical records (e.g., chart notes, laboratory values) documenting all of the following: a. Documented adherence to complete lipid lowering regimen as evidenced by consistent prescription fills including statin, PCSK 9, other Lipid Lowering Therapy (LLT) such as ezetimibe and/or lipid apheresis and patient has been compliant with and is continuing a low-fat diet and exercise regimen AND b. Greater than 50% LDL-C reduction after initiation of PCSK9 therapy OR c. For patients with HoFH: Greater than 20% LDL-C reduction after initiation of PCSK9 therapy. Quantity limit: 1. Diagnosis of HeFH or patients with primary hyperlipidemia with established clinical atherosclerotic CVD is two injections monthly. 2. Diagnosis of HoFH is three injections monthly.

### Pegasys (peginterferon alfa-2A)(Cent Care)

#### **Products Affected**

• Pegasys Subcutaneous Solution

PA Criteria	Criteria Details
<b>Covered Uses</b>	Treatment of Chronic Hepatitis C Infection
Exclusion Criteria	N/A
Required Medical Information	1. Patient must be diagnosed with Chronic Hepatitis C Infections including laboratory documentation of genotype and subtype 2. Patient must currently have detectable HCV RNA levels. 3. Patient must be free from alcohol and illicit drugs 6 months prior to initiation of therapy (must be documented in medical chart) NOTE: Patient may be in a treatment program for alcohol and/or drug abuse including medications used for treatment. 4. Patient must have one of the following: a. Documented stage 3 or stage 4 hepatic fibrosis defined as METAVIR score F3 or F4 using one of the following tests: liver biopsy, transient elastography (Fibroscan) score > 12.5kPa8, FibroTest/FibroSure score ? 0.58, FibroMeter score ? F3[F2-F4], APRI score > 1.54, radiological imaging consistent with cirrhosis as attested by prescribing physician. b. One of the following extra-hepatic manifestations: lymphoma, renal insufficiency felt to be secondary to HCV, cyroglobulinemia (may manifest as vasculitis, renal disease, neuropathy). c. Patient is liver transplant recipient. 5. When applicable, PHP prefers peginterferon containing course if all of the following: a. Patient is peginterferon eligible, b. Course is recommended in prescribing information and/or the current guidelines, c. Course would offer a shorter and equally effective treatment. 6. Patient is without severe hepatic impairment Child-Pugh score 10 ? 15 (Class C). Patients with severe hepatic impairment should be referred to a medical practitioner with expertise in that condition (ideally in a liver transplant center). Required chart note documentation and labs: a. Chart notes documenting presence/absence of: ascites, encephalopathy, b. Recent labs within the past 30 days: INR level, albumin, bilirubin.
Age Restrictions	18 years or greater
Prescriber Restrictions	Must be prescribed by a gastroenterologist, infectious disease specialist, hepatologist, provider experienced in the treatment of Chronic Hepatitis C, or from documented treatment recommendations by Project ECHO (ECHO consultation notes required).
Coverage	12 weeks
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PA Criteria	Criteria Details
Duration	
Other Criteria	1. HIV screening (lab documentation required). 2. Treatment history: Is member treatment experienced? If yes, answer a, b & c. If no, move to #3. a. Regimen patient has received including duration of therapy, b. Did patient complete regimen? If no, reason for discontinuation, c. What the patient?s response to therapy? 1) Responder: i. Relapse, ii Reinfection, 2) Non-responder: i Null responder (HCV RNA levels declined less than 2 log10 IU/ml by week 12), ii Partial responders (> 2 log10 IU/ml response whose virus remained detectable by week 24), 3. Hepatitis A and B screening including HBsAg, anti-HBs, anti-HBc, HAV Ab3 (labs required). 4. Additional required lab results (within the past 30 days): a. Aspartate transaminase (AST, including upper and lower limit), b. Alanine Transaminase (ALT), c. Platelet Count, d. Drug screen, e. Absolute Neutrophil Count (ANC), f. Hemoglobin (Hgb), g. Serum Creatinine (SCr) Preferred Specialty Pharmacy Dispensing Required.

### **Pheburane (sodium phenylbutyrate)**

### **Products Affected**

• Pheburane

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1. Diagnosis of a urea cycle disorder caused by one or more of the following, confirmed by enzymatic, biochemical, or genetic analysis: a. Carbamylphosphate synthetase deficiency. b. Ornithine transcarbamylase deficiency. c. Argininosuccinic acid synthetase deficiency. 2. Failure to control ammonia level with dietary restrictions and/or amino acid supplementation. 3. Required laboratory information (baseline and routine to be submitted with each request): a. Fasting ammonia and plasma amino acid levelsb. Measures of liver function. c. Nutritional markets (prealbumin, albumin, complete blood count). 4. Will be used in conjcution with a protein-restricted diet. 5. Will not exceed 20 grams or Pheburane per day. 6. Prescribed by or in consultation with a metabolic disease specialist.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months Continuation: 1 year
Other Criteria	

# Prevacid SoluTabs (lansoprazole orally disintegrating tablet)(Cent Care)

#### **Products Affected**

• Lansoprazole Oral Tablet Delayed Release Dispersible

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications AND 1. Patients with a feeding tube. OR 2. Patients under one year of age.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	up to 1 year
Other Criteria	N/A

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### Pulmonary Arterial Hypertension (COMM, EXC, CC)

#### **Products Affected**

• Ambrisentan

Sildenafil Citrate Oral Tablet 20 MG

PA Criteria	Criteria Details
Covered Uses	1. Meets diagnostic criteria for Pulmonary Arterial Hypertension as determined by a right heart catheterization. a. mPAP greater than 25mmHg at rest. b. Normal pulmonary arterial wedge pressure less than or equal to 15mmHg. c. Pulmonary Vascular Resistance (PVR) greater than 3 Wood units. 2. If the patient has a positive vasoreactive test, documents must show a trial of maximally tolerated calcium channel blocker (longacting nifedipine, diltiazem, or amlodipine). Positive vasoreactive test is defined as a fall in mPAP greater than or equal to 10mmHg to an mPAP less than or equal to 40mmHg, AND cardiac output must be unchanged or increased.
Exclusion Criteria	N/A
Required Medical Information	Documentation of the following additional information must be provided: a. WHO/NYHA modified functional class greater than or equal to 2 (treatment for functional class 1 is not recommended at this time). b. NT-proBNP at time of diagnosis. c. Cardiac Index. d. Sv,02 (mixed venous oxygen saturation). e. 6 minute walk distance.
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by a cardiologist or pulmonologist.
Coverage Duration	Initial Approval: 3 months. Continuation Approval: 1 year.
Other Criteria	Continuation Criteria - Documents showing 3 of the following must be provided for continued approval: 1. Improvement in WHO functional class from baseline (lower number is better). 2. Decrease in NT-proBNP from baseline. 3. Cardiac Index increased from baseline. 4. Sv,o2 increased from baseline. 5. Symptoms progression has decreased or stopped.

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### Remeron SolTab (mirtazapine ODT)(Cent Care)

### **Products Affected**

• Mirtazapine Oral Tablet Dispersible

PA Criteria	Criteria Details
Covered Uses	The patient is unable to take or swallow oral medication. They should not be on other oral medications. OR The patient is ?cheeking? the medication (cheeking is considered not swallowing the medication then spitting it out when the caregiver is not looking).
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	A psychiatrist must initiate therapy.
Coverage Duration	1 year
Other Criteria	Quantity Limit: 30 tablets for 30 days.

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### Retacrit (epoetin alpha-epbx) Criteria

#### **Products Affected**

 Retacrit Injection Solution 10000 UNIT/ML, 2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML, 40000 UNIT/ML

PA Criteria	Criteria Details
Covered Uses	Treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis. a. The maximum dose for the first 4 weeks of treatment is 9 mcg/kg. b. Hemoglobin must be less than 11g/dl. 2. For the treatment of anemia in patients with nonmyeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy. a. The maximum dose for the first 4 weeks of treatment is 9 mcg/kg. b. Hemoglobin must be less than 11g/dl. 3. Anemia due to HCV Treatment: a. Recent (within 2-3 weeks) hemoglobin less than 10g/dl AND b. Persists for at least 2 weeks after ribavirin dose reduction (may be reduced in 200mg incremental reductions or one-time reduction to 600mg/day) OR Patient is receiving peginterferon/ribavirin alone with documented evidence that the patient is post-liver transplantation or HIV/HCV co-infected.
Exclusion Criteria	The use of Procrit is considered experimental, investigational, and unproven for any indication not listed above, including but not limited to the following: a. Aplastic anemia, b. B-12 and folate deficiency anemias, c. Iron deficiency anemia, d. Post-hemorrhagic anemia Exceptions: Exceptions to the above conditions of coverage are considered through the Medical Exception process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed.
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	up to 6 months
Other Criteria	Quantity Limits:-2000 U/mL, 3000 U/mL, 4000 U/mL, 10000 U/mL: 12 vials (12 mL) per 28 days40000 U/mL: 4 vials (4 mL) per 28 days.Length of Approval: Up to 6 months.Code: J0885 (non-ESRD use). 1000 units = 1 billable unit Code: J0886 (ESRD on dialysis). 1000 units =

PA Criteria	Criteria Details
	1 billable unit

## Rexulti (brexpiprazole)

### **Products Affected**

• Rexulti

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Major Depressive Disorder (MDD) 2. Schizophrenia
Exclusion Criteria	
Required Medical Information	1. MDD: a. Trial and failure (minimum of 4 weeks) of one drug from the following classes: SSRI, SNRI, AND bupropion or mirtazapine - AND -b. Trial and failure of aripiprazole or quetiapine in combination with an antidepressant for at least 4 weeks. 2. Schizophrenia: a. Trial and failure of three atypical antipsychotics for a minimum of 4 weeks (non-responders) or 12 weeks (partial responders) - e.g., aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, first-generation antipsychotics, OR member has a current diagnosis of metabolic syndrome, pre-metabolic syndrome, or diabetes mellitus and has failed aripiprazole and ziprasidone, unless there is a documented contraindication or intolerance. b. Documentation explaining why clozapine is not a therapeutic option.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a Behavior Health Practitioner.
Coverage Duration	Up to one (1) year
Other Criteria	

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### Rinvoq (upadacitinib)

### **Products Affected**

• Rinvoq

• Rinvoq LQ

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. All FDA-approved indications not otherwise excluded. 1. Rheumatoid Arthritis (RA) - moderate to severe. 2. Psoriatic Arthritis (PsA) 3. Atopic Dermatitis (AD) 4. Ulcerative Colitis (UC). 5. Ankylosing Spondylitis (AS) 6. Non-radiographical Axial Spondyloarthritis 7. Crohn's Disease (CD). 8. Polyarticular Juvenile Idiopathic Arthritis (pJIA).
Exclusion Criteria	
Required Medical Information	1. RA: a. DAS-28 greater than 3.2 or CDAI greater than 10.1. b. The patient has received at least 3 months of current and continuous (minimum quarterly) follow-up. c. An adequate trial (3 months or more) of one of the following DMARDs: i. Hydroxychloroquine, ii. Leflunomide, iii. Methotrexate, vi. Sulfasalazine. d. Inadequate response to one or more TNF blockers (eg, Amjevita, Enbrel). 2. PsA: The patient has had at least a 3 month trial of ONE of the following: i. Cyclosporine, ii. Leflunomide, iii. Methotrexate. b. Inadequate response to one or more TNF blockers (eg, Amjevita, Enbrel). 3. AD: The member is at least 12 years of age, AND b. The member has a documented diagnosis of refractory, moderate to severe AD whose disease is not adequately controlled with other systemic, and topical drug products, including: i. A medium to high potency topical steroid (e.g., mometasone, fluocinolone, fluocinonide), AND ii. A topical calcineurin inhibitor, AND c. Validated Investigator's Global Assessment (vIGA-AD) score greater than or equal to 3, AND d. Eczema Area and Severity Index (EASI) score greater than or equal to 16, AND e. A minimum BSA involvement of greater than or equal to 10 percent. 4. UC: a. The member has had an inadequate response to one of the following: aminosalicylates (balsalazide, mesalamine, sulfasalazine), corticosteroids, thiopurines, or cyclosporine. b. Inadequate response to at least one or more TNF blockers (eg, Amjevita). 5. AS: a. Inadequate response to an NSAID and sulfasalazine (peripheral) or NSAID alone (axial). b. The member has had an inadequate response to one or more TNF blockers (eg., Amjevita).
Age Restrictions	
Prescriber	Prescribed by or in consultation with a rheumatologist, allergist,

PA Criteria	Criteria Details
Restrictions	immunologist, dermatologist, gastroenterologist
Coverage Duration	Up to 1 year.
Other Criteria	6. Non-radiographic Axial Spondyloarthritis: a. The patient has had a documented trial and failure of a non-steroidal anti-inflammatory drug (NSAID) or such treatment is contraindicated or not tolerated. 7.CD: a. For induction and maintaining clinical remission in patients with moderately to severely active Crohn's Disease who have had an inadequate response or intolerance to conventional therapy. Conventional therapy, for the purpose of this policy, includes the use of ONE of the following: i. Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide) ii. Methotrexate iii. Thiopurines (azathioprine, mercaptopurine) b. Inadequate response to at least one tumor necrosis factor (TNF) blocker (e.g., Amjevita). 8. pJIA: a. Prescribed by or in consultation with a rheumatologist. b. An adequate trial (3 months or more) of one of the following DMARDs: i. Leflunomide ii. Methotrexate iii. Sulfasalazine. c. Inadequate response to at least one tumor necrosis factor (TNF) blocker (e.g., Amjevita). For all indications, the following is required: 1.) Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test prior to initiation of therapy. 2.) Use of a Specialty Pharmacy is required. 3.) Continuation Criteria: Documentation of positive clinical response to therapy.

### **Rozerem** (ramelteon)(Cent Care)

### **Products Affected**

• Ramelteon

PA Criteria	Criteria Details
<b>Covered Uses</b>	Insomnia - Patient must have a documented treatment failure of all of the following: a. Zolpidem oral tablets, b. A formulary benzodiazepine used for the treatment of insomnia. C. Trazodone
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Quantity Limit: 30 tablets per 30 days.

### **RUXIENCE** (rituximab-PVVR)

### **Products Affected**

• Ruxience

PA Criteria	Criteria Details
Covered Uses	1.FDA approved indications 2.Black box warning regarding the risk of reactivation of the hepatitis B virus (HBV), all patients must be screened for HBV infection within a year prior to initiation of Rituxan.  3.Rheumatoid Arthritis (RA)
Exclusion Criteria	
Required Medical Information	Documentation showing that all of the following is be met:1.FDA approved indications 2.Black box warning regarding the risk of reactivation of the hepatitis B virus (HBV), all patients must be screened for HBV infection within a year prior to initiation of Rituxan. 3.For Rheumatoid Arthritis (RA): a.Diagnosis of rheumatoid arthritis (RA) b.The patient is 18 years or older.c.This must be prescribed by or in conjunction with a rheumatologist d.Documented presence of moderate to severe rheumatoid arthritis. Moderate to severe RA is defined as DAS-28 greater than 3.2 or CDAI greater than 10.1. e.The patient must have had a documented trial and failure of TWO preferred targeted immunomodulators for this indication f.Must be given in conjunction with methotrexate or leflunomide if the patient is intolerant to methotrexate. g.Will not be approved for use in combination with targeted immunomodulators h.Dosing criteria for RA - The recommended dose is two 500 -1000mg IV infusions separated by 14 days.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	See other criteria
Other Criteria	Approval Length:•NHL and CD20-positive CLL - 1 year. •Pemphigus Vulgaris - 1 year. Two 1000 mg doses two weeks apart initially, 500 mg at month 12, then 500 mg every 6 months thereafter •Rheumatoid Arthritis - 6 months. Continuation: 1) Continued use will require Prior Authorization and will only be approved if the course is to be administered six (6) months from the last course of treatment and there is documentation of improvement in disease activity after previous

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PA Criteria	Criteria Details
	infusions. 2) For retreatment earlier than 6 months since completion of the last course of therapy, there must be a documented increase in disease activity (i.e. increase of greater than or equal to 1 point on CDAI or increase of greater than or equal to 1 on DAS-28). Requests for retreatment sooner than 16 weeks since completion of the last course of treatment will not be approved. •All other diagnoses - a single round of therapy. Subsequent doses based on the patient's clinical evaluation prior to the next dose

### Sarafem (fluoxetine HCL) Tablets

#### **Products Affected**

• FLUoxetine HCl (PMDD) Oral Tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Pre- Menstrual Dysphoric Disorder (PMDD)
Exclusion Criteria	
Required Medical Information	Documented trial and failure of fluoxetine capsules (generic for Prozac) and at least one of the following: citalopram, escitalopram, sertraline
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) Year
Other Criteria	

### Secuado (asenapine)

### **Products Affected**

Secuado

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Schizophrenia
Exclusion Criteria	
Required Medical Information	. Schizophrenia: a. Trial and failure of three atypical antipsychotics for a minimum of 4 weeks (non-responders) or 12 weeks (partial responders) - e.g., aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, first-generation antipsychotics, unless there is a documented contraindication or intolerance.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a Behavior Health Practitioner
Coverage Duration	Up to one (1) year
Other Criteria	

### Sensipar (cinacalcet)(Cent Care)

### **Products Affected**

• Cinacalcet HCl

PA Criteria	Criteria Details
Covered Uses	1. The patient has a diagnosis of secondary hyperparathyroidism with chronic kidney disease on chronic dialysis and all of the following: a. Intact parathyroid hormone (iPTH) greater than 300 pg/ml b. Serum calcium level greater than 8.4 mg/dl (corrected for serum albumin) c. The patient has continued hyperparathyroidism despite management with standard therapy (i.e. dietary phosphate restriction, phosphate binders, and vitamin D) 2. The patient has a diagnosis of hypercalcemia with Parathyroid Carcinoma and all of the following: a. Serum calcium level greater than 12.5 mg/dl (corrected for serum albumin) b. Medication is being given to the patient to control hypercalcemia prior to surgical intervention in a patient who is not a surgical candidate or recurrence despite surgical intervention 3. Severe hypercalcemia (serum calcium level greater than 12.5 mg/dl corrected for serum albumin) in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A

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### Skyrizi (risankizumab-RZAA)

### **Products Affected**

Skyrizi

Skyrizi Pen

• Skyrizi (150 MG Dose)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. 1. Plaque Psoriasis (PsO) - moderate to severe. 2. Psoriatic Arthritis (PsA) 3. Crohn's Disease (CD) - moderately to severely active 4. Ulcerative Colitis (UC)
Exclusion Criteria	
Required Medical Information	1. PsO: a. Prescribed by or in consultation with a dermatologist. b. The patient must have greater than 3% of their body surface area (BSA) affected by plaque psoriasis). c. The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of at least 5 or more and/or a Dermatology Life Quality Index (DLQI) of more than 5. d. The patient has failed to adequately respond to, or is intolerant to a 3-month trial of a topical agent (topical corticosteroid, topical calcineurin inhibitor, topical vitamin D analogs, etc.). 2. PsA: a. a.Prescribed by or in consultation with a rheumatologist or dermatologist. b. And adequate trial (3 months or more) of one of the following DMARDs: i. Cyclosporine ii. Leflunomide iii. Methotrexate iv.Sulfasalazine 3. CD: a.For induction and maintaining clinical remission in patients with moderately to severely active Crohn's Disease who have had an inadequate response or intolerance to conventional therapy. For the purpose of this policy, conventional therapy includes the use of ONE of the following: i. Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide). ii. Methotrexate iii.Thiopurines (azathioprine, mercaptopurine) b. Prescribed by or in consultation with a gastroenterologist. 4. UC: a. Prescribed by or in consultation with a gastroenterologist. b. The patient must have an adequate trial (3 months or more) or intolerance to ONE of the following: i. 5-Aminosalicylates (balsalazide, mesalamine, sulfasalazine) ii. Cyclosporine iii.Steroids iv. Thiopurines (azathioprine, 6-MP).
Age Restrictions	Minimum 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist.
Coverage Duration	Up to 1 year

PA Criteria	Criteria Details
Other Criteria	1. CD/UC: a. Medical only members (No Rx): documentation showing that they have received approval by their pharmacy benefit manager for the self-administered maintenance treatment must be received before PHP can approve the office-administered induction treatment. b. Pharmacy only members (No Medical): documentation showing that they have received approval by their health plan for the office-administered induction treatment must be received before PHP can approve the self-administered maintenance treatment. 2. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test prior to initiation of therapy. 3. Use of a Specialty Pharmacy is required. 4. Continuation Criteria: Documentation of positive clinical response to Skyrizi therapy

### Soliris (eculizumab)

### **Products Affected**

• Soliris Intravenous Solution 300

MG/30ML

PA Criteria	Criteria Details
Covered Uses	1. Paroxysmal Nocturnal Hemoglobinuria (PNH)2. Atypical Hemolytic Uremic Syndrome (aHUS)3. Generalized Myasthenia Gravis (gMG) 4. Neuromyelitis optica spectrum disorder (NMOSD) with positive antiaquaporin-4 (AQP4) antibody
Exclusion Criteria	N/A
Required Medical Information	1.PNH-a) Hematocrit/Hemoglobin lab tests for the past one year and lab evidence for hemolysis must be submitted and the following diagnostic tests performed: (Flow Cytometric immunophenotyping (FCMI), PNH Gel Card Test (GAT), Ham Test, Sucrose Lysis Test (SLT) and b) The prescribing physician is a hematology/oncology specialist or c) The patient has prior history of blood transfusions (please provide number of blood transfusions administered per year) or d) The patient has prior use of erythropoietin (please provide number of doses administered per year) or e) The patient has history of failure of least two standard therapies for PNH(i.e. prednisone, danazol, azathioprine, and/or cyclosporine) "Failure" includes intolerable side effects or ongoing hemolysis resulting in symptomatic anemia requiring treatment. Prednisone failure includes stopping prednisone if the dose cannot be reduced to less than 20mg/day within a few months of starting therapy. 2. aHUS 3.Generalized Myasthenia Gravis (gMG) - a) Positive serologic test for antiacetylcholine receptor (anti-A ChR) antibodies. b)Myasthenia Gravis Foundation (MGFA) Clinical Classification Class II to IV. c) MG-Activities of Daily Living (MG-ADL) total score of 6 or more. d) Documented trial and failure of pyridostigmine. e) A documented trial and failure of at least a year with 2 or more immunosuppressant therapies (e.g. glucocorticoids, azathioprine, mycophenolate, cyclosporine, or tacrolimus). f) Patient required chronic plasmapheresis/plasma exchange or IVIG. 4. NMOSD-a)prescribed by neurologist b)AQP4 antibody positive c)documented meningococcal vaccine administered at least 2 weeks before Soliris treatment
Age Restrictions	N/A
Prescriber Restrictions	N/A

PA Criteria	Criteria Details
Coverage Duration	PNH - 3 months. aHUS - 3 months, gMG - 6 months, NMOSD- Up to 6 months
Other Criteria	The MG-ADL assessment and MGFA Clinical classifications can be found at http://www.myasthenia.org/HealthProfessionals/EducationalMaterials.asp x.Restrictions: As part a risk management program, providers and patients must enroll with SolirisTM OneSource Safety Registry prior to treatment initiation (1-888-765-4747). CONTINUATION CRITERIA: Chart notes and laboratory results must document patient response for authorization renewal. For MFGA-Documented improvement of MG-ADL score of at least 3 points required for renewal.Quantity Limit: PNH- IV 600 mg once weekly for 4 weeks followed by 900 mg one week later, then maintenance 900 mg every 2 weeks. aHUS and gMG: IV 900mg once weekly for 4 weeks followed by 1,200mg one week later, then maintenance 1,200mg every 2 weeks. Preferred Specialty Pharmacy Dispensing Required. Code: J9310. 10mg = 1 billable unit.

## Soriatane (acitretin)(Cent Care)

### **Products Affected**

• Acitretin

PA Criteria	Criteria Details
Covered Uses	The patient must have documented chronic severe plaque psoriasis and meet all of the following: 1. Involvement in greater than or equal to 10% of the patient?s body surface area. AND 2. Psoriasis Area Severity Index of 10 or more and/or Dermatology Life Quality Index of more than 10. AND 3. History of an adequate trial and treatment failure with phototherapy or photochemotherapy, or such treatment is contraindicated, not tolerated, or is unavailable. AND 4. History of an adequate trial and treatment failure with methotrexate, or such treatment is contraindicated or not tolerated.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Preferred Specialty Pharmacy Dispensing Required. Quantity Limit: 10mg, 17.5mg, 22.5mg tablets ? 30 tablets for 30 days, 25mg tablets ? 60 tablets for 30 days

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### **Spravato (esketamine)**

### **Products Affected**

• Spravato (56 MG Dose)

• Spravato (84 MG Dose)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy, aneurysmal vascular disease, history of intracerebral hemorrhage
Required Medical Information	Documents showing: A) 3 (three) formulary anti-depressants at an optimized dose for at least 8 (eight) weeks each and adherence is confirmed by prescription claims data, B) 2 (two) adjunct agents for at least 4 (four) weeks each(i.e. atypical anti-psychotics, lithium, thyroid hormone, electroconvulsive therapy), C) Major depressive disorder with acute suicidal ideation or behavior D)Baseline depression status using a standard rating scale, D)Prescriber and patient are enrolled in the Spravato REMS program, AND E)Documents showing what antidepressant will be used with Spravato F) Baseline depression status using an appropriate rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D).
Age Restrictions	at least 18 years old
Prescriber Restrictions	initiated by a behavioral health practitioner or in consultation with a behavioral health practitioner for all indications
Coverage Duration	Initial: 4 weeks, Continuation: 6 months
Other Criteria	Continuation: Documents must show clinical improvement as shown by standard rating scale

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## Sprycel (dasatinib)

### **Products Affected**

• Dasatinib

PA Criteria	Criteria Details
Covered Uses	1.Philadelphia chromosome positive chronic myeloid leukemia in chronic phase2.Philadelphia chromosome positive chronic myeloid leukemia in accelerated or blast phase.3.Philadelphia chromosome positive acute lymphoblastic leukemia
Exclusion Criteria	
Required Medical Information	Indications for Approval: 1.Philadelphia chromosome positive chronic myeloid leukemia in chronic phase a. Patient has a low-risk score and has intolerance, disease progression, or resistance to prior therapy with imatinib (Gleevec)OR b. Patient has an intermediate- or high - risk score. 2.Philadelphia chromosome positive chronic myeloid leukemia in accelerated or blast phase.Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec)3.Philadelphia chromosome positive acute lymphoblastic leukemia -Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Continuation Criteria: All of the following must be met:1.Documentation that the patient does not have evidence of disease progression must be submitted.2.Documentation that the patient does not have unacceptable toxicity from therapy must be submitted.

### Stelara (ustekinumab)

#### **Products Affected**

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

PA Criteria	Criteria Details
Covered Uses	1. Crohn's disease, moderate to severe (CD) 2. Psoriatic arthritis, Active (PsA) 3. Plaque psoriasis (psoriasis vulgaris), moderate to severe (PsO) 4. Ulcerative Colitis (UC)
Exclusion Criteria	
Required Medical Information	1)CD- Moderate to Severely Active: a. Inadequate response to at least one of the following: corticosteroids, methotrexate (MTX), thiopurines. b. Trial and failure, unless contraindicated or not tolerated, of Amjevita and Skyrizi. 2) PsA- a. An adequate trial (3 months or more) of one of the following: cyclosporine, leflunomide, MTX, sulfasalazine. b. Trial and failure, unless contraindicated or not tolerated, to TWO preferred agents (e.g., Amjevita, Enbrel, Orencia, Rinvoq, Skyrizi, Taltz). 3) PsO - a. Involvement of 3% or more Body Surface Area (BSA) b. Psoriasis Area Severity Index (PASI) of 5 or more and/or a Dermatology Life Quality Index (DLQI) of more than 5. c. Trial and failure, unless contraindicated or not tolerated, to at least a 3 month treatment with a topical agent (corticosteroid, calcineurin inhibitor, vitamin D analog). Trial and failure, unless contraindicated or not tolerated, to TWO preferred agents (e.g., Amjevita, Enbrel, Skyrizi, Taltz). 4) Ulcerative Colitis (UC), Moderately or Severely Active a. Patient must have an adequate trial (3 months or more) or intolerance to ONE of the following: i.5-Aminosalicylates (balsalazide, mesalamine, sulfasalazine) ii. Cyclosporine iii. Steroids iv. Thiopurines (azathioprine, 6-MP). b. Trial and failure, unless contraindicated or not tolerated, of Amjevita and Rinvoq.
Age Restrictions	
Prescriber Restrictions	1. CD- prescribed by or in consultation with a gastroenterologist 2.PsA-prescribed by or in consultation with a dermatologist or rheumatologist 3. PsO- prescribed by or in consultation with a dermatologist 4. UC-prescribed by or in consultation with a gastroenterologist
Coverage Duration	Initial: 6 months, Continuation: Up to 1 year
Other Criteria	For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or

PA Criteria	Criteria Details
	negative QuantiFERON-TB Gold test before the initiation of therapy, 2. The appropriate Disease Specific Criteria has been met. 3. Use of a Specialty Pharmacy is required. 4. Continuation Criteria: Documentation of positive clinical response to therapy. For CD and UC: 1. Medical only members (No Rx): documentation showing that they have received approval by their pharmacy benefit manager for the self-administered maintenance dosing must be received before PHP can approve the office-administered induction treatment. 5. Pharmacy only members (No Medical): documentation showing that they have received approval by their health plan for the office-administered.

### Strensiq (asfostase alfa) (COMM, EXCH, Cent Care)

### **Products Affected**

Strensiq

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia (HPP).
Exclusion Criteria	Strensiq will not be approved for use in patients with evidence of odontohypophosphatasia only, or for patients greater than 18 years without medical records to support diagnosis and onset of HPP prior to 18 years of age.
Required Medical Information	Chart notes documenting the following: 1. Age of onset, 2. clinical manifestations of HPP at age of onset (e.g., vitamin B6-dependent seizures, skeletal abnormalities), 3. radiographic imaging to support the diagnosis prior to age 18, 4. confirmation of ALPL mutations, 5. alkaline phosphatase (ALP) level in the absence of bisphosphonate use, 6. laboratory results of one of the following: beta-phenylethylamine (PEA), pyridoxal-5'-phosphate (PLP) or inorganic pyrophosphate (PPi). 7. Current patient weight.
Age Restrictions	Patient age of 18 or under, or age of onset at age 18 or under.
Prescriber Restrictions	The prescriber must be a specialist in the area of patient's disease (e.g., endocrinologist).
Coverage Duration	Initial Approval: 6 months. Continuation of Therapy: 1 year.
Other Criteria	1). Patient is 18 years of age or younger or was age 18 or younger at onset. 2). Patient has/had clinical manifestations consistent with HPP at the age of onset prior to age 18 such as: i. Vitamin B6-dependent seizures, ii. Skeletal abnormalities (rachitic chest deformity leading to respiratory problems or bowed arms/legs), iii. "Failure to thrive". c. Patient has radiographic imaging to support the diagnosis of HPP at the age of onset prior to age 18 (e.g. infantile rickets, alveolar bone loss, craniosynostosis). 3). Genetic testing has been completed confirming ALPL mutations. 4). Laboratory documentation of low serum alkaline phosphatase (ALP) in the absence of bisphosphonate use. 5). Laboratory documentation of one of the following: elevated PEA, elevated pyridoxal-5'-phosphate (PLP) in the absence of vitamin supplements or elevated inorganic pyrophosphate (PPi). 6). The requested dose is within the FDA approved dosing range. Continuation of Therapy Criteria: 1).Documentation that the patient has responded to treatment must be provided. 2).There must be evidence of

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PA Criteria	Criteria Details
	improvement and/or stabilization in respiratory status, growth, or radiographic findings.

### Sunlenca (lenacapavir)

### **Products Affected**

• Sunlenca

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1. 18 years of age or older. 2. Diagnosis of multidrug resistance HIV-1 infection with resistance to at least two drugs in each of at least three of the following classes: NRTIs, NNRTIs, PIs, and INSTIs. 3. Will be used in combination with an optimized background regimen. 4. Current antiretroviral regimen has been stable for at least 2 months and HIV-1 RNA is 400 copies/mL or greater. 5. Prescribed by or in consultation with an HIV specialist. 6. Will not be used in combination with a strong CYP3A inhibitor (including but not limited to carbamazepine, phenytoin, or rifampin).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	

### **SUNOSI** (solriamefetol)

### **Products Affected**

• Sunosi

PA Criteria	Criteria Details
<b>Covered Uses</b>	1.Excessive daytime sleepiness in narcolepsy 2. Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS)
Exclusion Criteria	
Required Medical Information	1. Excessive daytime sleepiness (EDS) in narcolepsy. All of the following are required: a. The patient has a documented trial and failure of, or intolerance to an adequate trial of a preferred formulary cerebral stimulant (methylphenidate or dextroamphetamine) and either armodafinil or modafinil 2.For Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS): a. Documentation that the member has been on CPAP for at least two months and is using it four or more hours a night is required b. Documented trial and failure of armodafinil or modafinil
Age Restrictions	at least 18 years old
Prescriber Restrictions	Neurologist or sleep specialist
Coverage Duration	1 year
Other Criteria	Quantity Limit: 30 tablets for 30 days.

### Symbyax (fluoxetine/olanzapine)

### **Products Affected**

• OLANZapine-FLUoxetine HCl

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	FOR BIPOLAR DEPRESSION: 1) prescription claim history for olanzapine OR documents must show that a trial of olanzapine in the past year FOR MAJOR DEPRESSIVE DISORDER: 1) documents showing a trial and failure of two (2) antidepressant therapies AND 2) a trial of an antidepressant (i.e. selective seretonin reuptake inhibitor or selective Norepinephrine reuptake inhibitor) combined with bupropion or lithium
Age Restrictions	
Prescriber Restrictions	for BIPOLAR DEPRESSION: Behavioral Healthcare Provider
Coverage Duration	One (1) year
Other Criteria	

# Symdeko (tezacaftor/ivacaftor)

## **Products Affected**

• Symdeko

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	All of the following must be met:1.Documentation that patient has a diagnosis of cystic fibrosis.2.Documentation of one of the following:i.Patient is homozygous for the F508del mutation in the CFTR gene. OR ii.Patient has at least one of the CFTR gene mutations as indicated in the FDA label. 3. Documentation of all of the following:i.Pretreatment ppFEV1 (within the past 30 days).ii.Patient has had two negative respiratory cultures for any of the following:  Burkholderia cenocepacia, Burkholderia dolasa, or Mycobacterium abseccus in the past 12 months.iii.Baseline ALT, AST, and bilirubin that are less than three times upper limit of normal. ALT and AST should be assessed every 3 months during the first year of treatment, and annually thereafter.iv.Baseline ophthalmic exam for pediatric patients.v.No dual therapy with another CFTR potentiator is planned
Age Restrictions	at least 6 years old
Prescriber Restrictions	
Coverage Duration	Initial Approval: 6 Months Reauthorization: 1 Year
Other Criteria	Continuation Criteria: All of the following must be met: 1. Patients response to therapy is documented (e.g. stable or improvement of ppFEV1 from baseline, weight gain, decreased exacerbations, etc.). 2. Patient has had two negative respiratory cultures for any of the following: Burkholderia cenocepacia, Burkholderia dolasa, or Mycobacterium abseccus in the past 12 months. 3. Documentation of annual testing of ALT, AST, and bilirubin levels after the first year of therapy. 4. No dual therapy with another CFTR potentiator is planned.

# Symlin (pramlintide)(Cent Care)

## **Products Affected**

- SymlinPen 120 Subcutaneous Solution Pen-Injector
- SymlinPen 60 Subcutaneous Solution Pen-Injector

PA Criteria	Criteria Details
Covered Uses	Indications for Approval: A Prior Authorization may be requested for refills only after therapy initiation by an endocrinologist, due to the stringent blood glucose monitoring requirements.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	Initial requests must be prescribed by endocrinologist.
Coverage Duration	1 year
Other Criteria	N/A

# Synagis (palivizumab) 2014-15(Cent Care)

## **Products Affected**

• Synagis

PA Criteria	Criteria Details
Covered Uses	One of the following must be met: 1. The patient is less than 12 months old (as of November 15) and with hemodynamically significant congenital heart disease (CHD). 2. The patient is less than 12 months old (as of November 15), born at less than 32 weeks, zero days and with chronic lung disease (CLD) of prematurity requiring oxygen of FiO2 greater than 21% for greater than 28 days after birth. Or The patient is less than 24 months old (as of November 15) with chronic lung disease (CLD) and continues on supplemental oxygen, diuretic or corticosteroid. 3. The patient is less than 24 months old (as of November 15) and with severe immunodeficiency. 4. The patient is less than 12 months old (as of November 15) and with severe neuromuscular disease with inability to clear secretions. 5. The patient is less than 12 months old (as of November 15) and with congenital abnormality of the airway with inability to clear secretions. 6. The patient is less than 12 months old (as of November 15) and born at 28 weeks, six days gestation or less. 7. The patient is less than 24 months old (as of November 15) and who undergo cardiac transplantation during the RSV season.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy.
Age Restrictions	Up to 24 months as of November 15th.
Prescriber Restrictions	N/A
Coverage Duration	Approved through end of RSV season
Other Criteria	All Synagis injections will be administered through Presbyterian Home Healthcare Statewide Network contracted home care agencies.

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# TAKHZYRO (lanadelumab-flyo)

## **Products Affected**

• Takhzyro

PA Criteria	Criteria Details
<b>Covered Uses</b>	Hereditary angioedema (HAE) type 1 or 2
Exclusion Criteria	Will not be approved in combination with other prophylactic treatments OR younger than 2 years old
Required Medical Information	Documentation of the following: 1) diagnosis was made by an allergist or immunologist 2)At least 2 years old 3)Recurrent episodes angioedema (without hives), laryngeal edema, abdominal pain and vomiting AND Family history AND age of onset was before thirty (30) years of age AND low C4 levels AND one of the following: a. low C1 inhibitor antigenic level (C1-INH) b. normal C1-INH and low C1-INH functional level 4) History of at least one moderate/severe attack per month 5) Baseline HAE attacks 6) Not taking an angiotensin converting enzyme inhibitor or estrogen replacement therapy 7) at least two (2) on demand treated episodes per month or limited emergency services 8) Has tried and failed tranexamic acid or danazol or there is a medical reason for not using this
Age Restrictions	At least 2 years of age
Prescriber Restrictions	
Coverage Duration	Initial: 4 weeks, Continuation: 6 months
Other Criteria	Continuation Criteria: 1) Medical records showing a decrease of at least 50% in frequency of attacks and significant improvement in severity and duration of attacks 2)If the patient is experiencing more than one acute HAE attack per month, medical records documenting use of a long-term prophylactic therapy (LTP) or the clinical rational for avoiding LTP must be provided. Preferred Specialty Pharmacy Dispensing Required.

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# Taltz (ixekizumab)

## **Products Affected**

• Taltz

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. 1.Ankylosing spondylitis, Active (AS) 2. Plaque psoriasis (psoriasis vulgaris), moderate to severe (PsO) 3. Psoriatic arthritis, Active (PsA) 4. Non-radiographic Axial Spondyloarthritis
Exclusion Criteria	
Required Medical Information	1)AS - a. The drug is being prescribed by or in consultation with a rheumatologist. b. The patient has a documented trial and failure with a non-steroidal anti-inflammatory drug (NSAID) or such treatment is contraindicated or not tolerated. c. Patients with peripheral arthritis must have a documented trial and failure with sulfasalazine or such treatment is contraindicated or not tolerated. d.Patients with axial disease and a trial and failure of, or a contraindication to, NSAIDs can be started on Taltz without a trial of sulfasalazine. 2)PsO - a. The drug is being prescribed by or in consultation with a dermatologist. b. The patient must have more than 3% of their body surface area (BSA) affected by plaque psoriasis c. The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) greater than 5 and/or Dermatology Life Quality Index (DLQI) greater than 5. d. The patient has failed to adequately respond to or is intolerant to a 3-month trial of a topical agent (topical corticosteroid, topical calcineurin inhibitor, topical vitamin D analogs, etc.). 3)PsA - a. The drug is being prescribed by or in consultation with a dermatologist or rheumatologist. b. An adequate trial (3 months or more) of one of the following DMARDs: i. Cyclosporine ii. Leflunomide iii. Methotrexate iv. Sulfasalazine
Age Restrictions	
Prescriber Restrictions	1. AS- prescribed by or in consultation with a rheumatologist 2. PsO-prescribed by or in consultation with a dermatologist 3. PsA- prescribed by or in consultation with a dermatologist or rheumatologist
Coverage Duration	Up to one (1) Year
Other Criteria	4. Non-radiographic Axial Spondyloarthritis a. Prescribed by or in consultation with a rheumatologist, b. The patient has had a documented

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PA Criteria	Criteria Details
	trial and failure of a non-steroidal anti-inflammatory drug (NSAID), or such treatment is contraindicated or not tolerated. For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy, 2. The appropriate Disease Specific Criteria has been met. 3. Use of a Specialty Pharmacy is required. 4. Continuation Criteria: Documentation of positive response with Taltz treatment

# Tasigna (nilotinib)

## **Products Affected**

• Tasigna

PA Criteria	Criteria Details
Covered Uses	1.Philadelphia chromosome positive chronic myeloid leukemia in chronic phase2.Philadelphia chromosome positive chronic myeloid leukemia in accelerated or blast phase.3.Philadelphia chromosome positive acute lymphoblastic leukemia
Exclusion Criteria	
Required Medical Information	Indications for Approval: 1.Philadelphia chromosome positive chronic myeloid leukemia in chronic phase?Patient has a low-risk score and has intolerance, disease progression, or resistance to prior therapy with imatinib (Gleevec)OR?Patient has an intermediate- or high - risk score. 2.Philadelphia chromosome positive chronic myeloid leukemia in accelerated or blast phase.?Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec)3.Philadelphia chromosome positive acute lymphoblastic leukemia ?Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Continuation Criteria: All of the following must be met:1.Documentation that the patient does not have evidence of disease progression must be submitted.2.Documentation that the patient does not have unacceptable toxicity from therapy must be submitted.

# **Testopel Pellets (testosterone pellets)(Cent Care)**

## **Products Affected**

• Testopel

PA Criteria	Criteria Details
Covered Uses	1. Primary hypogonadism in men (congenital or acquired). 2. Hypogonadotropic hypogonadism (congenital or acquired). 3. As a continuous therapy for gender dysphoria/gender identity disorder
Exclusion Criteria	Exclusions: 1. Due to a lack of controlled evaluations in women and the potential for virilizing effects, testosterone products will not be approved for use in women who do not meet criterion for gender dysphoria/gender identity disorder. 2. Testosterone replacement will not be covered for the treatment of sexual dysfunction.
Required Medical Information	1. Primary hypogonadism in men (congenital or acquired). Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals AND Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with an elevated LH and FSH. 2. Hypogonadotropic hypogonadism (congenital or acquired). Idiopathic gonadotropin or LHRH deficiency or pituitary hypothalamic injury from tumors, trauma, or radiation AND Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with a low or low-normal LH and FSH (If your patient has low LH and FSH levels, please follow-up on these low levels or consider a referral to an endocrinology provider). 3. As a continuous therapy for gender dysphoria/gender identity disorder when all of the following are met: a. The patient?s insurance benefit includes coverage for the treatment of gender dysphoria/gender identity disorder. b. The patient meets DSM 5 criteria for diagnosis of Persistent Gender Dysphoria documented by a qualified licensed mental health professional experienced in the field, i. If significant medical or mental health concerns are present, there must be documentation that they are well controlled. c. One of the following: i. Member has lived as their chosen or reassigned gender full-time for 12 months or more, ii. Treatment plan documents that the patient will live as their reassigned gender full-time for a minimum of 12 months while concurrently receiving continuous hormone therapy, iii. Patient has completed gender transition and requires continued hormone therapy to maintain physical characteristics more congruent with their gender identity.
Age Restrictions	18 years or greater

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PA Criteria	Criteria Details
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Must have a documented trial and failure of testosterone gel 1% (generic for Androgel 1%). Quantity Limit: 6 pellets for 3 months.

# Thiola (tiopronin)

## **Products Affected**

• Tiopronin Oral Tablet

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diagnosis of Cystinuria
Exclusion Criteria	
Required Medical Information	Member has a documented diagnosis of cystinuria AND Member has tried and failed conservative therapy including: high fluid intake, sodium and protein restriction, urinary alkalinization.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Continuation of therapy criteria: Documentation of benefit must be submitted (i.e. decrease in stone formation).

# **Tivicay PD (dolutegrvir sodium)**

## **Products Affected**

• Tivicay PD

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documents must show patient is unable to swallow tablets and are not currently taking other oral non-dissolving tablets or capsules
Age Restrictions	Maximum: 12 years of age
Prescriber Restrictions	
Coverage Duration	up to 1 year
Other Criteria	

## Trikafta (elexacaftor/tezacaftor/ivacaftor)

## **Products Affected**

• Trikafta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1.Cystic Fibrosis (all of the following must be met): a.Member is 2 years of age or older. b. Documented diagnosis of CF. c. Submission of laboratory results documenting that the patient has at least one of the following mutations in the CFTR gene: i. F508del mutation, or ii. A mutation that is responsive based on in vitro data (refer to prescribing information). d. Documentation of all of the following: i. Pretreatment of ppFEV1 within the past 30 days. ii. Member has had two negative respiratory cultures in the past 12 months for any of the following: Burkholderia cenocepacia, Burkholderia dolasa, or Mycobacterium abseccus. iii. Baseline ALT, AST, and bilirubin that are less than 3X ULN and are monitored every 3 months during the first year of treatment and annually thereafter. iv. Baseline ophthalmic exam for pediatric patients. v. No dual therapy with another CFTR potentiator is planned.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist.
Coverage Duration	Initial: 6 months Continuation: 1 year
Other Criteria	Quantity Limit:Oral tablets: 90 tablets per 30 daysOral granules: 60 packets per 30 days

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# **Trulicity (dulaglatide)**

## **Products Affected**

• Trulicity

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. To be used as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus.
Exclusion Criteria	
Required Medical Information	Indications for approval (all must be met):1. Diagnosis of type 2 diabetes mellitus (T2DM).2. Uncontrolled T2DM as evidenced by an HgbA1c of 7% or greater than has been measured within the past 90 days.3. Within the past 180 days: a. The member has been on a maximized therapeutic dose of metformin (e.g., 2000 mg daily) for at least 90 days, AND b. The member has tried and failed a 90-day course of either a sodium-glucose cotransporter 2 (SGLT2) inhibitor (e.g., Farxiga, Steglatro) or a dipeptidyl peptidase-4 (DPP-4) inhibitor (e.g., alogliptin). 4. Documented trial of Mounjaro or submission of clinical describing inability to use Mounjaro.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months Renewal: Up to 12 months
Other Criteria	Continuation criteria:1. HgbA1c must decrease by 0.5% or more if initial HgbA1c is less than or equal to 8%.2. HgbA1c must decrease by 1% or more if initial HgbA1c is greater than 8%.

# Tymlos (abaloparatide) Criteria

## **Products Affected**

• Tymlos

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. 1. Treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to others available osteoporosis therapy. 2. Treatment to increase bone density in men with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis thearpy.
Exclusion Criteria	
Required Medical Information	1. Bone Mineral Density (BMD) T-score -3.5 or less based on BMD measurements from lumbar spine, femoral neck, total hip, and/or one-third radius (wrist) -OR- 2.Bone mineral density (BMD) T-score between -2.5 and -3.5 in the lumbar spine, femoral neck, total hip, and/or one-third radius (wrist) -AND- a. History of one of the following: i. Vertebral compression fracture ii. Fracture of the hip iii. Fracture of the distal radius iv. Fracture of the pelvis v. Fracture of the proximal humerus -OR- 3. BMD T-score between -1.0 and -2.5 and one of the following FRAX 10-year fracture probabilities: i. Major osteoporotic fracture at 20% or more ii. Hip fracture at 3% or more -OR- 4. History of failure, contraindication, or intolerance to an intravenous bisphosphonate AND Prolia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year, no more than 2 years cumulative treatment with PTH analogs
Other Criteria	Please note parathyroid hormone (PTH) analogs should not be used for more than 2 years. Cumulative use of PTH analogs for greater than 2 years will not be approved. Specialty pharmacy required.

# Tysabri (natalizumab)(COMM, EXC, MCAID)

## **Products Affected**

• Tysabri

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	1. Patient must have relapsing form of multiple sclerosis. 2. Must be used as monotherapy. 3. Patient must have a documented trial and failure of Briumvi, unless contraindicated or not tolerated.
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by a neurologist
Coverage Duration	1 year
Other Criteria	Code: J2323. 1mg = 1 billable unit.

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# **Ultomiris** (ravuliumab-cwvz)

## **Products Affected**

• Ultomiris

PA Criteria	Criteria Details	
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. 1.) Paroxysmal Nocturnal Hemoglobinuria (PNH) 2.)Atypical hemolytic uremic syndrome (aHUS) 2.) Generalized Myasthenia Gravis (mGD)	
Exclusion Criteria		
Required Medical Information	Meningococcal vaccine given at least 2 (two) were of Ultomiris being given AND specific requiremed PNH-a) Hematocrit/Hemoglobin lab tests for the evidence for hemolysis and documents showing a b)Results of the following diagnostic tests: Labor diagnosis of PNH evidenced by detectable glycost (GPI)-deficient hematopoietic clones (Type III Ple cytometry (Flow cytometry testing must include a reagents tested on at least two cell lineages), great anchored proteins deficient polymorphonuclear complications (number of blood transfusions per year level 1.5 times the upper limit of normal range Diagnorphonuclear (MGB) 7g/dL or less OR b) HGB (Symptoms of anemia 2. aHUS-a)Chart notes doctor gMG-a)Member is at least 18 years of age. b) Doctor positive serologic test for anti-acetylcholine receptantibodies. c) Myasthenia Gravis Foundation of Aclassification class II to IV. d) Myasthenia Gravis Living (MG-ADL) total score greater than or equiversponse, intolerance, or contraindication to pyric response to two immunosuppressant therapies (e. cyclosporine, mycophenolate, methotrexate, tacro cyclophosphamide).	ents for diagnosis 1. past one year and lab ALL of the following a) ratory confirmed sylphosphatidylinostiol NH RBC) via flow at least two different atter than 50% of GPI- ells(PMNs) C) for history of blood ear is required), LDH one of the following og/dL or less AND umenting diagnosis. 3. coumentation of a ptor (anti-AChR) America (MGFA) clinical as-Activities of Daily al to 6. e) Inadequate dostigmine. f) Inadequate g., azathioprine,
Age Restrictions		
Prescriber Restrictions	For PNH: Hematologist or oncologist	
Coverage Duration	Initial: 3 months, Continuation: 6 months	
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PA Criteria	Criteria Details
Other Criteria	Continuation- 1) Meningococcal vaccination at least every five years while on Ultomiris 2)Specialty Pharmacy Mandated 3)FOR PNH: Improvement in fatigue and quality of life AND documentation showing positive clinical response from baseline (i.e. increased or stabilized HGB levels, reduction in number of transfusions) 4) FOR aHUS: benefit from treatment as documented by chart notes and improved laboratory results. 5) FOR gMD: Documentation of a positive clinical response and improvement in MG-ADL or Quantitative Myasthenia Gravis (QMG) score.

# Valcyte (valganciclovir)

## **Products Affected**

• valGANciclovir HCl

PA Criteria	Criteria Details
Covered Uses	1.Treatment of cytomegalovirus (CMV) retinitis in adult patients with acquired immunodeficiency syndrome (AIDS). 2. Prevention of CMV disease in adult patients at high-risk with kidney, heart, and kidney-pancreas transplants. 3. Prevention of CMV disease in pediatric patients at high risk with kidney or heart transplants. 4. Prevention and treatment of CMV disease in patients with a liver transplant.
Exclusion Criteria	
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to 6 months
Other Criteria	

## Valtoco (diazepam)

#### **Products Affected**

- Valtoco 10 MG Dose
- Valtoco 15 MG Dose

- Valtoco 20 MG Dose
- Valtoco 5 MG Dose

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of acute intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures).
Age Restrictions	6 years of age and older.
Prescriber Restrictions	
Coverage Duration	Up to one (1) year
Other Criteria	Quantity Limit: 10 delivery systems per 30 days

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## Varizig (Varicella-Zoster Immune Glob (Human) IM Inj 125 Unit/1.2ML)

#### **Products Affected**

• Varizig Intramuscular Solution

PA Criteria	Criteria Details
Covered Uses	Indications for Approval: 1. Immunocompromised patients without evidence of immunity. 2. Newborn infants whose mothers have signs and symptoms of varicella around the time of delivery (i.e. 5 days before to 2 days after). 3. Hospitalized premature infants born at equal to or greater than 28 weeks gestation whose mothers do not have evidence of immunity to varicella. 4. Hospitalized premature infants born at less than 28 weeks gestation or who weigh greater than 1,000 grams at birth, regardless of their mothers evidence of immunity to varicella. 5. Pregnant women without evidence of immunity.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	N/A
Other Criteria	Varizig should be administered as soon as possible within 10 days of varicella-zoster virus exposure.

# **VELTASSA** (patiromer)

## **Products Affected**

Veltassa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documents showing the following is required- 1. Baseline potassium 5.1 to less than 6.5mmol/liter at two screenings2. Patient is adhering to a low-potassium diet3. Medications known to cause hyperkalemia has been discontinued or reduced to the lowest effective dose4. Adequate trial of diuretics (loop or thiazides) or there are medical reasons for avoiding them. Adequate trial is defined as at least 4 weeks of a stable doseb. Loop diuretics are recommended if GFR is less than 40 ml/min/1.73m2
Age Restrictions	at least 12 years old
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

# Venofer (iron sucrose)(Cent Care)

## **Products Affected**

Venofer

PA Criteria	Criteria Details
Covered Uses	1.For the treatment of chemotherapy-induced iron deficiency anemia*.  2.For the treatment of iron deficiency anemia* in chronic kidney disease patients undergoing chronic hemodialysis. 3.For the treatment of documented iron deficiency anemia* in a patient who has a documented disorder of the gastrointestinal tract of which symptoms may be aggravated by oral iron therapy. Example: Inflammatory bowel disease.  4.For the treatment of a documented iron deficiency anemia* in a patient who has had a documented severe intolerance or treatment failure to an oral iron product after an adequate trial and after attempts have been made to identify and treat the underlying cause(s) of the deficiency.
Exclusion Criteria	N/A
Required Medical Information	Iron Deficiency Anemia defined as (without chronic kidney disease or acute or chronic inflammatory conditions): • Ferritin less than 30 ng/mL, OR • TSAT less than 20%, OR • Absence of stainable iron in bone marrow. Iron Deficiency Anemia defined as (with chronic kidney disease or acute or chronic inflammatory conditions): • Ferritin less than 100 ng/mL, OR • TSAT less than 20% (if serum ferritin 100-200 ng/mL, TSAT less than 20% is required to confirm iron deficiency).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 time
Other Criteria	Compendial Uses: Non-FDA approved uses for the injectable iron products that are considered to be "medically-accepted indications" based on the drug information sources that CMS has recognized to be authoritative compendia will be considered for approval for treatment if the diagnosis, dosing, frequency, and length of therapy are supported by, and are consistent with published medical literature. Continuation of treatment or retreatment with an injectable iron product for compendial uses will only be approved if medically necessary, if clinical improvement has been demonstrated, and if supported by published medical literature.

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# Vfend (voriconazole)

## **Products Affected**

• Voriconazole Intravenous

• Voriconazole Oral

PA Criteria	Criteria Details
Covered Uses	The patient has a documented diagnosis of one of the following: 1. Invasive aspergillosis. 2. Candida Krusei. 3. An organism known to be resistant to high dose fluconazole and susceptible to voriconazole.
Exclusion Criteria	N/A
Required Medical Information	Documentation must include a culture report or susceptibility report if applicable.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	
Other Criteria	Continuation of Therapy Criteria: To ensure that therapeutic blood levels have been reached, voriconazole trough levels must be provided with each subsequent request for continuation of therapy.

# Vraylar (cariprazine)

## **Products Affected**

• Vraylar

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Major Depressive Disorder (MDD) 2. Schizophrenia 3. Bipolar Disorder
Exclusion Criteria	
Required Medical Information	1. MDD: a. Trial and failure (minimum of 4 weeks) of one drug from the following classes: SSRI, SNRI, AND bupropion or mirtazapine - AND -b. Trial and failure of aripiprazole or quetiapine in combination with an antidepressant for at least 4 weeks. 2. Schizophrenia: a. Trial and failure of three atypical antipsychotics for a minimum of 4 weeks (non-responders) or 12 weeks (partial responders) - e.g., aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, first-generation antipsychotics, OR member has a current diagnosis of metabolic syndrome, pre-metabolic syndrome, or diabetes mellitus and has failed aripiprazole AND ziprasidone, unless there is a documented contraindication or intolerance. 3. Bipolar: a. Trial and failure of three alternatives from the following: i. lamotrigine, ii. lithium, iii. carbamazepine, iv. valproic acid, v. Atypical Antipsychotics (e.g., aripiprazole, lurasidone, quetiapine).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a Behavior Health Practitioner
Coverage Duration	Up to one (1) year
Other Criteria	

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## Vyvanse (lisdexamfetamine) Comm/HIX/CC

## **Products Affected**

• Lisdexamfetamine Dimesylate Oral Capsule

PA Criteria	Criteria Details
Covered Uses	1. Attention Deficit Hyperactivity Disorder (ADHD)in Adults and Pediatric Patients 6 Years of Age and Older. 2. Binge Eating Disorder (BED) in Adults.
Exclusion Criteria	N/A
Required Medical Information	1. ADHD - Note: For patients age 19 and up to treat ADHD, Cerebral Stimulant criteria also apply. a. Diagnosis of ADHD according to the DSM-5 criteria: i. Inattentive type ii. Hyperactive/Impulsive type iii. Combined type. b. Symptoms and/or behaviors have persisted for at least 6 months in at least 2 settings (e.g., school, home, etc). c. Symptoms have negatively impacted academic, social, and/or occupational functioning. d. If patients less than 17 years, at least 6 symptoms are necessary, in those 17 years or older, at least 5 symptoms are necessary (as defined by the DSM-5 criteria). e. Member has had an inadequate response, intolerance, or contraindication to 3 of the following: generic amphetamine/dextroamphetamine, dexmethylphenidate, dextroamphetamine, methylphenidate. 2. BED - a. Diagnosis of BED as defined by DSM-5 criteria. b. Recurrent episodes of binge eating. An episode of binge eating is characterized by both of the following: i. Eating, in a discrete period of time (e.g., with any 2-hour period), an amount of food that is definitely larger than what most people would eat in a similar period of time under similar circumstances. ii. A sense of lack of control over eating (e.g., a feeling that one cannot stop eating or control what or how much one is eating). c. Associated with three (or more) of the following: i. Eating much more rapidly than normal. ii. Eating until feeling uncomfortably full. iii. Eating large amounts of food when not feeling physically hungry. iv. Eating alone because of feeling embarrassed by how much one is eating. v. Feeling disgusted with oneself, depressed, or very guilty afterward. d. Marked distress regarding binge eating is present. e. Occurs, on average, at least once a week for 3 months. f. Not associated with the recurrent use of inappropriate compensatory behavior as in bulimia nervosa and does not occur exclusively during the course of bulimia or anorexia nervosa. g. Trial and failure of SSRI or topiramate
Age Restrictions	Minimum 6 years of age for ADHD. Minimum 18 years of age for BED

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PA Criteria	Criteria Details
Prescriber Restrictions	N/A
Coverage Duration	up to one year
Other Criteria	

# Vyxeos (daunorubicin and cytarabine)

## **Products Affected**

• Vyxeos Intravenous Suspension

Reconstituted 44-100 MG

PA Criteria	Criteria Details
Covered Uses	Newly diagnosed therapy-related Acute Myeloid Leukemia (t-AML) or Acute Myeloid Leukemia with myelodysplasia-related changes (AML-MRC).
Exclusion Criteria	N/A
Required Medical Information	Documentation of the following: 1) ECOG is equal to or less than 2. 2) Baseline LVEF is within normal limits. 3) Total cumulative doses of non-liposomal daunorubicin equal to or less than 550 mg/m2 or equal to or less than 400mg/m2 in patients who received radiation therapy to the mediastinum. 4) Will not be used in combination with other chemotherapy.
Age Restrictions	Age 1 year and older.
Prescriber Restrictions	N/A
Coverage Duration	6 months.
Other Criteria	Dosing Limits: Up to 2 cycles of induction (5 doses total) and 2 cycles of consolidation (4 doses total) will be authorized.

# **WAKIX** (pitolisant)

## **Products Affected**

• Wakix

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Must be using for an FDA approved indications of: a. Excessive daytime sleepiness (EDS) b. Cataplexy in adult patient with narcolepsy
Exclusion Criteria	
Required Medical Information	EDS: Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of narcolepsy with both of the following: a. the patient has daily lapses into sleep occurring for at least three months, b. A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a Multiple Sleep Latency Test (MLST) performed according to standard techniques following a normal overnight polysomnogram, AND, history of failure, contraindication, or intolerance to all of the following: 1. armodafinil (Nuvigil) or modafinil, 2. an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant, 3. Sunosi.Cataplexy with Narcolepsy: Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of narcolepsy with cataplexy (Narcolepsy Type 1) with both of the following: a. the patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months, 2. A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset REM periods (SOMREPs) are found on a Mean Sleep Latency Test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOMREPs on the MSLT.
Age Restrictions	At least 18 years of age
Prescriber Restrictions	
Coverage Duration	Up to 1 year
Other Criteria	EDS: Physician attestation to the following: other causes of sleepiness have been ruled out, including, but not limited to: obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or

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PA Criteria	Criteria Details
	medications or their withdrawal, sleep phase disorder, or other sleep disorders. Cataplexy with Narcolepsy: Physician attestation to the both of the following: patient has experienced cataplexy defined as more than one episode of sudden loss of muscle tone with retained consciousness, and other causes of sleepiness have been ruled out or treated, including but not limited to: obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disturbances. Quantity Limit 4.45mg: 14 tablets/7days, 17.8mg: 60 tablets/30days

# Xarelto 2.5mg (rivaroxaban) MCAID

## **Products Affected**

• Xarelto Oral Tablet 2.5 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	Coronary Artery Disease (CAD), Peripheral Arterial Disease (PAD)
Exclusion Criteria	
Required Medical Information	Documents must be provided showing the following: for CAD- 1. Over age 65 with any of the following conditions: I)MI within the previous 20 years OR II)Multi-vessel coronary disease with history of stable or unstable angina OR III)Multi-vessel percutaneous coronary intervention OR IV)Multi-vessel CABG surgery 2. Under 65 years old with one of the above conditions AND meets either of the following: a. Documented atherosclerosis or revascularization involving at least two of the following vascular beds: I)Coronary vasculature II)Aorta III)Arterial supply to the brain IV)Gastro-intestinal tract V)Lower limbs VI)Upper limbs VII)Kidneys b. Two additional risk factors from the list below: I)Smoker within the previous year II)Diabetes III)eGFR less than 60 ml/min IV)Heart failure (ejection fraction must be greater than 30%) V)Non-lacunar ischemic stroke at least one month prior to start of therapy B. Diagnosis of peripheral arterial disease: 1. Previous aorto-femoral bypass surgery, limb bypass surgery, or percutaneous trans-luminal angioplasty revascularization of the iliac, or infra-inguinal arteries, OR 2. Previous limb or foot amputation for arterial vascular disease, OR 3. History of intermittent claudication and one or more of the following: a. An ankle/arm blood pressure (BP) ratio less than 0.90, OR b. Significant peripheral artery stenosis (at least 50%) documented by angiography, or by duplex ultrasound, OR c. Previous carotid revascularization or asymptomatic carotid artery stenosis at least 50% as diagnosed by duplex ultrasound or angiography.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to 1 Year
Other Criteria	

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# Xeljanz/Xeljanz XR (tofacitinib) (CC)

## **Products Affected**

• Xeljanz

Xeljanz XR

PA Criteria	Criteria Details
Covered Uses	1. Rheumatoid Arthritis (RA)2. Psoriatic Arthritis (PsA) 3. Ulcerative Colitis (UC), moderate or severely active 4. Juvenile Idiopathic Arthritis (JIA) 5. Ankylosing Spondylitis (AS)
Exclusion Criteria	
Required Medical Information	1. RA: a. DAS-28 greater than 3.2 or CDAI greater than 10.1. b.An adequate trial (3 months or more) of one of the following DMARDs: i. Hydroxychloroquine ii. Leflunomide iii. Methotrexate iv. Sulfasalazine c. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents (e.g., Amjevita, Enbrel, Kevzara, Orencia, Rinvoq), one of which must be a tumor necrosis factor (TNF) blocker (e.g., Amjevita, Enbrel). 2. PsA: a. An adequate trial (3 months or more) of one of the following DMARDs: i. Cyclosporine ii. Leflunomide iii. Methotrexate iv. Sulfasalazine b. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents (e.g., Amjevita, Enbrel, Orencia, Rinvoq, Skyrizi, Taltz), one of which must be a tumor necrosis factor (TNF) blocker (e.g., Amjevita, Enbrel). 3. UC: a. The patient must have an adequate trial (3 months or more) or intolerance to ONE of the following: i. 5-Aminosalicylates (balsalazide, mesalamine, sulfasalazine) ii. Cyclosporine iii. Steroids iv.Thiopurines (azathioprine, 6-MP) b. Trial and failure, unless contraindicated or not tolerated, of Amjevita and Rinvoq. 4. JIA: a. An adequate trial (3 months or more) of one of the following DMARDs: i. Leflunomide ii. Methotrexate iii. Sulfasalazine b. Trial and failure to TWO preferred agents used to treat this indication (e.g., Amjevita, Enbrel, Orencia), one of which must be a tumor necrosis factor (TNF) blocker (e.g., Amjevita, Enbrel). 5. AS: a. The patient has had an inadequate response to an NSAID and sulfasalazine (for peripheral spondylitis) or NSAID alone (for axial spondylitis) b. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents (e.g., Amjevita, Enbrel, Taltz), one of which must be a tumor necrosis factor (TNF) blocker (e.g., Amjevita, Enbrel).
Age Restrictions	
Prescriber Restrictions	RA/JIA/AS- prescribed by or in consultation with a rheumatologist, PsA-prescribed by or in consultation with a dermatologist or rheumatologist,

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PA Criteria	Criteria Details
	UC- prescribed by or in consultation with a gastroenterologist
Coverage Duration	Up to 12 months
Other Criteria	For all Indications: 1) Current PPD (tuberculosis) negative skin test, negative QuantiFERON-TB Gold test, or documented treatment for latent tuberculosis prior to initiation of therapy. 2) Specialty Pharmacy is required 3) Continuation of Therapy Criteria: Documentation of clinical benefit is required.

# **Xenazine** (tetrabenazine)(COMM, EXC, CentCare)

## **Products Affected**

• Tetrabenazine

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Chorea associated with Huntington disease: 2. Tardive Dyskinesia. Disease specific criteria must be met. 3. Tics associated with Tourette syndrome.
Exclusion Criteria	N/A
Required Medical Information	Documentation of the following: 1. PATIENT does not have untreated or inadequately treated depression. 2. PATIENT is not actively suicidal. 3. PATIENT does not have hepatic impairment. 4. PATIENT is not taking a monoamine oxidase inhibitor or reserpine. 5. APPROPRIATE disease specific criteria must also be met: A) CHORIA ASSOCIATED WITH HUNTINGTON DISEASE- i) Patient must be ambulatory. ii) The baseline total maximal chorea score from the UHDRS must be provided. iii) Patient must have a documented trial and failure, or intolerance to, or a medical reason for avoiding the use of amantadine or riluzole. B) TARDIVE DYSKINESIA - i) Prescribed by a neurologist or psychiatrist, ii) Trial and failure of one of the following: amantadine, anticholinergic medication, or a benzodiazepine, iii) Documentation of tardive dyskinesia and baseline Abnormal Involuntary Movement Scale (AIMS) must be provided. C) TICS ASSOCIATED WITH TOURETTE SYNDROME - i) Documentation showing the tics are interfering with social interactions, school or job performance, activities of daily living or are causing discomfort, pain, or injury. ii) Inadequate response to or a medical reason for avoiding the use of the following modalities: For tics due to Tourette syndrome, risperidone or fluphenazine. For tics due to Tourette syndrome with concurrent ADHD, clonidine or guanfacine.
Age Restrictions	Approved for use in adults only.
Prescriber Restrictions	Must be prescribed by a neurologist or in consultation with a neurologist.
Coverage Duration	Initial approval: 6 months. Renewal: One year.
Other Criteria	Continuation of Therapy: 1. For all indications, documentation of continued monitoring for depression, suicidal ideation and hepatic impairment. 2. Huntington Disease chorea - documentation of

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PA Criteria	Criteria Details
	improvement in the total maximal chorea score from the UHDRS compared to baseline. 3. Tardive Dyskinesia: Documented improvement in AIMS compared to baseline. 4. Tics due to Tourette syndrome: Documented reduction in frequency and intensity of tics.

## Xermelo (telotristat) (COMM, EXCH, Cent Care)

## **Products Affected**

Xermelo

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diagnosis of carcinoid syndrome diarrhea.
Exclusion Criteria	N/A
Required Medical Information	Documentation of confirmed diagnosis, established therapy of a somatostatin analog (SSA) for at least 3 months, and number of bowel movements a day.
Age Restrictions	Patient age of 18 or older.
Prescriber Restrictions	Xermelo is prescribed by, or in consultation with, an oncologist or gastroenterologist.
Coverage Duration	Initial Approval: 12 weeks. Continuation of Therapy: Up to one year.
Other Criteria	1. The patient has been on a maximum tolerated dose of somatostatin analog (SSA) for at 3 months and continues to have 4 or more bowel movements a day. 2. The patient has tried and failed other antidiarrheal therapies (e.g. loperamide, ondansetron, bile acid sequestrants). 3. Xermelo will be used in combination with a SSA. 4. Specialty pharmacy is required.

# Xgeva (denosumab)(COMM, EXC)

## **Products Affected**

• Xgeva

PA Criteria	Criteria Details
Covered Uses	1. Documented diagnosis for the prevention of skeletal related events with bone metastases from multiple myeloma or solid tumors 2)Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. 3) Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.
Exclusion Criteria	N/A
Required Medical Information	1. Documented diagnosis for the prevention of skeletal related events with bone metastases from multiple myeloma or solid tumors with failure or intolerance, or clinical rationale for the avoidance of Zometa or Aredia. a. Example of failure would be a pathologic fracture while receiving Zometa or Aredia with compliance for at least 3 continuous months. b. Example of clinical rationale for avoidance of Zometa or Aredia would be a CrCl less than 35ml/min. OR Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. OR Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. 2. Documented serum calcium. 3. Evidence of concurrent treatment with calcium and vitamin D or rationale for avoidance.NOTE: The National Cancer Institute defines a solid tumor as an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign or malignant. Examples of solid tumors are sarcomas, carcinomas, and lymphomas.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Preferred Specialty Pharmacy Dispensing Required.Code: J0897. 1mg = 1 billable unit.

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# Xifaxan (rifaximin)

## **Products Affected**

• Xifaxan

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Traveler's diarrhea (200mg strength only) 2. Hepatic encephalopathy (200mg and 550mg strengths) 3. Irritable Bowel Syndrome, Diarrhea Predominant (IBS-D) 4. Small Intestine Bacterial Overgrowth (SIBO)
Exclusion Criteria	N/A
Required Medical Information	1. Traveler's diarrhea (200mg strength only) - Patient must meet all of the following criteria: Documented diagnosis of traveler's diarrhea due to a noninvasive strain of E.Coli. Documented treatment failure with an oral antibiotic such as azithromycin or ciprofloxacin. 2. Hepatic encephalopathy (200mg and 550mg strengths) - Patient must meet all of the following criteria: Documented diagnosis of hepatic encephalopathy. Documented treatment failure or documented intolerance or contraindication to lactulose. 3. Irritable Bowel Syndrome, Diarrhea Predominant (IBS-D) - Patient must meet all of the following criteria: Documented diagnosis of Irritable Bowel Syndrome with diarrhea as the predominant symptom.Documented trial and failure of dietary modification (e.g. low FODMAP diet, lactose avoidance, gluten avoidance). Documented trial and failure of at least two of the following: antidiarrheals (i.e. loperamide), antispasmodics, or tricyclic antidepressants. 4. Small Bacterial Overgrowth (SIBO) - Patient must meet all of the following criteria:?Documentation of a positive lactulose/glucose breath test must be submitted and one of the following are met:a.An absolute increase in hydrogen by at least 20 ppm above baseline within 90 minutes.b.A methane level by at least 10 ppm?The patient must have a documented trial and failure of one other antibiotic treatment (e.g., amoxicillin/clavulanate, metronidazole plus cephalexin, metronidazole plus sulfamethoxazole/trimethoprim double strength).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Traveler's Diarrhea: 1 time. Hepatic Encephalopathy: 1 year. IBS-D: 1 time. SIBO: 1 time
Other Criteria	Quantity Limits: For traveler's diarrhea - 9 tablets (200mg) for 3 days for

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PA Criteria	Criteria Details
	any one 30-day period. For hepatic encephalopathy - 200mg tablets(up to 180 tablets for 30 days), 550mg tablets - 60 tablets for 30 days. For IBS-D - 42 tablets (550mg) for 14 days for any one 30-day period. Patients who experience a recurrent of symptoms can be retreated up to two times with the same dosage regimen. SIBO - 42 tablets (550 mg) for 14 days

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# Xolair (omalizumab)(Cent Care)

### **Products Affected**

- Xolair Subcutaneous Solution Prefilled Syringe 150 MG/ML, 75 MG/0.5ML
- Xolair Subcutaneous Solution Reconstituted

PA Criteria	Criteria Details
Covered Uses	Treatment of Chronic Idiopathic Urticaria: All of the following must be met: 1. The patient must have a documented diagnosis of chronic idiopathic urticaria. 2. Must be prescribed by Allergist/Immunologist. 3. Documentation of all the following is required: a. Minimum 30 day trial of scheduled, high dose non-sedating anti-histamines in combination with montelukast. b. Minimum of one short course of corticosteroids. c. Minimum 30 day trial of immunosuppressant, immunomodulatory or anti-inflammatory agent (i.e. cyclosporine, mycophenolate, tacrolimus, dapsone, hydroxychloroquine, sulfasalazine or methotrexate). Continuation of treatment for Chronic Idiopathic Urticaria: Documentation of ALL the following is required: 1. Reduction in exacerbation frequency. 2. Reduction in exacerbation intensity. 3. Decrease in oral corticosteroid use. Treatment of Moderate to severe persistent asthma: All of the following must be met: 1. The requesting physician is an allergist or pulmonologist. 2. The patient age is 6 years or greater. 3. The patient has a documented IgE level greater than 30 IU/ml. 4. The diagnosis of allergic asthma is supported by clinical and lab findings such as positive skin tests, symptom patterns, etc. 5. The patient has a documented failure on a minimum 6-month trial of inhaled steroid and long-acting beta-2 agonist combination therapy at maximum doses. 6. There is sufficient evidence of persistent symptoms requiring frequent rescue therapy, practitioner visits despite inhaled corticosteroids, or emergency room visits.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CIU: 3 months initially. Asthma: 3 months initially. Subsequent approvals: up to 6 months.

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PA Criteria	Criteria Details
Other Criteria	Dosing for Chronic Idiopathic Urticaria: 150 mg or 300 mg by subcutaneous route every 4 weeks Dosing: Dosing of Xolair is considered medically necessary according to the FDA-approved labeling of Xolair (see Xolair prescribing information) Code: J2357. 5mg = 1 billable unit.

# Xtandi (enzalutamide)(Cent Care)

## **Products Affected**

• Xtandi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	1. Diagnosis of metastatic, castration-resistant or metastatic castration-sensitive prostate cancer AND a history of failure, contraindication, or intolerance to abiraterone (Zytiga), OR 2. Diagnosis os non-metastatic, castration-resistant prostate cancer AND a history of failure, contraindication, or intolerance to darolutamide (Nubeqa).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Up to 6 months
Other Criteria	For all non-FDA approved indications, there must be a Category 1 or 2 recommendation in the National Comprehensive Cancer Network (NCCN) compendium or there must be a Class I or II recommendation in the Thomson Micromedex DrugDex compendium.

# **Xyrem** (sodium oxybate)(Cent Care)

## **Products Affected**

• Sodium Oxybate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Exclusions: 1. Xyrem will not be approved if patient is being treated with sedative hypnotics or other CNS depressants. 2. Patients with succinic semialdehyde dehydrogenase deficiency. 3. Patients with a history of drug abuse.
Required Medical Information	1.A documented diagnosis of cataplexy in narcolepsy requiring treatment. All of the following are required: a. b. The patient has a documented trial and failure of, or intolerance to a tricyclic antidepressant or formulary selective serotonin receptor inhibitor (SSRI). 2. Excessive daytime sleepiness (EDS) in narcolepsy. All of the following are required: a. The patient has a documented trial and failure of, or intolerance to an adequate trial of a preferred formulary cerebral stimulant (methylphenidate or dextroamphetamine) AND armodafinil or modafinil AND Sunosi (solriamfetol) AND Wakix (pitolisant)
Age Restrictions	at least 7 years old
Prescriber Restrictions	Prescribed by a neurologist or sleep specialist
Coverage Duration	1 year
Other Criteria	For all indications: prescriber must participate in the Xyrem Success Program

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# **Zortress** (everolimus)(Cent Care)

## **Products Affected**

• Everolimus

PA Criteria	Criteria Details
<b>Covered Uses</b>	Criteria is dependent upon diagnosis: 1. Kidney transplant: a. Zortress is being administered in combination with basiliximab induction and concurrently with reduced doses of cyclosporine and corticosteroids. 2. Liver Transplant: a. Zortress is being administered no earlier than 30 days post-transplant with low dose tacrolimus and corticosteroids.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A

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# Zyflo CR (zileuton ER) (COMM, EXC, CC)

## **Products Affected**

• Zileuton ER

PA Criteria	Criteria Details
<b>Covered Uses</b>	The patient must have an adequate trial (at least two months) of an inhaled corticosteroid and a preferred formulary leukotriene receptor antagonist (montelukast or zafirlukast).
Exclusion Criteria	N/A
Required Medical Information	Documentation showing previous medication trials.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Up to one year.
Other Criteria	

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# Zyvox (linezolid)(Cent Care)

#### **Products Affected**

- Linezolid in Sodium Chloride
- Linezolid Intravenous Solution 600 MG/300ML
- Linezolid Oral
- Zyvox Intravenous Solution 200 MG/100ML

PA Criteria	Criteria Details
Covered Uses	1. An infectious disease specialist consult, chart notes and culture and sensitivities must be received with the request. AND 2. The patient must have failed other antibacterials that the culture shows sensitivities to or the patient has a contraindication to the other antibacterials.
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
Age Restrictions	N/A
Prescriber Restrictions	Infectious Disease Consultation must be documented.
Coverage Duration	1 time
Other Criteria	N/A

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# **Step Therapy Criteria**

# Aciphex (rabeprazole)

### **Products Affected**

• RABEprazole Sodium Tablet Delayed

Release 20 MG Oral

#### **Details**

Criteria	The patient must have a claim history of a 30-day trial of omeprazole or
	pantoprazole within the past 545 days.

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# **Actoplus Met (pioglitazone/metformin)**

### **Products Affected**

- Pioglitazone HCl-metFORMIN HCl Tablet 15-500 MG Oral
- Pioglitazone HCl-metFORMIN HCl Tablet 15-850 MG Oral

#### **Details**

The patient must have a 90-day prescription fill of at least one of the medications (Actos or metformin) that make up the combination medication within the past 120 days.
inedication within the past 120 days.

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# Amitiza (lubiprostone)

### **Products Affected**

- Lubiprostone Capsule 24 MCG Oral
- Lubiprostone Capsule 8 MCG Oral

## **Details**

	re must be a claim history of an osmotic laxative (PEG-3350 or alose) within the past 120 days
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## **ARBs** (Atacand, Atacand HCT, Diovan HCT)

#### **Products Affected**

- Candesartan Cilexetil Tablet 16 MG Oral
- Candesartan Cilexetil Tablet 32 MG Oral
- Candesartan Cilexetil Tablet 4 MG Oral
- Candesartan Cilexetil Tablet 8 MG Oral
- Candesartan Cilexetil-HCTZ Tablet 16-12.5 MG Oral
- Candesartan Cilexetil-HCTZ Tablet 32-12.5 MG Oral
- Candesartan Cilexetil-HCTZ Tablet 32-25
   MG Oral

- Valsartan-hydroCHLOROthiazide Tablet 160-12.5 MG Oral
- Valsartan-hydroCHLOROthiazide Tablet 160-25 MG Oral
- Valsartan-hydroCHLOROthiazide Tablet 320-12.5 MG Oral
- Valsartan-hydroCHLOROthiazide Tablet 320-25 MG Oral
- Valsartan-hydroCHLOROthiazide Tablet 80-12.5 MG Oral

#### **Details**

The patient must have a prescription claim history of a preferred formulary angiotensin converting enzyme (ACE) inhibitor or ACE
inhibitor/diuretic combination within the past six months.

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# **Avodart (dutasteride)**

### **Products Affected**

• Dutasteride Capsule 0.5 MG Oral

## **Details**

Criteria	The patient must have a claim history of finasteride within the past 4 months.
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# Boniva (ibandronate) tablets

### **Products Affected**

• Ibandronate Sodium Tablet 150 MG Oral

## **Details**

# Casodex (bicalutamide)

### **Products Affected**

• Bicalutamide Tablet 50 MG Oral

## **Details**

The patient must have a claim history of a 30-day trial of flutamide in the past 180 days.

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# Ciprodex (ages 12 and up)

## **Products Affected**

• Ciprofloxacin-Dexamethasone Suspension 0.3-0.1 % Otic

## **Details**

	Patients 12 years and older: The patient must have a claim history of ofloxacin 0.03% otic in the past 100 days.
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# **Combipatch Transdermal (estradiol/norethindrone)**

#### **Products Affected**

- CombiPatch Patch Twice Weekly 0.05- CombiPatch Patch Twice Weekly 0.05-0.14 MG/DAY Transdermal
  - 0.25 MG/DAY Transdermal

#### **Details**

Criteria	The patient must have a 90 day trial of a formulary estrogen and progesterone medication within the past 180 days.
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# Detrol/Detrol LA (tolterodine/tolterodine ER)

#### **Products Affected**

- Tolterodine Tartrate ER Capsule Extended Release 24 Hour 2 MG Oral
- Release 24 Hour 4 MG Oral Tolterodine Tartrate Tablet 1 MG Oral
- Tolterodine Tartrate ER Capsule Extended Tolterodine Tartrate Tablet 2 MG Oral

#### **Details**

Criteria	The patient must have a 30-day prescription fill of generic oxybutynin, oxybutynin XL, or oxybutynin transdermal (Oxytrol for Women) within
	the past 545 days.

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## dexmethylphenidate (Focalin or Focalin XR)

#### **Products Affected**

- Dexmethylphenidate HCl ER Capsule Extended Release 24 Hour 10 MG Oral
- Dexmethylphenidate HCl ER Capsule Extended Release 24 Hour 15 MG Oral
- Dexmethylphenidate HCl ER Capsule Extended Release 24 Hour 20 MG Oral
- Dexmethylphenidate HCl ER Capsule Extended Release 24 Hour 25 MG Oral
- Dexmethylphenidate HCl ER Capsule Extended Release 24 Hour 30 MG Oral
- Dexmethylphenidate HCl ER Capsule

- Extended Release 24 Hour 35 MG Oral
- Dexmethylphenidate HCl ER Capsule Extended Release 24 Hour 40 MG Oral
- Dexmethylphenidate HCl ER Capsule Extended Release 24 Hour 5 MG Oral
- Dexmethylphenidate HCl Tablet 10 MG Oral
- Dexmethylphenidate HCl Tablet 2.5 MG Oral
- Dexmethylphenidate HCl Tablet 5 MG Oral

#### **Details**

Cuitaria	The noticest mayor have a prescription claim history for mathylphonidete or
Criteria	The patient must have a prescription claim history for methylphenidate or
	methylphenidate extended-release within the past 180 days.

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# Diastat (diazepam gel)

#### **Products Affected**

- diazePAM Gel 10 MG Rectal
- diazePAM Gel 2.5 MG Rectal

## • diazePAM Gel 20 MG Rectal

## **Details**

Criteria	Step therapy is required for patients 18 years of age and older. The patient must have a claim history within the past 120 days of a 30-day fill of an
	anti- epileptic agent.

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## **DPP-4 Inhibitors, Preferred (Kazano, Nesina)**

#### **Products Affected**

- Alogliptin-metFORMIN HCl Tablet 12.5- 1000 MG Oral
- Alogliptin-metFORMIN HCl Tablet 12.5- Segluromet Tablet 7.5-1000 MG Oral 500 MG Oral
- Segluromet Tablet 2.5-1000 MG Oral
- Segluromet Tablet 2.5-500 MG Oral

  - Segluromet Tablet 7.5-500 MG Oral

#### **Details**

Criteria	The patient must have a 90-day prescription fill of metformin within the past 545 days.
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# **Duetact** (pioglitazone/glimepiride)

## **Products Affected**

MG Oral

• Pioglitazone HCl-Glimepiride Tablet 30-2 • Pioglitazone HCl-Glimepiride Tablet 30-4 MG Oral

#### **Details**

The patient must have previous use of at least one of the medications (pioglitazone or glimepiride) that make up the combination medication within past 120 days.
 within past 120 days.

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# **Duragesic Patch (fentanyl transdermal)**

#### **Products Affected**

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

### **Details**

Criteria The patient must have a claim history of morphine sulfate extended release tablet (MS Contin) within the past 90 days.	
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# Finacea (azelaic acid 15%) Gel, Foam

#### **Products Affected**

Azelaic Acid Gel 15 % External

• Finacea Foam 15 % External

## **Details**

Criteria	The patient must have a 30-day prescription fill of metronidazole topical within the past 120 days.
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# Freestyle (Continuous Glucose Monitor)

#### **Products Affected**

- FreeStyle Libre 14 Day Reader Device
- FreeStyle Libre 14 Day Sensor
- FreeStyle Libre 2 Plus Sensor
- FreeStyle Libre 2 Reader Device
- FreeStyle Libre 2 Sensor

- FreeStyle Libre 3 Plus Sensor
- FreeStyle Libre 3 Reader Device
- FreeStyle Libre 3 Sensor
- FreeStyle Libre Reader Device

#### **Details**

The patient must have a claim history of a 30-day supply of insulin in the past 120 days for new starts and continuations.
past 120 days for new starts and continuations.

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# **Herpes Simplex**

#### **Products Affected**

- Famciclovir Tablet 125 MG Oral
- Famciclovir Tablet 250 MG Oral

• Famciclovir Tablet 500 MG Oral

## **Details**

Criteria	Two pharmacy claims in the last 120 days of acyclovir
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# ICS/LABA combos (AirDuo, Dulera, Symbicort)

#### **Products Affected**

- Dulera Aerosol 100-5 MCG/ACT Inhalation
- Dulera Aerosol 200-5 MCG/ACT

### Inhalation

• Dulera Aerosol 50-5 MCG/ACT Inhalation

### **Details**

Criteria	The patient must have a prescription claim history of an orally inhaled corticosteroid or orally inhaled anticholinergic within the past 150 days
	OR FEV1 of less than 50%.

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# **Kytril (granisetron) tablets**

## **Products Affected**

• Granisetron HCl Tablet 1 MG Oral

## **Details**

Criteria The patient must have a prescription claim his of generic ondansetron oral tablets within the	•
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# LEVETIRACETAM EXTENDED RELEASE **TABLETS**

#### **Products Affected**

- Release 24 Hour 500 MG Oral
- levETIRAcetam ER Tablet Extended
   levETIRAcetam ER Tablet Extended Release 24 Hour 750 MG Oral

#### **Details**

Criteria	Pharmacy claim of levetiracetam immediate release in the last 180 days
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# **Lumigan 0.01% ophthalmic solution (bimatoprost)**

## **Products Affected**

• Lumigan Solution 0.01 % Ophthalmic

## **Details**

	The patient must have a prescription claim history for latanoprost 0.005% within the past 180 days.
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# Luvox CR (fluvoxamine)

#### **Products Affected**

- fluvoxaMINE Maleate ER Capsule Extended Release 24 Hour 100 MG Oral
- fluvoxaMINE Maleate ER Capsule Extended Release 24 Hour 150 MG Oral

#### **Details**

Criteria	The patient must have a 30-day trial of two of the following: clomipramine, fluoxetine, paroxetine, sertraline.
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## **Memantine ER**

#### **Products Affected**

- Donepezil HCl Tablet 10 MG Oral
- Donepezil HCl Tablet 5 MG Oral
- Memantine HCl ER Capsule Extended Release 24 Hour 14 MG Oral
- Memantine HCl ER Capsule Extended Release 24 Hour 21 MG Oral
- Memantine HCl ER Capsule Extended Release 24 Hour 28 MG Oral
- Memantine HCl ER Capsule Extended Release 24 Hour 7 MG Oral
- Memantine HCl Tablet 10 MG Oral
- Memantine HCl Tablet 5 MG Oral

#### **Details**

The patient must have a claim history of donepezil or Namenda immediate release tablets within the past 545 days.
1 2

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# mesalamine (Apriso, Asacol, Delzicol, Pentasa)

#### **Products Affected**

- Mesalamine Capsule Delayed Release 400 MG Oral
- Mesalamine ER Capsule Extended

Release 24 Hour 0.375 GM Oral

• Mesalamine Tablet Delayed Release 1.2 GM Oral

#### **Details**

	The patient must have a claim history within the past 545 days of a 30-day trial of balsalazide or sulfasalazine.
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## Midazolam injection for seizures

#### **Products Affected**

- Midazolam HCl (PF) Solution 10 MG/2ML Injection
- Midazolam HCl (PF) Solution 2 MG/2ML Injection
- Midazolam HCl (PF) Solution 5 MG/ML Injection
- Midazolam HCl Solution 10 MG/10ML Injection
- Midazolam HCl Solution 10 MG/2ML Injection

- Midazolam HCl Solution 2 MG/2ML Injection
- Midazolam HCl Solution 25 MG/5ML Injection
- Midazolam HCl Solution 5 MG/5ML Injection
- Midazolam HCl Solution 5 MG/ML Injection
- Midazolam HCl Solution 50 MG/10ML Injection

#### **Details**

Criteria	Step therapy is required for patients 18 years of age and older. The patient must have a claim history within the past 120 days of a 30-day fill of an anti- epileptic agent.
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# morphine sulfate ER (Avinza, Kadian)

#### **Products Affected**

- Morphine Sulfate ER Beads Capsule Extended Release 24 Hour 120 MG Oral
- Morphine Sulfate ER Beads Capsule Extended Release 24 Hour 30 MG Oral
- Morphine Sulfate ER Beads Capsule Extended Release 24 Hour 45 MG Oral
- Morphine Sulfate ER Beads Capsule Extended Release 24 Hour 60 MG Oral
- Morphine Sulfate ER Beads Capsule Extended Release 24 Hour 75 MG Oral
- Morphine Sulfate ER Beads Capsule Extended Release 24 Hour 90 MG Oral
- Morphine Sulfate ER Capsule Extended Release 24 Hour 10 MG Oral

- Morphine Sulfate ER Capsule Extended Release 24 Hour 100 MG Oral
- Morphine Sulfate ER Capsule Extended Release 24 Hour 20 MG Oral
- Morphine Sulfate ER Capsule Extended Release 24 Hour 30 MG Oral
- Morphine Sulfate ER Capsule Extended Release 24 Hour 40 MG Oral
- Morphine Sulfate ER Capsule Extended Release 24 Hour 50 MG Oral
- Morphine Sulfate ER Capsule Extended Release 24 Hour 60 MG Oral
- Morphine Sulfate ER Capsule Extended Release 24 Hour 80 MG Oral

#### **Details**

The patient must have claim history of fentanyl transdermal patches and oxymorphone ER within the past 90 days.

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### **Opana ER (oxymorphone ER)**

#### **Products Affected**

- oxyMORphone HCl ER Tablet Extended Release 12 Hour 10 MG Oral
- oxyMORphone HCl ER Tablet Extended Release 12 Hour 15 MG Oral
- oxyMORphone HCl ER Tablet Extended Release 12 Hour 20 MG Oral
- oxyMORphone HCl ER Tablet Extended
- Release 12 Hour 30 MG Oral
- OxyMORphone HCl ER Tablet Extended Release 12 Hour 40 MG Oral
- oxyMORphone HCl ER Tablet Extended Release 12 Hour 5 MG Oral
- oxyMORphone HCl ER Tablet Extended Release 12 Hour 7.5 MG Oral

#### **Details**

Criteria	The patient must have claim history of morphine sulfate extended release tablets (MS Contin) within the past 90 days.
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# Ophthalmic beta blockers (betaxolol ophthalmic 0.25% and 0.5%)

#### **Products Affected**

• Betaxolol HCl Solution 0.5 % Ophthalmic • Betoptic-S Suspension 0.25 % Ophthalmic

#### **Details**

The patient must have a prescription claim history for timolol maleate 0.5% ophthalmic solution within the past 180 days.

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# ophthalmic corticosteroids (Alrex, Lotemax)

#### **Products Affected**

- Alrex Suspension 0.2 % Ophthalmic
- Lotemax SM Gel 0.38 % Ophthalmic
- Loteprednol Etabonate Gel 0.5 %

#### Ophthalmic

• Loteprednol Etabonate Suspension 0.5 % Ophthalmic

#### **Details**

	ember must have a claim history within the past 120 days of a arry ophthalmic corticosteroid.
formula	ary ophthalmic corticosteroid.

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### Oseni (alogliptin and pioglitazone

#### **Products Affected**

- Alogliptin-Pioglitazone Tablet 12.5-15 MG Oral
- Alogliptin-Pioglitazone Tablet 12.5-30 MG Oral
- Alogliptin-Pioglitazone Tablet 12.5-45 MG Oral
- Alogliptin-Pioglitazone Tablet 25-15 MG Oral
- Alogliptin-Pioglitazone Tablet 25-30 MG Oral
- Alogliptin-Pioglitazone Tablet 25-45 MG Oral

#### **Details**

Criteria The patient must have a 90-day prescription fill of me within the past 545 days.	tformin or alogliptin
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### Paxil CR (paroxetine CR)

#### **Products Affected**

- PARoxetine HCl ER Tablet Extended Release 24 Hour 12.5 MG Oral
- PARoxetine HCl ER Tablet Extended
- Release 24 Hour 25 MG Oral
- PARoxetine HCl ER Tablet Extended Release 24 Hour 37.5 MG Oral

#### **Details**

The patient must have a 30-day trial and failure on 3 formulary generic selective serotonin reuptake inhibitors (SSRIs) within the past 545 days.
selective serotolini reuptake minoitors (SSKIS) within the past 343 days.

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### Prevacid (lansoprazole capsule)

#### **Products Affected**

- MG Oral
- Lansoprazole Capsule Delayed Release 15 Lansoprazole Capsule Delayed Release 30 MG Oral

#### **Details**

Criteria	The patient must have a claim history within the past 545 days of a 30-day trial of omeprazole and pantoprazole.
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### Ranexa

#### **Products Affected**

- Ranolazine ER Tablet Extended Release Ranolazine ER Tablet Extended Release 12 Hour 1000 MG Oral
  - 12 Hour 500 MG Oral

#### **Details**

Criteria	The member must have a claim history within the past 120 days of all of the following agents: a) Beta Blocker b) Calcium Channel Blocker c)
	Nitrate

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# Rhopressa (netarsudil)

#### **Products Affected**

• Rhopressa Solution 0.02 % Ophthalmic

#### **Details**

Criteria	Pharmacy claim in the past 120days of an ophthalmic prostaglandin indicated for glaucoma
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# **Sklice (ivermectin)**

#### **Products Affected**

• Ivermectin Lotion 0.5 % External

#### **Details**

	The patient must have a trial and failure of permethrin within the past 60 days.
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# **Sporanox (itraconazole)**

#### **Products Affected**

• Itraconazole Capsule 100 MG Oral

#### **Details**

<b>Criteria</b> The patient must have a claim history of terbinafine tablets or fluconazole tablets within the past 90 days.	Criteria
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### Steglatro (ertugliflozin)

#### **Products Affected**

- metFORMIN HCl ER Tablet Extended Release 24 Hour 500 MG Oral
- metFORMIN HCl ER Tablet Extended Release 24 Hour 750 MG Oral
- metFORMIN HCl Tablet 1000 MG Oral **Details**
- metFORMIN HCl Tablet 500 MG Oral
- metFORMIN HCl Tablet 850 MG Oral
- Steglatro Tablet 15 MG Oral
- Steglatro Tablet 5 MG Oral

Criteria	The member must have had a 90-day trial of metformin or a metformin-
	containing product within the past 120 days.

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# Stiolto Respimat (tiotropium/olodaterol)

#### **Products Affected**

• Stiolto Respimat Aerosol Solution 2.5-2.5 MCG/ACT Inhalation

#### **Details**

Criteria	The patient must have a 30- day prescription fill of a formulary long-acting anticholinergic or a long-acting beta agonist (LABA) product within the past 180 days. OR the patient is diagnosed with COPD and in Group D. Group D defined as: 2 or more exacerbations a year or 1 or more hospitalization for exacerbation; and a CAT equal to or greater than 10 or mMRC grade equal to or greater than 2.
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### Tresiba (insulin degludec)

#### **Products Affected**

- Insulin Degludec FlexTouch Solution Pen-Injector 100 UNIT/ML Subcutaneous
- Insulin Degludec FlexTouch Solution Pen-
- Injector 200 UNIT/ML Subcutaneous
- Insulin Degludec Solution 100 UNIT/ML Subcutaneous

#### **Details**

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### TZD (Actos, Avandia)

#### **Products Affected**

- Repaglinide Tablet 0.5 MG Oral
- Repaglinide Tablet 1 MG Oral

#### • Repaglinide Tablet 2 MG Oral

#### **Details**

	The patient must have a 90-day prescription fill of metformin in the past 545 days.
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# Vytorin (ezetimibe/simvastatin)

#### **Products Affected**

- Ezetimibe-Simvastatin Tablet 10-10 MG Oral
- Ezetimibe-Simvastatin Tablet 10-20 MG Oral
- Ezetimibe-Simvastatin Tablet 10-40 MG Oral
- Ezetimibe-Simvastatin Tablet 10-80 MG Oral

#### **Details**

The patient must have a trial and failure on at least one of the following statins within the past 180 days: lovastatin, pravastatin, or simvastatin.
stating within the past 100 days. To vastatin, pravastatin, or simily astatin.

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### **Xanax XR** (alprazolam extended-release tablets)

#### **Products Affected**

- ALPRAZolam ER Tablet Extended Release 24 Hour 0.5 MG Oral
- ALPRAZolam ER Tablet Extended Release 24 Hour 1 MG Oral
- ALPRAZolam ER Tablet Extended Release 24 Hour 2 MG Oral
- ALPRAZolam ER Tablet Extended Release 24 Hour 3 MG Oral
- ALPRAZolam XR Tablet Extended Release 24 Hour 0.5 MG Oral
- ALPRAZolam XR Tablet Extended Release 24 Hour 1 MG Oral
- ALPRAZolam XR Tablet Extended Release 24 Hour 2 MG Oral
- ALPRAZolam XR Tablet Extended Release 24 Hour 3 MG Oral

#### **Details**

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	The patient must have a prescription claim history for a preferred formulary benzodiazepine within the past 90 days.

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