

**Clinical Criteria Document for Commercial Large Group Non-Metal Level  
Health Insurance Plans**

**General Information and Definitions:**

- Inclusion in this list by itself does not imply approval of the drug.
- Established Therapy applies to patients/members who are new to Presbyterian Health Plan, within 90 days from effective eligibility date.
- Sampling does not qualify as Established Therapy. There must be record of use of formulary agents in the patient's profile.
- Prior Authorization (PA): Drug is on the formulary but requires a Prior Authorization request from the physician by fax, phone, or regular mail. If the patient meets established criteria for approval, the medication will be covered. Documentation of treatment failures and clinical justification is required with all requests.
- Step Therapy (ST): Automatic online review of certain medications that are available to patients if they meet established criteria. Coverage of the medication at the pharmacy requires the patient to have a prescription history of specific drugs within a specified time frame. This occurs electronically at the pharmacy.

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# Prior Authorization Criteria

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## Abilify Discmelt (aripiprazole orally disintegrating tablet)(COMM, EXC)

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### Products Affected

- ARIPIprazole Oral Tablet Dispersible

PA Criteria	Criteria Details
<b>Covered Uses</b>	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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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 efficacy to risperidone, or documentation that risperidone is not clinically

<b>PA Criteria</b>	<b>Criteria Details</b>
	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Must be initiated by a certified behavioral health provider (e.g. psychiatrist, CNP with psychiatry certification) for all indications.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

# Actemra (tocilizumab)(COMM, EXC)

## Products Affected

- Actemra
- Actemra ACTPen

PA Criteria	Criteria Details
<b>Covered Uses</b>	1) Juvenile Idiopathic Arthritis (JIA) 2) Rheumatoid Arthritis (RA) 3) Giant Cell Arteritis (adult patients)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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. Methotrexate iii. Sulfasalazine. c. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents used to treat this indication (e.g., Enbrel, Humira, Xeljanz). 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 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 d. Trial and failure, unless contraindicated or not tolerated, of Kevzara AND one of the following: Amjevita, Enbrel, Humira, Rinvoq, Xeljanz. 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial Approval: 6 months. Continuation: 1 year
<b>Other Criteria</b>	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: Documentation of clinical benefit is required. Dispensing Required. Code: J3262. 1mg = 1 billable unit

## Aczone (dapsons topical gel)(COMM, EXC)

### Products Affected

- Dapsone External

PA Criteria	Criteria Details
Covered Uses	Acne Vulgaris
Exclusion Criteria	N/A
Required Medical Information	Acne Vulgaris patient must have a documented treatment failure of all of the following: a. Benzoyl peroxide, b. A 30-day supply of an oral antibiotic indicated for the treatment of acne vulgaris such as doxycycline or minocycline, c. A topical retinoid such as tretinoin topical cream or gel
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A

## Ambien CR (zolpidem)(COMM, EXC)

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### Products Affected

- Zolpidem Tartrate ER

PA Criteria	Criteria Details
Covered Uses	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)

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## Products Affected

- Aminocaproic Acid Oral Solution

PA Criteria	Criteria Details
Covered Uses	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)

## Products Affected

- Amjevita Subcutaneous Solution Auto-Injector
- Amjevita Subcutaneous Solution Prefilled Syringe 40 MG/0.4ML
- Amjevita-Ped 10kg to <15kg
- Amjevita-Ped 15kg to <30kg Subcutaneous Solution Prefilled Syringe 20 MG/0.4ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	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. Psoriatic Arthritis (PsO) 8. Hidradenitis Suppurativa (HS) 9. Uveitis.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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, prednisolone, dexamethasone, budesonide). ii. Methotrexate iii. Thiopurines (azathioprine, mercaptopurine).

PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to 1 year
Other Criteria	<p>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 agent (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 non-infectious intermediate posterior and panuveitis 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.</p>

# Amnesteem/Claravis/Myorisan/Zenatane (isotretinoin capsules) Comm/HIX/CC

## Products Affected

- Amnesteem
- Claravis
- ISOTretinoin Oral
- Myorisan
- Zenatane

PA Criteria	Criteria Details
<b>Covered Uses</b>	A documented diagnosis of persistent or recurring severe recalcitrant nodular acne that is still present and requires additional therapy.
<b>Exclusion Criteria</b>	Long-term low doses equal to or less than 0.5mg/kg/day will not be authorized. Low dose therapy is only recommended for the first month to prevent initial worsening of acne.
<b>Required Medical Information</b>	1. Documentation showing a diagnosis of persistent or recurring severe recalcitrant nodular acne that is still present requiring additional therapy. 2. At least 8 weeks must have passed since the completion of the previous course of therapy. 3. Documentation of the patients current weight must be provided. 4. Documentation of the cumulative dose reached during the previous course of therapy must be provided. 5. Documentation of the expected time needed to reach the cumulative dose goal of 120mg/kg to 150mg/kg must be provided.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Twenty-four (24) weeks of therapy.
<b>Other Criteria</b>	Note: Twenty-four (24) weeks of therapy every 365 days covered without a prior authorization on the Medicaid and Commercial formularies.

# Ampyra (dalfampridine)(COMM, EXC)

## Products Affected

- Dalfampridine ER

PA Criteria	Criteria Details
<b>Covered Uses</b>	Treatment to improve walking in patients with multiple sclerosis (MS)
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Patient must have a documented diagnosis of Multiple Sclerosis AND must have documentation of ALL of the following: 1. Patient must not have a history of seizures. 2. Patient must currently require a walking assistance device (cane, walker, etc.) for every day ambulation. 3. Patient must have a CrCl greater than 50mL/min. Note: Ampyra is contraindicated in patients with moderate to severe renal impairment. 4. Patient must have a baseline Timed 25-foot walk (T25FW) between 8 and 46 seconds.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial Approval: 3 months. Continuation: 6 months
<b>Other Criteria</b>	Criteria for Continuation of Therapy: Must demonstrate a 20% improvement in T25FW initially at 3 months and maintain the initial 20% improvement in the T25FW at each 6 month interval. Approval will be discontinued if the T25FW declines. Quantity Limit: 60 tablets per 30 days.

# Androderm (testosterone transdermal patch)(COMM, EXC)

## Products Affected

- Androderm Transdermal Patch 24 Hour MG/ACT (1%)
- Testosterone Transdermal Gel 12.5

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
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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 (16 years of age and up)- Specific criteria apply. Refer to the Gender Dysphoria Treatment Criteria located on phs.org.
<b>Age Restrictions</b>	18 years or greater
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Must have a documented trial and failure of topical testosterone gels. Quantity Limits: Androderm 2mg = 60 patches per 30 days, Androderm 4mg = 30 patches per 30 days.

# AndroGel 1.62% (testosterone topical gel)(COMM, EXC)

## Products Affected

- Testosterone Transdermal Gel 1.62 %, 40.5 MG/2.5GM (1.62%), 50 MG/5GM 20.25 MG/1.25GM (1.62%), 20.25 (1%) MG/ACT (1.62%), 25 MG/2.5GM (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
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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 (16 years of age and up)- Specific criteria apply. Refer to the Gender Dysphoria Treatment Criteria located on phs.org.
<b>Age Restrictions</b>	18 years or greater
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Quantity Limits: Pump = 150gm for 30 days (4 actuations per day).

## Anzemet (dolasetron) Tablets(COMM, EXC)

### Products Affected

- Anzemet Oral

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Nausea and vomiting associated with moderately emetogenic cancer chemotherapy
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Quantity Limit: 3 tablets per 30 days

# Aranesp (darbepoetin alfa)(COMM, EXC)

## Products Affected

- Aranesp (Albumin Free) Injection 60 MCG/ML  
Solution 100 MCG/ML, 200 MCG/ML, 250 MCG/ML, 300 MCG/ML, 40 MCG/ML,
- Aranesp (Albumin Free) Injection  
Solution Prefilled Syringe

PA Criteria	Criteria Details
<b>Covered Uses</b>	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
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Up to 6 months
<b>Other Criteria</b>	Code: J0881. 1mcg (0.001mg) = 1 billable unit



# Aricept ODT (donepezil orally disintegrating) Criteria

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## Products Affected

- Donepezil HCl Oral Tablet Dispersible

PA Criteria	Criteria Details
Covered Uses	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)(COMM, EXC)

## Products Affected

- Fondaparinux Sodium

PA Criteria	Criteria Details
<b>Covered Uses</b>	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).
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 time
<b>Other Criteria</b>	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

# ASENAPINE

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**Products Affected**

- Asenapine Maleate
- Secuado

PA Criteria	Criteria Details
<b>Covered Uses</b>	1.The patient must have a documented diagnosis of schizophrenia or bipolar disorder, including manic and mixed episodes associated with bipolar disorder. AND 2. A documented trial and failure of, or intolerance to three (3) formulary atypical antipsychotics.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

## Astagraf XL (tacrolimus extended release)

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### Products Affected

- Astagraf XL

PA Criteria	Criteria Details
Covered Uses	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
Covered Uses	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 on dialysis 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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Approved for use in adults only.
<b>Prescriber Restrictions</b>	Must be prescribed by a neurologist or in consultation with a neurologist.
<b>Coverage Duration</b>	Initial approval: 6 months. Renewal: One year.
<b>Other Criteria</b>	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

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)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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. Has 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 photochemotherapy 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a rheumatologist, dermatologist, or gastroenterologist.
<b>Coverage</b>	One year



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.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	at least 12 years old
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	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.
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	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 20000IU/mL if HBeAG positive c) cirrhosis and HBV DNA greater than 2000IU/mL d)high risk factors (more than 40years 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
<b>Age Restrictions</b>	at least 2 years old
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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
<b>Covered Uses</b>	Insomnia. The patient must have a documented treatment failure of all of the following: a. Zolpidem oral tablets. b. A formulary benzodiazepine. c. Trazodone.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Up to one year.
<b>Other Criteria</b>	Quantity Limit: 30 tablets for 30 days.

# Benlysta (belimumab)(COMM, EXC)

## Products Affected

- Benlysta

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Autoantibody positive systemic lupus erythematosus (SLE)2. Lupus Nephritis
<b>Exclusion Criteria</b>	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 or more.
<b>Required Medical Information</b>	1. Documented diagnosis of active, autoantibody positive (e.g. ANA, anti-ds-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]).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Must be prescribed by rheumatologist
<b>Coverage Duration</b>	Initial Approval: 6 months. Continuation: 1 year
<b>Other Criteria</b>	Reauthorization Criteria: Documentation must be submitted demonstrating a clinical benefit has been established and maintained compared to baseline. Code: J0490. 10mg = 1 billable unit

# Berinert (C1 esterase inhibitor, human)(COMM, EXC)

## Products Affected

- Berinert

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diagnosis of hereditary angioedema (HAE)
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with an allergist or immunologist.
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	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 rationale for avoiding LTP must be provided. Preferred Specialty Pharmacy Dispensing Required. Code: J0597. 10 units = 1 billable unit.

# 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	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
<b>Covered Uses</b>	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) 14. Overactive bladder (OAB) (doses of 100 units or less). 15. Upper and lower limb spasticity (over 2 years of age) (doses- Adult: up to 400 units, pediatric upper limb: 200 units, pediatric lower limb: 300 units)
<b>Exclusion Criteria</b>	For migraine prophylaxis: Botox will not be approved if calcitonin gene-related peptide receptors (CGRP) has been used in the last 4 (four) months
<b>Required Medical Information</b>	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 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) in adults who have had an inadequate response to or are intolerant of two anticholinergic



<b>PA Criteria</b>	<b>Criteria Details</b>
	medications used for urinary incontinence such as oxybutynin and tolterodine. 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For migraine headache prophylaxis, Botox must be prescribed by, or in consultation with a neurologist.
<b>Coverage Duration</b>	One year.
<b>Other Criteria</b>	Code: J0585. 1 unit = 1 billable unit.

# Cabenua (cabotegravir / rilpivirine)

## Products Affected

- Cabenuva

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 6 months Renewal: 1 year
<b>Other Criteria</b>	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.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	

# CAPLYTA (lumateperone)

## Products Affected

- Caplyta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1. Schizophrenia - Documents showing trials of at least three (3) formulary atypical antipsychotics a. For a drug to be considered ineffective, you must have used it for at least four (4) weeks. b. If a drug is considered partially effective, you must have used it for at least twelve (12) weeks. 2. Bipolar Disorder I or II - documented diagnosis of bipolar I or II disorder. If using as adjunctive therapy, will be used with either lithium or valproate.
<b>Age Restrictions</b>	at least 18 years of age
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Up to One (1) year
<b>Other Criteria</b>	

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

### Products Affected

- Cayston

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Age 7 and up.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months.
<b>Other Criteria</b>	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
Covered Uses	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 Starter Kit Subcutaneous Prefilled Syringe Kit
- Cimzia Subcutaneous Prefilled Syringe Kit
- Cimzia Subcutaneous Kit 2 X 200 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. 1. Ankylosing spondylitis, Active (AS) 2. Crohns disease, moderate to severe (CD) 3. Plaque psoriasis (psoriasis vulgaris), moderate to severe (PsO) 4. Psoriatic arthritis, Active (PsA) 5. Rheumatoid arthritis, moderate to severe (RA) 6. Non-radiographic Axial Spondyloarthritis (NR-AXSPA)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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, including non-radiographic, 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, Humira, Rinvoq, Xeljanz). 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) c. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents used to treat this indication (e.g., Amjevita, Humira, Skyrizi, Stelara). 3. PsO, moderate to severe: 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 PsO. c. The disease is severe as defined by a total PASI of more than 5 and/or a DLQI score 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 analog, etc.). e. Trial and failure, unless contraindicated or not tolerated, to TWO preferred agents: Amjevita, Enbrel, Humira, Skyrizi, Stelara.

PA Criteria	Criteria Details
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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
<b>Coverage Duration</b>	Approval length: Up to one (1) Year
<b>Other Criteria</b>	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: i. Cyclosporine ii. Leflunomide iii.Methotrexate iv. Sulfasalazine 3. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents used to treat this indication (e.g., Amjevita, Enbrel, Humira, Rinvoq, Skyrizi, Stelara, Xeljanz). 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: i.Hydroxychloroquine ii. Leflunomide iii.Methotrexate iv. Sulfasalazine d. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents used to treat this indication (e.g., Amjevita, Enbrel, Humira, Rinvoq, Xeljanz). 6. NR-AXSPA 1. Trial and failure of NSAID 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)(COMM, EXC)

### Products Affected

- Cinryze

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diagnosis of hereditary angioedema (HAE)
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting: 1. The diagnosis of hereditary angioedema (HAE) has been clinically established by, or in consultation with, an allergist or immunologist, 2. Patient is at least 6 years of age. 3. 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, 4. The member has a history of more than one moderate to severe attack per month (i.e. swelling of the face, throat, or abdomen), 5. Baseline frequency of HAE attacks must be documented, 6. The member is not concurrently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy, 7. The member has had an insufficient response, contraindication, or intolerance to attenuated androgens (i.e. danazol).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with an allergist or immunologist.
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	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.

# CNS Stimulants Ages 19 and Over

## Products Affected

- Dexmethylphenidate HCl
- Dexmethylphenidate HCl ER

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Attention Deficit Hyperactivity Disorder (ADHD). 2. Narcolepsy. 3. Depression. 4. MS Fatigue.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1. ADHD medical records must be provided documenting the following: a. The existence of at least 5 inattentive symptoms or at least 5 hyperactive-impulsive symptoms for at least 6 months. b. Presence of inattentive or hyperactive-impulsive symptoms prior to 12 years of age. c. Inattentive or hyperactive-impulsive symptoms are present in two or more settings (e.g. at home, school, work, with friends or relatives in other activities). d. Symptoms impair or compromise normal functioning. e. Symptoms are not better explained by another mental disorder (e.g. schizophrenia, mood disorder, anxiety disorder, dissociative disorder, personality disorder, or substance abuse. f. The diagnosis has been verified using a standardized rating scale (e.g. Conners Adult ADHD Rating Scale, Wender Adult ADHD Rating Scale, or Adult ADHD Self-Report scale. 2. Narcolepsy - all of the following are required: a. The medication must be prescribed by a sleep specialist or neurologist. b. Diagnosis of narcolepsy with cataplexy or diagnosis of narcolepsy without cataplexy and diagnosis has been confirmed by the following sleep studies: i. polysomnogram ii. a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset random eye movement periods (SOREMPs) on a multiple sleep latency test (MSLT). 3. Depression - One of the following is required: a. Documentation of treatment resistant depression (for augmentation of antidepressant therapy). Treatment resistant depression is defined as a trial of two antidepressant medications at a therapeutic dose for an adequate duration without remission of symptoms. b. Documentation that the patient is with advanced illness and the medication is being used to rapidly treat symptoms of depression (i.e. apathy, fatigue).
<b>Age Restrictions</b>	19 years of age and older.
<b>Prescriber Restrictions</b>	
<b>Coverage</b>	One (1) year.

PA Criteria	Criteria Details
<b>Duration</b>	
<b>Other Criteria</b>	<p>Inattentive Symptoms: Fails to give close attention to details or makes careless mistakes in schoolwork, at work, or during other activities. Has difficulty sustaining attention in tasks or play activities. Does not seem to listen when spoken to directly. Does not follow through on instructions and fails to finish school work, chores, or duties in the workplace. Difficulty organizing tasks and activities. Avoids, dislikes, or is reluctant to engage in tasks that require sustained mental effort. Is easily distracted by extraneous stimuli. If forgetful of daily activities. Hyperactive-Impulsive Symptoms: Often fidgets with or taps hands or feet or squirms in seat. Often leaves seat in situations when remaining in seat is expected. Often runs about and climbs in situations where it is inappropriate. Often unable to play or engage in leisure activities quietly. Is often "on the go" acting as if driven by a motor. Often talks excessively. Often blurts out an answer before the question is completed. 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.</p>

# 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 15 MG, 30 MG
- Codeine Sulfate Oral Tablet 60 MG
- G Tussin AC
- Guaiaatussin AC
- GuaiFENesin AC
- guaiFENesin-Codeine Oral Solution 100-10 MG/5ML
- Promethazine-Codeine Oral Syrup
- traMADol HCl ER
- traMADol HCl Oral Tablet 50 MG
- traMADol-Acetaminophen
- Virtussin A/C

PA Criteria	Criteria Details
<b>Covered Uses</b>	(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.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Not covered for patients under 12 years of age. Prior authorization required for patients 12 to 18 years of age.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Up to 3 months.
<b>Other Criteria</b>	

# Continuous Glucose Monitors (CGM) and Supplies

## Products Affected

- Dexcom G6 Receiver
- Dexcom G6 Sensor
- Dexcom G6 Transmitter
- Dexcom G7 Receiver
- Dexcom G7 Sensor
- FreeStyle Libre 14 Day Reader
- FreeStyle Libre 14 Day Sensor
- FreeStyle Libre 2 Reader
- FreeStyle Libre 2 Sensor
- FreeStyle Libre 3 Reader
- FreeStyle Libre 3 Sensor
- FreeStyle Libre Reader
- FreeStyle Libre Sensor System
- 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
<b>Exclusion Criteria</b>	Patient is pregnant (Freestyle 14 Day and Dexcom 6 only), on dialysis, or critically ill.
<b>Required Medical Information</b>	<p>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.</p>
<b>Age Restrictions</b>	

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One (1) Year
<b>Other Criteria</b>	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.

## Crinone (progesterone gel) (COMM, EXC)

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### Products Affected

- Crinone Vaginal Gel 8 %

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting a cervical length of less than or equal to 20mm prior to 24 weeks and no history of preterm birth.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Through 36 weeks gestation.
<b>Other Criteria</b>	

# Crysvita (burosumab-twza) Criteria

## Products Affected

- Crysvita

PA Criteria	Criteria Details
<b>Covered Uses</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	(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 m <sup>2</sup> ) (7) Requested dose is recommended per the U.S. FDA approved labeling.
<b>Age Restrictions</b>	For XLH at least 6 months of age, for tumor induced osteomalacia at least 2 years of age
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a specialist experienced in the treatment of metabolic bone disorders (i.e., endocrinologist or nephrologist).
<b>Coverage Duration</b>	Initial Length of Approval: 6 months, Renewal Length of Approval: 1 year
<b>Other Criteria</b>	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



PA Criteria	Criteria Details
	vials of 30mg per 4 weeks

# CytoGam (Cytomegalovirus Immune Globulin)(Cent Care)

## Products Affected

- CytoGam

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Prevention of cytomegalovirus (CMV) disease in members undergoing transplantation of kidney, lung, liver, pancreas, or heart, 2. Prevention of CMV in recipients of a bone marrow allograft, 3. Treatment of CMV pneumonitis in combination with ganciclovir in recipients of a bone marrow allograft.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication and planned course of therapy
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Code: J0850. 1 vial = 1 billable unit

# 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)
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	18 years or greater
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Quantity Limit: 30 tablets per 30 days

# Dayvigo (lemborexant)

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**Products Affected**

- DayVigo

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Delatestryl (testosterone enanthate injection)(COMM, EXC)

## Products Affected

- Testosterone Enanthate Intramuscular Solution

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
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	1. Primary hypogonadism in men (congenital or acquired). Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, 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 (16 years of age and up)- Specific criteria apply. Refer to the Gender Dysphoria Treatment Criteria located on phs.org.
<b>Age Restrictions</b>	18 years or greater
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 alkalization. (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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Wilson's Disease: 1 year, Cystinuria: 6 months
<b>Other Criteria</b>	Cystinuria continuation of therapy criteria: Documentation of benefit must be submitted (i.e. decrease in stone formation).

# Depo-Testosterone (testosterone cypionate injection)(COMM, EXC)

## Products Affected

- Testosterone Cypionate Intramuscular Solution 100 MG/ML, 200 MG/ML

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
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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 (16 years of age and up)- Specific criteria apply. Refer to the Gender Dysphoria Treatment Criteria located on phs.org.
<b>Age Restrictions</b>	18 years or greater
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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 tolerated. -OR- 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.</p>
<b>Age Restrictions</b>	
<b>Prescriber</b>	



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Restrictions</b>	
<b>Coverage Duration</b>	One (1) year
<b>Other Criteria</b>	

## Dificid (fidaxomicin)(COMM, EXC)

### Products Affected

- Dificid Oral Suspension Reconstituted

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

# Dupixent (dupilumab)

## Products Affected

- Dupixent

PA Criteria	Criteria Details
<b>Covered Uses</b>	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)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 pre-bronchodilator 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. 12 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).
<b>Age Restrictions</b>	

PA Criteria	Criteria Details
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with an allergist, immunologist, dermatologist, pulmonologist, orolaryngologist, gastroenterologist.
<b>Coverage Duration</b>	Up to one (1) year
<b>Other Criteria</b>	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 (abobotulinum toxin A) (COMM/EXCH/Cent Care)

## Products Affected

- Dysport

PA Criteria	Criteria Details
<b>Covered Uses</b>	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 hallucis 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 upper or lower limb spasticity (ages 2 and older) in accordance with approved dosage listed in the prescribing information.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Up to one year.
<b>Other Criteria</b>	Code: J05865 units = 1 billable unit

# Edecrin (ethacrynic acid) Comm/HIX

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## 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 tosesemide.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of contraindications to formulary alternatives and/or previous therapeutic trials.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Up to one year.
<b>Other Criteria</b>	N/A

## Effient (prasugrel)(COMM, EXC)

### 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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Must be less than 75 years of age
<b>Prescriber Restrictions</b>	Must be prescribed by cardiologist
<b>Coverage Duration</b>	up to 1 year
<b>Other Criteria</b>	Quantity Limit: 30 tablets per 30 days

## Elmiron (pentosan)(COMM, EXC)

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### Products Affected

- Elmiron

PA Criteria	Criteria Details
Covered Uses	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(COMM, EXC)

## Products Affected

- Aprepitant Oral Capsule 150 MG
- Emend Intravenous Solution Reconstituted

PA Criteria	Criteria Details
<b>Covered Uses</b>	Prevention of chemotherapy induced nausea and vomiting (CINV)
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1. The patient must be receiving Emend in combination with a 5-HT3 antagonist and dexamethasone. AND 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Six (6) months
<b>Other Criteria</b>	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.

# 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)
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Six (6) months.
<b>Other Criteria</b>	Quantity Limit: Six (6) kits for 28 days.

## Emsam Patch (selegiline patch)(COMM, EXC)

### Products Affected

- Emsam

PA Criteria	Criteria Details
<b>Covered Uses</b>	Treatment of major depressive disorder
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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)
<b>Age Restrictions</b>	18 years or greater
<b>Prescriber Restrictions</b>	Must be prescribed by a psychiatrist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Quantity Limit: 30 patches per 30 days

# Enbrel (etanercept)(COMM, EXC)

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Ankylosing spondylitis (AS) 2. Polyarticular juvenile idiopathic arthritis (JIA), 3. Psoriatic arthritis (PsA), 4. Plaque psoriasis (PsO) 5. Rheumatoid arthritis (RA)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1)AS - Trial and failure of NSAID. Patient s with peripheral arthritis must have a trial of sulfasalazine. Patients with axial disease and failure of NSAIDs can be started on Enbrel without a trial of sulfasalazine. 2)JIA minimum of 3 months of current and continuous follow-up AND minimum of 3-month trial of ONE of the following: methotrexate, leflunomide, hydroxychloroquine, sulfasalazine, minocycline, or gold salt3)PsA at least a three months trial of one of the following: cyclosporine, leflunomide (LEF), MTX, SSZ 4)RA - DAS-28 over 3.2 or CDAI over 10.1, minimum of 3 months of current and continuous follow-up, min. 3 month trial of one of the following: azathioprine, gold salt, hydroxychloroquine, leflunomide, methotrexate, minocycline, sulfasalazine5)PsO Involvement of 10% or more Body Surface Area (BSA) (or 5% or more of BSA if psoriasis affects hands, feet, face or genitals). PASI of 10 or more or DLQI of 10 or more. Failure of a 3-month trial with phototherapy or photochemotherapy or MTX.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	1. AS- prescribed by or in consultation with a rheumatologist 2. JIA- prescribed by or in consultation with a rheumatologist 3. PsA- prescribed by or in consultation with a dermatologist or rheumatologist 4. PsO- prescribed by or in consultation with a dermatologist 5. RA- prescribed by or in consultation with a rheumatologist
<b>Coverage Duration</b>	Up to 1 year
<b>Other Criteria</b>	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

PA Criteria	Criteria Details
	Specialty Pharmacy is required. CONTINUATION CRITERIA: Documentation of positive response with Enbrel treatment

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

## Products Affected

- Entresto

PA Criteria	Criteria Details
<b>Covered Uses</b>	A documented diagnosis of NYHA Class II-IV heart failure with a LVEF equal to or less than 40%.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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 medications. 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/L Continuation 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.
<b>Age Restrictions</b>	Pediatric and adult patients at least one year of age.
<b>Prescriber Restrictions</b>	Prescribed by a cardiologist or in consultation with a cardiologist.
<b>Coverage Duration</b>	One year.
<b>Other Criteria</b>	Quantity limit of 60 tablets for 30 days.

# 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. Crohns disease, moderate to severe (CD) 2. Ulcerative Colitis (UC), moderate to severe
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) CD- Inadequate response to at least ONE of the following: corticosteroids, methotrexate (MTX), thiopurines, or antibiotics AND two 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
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist
<b>Coverage Duration</b>	Initial approval length: 4 months. Continuation approval length: 12 months
<b>Other Criteria</b>	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

# Erythromycin suspension for ages greater than 12 years old

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**Products Affected**

- E.E.S. Granules
- EryPed 200
- EryPed 400
- Erythromycin Ethylsuccinate Oral Suspension Reconstituted 200 MG/5ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Indications for Approval: Documentation that the patient is unable to swallow oral tablets or capsules AND The patient is not currently taking other medications in an oral tablet or capsule form.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Course of Therapy
<b>Other Criteria</b>	



# Ethyol (amifostine)(COMM)

## Products Affected

- Ethyol

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	N/A

# Eucrisa (crisaborole)

## Products Affected

- Eucrisa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Atopic Dermatitis
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documents must show 1) ISGA grade of at least 3 atopic dermatitis as defined at: <a href="http://www.eucrisahcp.com/study-design#tabbed-content-12">www.eucrisahcp.com/study-design#tabbed-content-12</a> ) Failure of at least one low potency topical corticosteroid AND 3) failure of at least one medium or high potency topical corticosteroid AND 4) failure of at least one topical immunomodulatory therapy such as pimecrolimus or tacrolimus
<b>Age Restrictions</b>	minimum 3 months
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Continuation criteria: Documents showing a decrease in severity by at least 2 (two) point from baseline

# Euflexxa (sodium hyaluronate 1%)(COMM, EXC)

## Products Affected

- Euflexxa Intra-Articular Solution Prefilled Syringe

PA Criteria	Criteria Details
<b>Covered Uses</b>	Osteoarthritis (OA) of the knee
<b>Exclusion Criteria</b>	Not covered for OA of joints other than knee joints
<b>Required Medical Information</b>	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 ( $2.00 \times 10^9/L$ ) 2. The pain cannot be attributed to other forms of joint disease (e.g. acute knee injuries, rheumatoid arthritis, patella-femoral 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial approval: One (1) series of 3 injections.
<b>Other Criteria</b>	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

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

# Feraheme (ferumoxytol)(COMM, EXC)

## Products Affected

- Ferumoxytol

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 time
<b>Other Criteria</b>	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.

# Ferrlecit (sodium ferric gluconate complex)(COMM, EXC)

## Products Affected

- Ferrlecit
- Na Ferric Gluc Cplx in Sucrose

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 time
<b>Other Criteria</b>	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

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)(COMM, EXC)

## Products Affected

- Icatibant Acetate

PA Criteria	Criteria Details
<b>Covered Uses</b>	Hereditary angioedema (HAE) type 1 or 2
<b>Exclusion Criteria</b>	Prophylaxis treatment OR Younger than 18 years of age
<b>Required Medical Information</b>	Documentation of the following: 1) diagnosis was made by an allergist or immunologist 2) 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 3) History of at least one moderate/severe attack per month 4) Baseline HAE attacks 5) Not taking an angiotensin converting enzyme inhibitor or estrogen replacement therapy 6) Patient must have tried and failed or have a medical reason for not using Berinert
<b>Age Restrictions</b>	At least 18 years of age
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 4 months, Continuation: 6 months
<b>Other Criteria</b>	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 rationale for avoiding LTP must be provided. Preferred Specialty Pharmacy Dispensing Required.



# Firdapse (amifampridine)

## Products Affected

- Firdapse

PA Criteria	Criteria Details
Covered Uses	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

## Flublok (influenza vaccine)

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**Products Affected**

- Flublok Quadrivalent

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documents must show that the patient has an allergy to eggs and/or egg containing products
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	up to six (6) months
<b>Other Criteria</b>	

# Forteo (teriparatide)(COMM, EXC)

## Products Affected

- Forteo Subcutaneous Solution Pen- Injector

PA Criteria	Criteria Details
<b>Covered Uses</b>	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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year, Cumulative use of PTH analogs for greater than 2 years will not be approved
<b>Other Criteria</b>	

# Fortesta (testosterone topical gel)(COMM, EXC)

## 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
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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 (16 years of age and up)- Specific criteria apply. Refer to the Gender Dysphoria Treatment Criteria located on phs.org.
<b>Age Restrictions</b>	18 years or greater
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Must have a documented trial and failure of topical testosterone gel. Quantity Limit: two (2) canisters (120 g) for 30 days.

# Fosrenol (lanthanum carbonate)

## Products Affected

- Lanthanum Carbonate

PA Criteria	Criteria Details
Covered Uses	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)(COMM, EXC)

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Up to 6 months
<b>Other Criteria</b>	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)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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 <math>100 \times 10^9/L</math>, neutrophils less than <math>1 \times 10^9/LD</math>. 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</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval: 2 months, Continuation: 3 months
<b>Other Criteria</b>	Continuation of therapy Criteria: Documentation of clinical improvement in symptoms

# Gamunex-C (Subcutaneous Immune Globulin)(COMM)

## Products Affected

- Flebogamma DIF

PA Criteria	Criteria Details
<b>Covered Uses</b>	Primary immunodeficiencies including, but not limited to: a. Congenital agammaglobulinemia (X-linked agammaglobulinemia), b. Hypogammaglobulinemia, c. Common variable immunodeficiency, d. X-linked immunodeficiency, e. Severe combined immunodeficiency, f. Wiskott-Aldrich syndrome.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required AND There is sufficient documentation of infusion reactions with IVIG or inability to obtain IV access.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	up to 1 year
<b>Other Criteria</b>	N/A



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

## Products Affected

- Gel-One Intra-Articular Prefilled Syringe

PA Criteria	Criteria Details
<b>Covered Uses</b>	Osteoarthritis (OA) of the knee
<b>Exclusion Criteria</b>	Not covered for OA of joints other than knee joints.
<b>Required Medical Information</b>	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 ( $2.00 \times 10^9/L$ ), 2. The pain cannot be attributed to other forms of joint disease (e.g. acute knee injuries, rheumatoid arthritis, patella-femoral 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	See Other Criteria section for coverage duration details.
<b>Other Criteria</b>	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

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

# GLP-1 Agonists (COMM/EXCH)

## Products Affected

- Mounjaro
- Trulicity

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diabetes Mellitus Type 2
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1.Diagnosis of Type 2 Diabetes Mellitus (T2DM).2.Uncontrolled T2DM as evidenced by an A1c of 7% or greater that has been measured within the past 90 days.3.The patient failed metformin, either as monotherapy or combinaton therapy,unless contraindicated or not tolerated.4.The member has tried and failed 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., Januvia), unless contraindicated or not tolerated.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	

# Granulocyte-Colony Stimulating Factors

## Products Affected

- |   |             |
|---|-------------|
| • Fulphila                                | Syringe     |
| • Neulasta Onpro                          | • Zarxio    |
| • Udenyca Subcutaneous Solution Prefilled | • Ziextenzo |

PA Criteria	Criteria Details
<b>Covered Uses</b>	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/mm <sup>3</sup> 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/mm <sup>3</sup> 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.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

PA Criteria	Criteria Details
<b>Coverage Duration</b>	Up to 1 Year
<b>Other Criteria</b>	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
<b>Covered Uses</b>	Hereditary angioedema (HAE) type 1 or 2
<b>Exclusion Criteria</b>	Will not be approved in combination with other prophylactic treatments. Younger than 12 years old.
<b>Required Medical Information</b>	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 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 9) Documented trial and failure of Takhzyro
<b>Age Restrictions</b>	At least 12 years of age
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 4 weeks, Continuation: 6 months
<b>Other Criteria</b>	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 rationale for avoiding LTP must be provided. Preferred Specialty Pharmacy Dispensing Required.

# Hepatitis C Treatment Criteria(COMM, EXC)

## Products Affected

- Mavyret
- Pegasys Subcutaneous Solution 180 MCG/ML
- Ribavirin Oral Capsule
- Ribavirin Oral Tablet 200 MG
- Sofosbuvir-Velpatasvir

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1. Patient must be diagnosed with Chronic Hepatitis Infection 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 requests (only patients with cirrhosis), g. Absolute Neutrophil Count (ANC), h. Hemoglobin (Hgb), i. Serum Creatinine (SCr).
<b>Age Restrictions</b>	3 years of age and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Length of approval will be dependent on multiple factors and must be recommended in either the medic
<b>Other Criteria</b>	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 log 10 IU/ml by week 12), ii. Partial responders (greater than 2 log 10 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.

# Humira (adalimumab)(COMM, EXC)

## Products Affected

- Humira (2 Syringe) Subcutaneous MG/0.4ML  
Prefilled Syringe Kit 20 MG/0.2ML, 40

PA Criteria	Criteria Details
<b>Covered Uses</b>	1.Ankylosing spondylitis (AS)2.Rheumatoid arthritis (RA)3.Polyarticular juvenile idiopathic arthritis (JIA)4.Psoriatic arthritis (PsA) 5.Plaque psoriasis (PsO)-chronic, moderate to severe6.Crohn's Disease (CD)-moderate to severe7.Ulcerative Colitis (UC)-moderate to severe8.Hidradenitis Suppurativa (HS)9.Uveitis
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1)AS - Trial and failure of NSAID. Patients with peripheral arthritis must have a trial of sulfasalazine (SSZ). Patients with axial disease and failure of NSAIDs can be started on Humira without a trial of SSZ. 2)PsA Three months or more trial of ONE of the following:cyclosporine, leflunomide (LEF), methotrexate (MTX), SSZ.3)JIA minimum of 3 months current and continuous follow-up AND at least 3 months trial of ONE of the following: Gold salt, hydroxychloroquine (HCQ), LEF, MTX, minocycline, SSZ. 4)RA-DAS-28 over 3.2 or CDAI over 10.1, minimum of 3 months of current and continuous follow-up, min. 3-month trial of one of the following: azathioprine (AZA), gold salt, HCQ, LEF, MTX, minocycline, SSZ. 5)CD- Induction and maintenance of remission in moderate to severe CD. Inadequate response to ONE (1) or more of the following: antibiotics (metronidazole, quinolones), corticosteroids (prednisone, prednisolone, dexamethasone, budesonide), MTX, thiopurines (AZA, mercaptopurine(6-MP)). 6)UC adequate trial (3 months or more) or intolerance to one of the following: 5-aminosalicylates (balsalazide, mesalamine, sulfasalazine), cyclosporine, steroids, thiopurines (azathioprine 6-MP), 7)PsO Involvement of 10% or more Body Surface Area (BSA) (or 5% or more of BSA if psoriasis affects hands, feet, face or genitals). PASI of 10 or more or DLQI of 10 or more. Adequate trial and failure of at least three (3) months of a topical agent (topical corticosteroid, topical calcineurin inhibitor, topical vitamin D analogs, etc.), 8)HS Hurley Stage III HS or refractory Hurley Stage II HS and a trial of antibiotic (topical 1% clindamycin, doxycycline) or hormonal therapy (finasteride),9)Uveitis Non-infectious intermediate, posterior and pan-uveitis in adults who have a trial and failure, contraindications, or intolerance to conventional therapy such as ophthalmic or systemic corticosteroids AND immunosuppressive drugs (e.g. AZA, cyclosporine,MTX, tacrolimus)



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	1.)AS, JIA, RA- prescribed by or in consultation with a rheumatologist 2.)PsA- prescribed by or in consultation with a dermatologist or rheumatologist 3.)CD, UC- prescribed by or in consultation with a gastroenterologist 4.)HS, PsO- prescribed by or in consultation with a dermatologist 5.) Uveitis- prescribed by or in consultation with an ophthalmologist or rheumatologist
<b>Coverage Duration</b>	Up to One (1) year
<b>Other Criteria</b>	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: Documents must show benefit with treatment

# Humira (adalimumab)(COMM, EXC, Cent Care)

## Products Affected

- Humira (2 Pen)
- Humira (2 Syringe) Subcutaneous Prefilled Syringe Kit 10 MG/0.1ML, 40 MG/0.8ML
- Humira-CD/UC/HS Starter
- Humira-Ped<40kg Crohns Starter
- Humira-Ped>=40kg Crohns Start
- Humira-Ped>=40kg UC Starter
- Humira-Psoriasis/Uveit Starter

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Rheumatoid arthritis (RA), 2. Polyarticular juvenile idiopathic arthritis (JIA), 3. Ankylosing spondylitis (AS), 4. Psoriatic arthritis (PsA), 5. Plaque psoriasis (PsO), 6. Crohn's Disease (CD), 7. Ulcerative Colitis (UC), 8. Hidradenitis Suppurativa (HS), 9. Uveitis
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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 Humira 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. 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. 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)
<b>Age Restrictions</b>	N/A

PA Criteria	Criteria Details
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	One Year
<b>Other Criteria</b>	<p>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: a. Prescribed by or in consultation with a dermatologist. b. Documented diagnosis of Hurley Stage III HS or refractory Hurley Stage II hidradenitis suppurativa and the following: i. A trial and failure of antibiotic therapy (i.e. topical 1% clindamycin, doxycycline) or hormonal therapy (finasteride). 9. Uveitis: a. Prescribed by or in consultation with an ophthalmologist or rheumatologist. b. Documented diagnosis of non-infectious intermediate, posterior and panuveitis in adult patients and meets the following: i. A documented trial and failure, contraindication, or intolerance to 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.</p>

## Humulin u-500 (insulin human regular)

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**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.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Up to One (1) year
<b>Other Criteria</b>	

# Hylenex (hyaluronidase Human)

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**Products Affected**

- Hylenex

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

# 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	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 Capsule
- Imbruvica Oral Suspension
- 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.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1.Chronic graft versus host disease (cGVHD): Patient must have a documented trial and failure of prednisone and a calcineurin 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	

# Imfinzi (durvalumab)

## Products Affected

- Imfinzi

PA Criteria	Criteria Details
Covered Uses	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)(COMM, EXC)

### Products Affected

- Increlex

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1. Severe Primary IGFD is defined by all of the following: a. Height standard deviation score of -3.0 or less, b. Basal IGF-1 standard deviation score of -3.0 or less, 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).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	up to 1 year
<b>Other Criteria</b>	Preferred Specialty Pharmacy Dispensing Required.

# INFeD (iron dextran)(COMM, EXC)

## Products Affected

- Infed

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 time
<b>Other Criteria</b>	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

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

# Injectafer (ferric carboxymaltose)(Cent Care)

## Products Affected

- Injectafer

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting: Iron Deficiency anemia defined as (without chronic kidney disease): -Hemoglobin (Hgb) less than 13 gm/dL for males and less than 12 gm/dL for females, AND-Ferritin less than or equal to 30 ng/mL, OR- FeSat less than or equal to 20% OR Iron Deficiency anemia defined as (with chronic kidney disease):-Hemoglobin (Hgb) less than 13 gm/dL for males and less than 12 gm/dL for females, AND-Ferritin less than or equal to 500 ng/mL-FeSat less than or equal to 30%
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 time
<b>Other Criteria</b>	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.

# Injectafer (ferric carboxymaltose)(COMM, EXC)

## Products Affected

- Injectafer

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 time
<b>Other Criteria</b>	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

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
<b>Covered Uses</b>	<p>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).</p>
<b>Exclusion Criteria</b>	<p>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,</p>

PA Criteria	Criteria Details
	<p>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.</p> <p>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.</p>
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Up to 1 year
<b>Other Criteria</b>	<p>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</p>



PA Criteria	Criteria Details
	<p>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 alloimmune 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 Syndrome 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.</p>

# Kalbitor (ecallantide)(COMM, EXC)

## Products Affected

- Kalbitor

PA Criteria	Criteria Details
<b>Covered Uses</b>	Hereditary angioedema (HAE) type 1 or 2- for abdominal, facial, or laryngeal acute attacks
<b>Exclusion Criteria</b>	Prophylaxis treatment Younger than 12 years of age
<b>Required Medical Information</b>	Documentation of the following: 1) diagnosis was made by an allergist or immunologist 2) 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 3) History of at least one moderate/severe attack per month 4) Baseline HAE attacks 5) Not taking an angiotensin converting enzyme inhibitor or estrogen replacement therapy 6) Patient must have tried and failed or have a medical reason for not using Berinert and Firazyr
<b>Age Restrictions</b>	At least 12 year of age
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 4 months, Continuation: 6 months
<b>Other Criteria</b>	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 rationale for avoiding LTP must be provided. Preferred Specialty Pharmacy Dispensing Required.

# Kalydeco (ivacaftor)

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 dolosa, or Mycobacterium abscessus 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.
<b>Age Restrictions</b>	Patient is within FDA approved ages
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial Approval: 6 months Reauthorization: 1 Year
<b>Other Criteria</b>	Continuation Criteria: All of the following must be met: 1. Patient's 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 dolosa, or Mycobacterium abscessus 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) COMM/EXCH

## Products Affected

- Kevzara

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Rheumatoid Arthritis, Moderate to Severe (RA), Polymyalgia Rheumatica (PMR)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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. 3. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents used to treat the same indication (e.g., Enbrel, Humira, Rinvoq, Xeljanz). PMR: 1. Inadequate response to corticosteroid therapy. 2. At least one episode of unequivocal PMR flare while attempting to taper corticosteroids.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Up to 12 months
<b>Other Criteria</b>	1. The patient must have a current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test prior to initiation of therapy. 2. Continuation criteria: Documentation of positive response to treatment with Kevzara.

# Kombiglyze XR (saxagliptin/metformin ER)(COMM, EXC)

## Products Affected

- sAXagliptin-metFORMIN ER

PA Criteria	Criteria Details
Covered Uses	Diabetes Mellitus Type 2
Exclusion Criteria	N/A
Required Medical Information	The patient must have a recent (within the past 3 months) documented A1C level of less than 11 AND the patient is concurrently taking a metformin product and has inadequate glycemic control after a trial at a therapeutic dose and requires the addition of another agent.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Continuation of Therapy Criteria: The A1C must decrease by 0.5% or more from the initial A1c. Quantity Limit: 30 tablets per 30 days. Quantity Limit: 2.5/1000mg - 60 tablets for 30 days, 5/500mg - 30 tablets for 30 days, 5-1000mg - 30 tablets for 30 days.

# Kuvan (sapropterin dihydrochloride) Criteria

## Products Affected

- Sapropterin Dihydrochloride Oral Packet

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diagnosis of phenylketonuria
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	(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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Metabolic disease specialist
<b>Coverage Duration</b>	Initial Length of Approval: 1 month, Continuation: Up to 1 year (dependent on response)
<b>Other Criteria</b>	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.

# Kynmobi (apomorphine HCl)

## Products Affected

- Kynmobi
- Kynmobi Titration Kit

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1. Documents showing current oral carbidopa/levodopa and attempts to adjust dosing or formulations 2. at least one other agent has been trialed for an adequate length of time to reduce number and frequency of off episodes
Age Restrictions	
Prescriber Restrictions	Started by a neurologist
Coverage Duration	Initial 6 months, Maintenance 1 year
Other Criteria	

# LAMICTAL XR (lamotrigine)

## Products Affected

- lamoTRIGine ER

PA Criteria	Criteria Details
Covered Uses	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	



# Latuda (lurasidone)

## Products Affected

- Lurasidone HCl

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documents showing the following: 1.Schizophrenia: a. The patient must have a trial and failure of three (3) 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 and aripiprazole or there is clinical documentation why they are not clinically appropriate. 2. Bipolar 1 Disorder, Depression (Bipolar 1 disorder with depressed phase): The patient must have a documented intolerance, side effects or lack of efficacy to quetiapine
Age Restrictions	N/A
Prescriber Restrictions	Must be initiated by a psychiatrist or in consultation with a psychiatrist for all indications.
Coverage Duration	Up to one Year
Other Criteria	

# Letairis (ambrisentan)(COMM, EXC)

## Products Affected

- Ambrisentan

PA Criteria	Criteria Details
<b>Covered Uses</b>	Documented primary or secondary pulmonary arterial hypertension (WHO Class II or III) which is defined as a mean pulmonary arterial pressure greater than 25mmHg at rest or greater than 30mmHg during exercise, with a normal pulmonary capillary wedge pressure. 2. In combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening pulmonary arterial hypertension (PAH), and to improve exercise ability.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial Approval: 6 months. Continuation: 1 year
<b>Other Criteria</b>	Continuation of Therapy: 1. Improved exercise capacity, 2. Delay in clinical worsening. Preferred Specialty Pharmacy Dispensing Required. Quantity Limit: 30 tablets per 30 days.

# Liquid drugs

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**Products Affected**

- Enalapril Maleate Oral Solution
- Qbrelis
- Xatmep

PA Criteria	Criteria Details
Covered Uses	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 from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	at least 18 years old
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	

# Lo-Loestrin Fe (norethindrone acetate and ethinyl estradiol, ethinyl estradiol and ferrous fumarate)

## Products Affected

- Lo Loestrin Fe

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Pharmacy claims for two different, 84-days supply of oral contraceptives, one of which must be considered and "ultra low" oral contraceptive (i.e. 20mcg of estrogen or less)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year
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
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Prior authorization only applies to quantities exceeding 30 syringes in a 90 day period
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	See below
<b>Other Criteria</b>	Active Cancer diagnosis: 6 months, Pregnancy: Up to 6 weeks after delivery Date, other indications: up to 6 months

# MAVENCLAD (cladribine)

## Products Affected

- Mavenclad (10 Tabs)
- Mavenclad (4 Tabs)
- Mavenclad (5 Tabs)
- Mavenclad (6 Tabs)
- Mavenclad (7 Tabs)
- Mavenclad (8 Tabs)
- Mavenclad (9 Tabs)

PA Criteria	Criteria Details
<b>Covered Uses</b>	Relapsing forms of multiple sclerosis, including relapsing-remitting and active secondary progressive disease.
<b>Exclusion Criteria</b>	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)
<b>Required Medical Information</b>	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 hepatitis, TB. 8. The patient has not already received two years of therapy with Mavenclad.
<b>Age Restrictions</b>	Over 18 years of age
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist in the treatment of MS (e.g.neurologist)
<b>Coverage Duration</b>	Up to six (6) months
<b>Other Criteria</b>	Specialty Pharmacy Required

# MAYZENT (SIPONIMOD)

## Products Affected

- Mayzent Oral Tablet 0.25 MG, 2 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	Secondary progressive multiple sclerosis(SPMS)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 must 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
<b>Age Restrictions</b>	Over 18 years of age
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist in the treatment of MS (e.g., neurologist)
<b>Coverage Duration</b>	Up to six (6) months
<b>Other Criteria</b>	Specialty Pharmacy Required. Quantity Limit: 0.25 mg tablet: 120 for 30 days, 2 mg: 30 tabs per 30 days



# Megace ES (megestrol)(COMM, EXC)

## Products Affected

- Megestrol Acetate Oral Suspension 400 MG/10ML, 625 MG/5ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A

# methyphenidate solution

## Products Affected

- Methyphenidate HCl Oral Solution

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For patients over the age of 12 years, documents must show that the patient is unable to swallow tablets and are not currently taking other oral non-dissolving tablets or capsulesFor patients age 19 and up to treat ADHD, the following Cerebral Stimulant Adult Criteria also apply - medical records documenting all of the following: a. The existence of at least 5 inattentive symptoms or at least 5 hyperactive-impulsive symptoms for at least 6 months, b. Presence of inattentive of hyperactive-impulsive symptoms prior to age 12, c. Inattentive or hyperactive-impulsive symptoms present in two or more settings. d. Symptoms impair or compromise normal functioning e. Symptoms are not better explained by another mental disorder.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Migraine

## Products Affected

- Aimovig

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Chronic Migraine 2. Episodic Migraine
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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.</p>
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or headache specialist.
<b>Coverage Duration</b>	Initial: 3 months. Continuation: Up to 12 months
<b>Other Criteria</b>	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.

# Mulpleta (lusutrombopag)

## Products Affected

- Mulpleta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Low risk procedures such as paracentesis, routine endoscopy, or central line placement
<b>Required Medical Information</b>	Documents must show that 1) procedure date is within 8(eight) to 14 (fourteen) days from request date 2)Baseline platelets are less than $50 \times 10^9/L$ 3) the procedure carries and intermediate to high risk of bleeding (i.e. spinal surgery, cardiac surgery, large polypectomy, liver biopsy)
<b>Age Restrictions</b>	at least 18 years old
<b>Prescriber Restrictions</b>	gastroenterologist, hematologist, or hepatologist
<b>Coverage Duration</b>	7 days (one course only)
<b>Other Criteria</b>	

## Multaq (dronedarone)(COMM, EXC)

### Products Affected

- Multaq

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Quantity Limit: 60 tablets for 30 days.

# MYOBLOC (rimabotulinumtoxinB)

## Products Affected

- Myobloc

PA Criteria	Criteria Details
<b>Covered Uses</b>	1.) Cervical Dystonia 2.) Chronic Sialorrhea (Excessive Salivation)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1.) Chart notes documenting medical indication. 2.)For Chronic Sialorrhea must have documented use on an anticholinergic (i.e. amitriptyline, atropine, glycopyrrolate, hyoscyamine, ipratropium bromide)
<b>Age Restrictions</b>	at least 18 years of age
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	up to one (1) year
<b>Other Criteria</b>	Code: J0587. 100 units = 1 billable unit

# NAYZILAM (midazolam)

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**Products Affected**

- Nayzilam

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	



# 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).
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	Initial Approval - one month. Continuation of therapy - 6 months.
<b>Other Criteria</b>	Quantity Limit: 60 tablets for 30 days.

# 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Must be prescribed by a sleep specialist or neurologist.
<b>Coverage Duration</b>	Up to one year.
<b>Other Criteria</b>	Quantity Limit: 30 tablets per 30 days

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

### Products Affected

- Ocrevus
- Oncaspar Injection

PA Criteria	Criteria Details
Covered Uses	A diagnosis of multiple sclerosis
Exclusion Criteria	N/A
Required Medical Information	Chart notes documenting diagnosis and previous medication trials and outcomes.
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by a neurologist.
Coverage Duration	Up to one year.
Other Criteria	A trial and failure of a preferred interferon or glatiramer. Specialty pharmacy required.

# Ofev (nintedanib)

## Products Affected

- Ofev

PA Criteria	Criteria Details
<b>Covered Uses</b>	Interstitial pulmonary fibrosis (IPF) or Interstitial lung disease (ILD)
<b>Exclusion Criteria</b>	Will not be approved in combination with Esbriet (pirfenidone)
<b>Required Medical Information</b>	(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
<b>Age Restrictions</b>	at least forty (40) years of age
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a Pulmonologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Continuation Criteria 1. Predicted FVC has not declined by 10% or more OR more than 200mL decrease 2. Patient continues to be smoke free

# Omnipod Dash

## Products Affected

- Omnipod 5 G6 Intro (Gen 5)
- Omnipod 5 G6 Pods (Gen 5)
- Omnipod DASH Intro (Gen 4)
- Omnipod DASH Pods (Gen 4)

PA Criteria	Criteria Details
<b>Covered Uses</b>	Diabetes Mellitus Type 1 or 2
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	1 year for pods
<b>Other Criteria</b>	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

# Omnitrope (somatotropin)(COMM, EXC)

## Products Affected

- Omnitrope Subcutaneous Solution Cartridge

PA Criteria	Criteria Details
Covered Uses	<p>Indications for approval in CHILDREN (up to age 18): All of 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 IGF-1 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 provided that 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 and less than 4 cm per year if greater than 3 years of age. c) Existing metabolic derangements (such as acidosis, secondary hyperparathyroidism, malnutrition) have been corrected. d) Documentation provided that 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 gestational age of more than 37 weeks or a birth weight or length below the 3rd percentile for gestational age. b. Documented lack of sufficient catch-up growth by age 2 and height less than 2 SD for chronological age 5. NOONAN SYNDROME AND PRADER-WILLI SYNDROME a. Diagnosis confirmed by appropriate genetic testing. b. Documentation provided that epiphyses are not closed. See Required Medical Information for additional</p>

PA Criteria	Criteria Details
	covered uses.
Exclusion Criteria	N/A
Required Medical Information	<p>ADULTS: All of 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.</p>
Age Restrictions	N/A
Prescriber Restrictions	Evaluation by an endocrinologist
Coverage Duration	up to 1 year
Other Criteria	<p>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 of 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</p>

PA Criteria	Criteria Details
	<p>for treatment with 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 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.</p>



# Oncology

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## Products Affected

- Abraxane
- Adcetris
- Alecensa
- Alimta
- Aliqopa
- Alunbrig
- Ayvakit Oral Tablet 100 MG, 200 MG, 300 MG
- Balversa
- Bavencio
- Beleodaq
- Besponsa
- Bexarotene Oral
- Blenrep
- Blynicyto
- Braftovi Oral Capsule 75 MG
- Brukinsa
- Calquence
- 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
- Imatinib Mesylate
- Inlyta
- Inqovi
- Jakafi
- Jaypirca
- Jelmyto
- Kadcyla
- Keytruda Intravenous Solution
- Kiskali (200 MG Dose)
- Kiskali (400 MG Dose)
- Kiskali (600 MG Dose)
- Kiskali Femara (200 MG Dose) Tablet Therapy Pack 200 & 2.5 MG Oral
- Kiskali Femara (400 MG Dose) Tablet Therapy Pack 200 & 2.5 MG Oral
- Kiskali Femara (600 MG Dose) Tablet Therapy Pack 200 & 2.5 MG Oral
- 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
- Lumoxiti
- Lynparza Oral Tablet
- Marqibo
- Matulane
- Mekinist Oral Tablet
- Mektovi
- Monjuvi
- Myleran
- Mylotarg Intravenous Solution

- Reconstituted 4.5 MG
- Nerlynx
- Nubeqa
- Odomzo
- Opdivo Intravenous Solution 100 MG/10ML, 240 MG/24ML, 40 MG/4ML
- Orserdu
- Padcev
- PAZOPanib HCl
- Pemazyre
- Perjeta
- Piqray (200 MG Daily Dose)
- Piqray (250 MG Daily Dose)
- Piqray (300 MG Daily Dose)
- Polivy
- Pomalyst
- Poteligeo
- Provenge Intravenous Suspension
- Qinlock
- Retevmo
- romiDEPsin Intravenous Solution
- Rozlytrek Oral Capsule
- Rubraca
- Rybrevant
- Rydapt
- Sarclisa
- SORafenib Tosylate
- Stivarga
- SUNItinib Malate
- Tabloid
- Tabrecta
- Tafenlar Oral Capsule
- Tagrisso
- Talzenna
- Tazverik
- Tecentriq
- Temozolomide
- Thalomid
- Tibsovo
- Trelstar Mixject
- Trodelvy
- Tukysa
- Ukoniq
- 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) Oral Tablet Therapy Pack 20 MG
- Xpovio (60 MG Twice Weekly)
- Xpovio (80 MG Once Weekly)
- Xpovio (80 MG Twice Weekly)
- Yervoy
- Zaltrap
- Zejula
- Zelboraf
- Zepzelca
- Zirabev
- Zolanza
- Zydelig

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.
<b>Exclusion Criteria</b>	
<b>Required</b>	

PA Criteria	Criteria Details
<b>Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	up to 6 months
<b>Other Criteria</b>	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.

# Ongentys (opicapone)

## Products Affected

- Ongentys Oral Capsule 50 MG

PA Criteria	Criteria Details
Covered Uses	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

# Onglyza (saxagliptin)(COMM, EXC)

## Products Affected

- sAXagliptin HCl

PA Criteria	Criteria Details
Covered Uses	Diabetes Mellitus Type 2
Exclusion Criteria	N/A
Required Medical Information	The patient must have a recent (within the past 3 months) documented A1C level of less than 11 AND one of the following: 1. The patient is concurrently taking a metformin product and has inadequate glycemic control after a trial at a therapeutic dose and requires the addition of another agent OR 2. Is unable to take a metformin product due to one of the following: a. Documented intolerance to metformin (Examples of intolerance include diarrhea after titration up to a therapeutic dose greater than or equal to 2000mg daily), b. Documented renal disease or renal dysfunction (For example, serum creatinine levels greater than or equal to 1.5mg/dl [males] or greater than or equal to 1.4mg/dl [females]), c. Documented hepatic disease (For example, cirrhosis or hepatitis). 3. Documented trial and failure of alogliptin AND Januvia
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Continuation of Therapy Criteria: The A1C must decrease by 0.5% or more from the initial A1c. Quantity Limit: 30 tablets per 30 days.

# Onpattro (patisiran)

## Products Affected

- Onpattro

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	at least 18 (eighteen) years old
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year
<b>Other Criteria</b>	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.

# Orencia (abatacept)(COMM, EXC)

## Products Affected

- Orencia ClickJect
- Orencia Intravenous
- Orencia Subcutaneous Solution Prefilled Syringe

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Adult Psoriatic Arthritis (PsA) 2. Juvenile Idiopathic Arthritis (JIA) 3. Rheumatoid arthritis (RA)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1. PsA: a. Drug must be 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. Methotrexate iii. Leflunomide iv. Sulfasalazine c. Trial and failure, unless contraindicated or not tolerated, to TWO preferred agents used to treat this indication (e.g., Enbrel, Humira, Rinvoq, Skyrizi, Stelara, Xeljanz). 2. JIA: a. Drug must be 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. Trial and failure of TWO preferred agents (e.g., Enbrel, Humira, Xeljanz). 3. RA: a. Prescribed by or in consultation with a rheumatologist. b. Documented presence of moderate to severe rheumatoid arthritis (RA). Moderate to severe is defined as: DAS28 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 TWO preferred agents used to treat this indication (e.g., Enbrel, Humira, Rinvoq, Xeljanz).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	1. PsA- prescribed by or in consultation with a dermatologist or rheumatologist 2. JIA and RA- prescribed by or in consultation with a rheumatologist
<b>Coverage Duration</b>	Up to 12 months
<b>Other Criteria</b>	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

PA Criteria	Criteria Details
	<p>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.</p>



# 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.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	INITIAL: 6 months, CONTINUATION: 1 year up to a total of 24 months of treatment
<b>Other Criteria</b>	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.
<b>Exclusion Criteria</b>	Pregnancy, Osteoporosis, Severe hepatic impairment, Concomitant use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine and gemfibrozil)
<b>Required Medical Information</b>	Documents showing trial and failure of at least two of the following: a. Nonsteroidal anti-inflammatory medication b. Hormonal contraceptive c. GnRH agonist
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 3 months, Continuation: 150mg: 1 Year, 200mg: 3 months
<b>Other Criteria</b>	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.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 dolosa, or Mycobacterium abscessus 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.
<b>Age Restrictions</b>	At least 6 years old
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial Approval: 6 months. Reauthorization: 1 Year
<b>Other Criteria</b>	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 dolosa, or Mycobacterium abscessus 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
- Otezla Oral Tablet Therapy Pack

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. 1.Behcets Syndrome 2. Plaque psoriasis (psoriasis vulgaris) (PsO) 3. Psoriatic arthritis, Active (PsA)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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, Humira, Rinvoq, Skyrizi, Stelara, Xeljanz). 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, Humira, Skyrizi, Stelara).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	1. Behcet's Syndrome-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
<b>Coverage Duration</b>	Approval length: Up to one (1) Year
<b>Other Criteria</b>	For all diagnoses: 1. The appropriate Disease Specific Criteria has been

PA Criteria	Criteria Details
	met. 2. Use of a Specialty Pharmacy is required. Continuation Criteria: 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	(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
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Metabolic disease specialist
<b>Coverage Duration</b>	See Below
<b>Other Criteria</b>	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 authorized.-QUANTITY 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

PA Criteria	Criteria Details
	<p>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.</p>

# Paxil (paroxetine) oral suspension

## Products Affected

- PARoxetine HCl Oral Suspension

PA Criteria	Criteria Details
Covered Uses	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 AND The 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 Pushtronex System
- Repatha SureClick

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	Will not be approved when used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.
<b>Required Medical Information</b>	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	<p>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.</p>

# Procrit (epoetin alpha)(COMM, EXC)

## Products Affected

- Procrit Injection Solution 10000

UNIT/ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	up to 6 months
<b>Other Criteria</b>	Code: J0885 (non-ESRD use). 1000 units = 1 billable unit Code: J0886 (ESRD on dialysis). 1000 units = 1 billable unit

# Provigil (modafinil)(COMM, EXC)

## Products Affected

- Modafinil Oral

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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1. A documented diagnosis of narcolepsy. The member must have a documented treatment failure, inability to tolerate, or other medical contraindication (including but not limited to: cardiovascular disease) to one or more formulary alternative medications 2. A documented diagnosis of 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 3. A documented diagnosis of Shift Work Sleep Disorder (SWSD): a. A letter from the employer is required stating the member is working a variable, alternating, or third shift. 4. Multiple Sclerosis Related Fatigue
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Medication must be prescribed by a sleep specialist or neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Quantity Limit: 30 tablets for 30 days.

# Pulmonary Arterial Hypertension (COMM, EXC, CC)

## Products Affected

- Ambrisentan
- Sildenafil Citrate Oral Tablet 20 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	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 (long-acting 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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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,O2 (mixed venous oxygen saturation). e. 6 minute walk distance.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Must be prescribed by a cardiologist or pulmonologist.
<b>Coverage Duration</b>	Initial Approval: 3 months. Continuation Approval: 1 year.
<b>Other Criteria</b>	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.

# Restasis (cyclosporine ophthalmic emulsion)(COMM, EXC)

## Products Affected

- cycloSPORINE Ophthalmic

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. The patient has a diagnosis of keratoconjunctivitis sicca or a diagnosis of Sjogren's disease. AND 2. The patient has failed a 30-day trial of artificial tears.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Must be prescribed by an optometrist or ophthalmologist.
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Quantity limit: Vials - 60 vials for 30 days. Multidose bottle - 5.5mL for 30 days.

# Retacrit (epoetin alpha-epbx) Criteria

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	up to 6 months
<b>Other Criteria</b>	Quantity Limits:-2000 U/mL, 3000 U/mL, 4000 U/mL, 10000 U/mL: 12 vials (12 mL) per 28 days.-40000 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



# Rinvoq (upadacitinib)

## Products Affected

- Rinvoq

PA Criteria	Criteria Details
<b>Covered Uses</b>	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)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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, Humira). 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, Humira). 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, Humira). 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(e.g., Amjevita, Enbrel, Humira).
<b>Age Restrictions</b>	
<b>Prescriber</b>	Prescribed by or in consultation with a rheumatologist, allergist,

PA Criteria	Criteria Details
<b>Restrictions</b>	immunologist, dermatologist, gastroenterologist
<b>Coverage Duration</b>	Up to 1 year.
<b>Other Criteria</b>	<p>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. b. Inadequate response, unless contraindicated or not tolerated to a tumor necrosis factor (TNF) blocker, e.g., Amjevita, Enbrel, Humira. 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, Humira). 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.</p>

# Risperdal M-Tab (risperidone orally disintegrating tablet)(COMM, EXC)

## Products Affected

- risperiDONE Oral Tablet Dispersible

PA Criteria	Criteria Details
<b>Covered Uses</b>	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).
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	A psychiatrist must initiate therapy.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Quantity Limit: 0.25mg, 0.5mg, 1mg, 2mg, 3mg ? 60 tablets for 30 days 4mg ? 120 tablets for 30 days

## Rozerem (ramelteon)(COMM, EXC)

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**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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Quantity Limit: 30 tablets per 30 days.

# RUXIENCE (rituximab-PVVR)

## Products Affected

- Ruxience

PA Criteria	Criteria Details
<b>Covered Uses</b>	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)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	See other criteria
<b>Other Criteria</b>	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

PA Criteria	Criteria Details
	<p>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</p>

# Sensipar (cinacalcet)(COMM, EXC)

## Products Affected

- Cinacalcet HCl

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Up to 1 year
<b>Other Criteria</b>	N/A

# Skyrizi (risankizumab-RZAA)

## Products Affected

- Skyrizi
- Skyrizi (150 MG Dose)
- Skyrizi Pen

PA Criteria	Criteria Details
<b>Covered Uses</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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. c. 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. d.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.
<b>Age Restrictions</b>	Minimum 18 years of age
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist.



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Up to 1 year
<b>Other Criteria</b>	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 Skyrizi therapy

# Soliris (eculizumab)

## Products Affected

- Soliris Intravenous Solution 300 MG/30ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Paroxysmal Nocturnal Hemoglobinuria (PNH)2. Atypical Hemolytic Uremic Syndrome (aHUS)3. Generalized Myasthenia Gravis (gMG) 4. Neuromyelitis optica spectrum disorder (NMOSD) with positive anti-aquaporin-4 (AQP4) antibody
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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 anti-acetylcholine 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
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A

PA Criteria	Criteria Details
<b>Coverage Duration</b>	PNH - 3 months. aHUS - 3 months, gMG - 6 months, NMOSD- Up to 6 months
<b>Other Criteria</b>	<p>The MG-ADL assessment and MGFA Clinical classifications can be found at <a href="http://www.myasthenia.org/HealthProfessionals/EducationalMaterials.aspx">http://www.myasthenia.org/HealthProfessionals/EducationalMaterials.aspx</a>. Restrictions: As part a risk management program, providers and patients must enroll with Soliris™ 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.</p>

# Soriatane (acitretin)(COMM, EXC)

## Products Affected

- Acitretin

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

# 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.
<b>Exclusion Criteria</b>	Pregnancy, aneurysmal vascular disease, history of intracerebral hemorrhage
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	at least 18 years old
<b>Prescriber Restrictions</b>	initiated by a behavioral health practitioner or in consultation with a behavioral health practitioner for all indications
<b>Coverage Duration</b>	Initial: 4 weeks, Continuation: 6 months
<b>Other Criteria</b>	Continuation: Documents must show clinical improvement as shown by standard rating scale

# Sprycel (dasatinib)

## Products Affected

- Sprycel

PA Criteria	Criteria Details
<b>Covered Uses</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	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 Intravenous
- Stelara Subcutaneous Solution 45 MG/0.5ML
- Stelara Subcutaneous Solution Prefilled Syringe

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. 1. Crohns disease, moderate to severe (CD) 2. Psoriatic arthritis, Active (PsA) 3. Plaque psoriasis (psoriasis vulgaris), moderate to severe (PsO) 4. Ulcerative Colitis (UC)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) CD- Inadequate response to at least one of the following: corticosteroids, methotrexate (MTX), or thiopurines. 2) PsA A trial of at least three (3) months of cyclosporine, leflunomide, MTX, or sulfasalazine 3) PsO I. Involvement of 3% or more Body Surface Area (BSA). ii. Psoriasis Area Severity Index (PASI) of 5 or more and/or a Dermatology Life Quality Index (DLQI) of more than 5. iii. At least three months trial of a topical agent (corticosteroid, calcineurin inhibitor, vitamin D analog, etc.). 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>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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
<b>Coverage Duration</b>	Up to one (1) Year
<b>Other Criteria</b>	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 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

PA Criteria	Criteria Details
	<p>maintenance treatment must be received before PHP can approve the office-administered induction treatment. 2.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.</p>



# 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).
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Patient age of 18 or under, or age of onset at age 18 or under.
<b>Prescriber Restrictions</b>	The prescriber must be a specialist in the area of patient's disease (e.g., endocrinologist).
<b>Coverage Duration</b>	Initial Approval: 6 months. Continuation of Therapy: 1 year.
<b>Other Criteria</b>	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

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

# Subutex (buprenorphine)

## Products Affected

- Buprenorphine HCl Sublingual

PA Criteria	Criteria Details
<b>Covered Uses</b>	Opioid type dependence
<b>Exclusion Criteria</b>	1. Buprenorphine will not be approved for the treatment of pain. 2. Buprenorphine will not be approved for use in conjunction with any opioid analgesic, including tramadol. These are contraindicated for patients receiving buprenorphine. 3. Early refill for replacement of lost or stolen buprenorphine is not permitted.
<b>Required Medical Information</b>	Buprenorphine is only covered for pregnancy and for breastfeeding with clinical justification or documented naloxone hypersensitivity 1. The patient has been diagnosed with opioid type dependence 2. The patient is at least 16 years old. 3. The patient is not taking any opioid analgesic, including tramadol. 4. The provider must document that a current urine drug screen (screening for opiates, benzodiazepines and buprenorphine) was performed. Any relapses by the patient, indicated by a urine drug screen positive for other opiates, must be addressed by the provider. A urine drug screen negative for buprenorphine also alerts the provider to possible diversion of buprenorphine and steps for discontinuance of buprenorphine prescriptions can be considered. 5. The requesting provider must pull the New Mexico Board of Pharmacy Prescription Monitoring Program (PMP) report and certify the patient is not taking any other opiate after induction. Appropriate clinical information should be provided with the renewal request explaining how relapsed or concurrent use of opioids will be addressed. 6. buprenorphine should not be taken with benzodiazepines, sedative/hypnotics, carisoprodol, or meprobamate due to increased incidence of respiratory depression. If the patient is going to take buprenorphine with benzodiazepines or sedative/hypnotics, justification for the combined use and documentation that the patient was counseled on the risks of the combination must be submitted. 7. A treatment plan, agreed to and signed by the patient must be submitted by the requesting provider.
<b>Age Restrictions</b>	at least 16 years old
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	See below

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>APPROVAL LENGTHS: -Patients approved based on pregnancy will be approved through 30 days after their expected delivery date. Transition to a buprenorphine/naloxone combination product is required for ongoing treatment unless the patient is breast feeding. -Patients approved based on breastfeeding, will be approved for up to 12 months following delivery. Transition to a buprenorphine/naloxone combination product is required for ongoing treatment thereafter. -Patients approved based on documented serious adverse reaction to naloxone will be approved for 1 year. Note: Requests for buprenorphine doses greater than 24mg per day will only be considered for approval a maximum duration of three months.</p>

# 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)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	at least 18 years old
<b>Prescriber Restrictions</b>	Neurologist or sleep specialist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Quantity Limit: 30 tablets for 30 days.

# Symdeko (tezacaftor/ivacaftor)

## Products Affected

- Symdeko

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 dolosa, or Mycobacterium abscessus 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
<b>Age Restrictions</b>	at least 6 years old
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial Approval: 6 Months Reauthorization: 1 Year
<b>Other Criteria</b>	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 dolosa, or Mycobacterium abscessus 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)(COMM, EXC)

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial requests must be prescribed by endocrinologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A

# Synagis (palivizumab) 2014-15(COMM, EXC)

## Products Affected

- Synagis

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy.
<b>Age Restrictions</b>	Up to 24 months as of November 15th.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Approved through end of RSV season
<b>Other Criteria</b>	All Synagis injections will be administered through Presbyterian Home Healthcare Statewide Network contracted home care agencies.



# TAKHZYRO (lanadelumab-flyo)

## Products Affected

- Takhzyro

PA Criteria	Criteria Details
<b>Covered Uses</b>	Hereditary angioedema (HAE) type 1 or 2
<b>Exclusion Criteria</b>	Will not be approved in combination with other prophylactic treatments OR Younger than 2 years old
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	At least 2 years of age
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 4 weeks, Continuation: 6 months
<b>Other Criteria</b>	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 rationale for avoiding LTP must be provided. Preferred Specialty Pharmacy Dispensing Required.

# Taltz (ixekizumab)

## Products Affected

- Taltz

PA Criteria	Criteria Details
<b>Covered Uses</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 e. Trial and failure to TWO preferred agents used to treat this indication (e.g., Amjevita, Enbrel, Humira, Rinvoq, Xeljanz). 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 a 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.). e. Trial and failure of, or contraindication or intolerance to, TWO preferred agents used to treat this indication (e.g., Amjevita, Enbrel, Humira, Skyrizi, Stelara). 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 c. Trial and failure, unless contraindicated or not tolerated, of TWO preferred agents used to treat this indication (e.g., Enbrel, Humira, Amjevita, Rinvoq, Skyrizi, Stelara, Xeljanz).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	1. AS- prescribed by or in consultation with a rheumatologist 2. PsO- prescribed by or in consultation with a dermatologist 3. PsA- prescribed

PA Criteria	Criteria Details
	by or in consultation with a dermatologist or rheumatologist
<b>Coverage Duration</b>	Up to one (1) Year
<b>Other Criteria</b>	4. Non-radiographic Axial Spondyloarthritis: a.Prescribed by or in consultation with a rheumatologist, b. The patient has had a documented trial and failure of a non-steroidal anti-inflammatory drug (NSAID) ro such treatment is contraindicated or not tolerated. c. Trial and failure, unless contraindicated or not tolerated, of Rinvoq. 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
<b>Covered Uses</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	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)(COMM, EXC)

## Products Affected

- Testopel

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
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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 (16 years of age and up)- Specific criteria apply. Refer to the Gender Dysphoria Treatment Criteria located on phs.org.
<b>Age Restrictions</b>	18 years or greater
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Must have a documented trial and failure of testosterone topical gel. Quantity Limit: 6 pellets for 3 months.

# Thiola (tiopronin)

## Products Affected

- Tiopronin Oral

PA Criteria	Criteria Details
Covered Uses	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 alkalization.
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 (dolutegravir sodium)

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**Products Affected**

- Tivicay PD

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

# Trelegy (fluticasone furoate/umeclidinium/vilanterol)

## Products Affected

- Trelegy Ellipta Inhalation Aerosol Powder 200-62.5-25 MCG/ACT  
Breath Activated 100-62.5-25 MCG/ACT,

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1. Member is using for the maintenance treatment of chronic obstructive pulmonary disease (COPD), OR 2.Member is using for the maintenance treatment of asthma. 3. Trelegy will not be approved for: a. The acute treatment of asthma or COPD. b.Concurrent therapy with another agent containing a long-acting beta-2 agonist, long-acting muscarinic antagonist, and/or an inhaled corticosteroid. c. Individuals with a hypersensitivity to milk proteins.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Quantity Limits: one (1) inhaler per 30 days.



# Trikafta (elexacaftor/tezacaftor/ivacaftor)

## Products Affected

- Trikafta

PA Criteria	Criteria Details
Covered Uses	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 dolosa, or Mycobacterium abscessus. 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

# Tymlos (abaloparatide) Criteria

## Products Affected

- Tymlos

PA Criteria	Criteria Details
<b>Covered Uses</b>	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 therapy.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year, no more than 2 years cumulative treatment with PTH analogs
<b>Other Criteria</b>	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)

## Products Affected

- Tysabri

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Patient must have relapsing form of multiple sclerosis. 2. Must be used as monotherapy. 3. Patient must have a documented trial and failure or inability to tolerate: a. Glatopa AND b. An interferon beta 1A or 1B product such as Avonex, Rebif, Extavia.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Must be prescribed by a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Code: J2323. 1mg = 1 billable unit.

# Uloric (febuxostat)(COMM, EXC)

## Products Affected

- Febuxostat

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Gout Prophylaxis AND 2. One of the following criteria must be met: a. Documented failure at maximal therapeutic doses (600mg/day) of allopurinol. A documented failure is considered as non-resolution of tophi or at least 4 gout attacks (joint flares) per year with demonstrated medication compliance. OR b. Documented intolerance to allopurinol. Examples of intolerance include skin reactions or cytopenias. OR c. Treatment failure of allopurinol due to documented renal insufficiency. Example: CrCl ? 30ml/min.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Quantity Limit: 30 tablets for 30 days.

# Ultomiris (ravuliumab-cwvz)

## Products Affected

- Ultomiris

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. 1.) Paroxysmal Nocturnal Hemoglobinuria (PNH) 2.) Atypical hemolytic uremic syndrome (aHUS) 3.) Generalized Myasthenia Gravis (gMG)
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Meningococcal vaccine given at least 2 (two) weeks prior to the first dose of Ultomiris being given AND specific requirements for diagnosis</p> <p>1. PNH-a) Hematocrit/Hemoglobin lab tests for the past one year and lab evidence for hemolysis and documents showing ALL of the following a) b) Results of the following diagnostic tests: Laboratory confirmed diagnosis of PNH evidenced by detectable glycosylphosphatidylinositol (GPI)-deficient hematopoietic clones (Type III PNH RBC) via flow cytometry (Flow cytometry testing must include at least two different reagents tested on at least two cell lineages), greater than 50% of GPI-anchored proteins deficient polymorphonuclear cells (PMNs) C) Symptoms of thromboembolic complications, Prior history of blood transfusions (number of blood transfusions per year is required), LDH level 1.5 times the upper limit of normal range D) one of the following a) hemoglobin (HGB) 7g/dL or less OR b) HGB 9g/dL or less AND symptoms of anemia 2. aHUS- a) Chart notes documenting diagnosis. 3. gMD - a. Member is at least 18 years of age. b. Documentation of a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies. c. Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV. d. Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score greater than or equal to 6. e. Inadequate response, intolerance, or contraindication to pyridostigmine. f. Inadequate response to two immunosuppressant therapies (e.g., azathioprine, cyclosporine, mycophenolate, methotrexate, tacrolimus, cyclophosphamide).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	For PNH: Hematologist or oncologist
<b>Coverage Duration</b>	Initial: 3 months, Continuation: 6 months

PA Criteria	Criteria Details
<b>Other Criteria</b>	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: b.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
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Up to 6 months
<b>Other Criteria</b>	

## Valtoco (diazepam)

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**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.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of acute intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures).
<b>Age Restrictions</b>	6 years of age and older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Up to one (1) year
<b>Other Criteria</b>	Quantity Limit: 10 delivery systems per 30 days



# Vancocin (vancomycin) 250 mg capsules

## Products Affected

- Vancomycin HCl Oral Capsule 250 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Indications for Approval:1.A microbial culture or toxin is positive for Clostridium difficile.AND2.Documentation that the patient has an initial episode of severe or fulminant Clostridium difficile.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One time, no refills
<b>Other Criteria</b>	This Prior Authorization is based on a recommendation of the Centers for Disease Control (CDC) to limit the use of this drug. The use of this drug orally has been suggested to promote the emergence of resistant organisms, especially multi-drug resistant Enterococcus. Oral vancomycin is not absorbed systemically and will not effectively treat infections outside the gastrointestinal tract.

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

## Products Affected

- VariZIG Intramuscular Solution

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	N/A
<b>Other Criteria</b>	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.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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
<b>Age Restrictions</b>	at least 12 years of age
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	

# Venofer (iron sucrose)(COMM, EXC)

## Products Affected

- Venofer

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 time
<b>Other Criteria</b>	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.

# Vfend (voriconazole)(COMM, EXC)

## Products Affected

- Voriconazole Oral

PA Criteria	Criteria Details
<b>Covered Uses</b>	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. *Documentation must include a culture report or susceptibility report if applicable.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Up to 6 months
<b>Other Criteria</b>	Continuation of Therapy Criteria: To ensure that therapeutic blood levels have been reached, voriconazole trough levels (see below) must be provided with each subsequent request for continuation of therapy. Notes: Voriconazole levels may have up to a 100-fold inter-patient and intra-patient variance depending on age, concurrent illness, liver function, drug interactions or genetic polymorphisms. The therapeutic trough interval for voriconazole is 1mg to 5.5mg/L. Below 1mg/L the dose is too low and the patient may not receive any clinical benefit and levels above 5.5mg/L may lead to associated toxicities. Levels should be taken 5 to 7 days after initiation or change of voriconazole therapy. The procedure for collecting levels can be found at: <a href="http://www.tricore.org/Healthcare-Professionals/Directory-of-Services.aspx?keyword=voricon">http://www.tricore.org/Healthcare-Professionals/Directory-of-Services.aspx?keyword=voricon</a> Quantity Limit: 60 tablets for 30 days.

## Viibryd (vilazodone)(COMM, EXC)

### Products Affected

- Vilazodone HCl

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Diagnosis of major depressive disorder AND 2. A documented trial and failure of all of the following: a. Selective serotonin reuptake inhibitor (SSRI), b. Serotonin-norepinephrine reuptake inhibitor (SNRI)
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Quantity Limit: 30 tablets for 30 days.

# Vyvanse (lisdexamfetamine) Comm/HIX/CC

## Products Affected

- Lisdexamfetamine Dimesylate Oral Capsule

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Attention Deficit Hyperactivity Disorder (ADHD) in Adults and Pediatric Patients 6 Years of Age and Older. 2. Binge Eating Disorder (BED) in Adults.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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, amphetamine/dextroamphetamine, dexamethylphenidate, 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
<b>Age Restrictions</b>	Minimum 6 years of age for ADHD Minimum 18 years of age for BED

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	up to one year
<b>Other Criteria</b>	Chart notes documenting previous medication trials and failures including dose and duration of trials



# WAKIX (pitolisant)

## Products Affected

- Wakix

PA Criteria	Criteria Details
<b>Covered Uses</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	At least 18 years of age
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Up to 1 year
<b>Other Criteria</b>	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

PA Criteria	Criteria Details
	<p>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</p>

# Wegovy (semaglutide) FEDERAL EMPLOYEE PLANS ONLY

## Products Affected

- Wegovy

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Indications for Approval (all must be met): 1. 18 years of age or older. BMI of 30 kg/m <sup>2</sup> , or 27 kg/m <sup>2</sup> in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes, or dyslipidemia). 3. Has been involved in a weight-loss program for at least 6 months that includes behavioral modification and dietary restriction. a. A calorie deficit of approximately 30% (i.e., 500 kcals relative to their estimated total energy expenditure) in calories per day has been by achieved for at least 6 month, AND b. An exercise goal of completing at least 150 minutes of exercise per week has been achieved for at least 6 months, OR i. Exercise requirements cannot be met due to clinical limitations (including, but not limited to, cardiovascular conditions, physical limitations, fall risk), AND c. Member has been unable to achieve at least a 5% weight reduction with calorie deficit goals, exercise, goals, and behavior therapy. 4. Recent chart notes (within one month) that document current weight and height. 5. Member has had at least a 3-month trial and failure of at least two preferred oral agents (3 months each), unless contraindicated or not tolerated: benzphetamine, diethylpropion, phendimetrazine, phentermine, Contrave. a. For the purpose of this policy, failure is defined as not having achieved at least a 5% reduction in weight from baseline after a 90-day period. 6. Will not be used in combination with another medication indicated for weight-loss or another GLP-1 agonist.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 3 months. Continuation: Up to 6 months
<b>Other Criteria</b>	Continuation criteria: 1. Member at lost five (5) percent or more of their

PA Criteria	Criteria Details
	<p>body weight after an initial three (3) month trial of Wegovy.2.Member continues to be actively engaged in a weight loss program that includes behavioral modification, increased physical activity, and dietary restrictions.3.Member maintains weight loss of at least five (5) percent or more from baseline.4.Recent chart notes (within one month) that document current weight and height.</p>

# Weight Loss (COMM, EXC)

## Products Affected

- Benzphetamine HCl
- Contrave
- Diethylpropion HCl Oral
- Phendimetrazine Tartrate
- Phendimetrazine Tartrate ER
- Phentermine HCl Oral Capsule

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1. The patient has a body mass index (BMI) of 27kg/ m <sup>2</sup> or greater with 1 or more comorbidities (e.g. hypertension, type 2 diabetes mellitus, dyslipidemia) or BMI of 30kg/m <sup>2</sup> or greater. 2.Current (within one month) height, weight and dates recorded must be provided with each request. 3. Patient is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to pharmacologic therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial approval: 3 months. Continuation: Up to 6 months.
<b>Other Criteria</b>	Current height, weight and dates recorded must be provided with each request. Initial approval is for a three (3) month supply of medication. If the patient has lost five (5) percent or more of their initial body weight, then an additional six (6) month supply of medication may be approved.

# Xeljanz (tofacitinib)(COMM, EXC)

## Products Affected

- Xeljanz
- Xeljanz XR

PA Criteria	Criteria Details
<b>Covered Uses</b>	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)
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1. RA: a. Documented presence of moderate to severe RA: 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, to at least one tumor necrosis factor (TNF) blocker (e.g., Amjevita, Enbrel, Humira). 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, to at least one tumor necrosis factor (TNF) blocker (e.g., Amjevita, Enbrel, Humira). 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 to at least one tumor necrosis factor (TNF) blocker (e.g., Amjevita, Humira). 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 at least one tumor necrosis factor (TNF) blocker (e.g., Amjevita, Enbrel, Humira). 5. AS: a. The patient has a documented trial and failure with 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 or such treatment is contraindicated or not tolerated. c. Patients with axial disease and a trial a trial/failure of NSAIDs can be started on Xeljanz. d. 5. Trial and failure of at least one tumor necrosis factor (TNF) blocker (e.g., Amjevita, Enbrel, Humira).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA//JIA/AS- prescribed by or in consultation with a rheumatologist, PsA- prescribed by or in consultation with a dermatologist or rheumatologist, UC- prescribed by or in consultation with a gastroenterologist

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Up to 12 months
<b>Other Criteria</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Approved for use in adults only.
<b>Prescriber Restrictions</b>	Must be prescribed by a neurologist or in consultation with a neurologist.
<b>Coverage Duration</b>	Initial approval: 6 months. Renewal: One year.
<b>Other Criteria</b>	Continuation of Therapy: 1. For all indications, documentation of continued monitoring for depression, suicidal ideation and hepatic impairment. 2. Huntington Disease chorea documentation of



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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of confirmed diagnosis, established therapy of a somatostatin analog (SSA) for at least 3 months, and number of bowel movements a day.
<b>Age Restrictions</b>	Patient age of 18 or older.
<b>Prescriber Restrictions</b>	Xermelo is prescribed by, or in consultation with, an oncologist or gastroenterologist.
<b>Coverage Duration</b>	Initial Approval: 12 weeks. Continuation of Therapy: Up to one year.
<b>Other Criteria</b>	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
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Preferred Specialty Pharmacy Dispensing Required.Code: J0897. 1mg = 1 billable unit.

# Xifaxan (rifaximin)

## Products Affected

- Xifaxan

PA Criteria	Criteria Details
<b>Covered Uses</b>	1. Travelers 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)
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1. Travelers diarrhea (200mg strength only) Patient must meet all of the following criteria: Documented diagnosis of travelers 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).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Traveler's Diarrhea: 1 time. Hepatic Encephalopathy: 1 year. IBS-D: 1 time. SIBO: 1 time
<b>Other Criteria</b>	Quantity Limits: For traveler's diarrhea - 9 tablets (200mg) for 3 days for

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

# Xolair (omalizumab)(COMM, EXC)

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	<p>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.</p> <p>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.</p>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	CIU: 3 months initially. Asthma: 6 months initially. Subsequent approvals: Up to 6 months

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

## Products Affected

- Xtandi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1. Diagnosis of metastatic, castration-resistant prostate cancer AND history of failure, contraindication, or intolerance to abiraterone (Zytiga), OR diagnosis of metastatic, castration-sensitive prostate cancer AND history of failure, contraindication, or intolerance to abiraterone (Zytiga), OR diagnosis of non-metastatic, castration-resistant prostate cancer AND history of failure, contraindication, or intolerance to darolutamide (Nubeqa).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Six (6) months
<b>Other Criteria</b>	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)(COMM, EXC)

### Products Affected

- Sodium Oxybate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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 adequate trial and failure of, or intolerance to a preferred formulary cerebral stimulant (methylphenidate or dextroamphetamine) AND armodafinil or modafinil AND Sunosi (solriamfetol) AND Wakix (pitolisant)
<b>Age Restrictions</b>	at least 7 years old
<b>Prescriber Restrictions</b>	Prescribed by a neurologist or sleep specialist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For all indications: prescriber must participate in the Xyrem Success Program

## Zortress (everolimus)(COMM, EXC)

### 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.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Up to 1 year
<b>Other Criteria</b>	

## 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).
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation showing previous medication trials.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Up to one year.
<b>Other Criteria</b>	

## Zyvox (linezolid)(COMM, EXC)

### Products Affected

- Linezolid Oral

PA Criteria	Criteria Details
<b>Covered Uses</b>	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.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chart notes documenting medical indication, planned course of therapy and previous therapies attempted (if applicable) including dose, duration, and result(s) are required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Infectious Disease Consultation must be documented.
<b>Coverage Duration</b>	1 time
<b>Other Criteria</b>	N/A

# Step Therapy Criteria

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## Aciphex (rabeprazole)

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### Products Affected

- RABEprazole Sodium Tablet Delayed                      Release 20 MG Oral

### Details

<b>Criteria</b>	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)

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## Products Affected

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

## Details

<b>Criteria</b>	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.
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# Amitiza (lubiprostone)

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## Products Affected

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

## Details

<b>Criteria</b>	The patient must have a claim history of an osmotic laxative (PEG-3350 or lactulose) within the past 120 days.
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# Beconase AQ (beclomethasone nasal spray)

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## Products Affected

- Beconase AQ Suspension 42 MCG/SPRAY Nasal

## Details

<b>Criteria</b>	The member must have a claim history of one generic formulary nasal steroid in the past 545 days.
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# Boniva (ibandronate) tablets

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## Products Affected

- Ibandronate Sodium Tablet 150 MG Oral

## Details

<b>Criteria</b>	The patient must have a 90-day prescription fill or documented trial and fail of alendronate.
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# Chantix (varenicline)

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## Products Affected

- Chantix Starting Month Pak Tablet 0.5 MG X 11 & 1 MG X 42 Oral
- Nicotrol Inhaler 10 MG Inhalation
- Nicotrol NS Solution 10 MG/ML Nasal
- Varenicline Tartrate Tablet 0.5 MG Oral
- Varenicline Tartrate Tablet 1 MG Oral

## Details

<b>Criteria</b>	The patient must have a claim history of one over-the-counter (OTC) nicotine product and bupropion ER.
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# Ciprodex (ages 12 and up)

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## Products Affected

- Ciprofloxacin-Dexamethasone Suspension      0.3-0.1 % Otic

## Details

<b>Criteria</b>	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)

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## Products Affected

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

## Details

<b>Criteria</b>	The patient must have a 90 day trial of a formulary estrogen and progesterone medication within the past 180 days.
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## D.H.E. 45 (dihydroergotamine 1mg/mL inj)

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### Products Affected

- Dihydroergotamine Mesylate Solution 1      MG/ML Injection

### Details

<b>Criteria</b>	The patient must have a claim history of two (2) formulary triptan medications within the past 120 days.
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## Detrol LA (tolterodine ER)/Vesicare (solifenacin)

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### Products Affected

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

### Details

<b>Criteria</b>	The patient must have a 30-day prescription fill of generic oxybutynin or oxybutynin XL within the past 545 days.
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# Diastat (diazepam gel)

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## Products Affected

- diazePAM Gel 10 MG Rectal
- diazePAM Gel 2.5 MG Rectal
- diazePAM Gel 20 MG Rectal

## Details

<b>Criteria</b>	Step therapy applies to patients 18 years of age and older only. The patient must have a claim history within the past 120 days of a 30-day fill of an anti- epileptic agent. Quantity is limited to 5 delivery systems per 30 days.
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## DPP-4 Inhibitors, Preferred (Januvia, Janumet, Janumet XR, Kazano, Nesina)

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### Products Affected

- Alogliptin Benzoate Tablet 12.5 MG Oral Hour 50-1000 MG Oral
- Alogliptin Benzoate Tablet 25 MG Oral • Janumet XR Tablet Extended Release 24
- Alogliptin Benzoate Tablet 6.25 MG Oral Hour 50-500 MG Oral
- Alogliptin-metFORMIN HCl Tablet 12.5-1000 MG Oral • Januvia Tablet 100 MG Oral
- Alogliptin-metFORMIN HCl Tablet 12.5-500 MG Oral • Januvia Tablet 25 MG Oral
- Janumet Tablet 50-1000 MG Oral • Januvia Tablet 50 MG Oral
- Janumet Tablet 50-500 MG Oral • Segluromet Tablet 2.5-1000 MG Oral
- Janumet XR Tablet Extended Release 24 Hour 100-1000 MG Oral • Segluromet Tablet 2.5-500 MG Oral
- Janumet XR Tablet Extended Release 24 • Segluromet Tablet 7.5-1000 MG Oral
- • Segluromet Tablet 7.5-500 MG Oral
- • Steglujan TABLET 15-100 MG Oral
- • Steglujan TABLET 5-100 MG Oral

### Details

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

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## Products Affected

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

## Details

<b>Criteria</b>	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.
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# Farxiga (dapagliflozin)

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## Products Affected

- Farxiga Tablet 10 MG Oral
- Farxiga Tablet 5 MG Oral

## Details

<b>Criteria</b>	Must have had a 90-day prescription fill within the past 180 days of metformin, an Angiotensin Converting Enzyme (ACE) Inhibitor, an Angiotensin Receptor Blocker (ARB), or Entresto.
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# Humulin 70/30 (human insulin isophane susp/human regular insulin)

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## Products Affected

- HumuLIN 70/30 KwikPen Suspension Pen-Injector (70-30) 100 UNIT/ML Subcutaneous
- HumuLIN 70/30 Suspension (70-30) 100 UNIT/ML Subcutaneous

## Details

<b>Criteria</b>	The patient must have a claim history of Novolin 70/30 within the past 120 days.
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# Humulin N (human insulin isophane sus)

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## Products Affected

- HumuLIN N KwikPen Suspension Pen-Injector 100 UNIT/ML Subcutaneous
- HumuLIN N Suspension 100 UNIT/ML Subcutaneous

## Details

<b>Criteria</b>	The patient must have a claim history of Novolin N within the past 120 days.
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# Humulin R U-100/Humulin R U-500 (regular human insulin)

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## Products Affected

- HumuLIN R Solution 100 UNIT/ML                      Injection

## Details

<b>Criteria</b>	The patient must have a claim history of Novolin R within the past 120 days.
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# Kytril (granisetron) tablets

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## Products Affected

- Granisetron HCl Tablet 1 MG Oral

## Details

<b>Criteria</b>	The patient must have a prescription claim history of at least a 5-day trial of generic ondansetron oral tablets within the past 120 days.
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# Memantine ER

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## Products Affected

- 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

## Details

<b>Criteria</b>	The member must have a claim history of donepezil or Namenda immediate release tablets within the past 545 days.
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# mesalamine ORAL

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## 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

<b>Criteria</b>	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

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## 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

<b>Criteria</b>	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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# Migranal (dihydroergotamine 4mg/mL nasal spray)

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## Products Affected

- Dihydroergotamine Mesylate Solution 4      MG/ML Nasal

## Details

<b>Criteria</b>	The patient must have a claim history of two (2) formulary triptan medications within the past 120 days.
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## morphine sulfate ER (Avinza, Kadian)

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### 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

<b>Criteria</b>	The patient must have claim history of fentanyl transdermal patches and oxymorphone ER within the past 90 days.
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# Nasonex (mometasone nasal spray)

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## Products Affected

- Mometasone Furoate Suspension 50 MCG/ACT Nasal

## Details

<b>Criteria</b>	The member must have a claim history of one generic formulary nasal steroid prescription within the past 545 days.
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# Non-Preferred ICS/LABA

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## Products Affected

- Dulera Aerosol 100-5 MCG/ACT Inhalation
- Dulera Aerosol 200-5 MCG/ACT Inhalation
- Dulera Aerosol 50-5 MCG/ACT Inhalation
- Fluticasone-Salmeterol Aerosol Powder Breath Activated 100-50 MCG/ACT Inhalation
- Fluticasone-Salmeterol Aerosol Powder Breath Activated 250-50 MCG/ACT Inhalation
- Fluticasone-Salmeterol Aerosol Powder Inhalation
- Fluticasone-Salmeterol Aerosol Powder Breath Activated 500-50 MCG/ACT Inhalation
- Wixela Inhub Aerosol Powder Breath Activated 100-50 MCG/ACT Inhalation
- Wixela Inhub Aerosol Powder Breath Activated 250-50 MCG/ACT Inhalation
- Wixela Inhub Aerosol Powder Breath Activated 500-50 MCG/ACT Inhalation

## Details

<b>Criteria</b>	For Asthma: patient must have a prescription claims history of fluticasone/salmeterol (55-14mcg/actuation, 113-14 mcg/actuation, 232-14 mcg/actuation) AND Symbicort within the past 150 days For chronic obstructive pulmonary disease (COPD):a prescription claim history of Symbicort in the past 150 days is required
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# Opana ER (oxymorphone ER)

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## 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

<b>Criteria</b>	The patient must have claim history of morphine sulfate extended release tablets (MS Contin) within the past 90 days.
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## ophthalmic corticosteroids (Alrex, Lotemax)

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### Products Affected

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

### Details

<b>Criteria</b>	The member must have a claim history within the past 120 days of a formulary ophthalmic corticosteroid.
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# Oseni (alogliptin and pioglitazone)

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## 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

<b>Criteria</b>	The patient must have a 90-day prescription fill of metformin or alogliptin within the past 545 days.
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## Paxil CR (paroxetine CR)

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### 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

<b>Criteria</b>	The patient must have a 30-day trial and failure on 3 formulary generic selective serotonin reuptake inhibitors (SSRIs) within the past 545 days.
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# Prevacid Capsules (lansoprazole capsules)

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## Products Affected

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

## Details

<b>Criteria</b>	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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# QVAR (beclomethasone dipropionate)

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**Products Affected**

- Qvar RediHaler Aerosol Breath Activated 40 MCG/ACT Inhalation
- Qvar RediHaler Aerosol Breath Activated 80 MCG/ACT Inhalation

**Details**

<b>Criteria</b>	Member must have had a 30-day prescription fill history of Flovent Diskus, Flovent HFA, or Arnuity Ellipta within the past 180 days.
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# Ranexa (ranolazine)

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## Products Affected

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

## Details

<b>Criteria</b>	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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# Rhinocort Nasal (budesonide 32mcg spray)

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## Products Affected

- Budesonide Suspension 32 MCG/ACT      Nasal

## Details

<b>Criteria</b>	The member must have a claim history of one generic formulary nasal steroid prescription within the past 545 days.
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# Rhopressa (netarsudil)

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## Products Affected

- Rhopressa Solution 0.02 % Ophthalmic

## Details

<b>Criteria</b>	Pharmacy claim in the past 120days of an ophthalmic prostaglandin indicated for glaucoma
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## Sanctura/Sanctura XR (trospium/trospium ER)

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### Products Affected

- Trospium Chloride ER Capsule Extended Release 24 Hour 60 MG Oral
- Trospium Chloride Tablet 20 MG Oral

### Details

<b>Criteria</b>	The patient must have a claim history of generic oxybutynin XL within the past 545 days.
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# SGLT2 Inhibitors

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## Products Affected

- Steglatro Tablet 15 MG Oral
- Steglatro Tablet 5 MG Oral
- Xigduo XR Tablet Extended Release 24 Hour 10-1000 MG Oral
- Xigduo XR Tablet Extended Release 24 Hour 10-500 MG Oral
- Xigduo XR Tablet Extended Release 24 Hour 2.5-1000 MG Oral
- Xigduo XR Tablet Extended Release 24 Hour 5-1000 MG Oral
- Xigduo XR Tablet Extended Release 24 Hour 5-500 MG Oral

## Details

<b>Criteria</b>	The patient must have a 90-day prescription fill of metformin within the past 545 days.
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# Sklice (ivermectin)

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## Products Affected

- Ivermectin Lotion 0.5 % External

## Details

<b>Criteria</b>	The patient must have a trial and failure of permethrin within the past 60 days.
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# Sporanox (itraconazole)

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## 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.
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# Tazorac (tazarotene)

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## Products Affected

- Tazarotene Cream 0.1 % External
- Tazarotene Gel 0.05 % External
- Tazarotene Gel 0.1 % External
- Tazorac Cream 0.05 % External

## Details

<b>Criteria</b>	The patient must have a 30-day prescription fill of one of the following within the past 120 days: tretinoin topical, adapalene topical, or a medium to high potency topical steroid.
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# **Triptans (Amerge, Maxalt, Zomig, Zomig ZMT)**

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## **Products Affected**

- ZOLMiptan Tablet 2.5 MG Oral Oral
- ZOLMiptan Tablet 5 MG Oral • ZOLMiptan Tablet Dispersible 5 MG
- ZOLMiptan Tablet Dispersible 2.5 MG Oral

## **Details**

<b>Criteria</b>	The patient must have a claim history of a sumatriptan product (tablets, nasal spray, or injection) in the past 120 days.
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## **Triptans, Non-Preferred (Axert, Frova, Relpax)**

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### **Products Affected**

- Almotriptan Malate Tablet 12.5 MG Oral
- Almotriptan Malate Tablet 6.25 MG Oral
- Eletriptan Hydrobromide Tablet 20 MG Oral
- Eletriptan Hydrobromide Tablet 40 MG Oral
- Frovatriptan Succinate Tablet 2.5 MG Oral

### **Details**

<b>Criteria</b>	The patient must have a claim history of a sumatriptan product (tablets, nasal spray, or injection) in the past 120 days and naratriptan or rizatriptan tablets in the past 120 days.
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# Vectical (calcitriol) Ointment

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## Products Affected

- Calcitriol Ointment 3 MCG/GM External

## Details

<b>Criteria</b>	The patient must have a claim history of one of the following within the past 120 days: tretinoin topical, adapalene topical, or a medium to high potency topical steroid.
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# Vimpat (lacosamide)

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## Products Affected

- Lacosamide Solution 10 MG/ML Oral
- Lacosamide Tablet 100 MG Oral
- Lacosamide Tablet 150 MG Oral
- Lacosamide Tablet 200 MG Oral
- Lacosamide Tablet 50 MG Oral

## Details

<b>Criteria</b>	The patient must have a claim history for two formulary anticonvulsants within the past 180 days.
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# Xopenex (levalbuterol)

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## Products Affected

- Levalbuterol Tartrate Aerosol 45 MCG/ACT Inhalation

## Details

Criteria	The patient must have a claim history within the past 120 days of albuterol metered dose inhaler or albuterol nebulizer solution.
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