

**CareOregon 2010 PA Criteria**

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## B VS D - PART B VERSUS PART D COVERAGE PA

### Affected Drugs

AMINOSYN II 3.5% M-DEXTROSE 5%®  
AMINOSYN II 3.5%-DEXTROSE 25%®  
AMINOSYN II 3.5%-DEXTROSE 5%®  
AMINOSYN II 4.25%-DEXTROSE 25%®  
AMINOSYN II 5% IN 25% DEXTROSE®  
AMINOSYN II IN DEXTROSE®  
AMINOSYN II WITH LYTES-CA-DW®  
AMINOSYN II®  
AMINOSYN M®  
AMINOSYN WITH ELECTROLYTES®  
AMINOSYN®  
AMINOSYN-HBC®  
AMINOSYN-HF®  
AMINOSYN-PF®  
AZASAN®  
AZATHIOPRINE  
AZATHIOPRINE SODIUM  
CANCIDAS®  
CELLCEPT®  
CLINIMIX E®  
CLINIMIX®  
COMVAX®  
CYCLOSPORINE  
CYCLOSPORINE MODIFIED  
DEXTROSE 5%-ELECTROLYTE #48  
ENGERIX-B®  
ERAXIS (WATER DILUENT)®  
FREAMINE III®  
GENGRAF  
HEPATASOL®  
INTRALIPID®  
IONOSOL B WITH DEXTROSE 5%®  
IONOSOL MB-DEXTROSE 5%®  
IONOSOL T-DEXTROSE 5%®  
ISOLYTE H WITH DEXTROSE®  
ISOLYTE M WITH DEXTROSE®

ISOLYTE P WITH DEXTROSE®  
ISOLYTE S WITH DEXTROSE®  
ISOLYTE S®  
LIPOSYN II®  
LIPOSYN III  
MYCAMINE®  
MYCOPHENOLATE MOFETIL  
MYFORTIC®  
NEBUPENT®  
NEPHRAMINE®  
NORMOSOL-M AND DEXTROSE®  
NORMOSOL-R AND DEXTROSE®  
NORMOSOL-R PH 7.4®  
PEDIARIX®  
PENTAM 300®  
PLASMA-LYTE 148 IN DEXTROSE®  
PLASMA-LYTE 148®  
PLASMA-LYTE 56 IN DEXTROSE®  
PLASMA-LYTE 56®  
PLASMA-LYTE A PH 7.4®  
PLASMA-LYTE R®  
PREMASOL®  
PROCALAMINE®  
PROGRAF®  
PULMOZYME®  
QUICK MIX W/LYTES®  
QUICK MIX WITH LYTES®  
RAPAMUNE®  
RECOMBIVAX HB®  
RENAMIN®  
SIMULECT®  
SYNERCID®  
TACROLIMUS ANHYDROUS  
TPN ELECTROLYTES®  
TRAVASOL WITH DEXTROSE®  
TRAVASOL WITH ELECTROLYTES®  
TRAVASOL®  
TREANDA®  
TROPHAMINE®

TWINRIX®  
VIBATIV®  
VIMPAT®  
ZENAPAX®

**Covered Uses**

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

## 5HT-3 ANTAGONISTS

### Affected Drugs

GRANISETRON HCL  
ONDANSETRON HCL  
ONDANSETRON ODT

### Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

### Exclusion Criteria

N/A

### Required Medical Information

Prevention or treatment of nausea and vomiting associated with cancer chemotherapy or radiation: documentation of current treatment with 1) moderately or highly emetogenic chemotherapy or 2) total body, upper hemi-body or abdominal irradiation.

### Age Restrictions

N/A

### Prescriber Restrictions

N/A

### Coverage Duration

Nausea and vomiting, cancer treatment: 12 months Post-operative nausea and vomiting: one dose.

### Other Criteria

1) Not receiving concurrent oral or IV Zofran, Kytril, Anzemet or Emend. 2) Approve under Part B benefit if use is related to cancer treatment and a full replacement for IV administration within 48 hours of cancer treatment. 2) Requests for the treatment of nausea and vomiting of pregnancy and hyperemesis gravidarum require Medical Director review for medical necessity. 3) Brand name medications will be approved only upon provision of substantial evidence of medical necessity over generic formulations.

**ACTIMMUNE****Affected Drugs**

ACTIMMUNE®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

Applies to new starts only.

**Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

12 months.

**Other Criteria**

N/A

## **ADCIRCA**

### **Affected Drugs**

ADCIRCA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Concurrent therapy with a) Viagra, Cialis, Levitra, b) Nitrates.

### **Required Medical Information**

Initial: 1) Cardiac cath: mPAP of at least 25 mmHg at rest, PCWP of less than 16 mmHg at rest, and NYHA Class II or III, 2) Specific and measurable goals to assess response, such as significant increase in 6 minute walk test, decrease in dyspnea fatigue rating and other symptoms, evidence of hemodynamic improvement such as a reduction in mPAP and PVR or lack of functional decline. Renewal: Pre-defined treatment goals are being met.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Pulmonologist or Cardiologist.

### **Coverage Duration**

Initial: 12 weeks Renewal: 12 months.

### **Other Criteria**

1) If positive response to vasoreactivity testing such as at least 25% reduction in mean PVR, fall in mean PAP of at least 10 and 40 mmHg or increase or unchanged in cardiac output, then documentation of failure or contraindication to a calcium channel blocker. 2) Requests for combination therapy with other PAH [Pulmonary Arterial Hypertension] or PPH drugs requires Medical Director review of medical necessity.

**AFINITOR****Affected Drugs**

AFINITOR®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

Investigational use.

**Required Medical Information**

Applies to new starts only. Initial: 1) Failure of or contraindications to sunitinib or sorafenib. Renewal: Documented hematologic or cytogenetic response.

**Age Restrictions**

N/A

**Prescriber Restrictions**

Oncologist or Hematologist.

**Coverage Duration**

12 months.

**Other Criteria**

N/A

## **ALFERON**

### **Affected Drugs**

ALFERON N®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

Age at least 18 years.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

8 weeks.

### **Other Criteria**

Documentation of failure of or contraindications to conventional treatment with at least: 1) one patient-administered treatment including podofilox or imiquimod and 2) one provider-administered treatment including cryotherapy, trichloroacetic acid, podophyllum resin or surgical excision.

## ALPHA-1 PROTEINASE INHIBITORS

### Affected Drugs

ARALAST NP®  
PROLASTIN®  
ZEMAIRA®

### Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

### Exclusion Criteria

N/A

### Required Medical Information

Initial: 1) documented ZZ or Z/null AAT [Alpha 1-antitrypsin] deficiency and 2) AAT [Alpha 1-antitrypsin] serum level less than or equal to 11 $\mu$ M or 50mg/dL and 3) moderate emphysema and/or FEV1 between 30% to 65% and 4) the member has undergone or is currently undergoing pulmonary rehabilitation, weight loss and nutritional support if indicated and 5) nonsmoker or currently enrolled in smoking cessation program and 6) the provider has outlined specific, measurable treatment goals such as slowing of FEV1 decline or lack of disease progression. Renewal: 1) documentation member is meeting treatment goals such as slowing FEV1 decline or lack of disease progression and 2) continued abstinence from smoking.

### Age Restrictions

N/A

### Prescriber Restrictions

Pulmonologist.

### Coverage Duration

Initial: 3 months Renewal: 12 months.

### Other Criteria

N/A

## **AMEVIVE**

### **Affected Drugs**

AMEVIVE®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Initial: Plaque psoriasis for at least 6 months covering more than 10% of body surface area and causes functional impairment or location of disease causes reduced quality of life and meets criteria for Enbrel or Humira. Renewal: 1) Minimum of 12 weeks has elapsed since initial 12-week course of treatment and 2) At least a 50% improvement in affected BSA [Body surface area], plaque severity and/or functioning.

### **Age Restrictions**

Age at least 18 years.

### **Prescriber Restrictions**

Dermatologist.

### **Coverage Duration**

3 months.

### **Other Criteria**

Initial: Documented failure of or contraindications to 1) Enbrel or Humira, and 2) phototherapy or phytochemotherapy.

## **AMITIZA**

### **Affected Drugs**

AMITIZA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

1) Chronic Idiopathic Constipation, initial: documentation of fewer than 3 spontaneous bowel movements per week and a 6 month history of one or more of the following symptoms at least 25% of the time including straining, hard stools, or sensation of incomplete evacuation. 2) Irritable Bowel Syndrome, initial: female gender . Renewal: Documentation of a significant reduction in constipation measured objectively and abdominal pain.

### **Age Restrictions**

Age at least 18 years.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Initial: 6 weeks Renewal: 12 months.

### **Other Criteria**

Chronic Idiopathic Constipation, initial: failure of or contraindication to non-pharmacologic therapy including behavioral, exercise, and diet AND 2 of the following: methylcellulose, psyllium, lactulose, magnesium hydroxide, docusate, mineral oil, bisacodyl, senna, polyethylene glycol 3350. Irritable Bowel Syndrome, initial: failure of or contraindication to non-pharmacologic therapy including behavioral, exercise, and diet AND 2 of the following: methylcellulose, psyllium, lactulose, magnesium hydroxide, docusate, mineral oil, bisacodyl, senna, polyethylene glycol 3350.

**ANADROL-50****Affected Drugs**

ANADROL-50®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

1) Carcinoma of the prostate or breast in males. 2) Carcinoma of the breast in females with hypercalcemia. 3) Known or suspected pregnancy. 4) Nephrosis or the nephrotic phase of nephritis. 5) Severe hepatic dysfunction.

**Required Medical Information**

N/A

**Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

12 months.

**Other Criteria**

N/A

**APOKYN****Affected Drugs**

APOKYN®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

Renewal: Documentation that the patient's "off" time has been reduced with Apokyn.

**Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

Initial: 1 month Renewal: 12 months.

**Other Criteria**

Initial: Documentation that the patient's "off" episodes can not be adequately controlled by oral levodopa/carbidopa.

## **ARIXTRA**

### **Affected Drugs**

ARIXTRA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Prophylaxis: up to 5 weeks Treatment: until within therapeutic INR with warfarin.

### **Other Criteria**

1) Prophylaxis of DVT following knee surgery- up to 11 days post procedure, 2) Prophylaxis of DVT following hip surgery- 5 weeks post procedure, 3) Prophylaxis of DVT following abdominal surgery- 4 weeks post procedure, 4) Acute DVT or PE up to 5 days or longer as required when administered with warfarin until within therapeutic INR of 2-3.

## **AZILECT**

### **Affected Drugs**

AZILECT®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Renewal: Reduction in specific Parkinson's symptoms such as tremor, rigidity and bradykinesia.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Initial: 6 months Renewal: lifetime.

### **Other Criteria**

Initial: Documentation of failure of or contraindication to oral selegiline and is not concurrently taking any of the following: MAO inhibitors or sympathomimetic amines including amphetamines, cyclobenzaprine, meperidine, methadone, morphine, propoxyphene and tramadol.

## **BOTULINUM TOXIN**

### **Affected Drugs**

BOTOX®  
MYOBLOC®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D and 1) Cervical dystonia, 2) Laryngeal dysphonia, 3) Hemifacial spasm, 4) Pediatric limb spasticity associated with cerebral palsy, 5) Hereditary spastic paraplegia and 6) Spastic hemiplegia, paraplegia or quadriplegia secondary to stroke, spinal cord injury, brain injury or multiple sclerosis.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Initial: Documentation of significant functional impairment. Renewal: Documentation that treatment goals have been partially or completely met, including decrease in severity of dystonia, decrease in pain, improvement in function and decrease in disability.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months, 4 dose series.

### **Other Criteria**

Initial: Failure of or contraindication to 2 oral agents such as baclofen, dantrolene, tizanidine, and gabapentin when appropriate based on the indication. For spasticity of central origin, such as in cerebral palsy, post-stroke, spinal cord injury, or multiple sclerosis also require documentation of non-pharmacologic therapy has been ineffective or cannot be maximized secondary to significant contracture.

## **BUPRENORPHINE**

### **Affected Drugs**

BUPRENORPHINE HCL  
SUBOXONE®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Initial: Documentation of adequate psychosocial support for office-based therapy.  
Renewal: Documentation of compliance with provider visits, counseling and negative toxicology screens.

### **Age Restrictions**

Greater than or equal to 16 years.

### **Prescriber Restrictions**

Prescribers authorized to prescribe buprenorphine.

### **Coverage Duration**

Initial: 3 month Renewal: 6 months at a time.

### **Other Criteria**

Initial: 1) Contraindication to or failure of methadone maintenance therapy (MMT) or unable to go to a MMT facility due to location of residence, and 2) Not taking concurrent opioids for chronic pain . Buprenorphine is not covered for treatment of pain.

## **BYETTA**

### **Affected Drugs**

BYETTA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Initial: 1) HbA1c above 7%. 2) No history of gastroparesis or end stage renal disease. Renewal: At least a 10% reduction in HbA1c or has reached target HbA1c.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Initial: 6 months Renewal: 12 months.

### **Other Criteria**

Initial: 1) Failure of or contraindication to a minimum 3 month course of a) maximum tolerated dose of metformin plus sulfonylurea or b) maximum tolerated dose of metformin or sulfonylurea plus thiazolidinedione. 2) Not receiving concurrent treatment with pramlintide.

## **CELEBREX**

### **Affected Drugs**

CELEBREX®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

1) History of GI bleed or 2) Active peptic ulcer documented through endoscopy.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

5 years.

### **Other Criteria**

N/A

## **CICLOPIROX NAIL LACQUER**

### **Affected Drugs**

CICLOPIROX

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

1) Diagnosis confirmed by a positive KOH stain, positive PAS [histologic examination] stain, or positive fungal culture, and 2) One of the following medical conditions: a) Immunodeficiency, b) Diabetes mellitus, c) Vascular compromise: venous ulcers, venostasis dermatitis, poor arterial circulation, vascular insufficiency, severe peripheral vascular disease or claudication, or d) Vasculitis.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

Contraindication to or failure of terbinafine.

## **CIMZIA**

### **Affected Drugs**

CIMZIA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Crohn's Initial: Documentation of moderate to severe Crohn's disease supported by the following: prominent symptoms including fevers, significant weight loss, abdominal pain or tenderness, intermittent nausea or vomiting, or significant anemia, evidence of intestinal obstruction, cachexia, or evidence of abscess. Crohn's Renewal: Objective evidence of response such as a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. RA [Rheumatoid Arthritis] Renewal: Medical record documentation of a 20% or greater improvement in tender joint count and swollen joint count or a reduction in specific, objective pain symptoms and/or improved functioning.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Gastroenterologist or rheumatologist.

### **Coverage Duration**

Initial: 6 months Renewal 12 months.

### **Other Criteria**

Crohn's: Failure of or contraindication to a TNF [Tumor necrosis factor] inhibitor such as infliximab or adalimumab. RA [Rheumatoid Arthritis] Initial: 1) Failure or contraindication to one of the following: methotrexate, leflunomide, cyclosporine, hydroxychloroquine, azathioprine or sulfasalazine.

## **COLONY STIMULATING FACTORS**

### **Affected Drugs**

LEUKINE®  
NEULASTA®  
NEUPOGEN®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Documentation of one the following: a) receiving myelosuppressive chemotherapy for a non-myeloid malignancy or post-induction chemotherapy for AML [Acute Myeloid Lymphoma] (leukine only) or b) BMT [Bone Marrow Transplant] (allogeneic or autologous) or c) autologous peripheral blood progenitor cell (PBPC) transplant or d) severe chronic neutropenia and not on interferon-ribavirin based Hepatitis C treatment or e) AIDS or f) myelodysplastic syndromes.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

3 months.

### **Other Criteria**

Neutropenia associated with inteferon and/or ribavirin treatment requires review by Medical Director for medical necessity.

## **CYMBALTA**

### **Affected Drugs**

CYMBALTA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

1) Renal impairment CrCl less than 30ml/min or ESRD. 2) Hepatic impairment or chronic liver disease. 3) Concurrent use of thioridazine or MAOIs. 4) Uncontrolled narrow angle glaucoma.

### **Required Medical Information**

Fibromyalgia: Documentation of diagnosis based on ACR classification criteria.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

1) Depression: Applies to new starts only. Failure of or contraindication to at least one formulary SSRI [Selective Serotonin Reuptake Inhibitor] (citalopram, fluoxetine, paroxetine or sertraline) and venlafaxine. 2) Generalized Anxiety Disorder: failure of or contraindication to buspirone and paroxetine.

## **ELIDEL AND PROTOPIC**

### **Affected Drugs**

ELIDEL®  
PROTOPIC®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Renewal: Significant reduction in number or severity of cutaneous lesions.

### **Age Restrictions**

Age at least 2 years.

### **Prescriber Restrictions**

Dermatologist.

### **Coverage Duration**

Initial: 6 weeks Renewal: 6 months.

### **Other Criteria**

Initial: Documented failure of or contraindication to at least 4 weeks of all of the following: 1) non-pharmacologic treatment (food and environmental allergen avoidance, hygiene, etc. ) and 2) emollients and 3) mid-to-high potency corticosteroids.

## **EMEND**

### **Affected Drugs**

EMEND®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Confirmation of diagnosis and use as prophylaxis and not for established nausea and vomiting.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

PONV: one dose Chemotherapy: 12 months.

### **Other Criteria**

Chemotherapy: 1) Documentation of failure of or contraindication to a standard regimen of 5HT-3 antagonist (Zofran, Kytril, Aloxi) plus dexamethasone and 2) Requires concurrent treatment with IV or oral Zofran (ondansetron) or Kytril (granisetron) or Aloxi (palonosetron) and dexamethasone. Approve under Part B benefit if used as part of an anti-cancer chemotherapeutic regimen and as a full therapeutic replacement for an intravenous anti-emetic drug within 48 hours of chemotherapy administration. Otherwise, approve under Part D benefit.

## **EMSAM**

### **Affected Drugs**

EMSAM®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

1) Use of the any of the following medications within the past week: SSRIs [Selective Serotonin Reuptake Inhibitors], SNRIs [Selective Norepineprine Reuptake Inhibitors], TCAs [Tricyclic Antidepressants], MAOIs, meperidine, tramadol, methadone, and propoxyphene, mirtazapine, bupropion, or buspirone. 2) Use of fluoxetine within the past 5 weeks. 3) Concurrent treatment with oral selegiline.

### **Required Medical Information**

Applies to new starts only.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

Failure of or contraindication to at least 2 trials of adequate dose and duration of a) SSRI [Selective Serotonin Reuptake Inhibitor] (citalopram, fluoxetine, paroxetine, sertraline), b) SNRI [Selective Norepineprine Reuptake Inhibitor] (venlafaxine), c) bupropion, d) mirtazapine.

## **ENBREL**

### **Affected Drugs**

ENBREL®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

1) Rheumatoid arthritis (RA) renewal: improved functioning and/or 20% or greater improvement in tender joint count and swollen joint count. 2) Psoriasis with arthropathy (PsA) renewal: improved functioning and/or 20% or greater improvement in tender joint count and swollen joint count. 3) Ankylosing spondylitis (AS) Renewal: Improved functioning and/or symptoms. 4) Plaque psoriasis (PP) renewal: 50% or greater improvement in affected BSA [Body surface area], plaque severity and/or functioning. 5) Juvenile idiopathic arthritis (JIA) renewal: Improved functioning and/or 20% or greater improvement in tender joint count and swollen joint count.

### **Age Restrictions**

JIA [Juvenile Idiopathic Arthritis]: age 2 or older.

### **Prescriber Restrictions**

Rheumatologist or Dermatologist.

### **Coverage Duration**

Initial: 6 months Renewal: 12 months.

### **Other Criteria**

1) RA [Rheumatoid Arthritis] Initial: failure of or contraindication to methotrexate and at least one other DMARD [Disease-modifying antirheumatic drug] such as leflunomide, cyclosporine, sulfasalazine, azathioprine or hydroxychloroquine. 2) PsA [Psoriatic arthritis] initial: failure of or contraindication to at least one NSAID [Non-steroidal anti-inflammatory drug] and methotrexate. 3) AS initial: failure of or contraindication to at least one NSAID [Non-steroidal anti-inflammatory drug] and sulfasalazine or methotrexate in patients with peripheral disease (not required for axial disease). 4) PP initial: failure of or contraindication to a) methotrexate or cyclosporine and b)

phototherapy or phytochemotherapy. 5) JIA [Juvenile Idiopathic Arthritis] initial: failure of or contraindication to methotrexate. 6) For all diagnoses: not on concurrent therapy with other immune modulators such as adalimumab, anakinra, abatacept, and infliximab.

## ERYTHROPOIESIS-STIMULATING AGENTS

### Affected Drugs

ARANESP®  
EPOGEN®  
PROCRIT®

### Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

### Exclusion Criteria

N/A

### Required Medical Information

1) Anemia associated with chronic kidney disease (CKD): a) Hgb below 10 g/dL or Hct below 30% and b) ferritin at least 100 ng/mL and/or c) transferrin saturation at least 20%. 2) Anemia associated with cancer treatment (HIV): a) Hgb below 10 g/dL or Hct below 30% and b) ferritin at least 100 ng/mL and/or c) transferrin saturation at least 20%. 3) Anemia associated with Zidovudine therapy: a) Hgb below 10 g/dL or Hct below 30% and b) transferrin saturation at least 20% and c) endogenous erythropoietin below 500 IU/L. 4) Surgery: a) high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery and b) baseline Hgb greater than 10g/dL, but below 13g/dL.

### Age Restrictions

N/A

### Prescriber Restrictions

N/A

### Coverage Duration

CKD [Chronic Kidney Disease] and HIV: 12 months Cancer: 6 months Surgery: 1 month.

### Other Criteria

1) Anemia associated with zidovudine therapy: zidovudine dose less than 4200mg per week verified by claim history. 2) Anemia associated with inteferon and/or ribavirin treatment requires review by Medical Director for medical necessity.

## **EXJADE**

### **Affected Drugs**

EXJADE®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Initial: Serum ferritin 1000-8000ng/ml. Renewal: 1) Documentation of compliance with recommended monitoring of monthly ferritin, serum creatinine, urine protein, LFTs, and yearly auditory and ophthalmic testing and 2) reduction in total body iron, evidenced by decreased ferritin levels.

### **Age Restrictions**

Age at least 2 years.

### **Prescriber Restrictions**

Hematologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

Initial: Failure of or contraindication to desferrioxamine.

**FANAPT****Affected Drugs**

FANAPT®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

Applies to new starts only.

**Age Restrictions**

Age at least 18 years.

**Prescriber Restrictions**

N/A

**Coverage Duration**

Lifetime.

**Other Criteria**

Failure or contraindication to risperidone and at least one other atypical antipsychotic including olanzapine, ziprasidone, aripiprazole, and quetiapine.

## **FENTANYL TRANSDERMAL**

### **Affected Drugs**

FENTANYL

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

Unable to take oral long-acting opioids or failed or have contraindications to sustained-release morphine.

## **FORTEO**

### **Affected Drugs**

FORTEO®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Patients who are at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, or prior external beam or implant radiation therapy involving the skeleton).

### **Required Medical Information**

1) Postmenopausal female with either a) evidence of recent radiographic osteoporotic fracture while compliant on a bisphosphonate for at least 12 months or b) high risk of osteoporotic fracture. 2) Male with primary or hypogonadal osteoporosis and either a) evidence of history of osteoporotic fracture or b) multiple risk factors for osteoporotic fractures such as BMD [Bone mass density] less than -2.5 SD, low BMI, history of hip fracture in 1st degree relative, tall stature, and chronic daily use of tobacco. 3) Female or male with steroid-induced osteoporosis and ALL of the following: a) steroid use for greater than 3 months at a dose of 5mg per day prednisone (or equivalent), b) BMD [Bone mass density] T-score less than -2.5, and c) evidence of fracture while compliant on a bisphosphonate.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

2 years.

### **Other Criteria**

Failure of or contraindication to oral bisphosphonate for at least 12 months despite proper administration and adherence.

**GARDASIL****Affected Drugs**

GARDASIL®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

N/A

**Age Restrictions**

Age 9-26 years.

**Prescriber Restrictions**

N/A

**Coverage Duration**

Series of 3 doses.

**Other Criteria**

N/A

## HEDIS DRUGS TO AVOID IN THE ELDERLY

### Affected Drugs

AMPHETAMINE SALT COMBO  
ATROPINE SULFATE  
CHLORZOXAZONE  
CYCLOBENZAPRINE HCL  
DEXMETHYLPHENIDATE HCL  
DEXTROAMPHETAMINE SULFATE  
DICYCLOMINE HCL  
DIPHENHYDRAMINE HCL  
DIPHENOXYLATE-ATROPINE  
DIPYRIDAMOLE  
ESTROPIPATE  
LONOX  
MENEST®  
METHOCARBAMOL  
METHYLIN  
METHYLIN ER  
METHYLPHENIDATE HCL  
METHYLPHENIDATE SR  
NITROFURANTOIN  
NITROFURANTOIN MONO-MACRO  
ORPHENADRINE CITRATE  
ORTHO-EST®  
PROPANTHELINE BROMIDE  
TRIMETHOBENZAMIDE HCL

### Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

### Exclusion Criteria

N/A

### Required Medical Information

N/A

### Age Restrictions

Age less than 65 years.

**Prescriber Restrictions**

N/A

**Coverage Duration**

5 years.

**Other Criteria**

N/A

## HEDIS DRUGS TO AVOID IN THE ELDERLY - THIORIDAZINE

### Affected Drugs

THIORIDAZINE HCL

### Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

### Exclusion Criteria

N/A

### Required Medical Information

N/A

### Age Restrictions

Age less than 65 years.

### Prescriber Restrictions

N/A

### Coverage Duration

5 years.

### Other Criteria

N/A

## HEPATITIS C AGENTS

### Affected Drugs

PEGASYS®  
PEGINTRON REDIPEN®  
PEGINTRON®  
RIBASPHERE  
RIBAVIRIN

### Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

### Exclusion Criteria

Decompensated cirrhosis or autoimmune hepatitis.

### Required Medical Information

1) HCV Initial: a) If applicable, abstinence from IV drug or alcohol abuse for more than 6 months, b) no evidence of severe or uncontrolled psychiatric disorder, autoimmune disease, myelosuppression, unstable cardiovascular disease, renal impairment, c) detectable HCV RNA greater than 50 IU/mL, d) documented HCV genotype. 2) HCV Renewal: undetectable HCV RNA or at least a 2-log reduction in HCV RNA after 12 weeks of therapy. 3) HBV: a) Compensated cirrhosis and HBV DNA greater than 2000 IU/ml or b) If HBeAg positive, HBV DNA at least 20,000 IU/ml and serum ALT is persistently elevated after 3-6 months or liver biopsy shows at least moderate inflammation or significant fibrosis or c) If HBeAg negative, HBV DNA greater than 2000 IU/ml and serum ALT is persistently elevated after 3-6 months or liver biopsy shows at least moderate inflammation or fibrosis.

### Age Restrictions

N/A

### Prescriber Restrictions

N/A

### Coverage Duration

HCV Initial: 4 months HCV G1, G4 Renewal: 8 months HCV G2, G3 Renewal: 2 months HBV: 12 months.

### Other Criteria

HCV: Prior history of treatment with pegylated interferon and ribavirin requires case-by-case Medical Director review for medical appropriateness/ necessity. HBV: 1) Prior treatment with pegylated interferon requires Medical Director review for medical appropriateness/ necessity. 2) If the request is for combination therapy with Eпивir, Hepsera, Baraclude, or Tyzeka requires Medical Director review for medical appropriateness/ necessity.

## **HUMIRA**

### **Affected Drugs**

HUMIRA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

1) Crohn's disease (CD) renewal: a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. 2) Rheumatoid arthritis (RA) renewal: improved functioning and/or 20% or greater improvement in tender joint count and swollen joint count. 3) Psoriasis with arthropathy (PsA) renewal: improved functioning and/or 20% or greater improvement in tender joint count and swollen joint count. 4) Ankylosing spondylitis (AS) renewal: improved functioning and/or signs and symptoms of AS. 5) Juvenile idiopathic arthritis (JIA) renewal: improved functioning and/or 20% or greater improvement in tender joint count and swollen joint count. 6) Plaque psoriasis (PP) initial: PP for at least 6 months covering more than 10% of body surface area and causes functional impairment or location of disease causes reduced quality of life. PP Renewal: At least 50% improvement in affected BSA [Body surface area], plaque severity and/or functioning.

### **Age Restrictions**

JIA [Juvenile Idiopathic Arthritis]: Age 4 years or older.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Initial: 6 months Renewal: 12 months.

### **Other Criteria**

1) CD [Crohn's Disease] initial: failure of or contraindication to conventional therapy with at least one agent from the following drug classes a) aminosalicylic acid derivatives (sulfasalazine or mesalamine) and b) immunosuppressants (azathioprine or methotrexate). 2) RA [Rheumatoid Arthritis] initial: a) failure of or contraindication to

methotrexate and at least one other DMARD [Disease-modifying antirheumatic drug] such as leflunomide, cyclosporine, sulfasalazine, azathioprine, or hydroxychloroquine. 3) PsA [Psoriatic arthritis] Initial: a) failure of or contraindications to conventional management with at least one NSAID [Non-steroidal anti-inflammatory drug] and methotrexate. 4) AS initial: a) failure of or contraindication to at least one NSAIDs [Non-steroidal anti-inflammatory drugs] and sulfasalazine or methotrexate in patients with peripheral disease (not required for axial disease). 5) JIA [Juvenile Idiopathic Arthritis] Initial: failure of or contraindication to an 8 week trial of methotrexate. 6) PP Initial: failure of or contraindication to a) methotrexate or cyclosporine and b) phototherapy or phytochemotherapy. 7) For all diagnoses: not on concurrent therapy with another immune modulator such as etanercept, abatacept, anakinra or infliximab.

## **INCRELEX**

### **Affected Drugs**

INCRELEX®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

1) Evidence of closure of epiphyseal plate. 2) Active or suspected neoplasia.

### **Required Medical Information**

1) Primary IGF-1 Deficiency Initial: a) Secondary causes have been ruled out, such as growth hormone deficiency, malnutrition, hypothyroidism, and chronic corticosteroid therapy, b) Height standard deviation score less than or equal to -3 and basal IGF-1 standard deviation score of less than or equal to -3 and normal or elevated growth hormone. 2) Growth Hormone Gene Deletion Initial: evidence of gene deletion and (+) neutralizing antibodies to growth hormone.

### **Age Restrictions**

Age 2-18 years.

### **Prescriber Restrictions**

Endocrinologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

N/A

## **INFERGEN**

### **Affected Drugs**

INFERGEN®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Decompensated cirrhosis or autoimmune hepatitis.

### **Required Medical Information**

Chronic Hepatitis C Initial: 1) No history of severe or uncontrolled psychiatric disorder, autoimmune disorders, unstable cardiovascular disease, myelosuppression, 2) No recent IV drug use or alcohol abuse within the past 6 months, 3) Detectable viral load greater than 50IU/mL and 4) Documented HCV genotype. Renewal: Undetectable HCV RNA or at least a 2-log reduction (+/- one standard deviation) in HCV RNA after 12 weeks.

### **Age Restrictions**

At least 18 years.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Initial: 16 week Renewal G1, G4: 36 week Renewal G2, G3: 12 week Renewal HIV-Coinfxn: 36 week.

### **Other Criteria**

1) Initial: Failure of or contraindication to pegylated-interferon ribavirin therapy. 2) History of treatment with interferon and ribavirin therapy requires Medical Director review for medical necessity.

## **INTERFERON ALFA-2B**

### **Affected Drugs**

INTRON A®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Decompensated cirrhosis or autoimmune hepatitis.

### **Required Medical Information**

Chronic Hepatitis C (HCV): Initial: 1) Detectable viral load greater than 50IU/mL and 2) Documented HCV genotype. HCV Renewal: Undetectable HCV RNA or at least a 2-log reduction (+/- one standard deviation) in HCV RNA after 12 weeks. Chronic Hepatitis B (HBV): 1) Compensated cirrhosis and HBV DNA greater than 2000 IU/ml or 2) If HBeAg positive, HBV DNA at least 20, 000 IU/ml and serum ALT is persistently elevated after 3-6 months or liver biopsy shows at least moderate inflammation or significant fibrosis or 3) If HBeAg negative, HBV DNA greater than 2000 IU/ml and serum ALT is persistently elevated after 3-6 months or liver biopsy shows at least moderate inflammation or fibrosis.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Oncologist or Infectious Disease Specialist or GI specialist.

### **Coverage Duration**

Cancer: up to 6 months HBV: 12 months HCV: Initial: 16 weeks Renewal: 12 months CA: 3 weeks.

### **Other Criteria**

HCV: 1) Failure of or contraindication to pegylated-interferon ribavirin therapy. 2) History of treatment with pegylated-interferon ribavirin therapy requires Medical Director review for medical necessity. Condyloma Acuminatum (CA): 1) Documentation of failure of or contraindications to conventional treatment with at least 1 patient-administered treatment such as podofilox or imiquimod and 1 provider-administered treatment such as cryotherapy or trichloroacetic acid or podophyllum resin or surgical excision. HBV: 1)

Has not received previous treatment with interferon. 2) If the request is for combination therapy with Epivir, Hepsara, Baraclude, or Tyzeka requires Medical Director review for medical appropriateness/ necessity.

## **INTRAVENOUS IMMUNE GLOBULIN**

### **Affected Drugs**

ATGAM®  
CARIMUNE NF NANOFILTERED®  
FLEBOGAMMA®  
GAMASTAN S-D®  
GAMMAGARD LIQUID®  
GAMUNEX®  
OCTAGAM®  
POLYGAM S-D®  
THYMOGLOBULIN®  
VIVAGLOBIN®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D and HIV, Allogeneic bone marrow transplant (BMT), pregnancy-associated idiopathic thrombocytopenic purpura, Myasthenia Gravis (MG), Autoimmune Mucocutaneous Blistering Disease (AMBD), Autoimmune Hemolytic Anemia, Warm Type (AHA-W), Polymyositis and Dermatomyositis.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

1) Acute Idiopathic Thrombocytopenic Purpura: platelet less than 30, 000 or need to increase platelet prior to major, invasive surgery. 2) Chronic ITP [Immune thrombocytopenic purpura]: duration of illness less than 6 months, no concurrent illness/disease explaining thrombocytopenia, platelets persistently below 20, 000. 3) ITP [Immune thrombocytopenic purpura] in pregnancy: previous deliveries of children with autoimmune thrombocytopenia or platelets below 30, 000 associated with bleeding before delivery, or platelets below 75, 000 during the current pregnancy or history of splenectomy. 4) Chronic B-Cell Lymphocytic Leukemia with hypogammaglobulinemia: IgG below 600 and evidence of specific antibody deficiency and repeated bacterial infections. 5) HIV: CD4+ greater than 200/mm<sup>3</sup>, and clinically symptomatic. 6) BMT [Bone Marrow Transplant]: hematologic neoplasm, seropositive for CMV prior to transplant, severe hypogammaglobulinemia defined as IgG less than 400 within the first 100 days post transplant, and seronegative donor. 7) Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) including Guillain-Barre Syndrome: Difficulty with

venous access for plasmaphoresis, or rapidly progressive form of disease with symptoms less than 2 weeks or deteriorating ability to ambulate, or deteriorating PFTs. 8) Autoimmune Mucocutaneous Blistering Disease (AMBD): Diagnosis of pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid or epidermolysis bullous acquisita. 9) Autoimmune Hemolytic Anemia, Warm Type: Predominance of IgG antibodies or comorbid hepatomegaly or hepatosplenomegaly. 10) Polymyositis and Dermatomyositis: associated with severe disability. 11) Acute Myasthenia Gravis (AMG): a) Myasthenic exacerbation defined by difficulty swallowing, acute respiratory failure, or major functional disability or b) presurgical treatment.

**Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

PI: Lifetime All other diagnoses: 3 months per request.

**Other Criteria**

Approvable under Medicare Part B for primary immunodeficiencies only. Chronic ITP [Immune thrombocytopenic purpura] requires failure of or contraindication to prednisone. CIDP requires failure of or contraindication to plasma exchange. AMG requires failure of or contraindication to two of the following: pyridostigmine, prednisone, azathioprine, methotrexate or plasmapheresis. AMBD requires 1) failure of or contraindication to a) prednisone and b) at least one of the following: methotrexate, azathioprine, cyclosporine or cyclophosphamide or 2) evidence of rapid disease progression and urgent administration of IVIG [Intravenous Immune Globulin] is medically necessary. Polymyositis and Dermatomyositis require failure of or contraindication to a) prednisone and b) at least one of the following: methotrexate, azathioprine, cyclosporine or cyclophosphamide.

**INVEGA****Affected Drugs**

INVEGA®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

N/A

**Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

2 years.

**Other Criteria**

Documented contraindication to risperidone such as significant CYP450 drug interactions.

## **INVEGA SUSTENNA**

### **Affected Drugs**

INVEGA SUSTENNA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Applies to new starts only.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

2 years.

### **Other Criteria**

Documented failure of or contraindication to Risperdal Consta.

**IRESSA****Affected Drugs**

IRESSA®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

Continuation of treatment: documented hematologic or cytogenic response.

**Age Restrictions**

N/A

**Prescriber Restrictions**

Oncologist.

**Coverage Duration**

12 months.

**Other Criteria**

N/A

## **JANUVIA**

### **Affected Drugs**

JANUVIA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Initial: HbA1c above 7%.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

1) Monotherapy Initial: Failure of or contraindication to a minimum 3 month course of maximum tolerated doses of 2 of the following: metformin, sulfonylurea and thiazolidinedione. 2) Combination Therapy Initial: Failure of or contraindication to a minimum 3 month course at maximum tolerated doses of combination therapy with 2 of the following: metformin, sulfonylurea and thiazolidinedione.

## **KINERET**

### **Affected Drugs**

KINERET®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Renewal: Improved functioning and/or 20% or greater improvement in tender joint count and swollen joint count.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Rheumatologist.

### **Coverage Duration**

Initial: 6 months Renewal: 12 months.

### **Other Criteria**

Initial: failure of or contraindication to 1) methotrexate and 2) at least one other DMARD [Disease-modifying antirheumatic drug] including leflunomide, cyclosporine, sulfasalazine, azathioprine or hydroxychloroquine and 3) Not on concurrent therapy with another immune modulator such as abatacept, infliximab, etanercept, or adalimumab.

**KUVAN****Affected Drugs**

KUVAN®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

Initial: Documentation that member is currently on and adherent to a phenylalanine-restricted diet. Renewal: Documentation of response to therapy.

**Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

12 months.

**Other Criteria**

N/A

## **LETAIRIS**

### **Affected Drugs**

LETAIRIS®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

- 1) Pregnant or of childbearing age and not using 2 reliable methods of birth control.
- 2) Baseline liver aminotransferases greater than 3x ULN.

### **Required Medical Information**

Initial: 1) Pulmonary hypertension not associated with portal hypertension or sickle cell disease, 2) Cardiac cath: Mean PAP greater than 24mm Hg at rest, and PCWP less than 15mm Hg at rest, and WHO Class II or III, and 3) nonsmoker or enrolled in smoking cessation, and 4) specific and measurable treatment goals to assess response to a 12-16 week trial such as a significant increase in the 6-minute walk test, or decrease in dyspnea fatigue rating and other symptoms, or evidence of improvement in hemodynamic mPAP or PVR or WHO class, or lack of functional or hemodynamic deterioration. Renewal: Monthly monitoring of LFTs and treatment goals met.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Pulmonologist or Cardiologist.

### **Coverage Duration**

Initial: 16 weeks Renewal: 12 months.

### **Other Criteria**

If positive response to vasoreactivity testing such as documentation of at least 25% reduction in mean PVR, or fall in mean PAP of at least 10 and PAP at least 40mm Hg, or increase or unchanged cardiac output, then documentation of failure of or contraindication to nifedipine, amlodipine, or diltiazem is required. Requests for combination therapy with other PAH [Pulmonary Arterial Hypertension] or PPH drugs requires Medical Director review of medical necessity.

## **LIDODERM**

### **Affected Drugs**

LIDODERM®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Renewal: Medical record documentation of a reduction in specific, objective pain symptoms and/or improved functioning.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Initial: 3 months Renewal: 12 months.

### **Other Criteria**

Failure of or contraindication to gabapentin.

## **LOTRONEX**

### **Affected Drugs**

LOTRONEX®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

1) Severe bowel disorder, 2) Constipation, 3) Concomitant use with fluvoxamine, 4) Severe hepatic impairment, 5) Hypercoaguable state, 6) Thrombophlebitis.

### **Required Medical Information**

Initial: Medical record documentation of predominant symptom is severe diarrhea lasting at least 6 months and defined as frequent and severe abdominal pain/discomfort, frequent bowel urgency or fecal incontinence, or disability or restriction of daily activities due to IBS. Renewal: Medical record documentation of a significant reduction in diarrhea frequency and abdominal pain and/or improvement in quality of life during the one-month trial on Lotronex.

### **Age Restrictions**

Greater than or equal to 18 years.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Initial: 1 month Renewal: 12 months.

### **Other Criteria**

Failure of or contraindication to at least one antidiarrheal such as loperamide or diphenoxylate and one antispasmodic such as dicyclomine or hyoscyamine.

## **LYRICA**

### **Affected Drugs**

LYRICA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Applies to new starts for seizure disorder only. 1) Fibromyalgia (FM) Initial: Documentation of diagnosis based on ACR classification criteria. Renewal required for all covered uses except seizure disorder: Medical record documentation of a reduction in specific, objective pain symptoms and/or improved functioning.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Seizure disorder: 5 years DPN, PHN, FM Initial: 3 months DPN, PHN, FM Renewal: 12 months.

### **Other Criteria**

Post-herpetic neuralgia (PHN): failure of or contraindication to gabapentin.

## **MARINOL**

### **Affected Drugs**

DRONABINOL

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D and 1) cancer-related anorexia 2) nausea and vomiting associated with HIV/AIDS.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

HIV/AIDS-wasting and cachexia: 12 months All others 3 month.

### **Other Criteria**

N/V associated with cancer or HIV: 1) failure of or contraindication to at least one of the following antiemetics- dimenhydrinate, meclizine, metoclopramide, promethazine, or prochlorperazine and 2) ondansetron and 3) not concurrently using Megace or ondansetron.

## **MULTAQ**

### **Affected Drugs**

MULTAQ®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

1) Concurrent use of QT prolonging drugs (eg, chlorpromazine, clarithromycin, disopyramide, dofetilide, erythromycin, felbamte, levofloxacin, moxifloxacin, paroxetine, risperidone, quetiapine, sotalol, thioridazine and ziprasidone), 2) Concurrent use of strong CYP3A inhibitors (eg, ketoconazole, itraconazole, voriconazole, cyclosporine, telithromycin, clarithromycin, nefazodone and ritonavir), 3) Heart failure, NYHA Class II or III with recent decompensation requiring hospitalization or specialized heart failure clinic referral, 4) Heart failure, NYHA Class IV.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Lifetime.

### **Other Criteria**

Documentation of failure of or contraindication to amiodarone.

**NAFTIN****Affected Drugs**

NAFTIN®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

N/A

**Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

1 month.

**Other Criteria**

Documentation of clinical or microbiological failure with ketoconazole, clotrimazole, nystatin, or econazole.

## **NAMENDA**

### **Affected Drugs**

NAMENDA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Initial: 1) Mini-Mental State Exam (MMSE) less than 20 or other documentation supporting diagnosis if MMSE is clinically inappropriate and 2) Able to perform at least one of the following ADLs unassisted (toileting, feeding, grooming, ambulating, bathing, dressing). Renewal: maintenance of cognitive and functional ability or reduction in the rate of cognitive and functional decline.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Initial: 6 months Renewal: 6 months.

### **Other Criteria**

If requesting combination therapy with an acetylcholinesterase inhibitor, then medical record documentation that there was an inadequate or poor clinical response to monotherapy such as: deterioration in cognition, functional ability, ability to carry out activities of daily living, behavior, mood or MMSE score.

## **NEXAVAR**

### **Affected Drugs**

NEXAVAR®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Applies to new starts only. 1) Renal Cell Carcinoma (RCC) Initial: Stage IV and medically untreatable or surgically unresectable disease. 2) Hepatocellular carcinoma Initial: Unresectable disease. Renewal: Documented hematologic or cytogenetic response.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Oncologist or Hematologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

RCC: Contraindication to or failure of cytokine-based therapy, such as interferon alfa or interleukin-2, due to disease progression, or unacceptable toxicity.

## **ONGLYZA**

### **Affected Drugs**

ONGLYZA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

HbA1c above 7%.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

1) Monotherapy: Failure of or contraindication to a minimum 3 month course of maximum tolerated doses of 2 of the following: metformin, sulfonylurea and thiazolidinedione. 2) Combination Therapy: Failure of or contraindication to a minimum 3 month course at maximum tolerated doses of combination therapy with 2 of the following: metformin, sulfonylurea and thiazolidinedione.

## **ORENCIA**

### **Affected Drugs**

ORENCIA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

No evidence of COPD [Chronic Obstructive Pulmonary Disease]. Renewal: Improved functioning and/or 20% or greater improvement in tender joint count and swollen joint count.

### **Age Restrictions**

JIA [Juvenile Idiopathic Arthritis]: age 6 or older.

### **Prescriber Restrictions**

Rheumatologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

1) Rheumatoid arthritis: a) failure of or contraindication to two of the following: etanercept, adalimumab or anakinra, and b) requires concurrent use with methotrexate or another oral DMARD [Disease-modifying antirheumatic drug] such as leflunomide, azathioprine, cyclosporine, hydroxychloroquine, or sulfasalazine and c) Not on concurrent therapy with another immune modulator such as anakinra, etanercept, adalimumab or infliximab. 2) Juvenile idiopathic arthritis (JIA): Failure of or contraindication to etanercept or adalimumab, and requires concurrent use with methotrexate unless contraindicated.

## **OXANDROLONE**

### **Affected Drugs**

OXANDROLONE

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

1) Carcinoma of the prostate or breast in males. 2) Carcinoma of the breast in females with hypercalcemia. 3) Hypercalcemia. 4) Nephrosis. 5) Pregnancy.

### **Required Medical Information**

1) Wasting syndrome (weight loss/cachexia): Weight loss of at least 10% and BMI less than 20 in the past 4 months  
Renewal: Maintenance or increase in weight and BMI.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Wasting Syndrome: 6 months  
Others: 12 months.

### **Other Criteria**

Bone pain associated with osteoporosis requires failure of or contraindication to at least 1 NSAID [Non-steroidal anti-inflammatory drug] and 1 long-acting opioid analgesic.

## **OXYCONTIN**

### **Affected Drugs**

OXYCODONE HCL  
OXYCONTIN®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

Documentation of contraindication to or failure of adequate trials of sustained release morphine sulfate and not receiving concurrent therapy with another long-acting opioid, such as fentanyl or sustained release morphine sulfate.

**PALIFERMIN****Affected Drugs**

KEPIVANCE®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

N/A

**Age Restrictions**

N/A

**Prescriber Restrictions**

Oncologist.

**Coverage Duration**

6 doses.

**Other Criteria**

N/A

## **PARENTERAL BIPHOSPHONATES**

### **Affected Drugs**

PAMIDRONATE DISODIUM  
ZOMETA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

For hypercalcemia of malignancy: albumin-corrected serum calcium above 12mg/dL.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

Osteoporosis: failure of or contraindication to oral bisphosphonates.

**PRISTIQ****Affected Drugs**

PRISTIQ®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

Applies to new starts only.

**Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

12 months.

**Other Criteria**

Documentation of lack of efficacy, significant adverse effects with, or contraindication to 1) at least one SSRI [Selective Serotonin Reuptake Inhibitor] such as sertraline, paroxetine, fluoxetine, and citalopram and 2) venlafaxine or venlafaxine XR.

## **PROVIGIL**

### **Affected Drugs**

PROVIGIL®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Daytime sleepiness associated with sleep apnea/hypopnea syndrome, Initial: Documentation of compliance with CPAP [Continuous positive airway pressure] or BiPAP for at least 4 hours per nights for at least 2 months. Shift work sleep disorder, Initial: Documentation that sleep disorder causes significant, objective functional impairment for at least 3 months. Renewal: documentation of significant improvement in daytime sleepiness and functioning.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Initial: 3 months Renewal: 6 months.

### **Other Criteria**

Excessive sleepiness associated with narcolepsy, Initial: Documented failure of or contraindication to formulary stimulants such as methylphenidate or dextroamphetamine. Shift work sleep disorder: Non-pharmacologic treatment has failed.

## **RANEXA**

### **Affected Drugs**

RANEXA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

1) Clinically significant hepatic impairment. 2) Concurrent treatment with CYP3A inducers (eg, rifampin, rifapentine, phenobarbital, phenytoin, carbamazepine) or strong CYP3A inhibitors (eg, ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir, and saquinavir).

### **Required Medical Information**

No history of QT prolongation.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Cardiologist.

### **Coverage Duration**

5 years.

### **Other Criteria**

Documentation of angina limiting daily activities despite treatment with at least 2 of the following: long-acting nitrate, beta-blocker, and calcium channel blocker.

## **REGRANEX**

### **Affected Drugs**

REGRANEX®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Renewal: documentation of a reduction in ulcer size by at least approximately 30%.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Surgeon or Podiatrist or Endocrinologist.

### **Coverage Duration**

Initial: 3 months Renewal: 2 months.

### **Other Criteria**

N/A

## **RELISTOR**

### **Affected Drugs**

RELISTOR®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Known or suspected mechanical gastrointestinal obstruction.

### **Required Medical Information**

1) Advanced illness defined as terminal disease such as incurable cancer or other end-stage disease with a life expectancy of less than 6 months, and 2) Receiving hospice care and/or palliative care and 3) Receiving chronic opioid therapy.

### **Age Restrictions**

Age at least 18 years.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

4 months.

### **Other Criteria**

Contraindication to or failure of combination therapy with at least 2 of the following laxatives appropriate for the treatment of opioid-induced constipation including polyethylene glycol 3350, senna, bisacodyl, lactulose, glycerin, magnesium citrate, magnesium hydroxide, sodium phosphate.

## REMICADE

### Affected Drugs

REMICADE®

### Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

### Exclusion Criteria

1) Moderate to severe heart failure.

### Required Medical Information

1) Crohn's disease (CD): Renewal: a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. 2) Ulcerative Colitis (UC) Renewal: decrease in frequency of bloody stools and/or elimination of signs of toxicity. 3) Rheumatoid Arthritis (RA) Renewal: Improvement in # of tender, swollen joints, improved function, ability to perform ADLs and/or pain. 4) Psoriatic Arthritis (PsA) Renewal: Improved functioning and/or decreased in # of tender, swollen joints and reduction in skin lesions and/or has disease stability. 5) Ankylosing Spondylitis (AS) Renewal: Improved functioning. 6) Plaque Psoriasis (PP) Initial: a) plaque psoriasis affecting at least 10% of BSA [Body surface area] and causing functional impairment or location of disease causes reduced quality of life. PP Renewal: At least 50% improvement in affected BSA [Body surface area], plaque severity and/or functioning.

### Age Restrictions

N/A

### Prescriber Restrictions

Gastroenterologist or rheumatologist or dermatologist.

### Coverage Duration

Initial: 6 months Renewal: 12 months.

### Other Criteria

1) CD [Crohn's Disease] Initial: a) failure of or contraindication to adalimumab. 2) UC [Ulcerative colitis] initial: a) failure of or contraindication to a 12 week trial of two of the following: aminosalicylates, prednisone, azathioprine or purinethol. 3) RA [Rheumatoid Arthritis] initial: a) failure of or contraindication to at least one self-administered biologic DMARD [Disease-modifying antirheumatic drug] such as etanercept, adalimumab or

anakinra and b) concurrent use with methotrexate unless contraindicated. 4) PsA [Psoriatic arthritis] Initial: a) failure of or contraindication to at least one self-administered biologic DMARD [Disease-modifying antirheumatic drug] such as etanercept or adalimumab and b) concurrent use with methotrexate unless contraindicated. 5) AS initial: a) failure of or contraindication to at least one self-administered biologic DMARD [Disease-modifying antirheumatic drug] such as etanercept or adalimumab. 6) PP initial: a) failure of or contraindication to at least one self-administered biologic DMARD [Disease-modifying antirheumatic drug] such as etanercept or adalimumab. 7) For all diagnoses: not on concurrent therapy with another immune modulator such as abatacept, anakinra, etanercept, or adalimumab.

## **REMODULIN**

### **Affected Drugs**

REMODULIN®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Initial: 1) Pulmonary arterial hypertension not associated with portal hypertension, sickle cell disease or thromboembolic disease, 2) Cardiac cath: mPAP of at least 25 mmHg at rest and PCWP of less than 16 mmHg at rest and NYHA Class II to IV, 3) nonsmoker or currently enrolled in a smoking cessation program, 4) specific and measurable goals to assess response, such as significant increase in 6 minute walk test, decrease in dyspnea fatigue rating and other symptoms, evidence of hemodynamic improvement such as a reduction in mPAP and PVR or lack of functional decline. Renewal: Defined treatment goals are being met.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Pulmonologist or Cardiologist.

### **Coverage Duration**

Initial: 16 weeks Renewal: 12 months.

### **Other Criteria**

1) If positive response to vasoreactivity testing such as at least 25% reduction in mean PVR, fall in mean PAP of at least 10 and 40 mmHg or increase or unchanged cardiac output, then documentation of failure of or contraindications to a calcium channel blocker is required and 2) Failure of or contraindications to Tracleer or Letairis. 3) Requests for combination therapy with other PAH [Pulmonary Arterial Hypertension] or PPH drugs requires Medical Director review of medical necessity.

## **REVATIO**

### **Affected Drugs**

REVATIO®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Concurrent therapy with a) Viagra, Cialis, Levitra, b) Nitrates.

### **Required Medical Information**

Initial: 1) Cardiac cath: mPAP of at least 25 mmHg at rest, PCWP of less than 16 mmHg at rest, and NYHA Class II or III, and 2) Documentation of specific and measurable goals to assess response, such as significant increase in 6 minute walk test, decrease in dyspnea fatigue rating and other symptoms, evidence of hemodynamic improvement such as a reduction in mPAP and PVR or lack of functional decline.

Renewal: Predefined treatment goals are being met.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Pulmonologist or Cardiologist.

### **Coverage Duration**

Initial: 12 weeks Renewal: 12 months.

### **Other Criteria**

1) If positive response to vasoreactivity testing such as at least 25% reduction in mean PVR, fall in mean PAP of at least 10 and 40 mmHg or increase or unchanged cardiac output, then documentation of failure or contraindications to a calcium channel blocker. 2) Requests for combination therapy with other PAH [Pulmonary Arterial Hypertension] or PPH drugs requires Medical Director review of medical necessity.

## REVLIMID

### Affected Drugs

REVLIMID®

### Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

### Exclusion Criteria

N/A

### Required Medical Information

Applies to new starts only. 1) Myelodysplastic syndrome (MDS): Renewal: Documentation of response defined as at least a 50% reduction in blood transfusion and transfusion independence and an increase in Hgb at least 1g/dl over baseline and cytogenetic response (the absence of the pretreatment cytogenetic abnormality or a reduction in the number of abnormal cells of at least 50%).

### Age Restrictions

N/A

### Prescriber Restrictions

N/A

### Coverage Duration

MDS [Myelodysplastic syndrome] Initial: 4 months MDS [Myelodysplastic syndrome] Renewal: 6 months MM: 12 months.

### Other Criteria

1) MDS [Myelodysplastic syndrome]: Initial: received 2 or more units of PRBC in the previous 8 weeks. 2) Multiple myeloma (MM) Initial: failure of or contraindication to treatment with thalidomide plus dexamethasone.

## **RITUXAN**

### **Affected Drugs**

RITUXAN®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Applies to new starts only for non-Hodgkin's lymphoma.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

5 years.

### **Other Criteria**

Rheumatoid arthritis: Failure of or contraindication to two of the following immune modulators including abatacept, etanercept, adalimumab, infliximab or anakinra.

## **SABRIL**

### **Affected Drugs**

SABRIL®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Applies to new starts only. Complex Partial Seizures (CPS) Initial: Requires use with another anticonvulsant as combination therapy. CPS Renewal: Medical record documentation of a reduction in seizures and ongoing monitoring for vision loss. Infantile Spasms (IS) Renewal: Medical record documentation of a reduction in spasms or ongoing assessment that continuation of therapy is medically necessary.

### **Age Restrictions**

Infantile Spasm: age less than 2 years.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

CPS Initial: 3 mths CPS Renew: 12 mths IS Initial: 1 mth IS Renew: 6 mths or less if close to age 2.

### **Other Criteria**

CPS: Failed or contraindication to adjunctive treatment with at least two of the following: topiramate, felbamate, gabapentin, lamotrigine, tiagabine, levetiracetam, oxcarbazepine, zonisamide or lacosamide.

## **SAPHRIS**

### **Affected Drugs**

SAPHRIS®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Applies to new starts only.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Lifetime.

### **Other Criteria**

Failure or contraindication to risperidone and at least one other atypical antipsychotic: olanzapine, ziprasidone, aripiprazole, and quetiapine.

## SOMATROPINS

### Affected Drugs

GENOTROPIN®  
HUMATROPE®  
NORDITROPIN NORDIFLEX®  
NORDITROPIN®  
NUTROPIN AQ®  
NUTROPIN®  
OMNITROPE®  
SAIZEN®  
TEV-TROPIN®  
ZORBTIVE®

### Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

### Exclusion Criteria

N/A

### Required Medical Information

1) Growth Hormone Deficiency (GHD): a) one of the following: (i) height more than 3 SD below mean for age and gender or (ii) height less than 3% for age and gender or (iii) height more than 2 SD below mean and growth velocity (GV) less than 25% for age and gender or (iv) growth velocity less than 2 SD below the mean for age and gender AND b) 1 of the following: (i) 2 GH [growth hormone] stimulation tests (GHST) less than 10ng/ml or (ii) 1 GHST less than 15ng/ml plus IGF-1 below normal for age and gender  
2) Prader-Willi syndrome: decreased muscle tone by exam. 3) Pre-transplant chronic renal insufficiency: optimization of nutritional status and correction of metabolic abnormalities. 4) Non-GHD short stature (SS) or idiopathic SS: a) Height more than 2.25 SD AND b) growth rate not likely to attain normal adult height. 5) Small for gestational age with no catch-up growth by age 2 to 4 years: evidence of height remains less than 2 SD below the mean for age and gender. Renewal of 1-5: a) GV more than 2.5 cm/year AND b) Bone age less than height potential. 6) Short bowel syndrome: documentation of optimal nutritional support. 7) Adult-Onset GHD: a) Pituitary or hypothalamic disease and GHD as a result of tumor, irradiation, surgery or trauma AND b) 2 GHST less than 5ng/ml or 1 GHST less than 5ng/ml plus 2 pituitary hormone deficiencies or 3 pituitary hormone deficiencies plus IGF-1 less than 80ng/ml.  
8) Childhood-Onset Adult GDH: a) GV less than 2.5 cm/year AND b) 1 of the following:

(i) 2 GHST less than 5ng/ml after stopping GH [growth hormone] treatment at least 1 month or (ii) 2 pituitary hormone deficiencies and IGF-I level less than lower limit of normal after stopping GH [growth hormone] treatment at least 1 month. Renewal of 7-8:  
a) Improved QOL and clinical benefit AND b) Documentation of IGF-I monitoring.

**Age Restrictions**

SBS [Short Bowel Syndrome]: Age greater than 17 years.

**Prescriber Restrictions**

Endocrinologist, Gastroenterologist, or Nephrologist.

**Coverage Duration**

SBS [Short Bowel Syndrome]: 4 weeks All other indications: 12 months.

**Other Criteria**

N/A

## **SOMATULINE DEPOT**

### **Affected Drugs**

SOMATULINE DEPOT®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

5 years.

### **Other Criteria**

Failure or contraindication to a) surgery and/or radiotherapy and b) octreotide.

**SOMAVERT****Affected Drugs**

SOMAVERT®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

Baseline liver function tests are not greater than 3 times the upper limit of normal.

**Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

5 years.

**Other Criteria**

Failure or contraindication to a) surgery and/or radiotherapy and b) octreotide.

**SPRYCEL****Affected Drugs**

SPRYCEL®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

Applies to new starts only. Renewal: documented hematologic or cytogenic response on Sprycel.

**Age Restrictions**

N/A

**Prescriber Restrictions**

Oncologist or Hematologist.

**Coverage Duration**

12 months.

**Other Criteria**

Initial criteria: documentation of clinical or hematologic or cytogenic failure of imatinib.

## **SUTENT**

### **Affected Drugs**

SUTENT®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Applies to new starts only. Renal Cell Carcinoma (RCC) initial criteria: documented relapsed or Stage IV and medically or surgically unresectable disease. Gastrointestinal Stromal Tumor (GIST) and RCC Renewal: Documented hematologic or cytogenetic response.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Oncologist or Hematologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

GIST Initial Criteria: documented intolerance to or disease progression with imatinib.

## **SYMLIN**

### **Affected Drugs**

SYMLIN®  
SYMLINPEN 120®  
SYMLINPEN 60®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

1) Hypoglycemia unawareness. 2) Gastroparesis.

### **Required Medical Information**

Initial: a) HbA1c less than 9%.

### **Age Restrictions**

Age at least 18 years.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Initial: 3 months Renewal: 12 months.

### **Other Criteria**

1) Not receiving concurrent therapy with exenatide. 2) Documentation of failure to achieve HbA1c less than 7% with intensive basal and bolus insulin dosing regimen (such as Lantus or NPH plus short-acting or rapid acting insulin) despite compliance with treatment.

## **SYNAGIS**

### **Affected Drugs**

SYNAGIS®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

1) Patient is RSV [Respiratory syncytial virus] negative and 2) a) current age is less than 24 months and has chronic lung disease and in the past 6 months has required a bronchodilator, corticosteroid or home oxygen therapy or b) current age is less than 24 months and has hemodynamically significant congenital heart disease and is receiving treatment for congestive heart failure or has moderate to severe pulmonary hypertension or has cyanotic heart disease or c) current age is less than or equal to 12 months and gestational age less is than or equal to 28 weeks or d) current age is less than 12 months and gestational age is less than or equal to 34 weeks and 6 days with congenital abnormalities of the airway or neuromuscular disease or e) current age is less than 6 months and gestational age is less than or equal to 29 to 31 weeks and 6 days or f) current age is less than 90 days and gestational age is less than or equal to 32 to 34 weeks and 6 days with at least one of the following risk factors: daycare attendance or siblings less than 5 years of age.

### **Age Restrictions**

Less than 24 months of age.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Indications a-e: 1-5 doses based on month of request. Indication f: 1-3 doses until 90 days of age.

### **Other Criteria**

N/A

**SYNAREL****Affected Drugs**

SYNAREL®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

Endometriosis: requires laparoscopic confirmation of diagnosis.

**Age Restrictions**

Central precocious puberty: Age less than 11 years for females and less than 12 years for males.

**Prescriber Restrictions**

N/A

**Coverage Duration**

Endometriosis: 6 months Central precocious puberty: 12 months.

**Other Criteria**

N/A

## **TARCEVA**

### **Affected Drugs**

TARCEVA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Applies to new starts only. Pancreatic cancer initial criteria: 1) documented locally advanced, unresectable, or metastatic disease and 2) concurrent use with gemcitabine. Renewal criteria for non-small cell lung cancer (NSCLC) and pancreatic cancer: Documented hematologic or cytogenetic response.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Oncologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

NSCLC, Initial: documented disease progression or intolerance to one of the following: platinum-based regimen (cisplatin or carboplatin + paclitaxel, gemcitabine, vinorelbine, irinotecan, docetaxel) or docetaxel-based regimen (docetaxel + vinorelbine, ifosfamide, gemcitabine).

## **TASIGNA**

### **Affected Drugs**

TASIGNA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Applies to new starts only. Renewal: Documented hematologic or cytogenic response on Tasigna.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Oncologist or Hematologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

1) Documentation of clinical or hematologic or cytogenic failure of imatinib. 2) For all other diagnoses or for chronic myelogenous leukemia with no prior history of failure with imatinib, request requires medical director review for medical appropriateness/necessity.

## **TEKTURNA**

### **Affected Drugs**

TEKTURNA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

5 years.

### **Other Criteria**

Failure of or contraindications to at least one combination of 2 of the following: thiazide diuretic, ACE inhibitor, angiotensin II receptor antagonist, and calcium channel blocker.

## TESTOSTERONE-SYSTEMIC

### Affected Drugs

METHITEST®  
TESTOSTERONE CYPIONATE  
TESTOSTERONE ENANTHATE

### Covered Uses

All FDA-approved indications not otherwise excluded from Part D and AIDS-Wasting Syndrome.

### Exclusion Criteria

1) Men with carcinoma of the breast. 2) Men with known or suspected carcinoma of the prostate. 3) Men with untreated prolactinoma.

### Required Medical Information

1) AIDS-Wasting Syndrome: involuntary loss of more than 10% of body weight. 2) Primary or secondary hypogonadism for new starts a) total testosterone level less than 300 ng/dL or b) free testosterone level below the normal range for age and gender. 3) Primary or secondary hypogonadism for continuation of therapy in new enrollees: covered diagnosis (AIDS-Wasting Syndrome or primary or secondary hypogonadism). 4) Delayed puberty: Skeletal age of at least 12 or chronological age of at least 14.

### Age Restrictions

Age at least 12 years.

### Prescriber Restrictions

For metastatic breast cancer: oncologist.

### Coverage Duration

Delayed puberty: 6 months All others: 5 years.

### Other Criteria

N/A

## TESTOSTERONE-TOPICAL

### Affected Drugs

ANDRODERM®  
ANDROGEL®

### Covered Uses

All FDA-approved indications not otherwise excluded from Part D and AIDS-Wasting Syndrome.

### Exclusion Criteria

1) Men with carcinoma of the breast. 2) Men with known or suspected carcinoma of the prostate. 3) Men with untreated prolactinoma. 4) Female gender.

### Required Medical Information

1) AIDS-Wasting Syndrome: involuntary loss of more than 10% of body weight. 2) Primary or secondary hypogonadism for new starts a) total testosterone level less than 300 ng/dL or b) free testosterone level below the normal range for age and gender. 3) Primary or secondary hypogonadism for continuation of therapy in new enrollees: covered diagnosis (AIDS-Wasting Syndrome or primary or secondary hypogonadism).

### Age Restrictions

Age at least 12 years.

### Prescriber Restrictions

N/A

### Coverage Duration

5 Years.

### Other Criteria

Documented failure of testosterone cypionate or enanthate.

## **THIAZOLIDINEDIONES**

### **Affected Drugs**

ACTOS®  
AVANDIA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Heart Failure NYHA Class III and IV.

### **Required Medical Information**

Applies to new starts only.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

5 years.

### **Other Criteria**

1) Failure of a minimum 3 month trial with maximum tolerated doses of a sulfonylurea and metformin combination therapy evidenced by HgbA1c greater than 7% or 2) Contraindications to sulfonylurea and metformin combination therapy such as serum creatinine greater than 1.5 mg/dL, metabolic acidosis, or heart failure NYHA Class I or II requiring treatment. or 3) Currently on more than 100 units of insulin per day.

## **TRELSTAR**

### **Affected Drugs**

TRELSTAR DEPOT®  
TRELSTAR LA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Applies to new starts only. Renewal: Documented hematologic or cytogenic response.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

N/A

## **TYGACIL**

### **Affected Drugs**

TYGACIL®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

1) Complicated infection of skin and/or subcutaneous tissue: Culture and sensitivity indicates resistance to vancomycin plus aztreonam. 2) Complicated infectious disease of abdomen: Culture and sensitivity indicates resistance to imipenem/cilastin. 3) Community acquired pneumonia: a) Severity of infection necessitates IV treatment and a) Culture and sensitivity indicates resistance to i) a beta-lactam, such as cefotaxime, ceftriaxone plus azithromycin or clarithromycin and ii) fluoroquinolone such as levofloxacin or moxifloxacin.

### **Age Restrictions**

Age at least 18 years.

### **Prescriber Restrictions**

Infectious disease specialist.

### **Coverage Duration**

As requested by physician.

### **Other Criteria**

N/A

**TYKERB****Affected Drugs**

TYKERB®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

Applies to new starts only. Renewal: Documented hematologic or cytogenic response.

**Age Restrictions**

N/A

**Prescriber Restrictions**

Oncologist.

**Coverage Duration**

12 months.

**Other Criteria**

1) Failure of or contraindication to prior therapy with a regimen including all of the following: an anthracycline, a taxane, and Herceptin and 2) Concurrent treatment with Xeloda.

## **TYSABRI**

### **Affected Drugs**

TYSABRI®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Crohn's disease: 1) Baseline CRP greater than 2. 87ml/L and 2) if the patient is currently on oral corticosteroids, requires documentation of a steroid taper plan. Renewal criteria for Crohn's disease: documentation of a) reduction in CDAI or number of disease flares and/or improved quality of life, b) If previously on oral steroids, steroid has been successfully discontinued, and c) no history of serious infection or evidence of liver toxicity since the previous authorization.

### **Age Restrictions**

Age at least 18 years.

### **Prescriber Restrictions**

Neurologist or gastroenterologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

1) Multiple sclerosis: failure of or contraindications to interferon-beta or glatiramer acetate with documentations of all of the following a) patient adherence with previous regimens, b) continuation of clinical relapses c) CNS lesion progression on MRI or worsening disability and d) not on combination therapy with Avonex, Rebif, Betaseron or Copaxone. 2) Crohn's disease: failure of or contraindications to at least one DMARD [Disease-modifying antirheumatic drug] including azathioprine, mercaptopurine, cyclosporine or methotrexate and one TNF [Tumor necrosis factor] inhibitor including infliximab or adalimumab.

**VALTREX****Affected Drugs**

VALACYCLOVIR

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

N/A

**Age Restrictions**

Varicella: age at least 2 years.

**Prescriber Restrictions**

N/A

**Coverage Duration**

HSV and herpes zoster: 10 days HSV prophylaxis: 12 mo Herpes labialis: 1 day  
Varicella: 5 days.

**Other Criteria**

Failure of or contraindication to acyclovir.

## **VENTAVIS**

### **Affected Drugs**

VENTAVIS®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Initial criteria: 1) Pulmonary arterial hypertension not associated with portal hypertension, sickle cell disease or thromboembolic disease. 2) Nonsmoker or currently enrolled in a smoking cessation program. 3) Cardiac cath: a) mPAP above 25 mmHg at rest and b) PCWP below 15 mm Hg at rest and c) NYHA Class III or IV. 4) Physician documentation of specific and measurable goals to assess response to a 12 to 16 weeks trial such as a significant increase in the 6-minute walk test or decrease in dyspnea fatigue rating and other symptoms or evidence of hemodynamic improvement such as a reduction in mPAP and PVR or improvement in NYHA class or lack of functional or hemodynamic deterioration. Renewal criteria: documentation of meeting treatment goals defined above.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Pulmonologist or cardiologist.

### **Coverage Duration**

Initial: 4 months Renewal: 12 months.

### **Other Criteria**

1) If positive response to vasoreactivity testing such as more than 25% reduction in mean PVR or failed in mPAP of at least 10 and below 40mm Hg or increase or unchanged cardiac output, a trial of a calcium channel blocker such as nifedipine, amlodipine or diltiazem is required unless contraindicated. 2) Failure of or contraindication to bosentan or ambrisentan. 3) Requests for combination therapy with

other PAH [Pulmonary Arterial Hypertension] or PPH drugs requires Medical Director review of medical necessity.

## **VFEND**

### **Affected Drugs**

VFEND IV®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Concurrent use of: astemizole, cisapride, pimozide, quinidine, sirolimus, rifampin, carbamazepine, long-acting barbiturates, high-dose ritonavir (800mg/day), efavirenz, rifabutin, ergot alkaloids.

### **Required Medical Information**

1) Esophageal candidiasis, candidemia or disseminated candidiasis: patient is not neutropenic.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Infectious disease specialist.

### **Coverage Duration**

As requested by physician.

### **Other Criteria**

1) For esophageal candidiasis, candidemia or disseminated candidiasis: failure of fluconazole. 2) For invasive aspergillosis or infection caused by *Scedosporium apiospermum* or *Fusarium* species: contraindications to or refractory to other therapies including azole antifungals and amphotericin.

**VIMPAT****Affected Drugs**

VIMPAT®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

Applies to new starts only.

**Age Restrictions**

Age at least 17 years.

**Prescriber Restrictions**

N/A

**Coverage Duration**

Lifetime.

**Other Criteria**

Failure of at least one other antiepileptic drug such as carbamazepine, oxcarbazepine, phenytoin, topiramate, or valproic acid.

## **VOTRIENT**

### **Affected Drugs**

VOTRIENT®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Applies to new starts only. Renewal: Documented hematologic or cytogenetic response.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Oncologist or Hematologist.

### **Coverage Duration**

Initial: 12 months Renewal: 12 months.

### **Other Criteria**

If on concomitant strong CYP 3A4 inducers or drugs metabolized by CYP3A4, CYP2D6, or CYP2C8, Votrient should be avoided. If on strong CYP3A4 inhibitors, Votrient dose should be reduced to 400mg daily.

## **XOLAIR**

### **Affected Drugs**

XOLAIR®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Initial: 1) Positive skin prick test or in-vitro specific IgE test (such as RAST, MAST, FAST, ELISA) to one or more perennial allergens, 2) Total serum IgE 30 -700 IU/ml, 3) Documentation supporting poor asthma control such as multiple asthma exacerbations resulting in repeated uses of health care services including urgent care, ED visits or hospitalizations and/or limitation in activities of daily living. Renewal: Documentation of a reduction in asthma exacerbations and frequency of office visits, ED or urgent care visits, hospitalizations and in the use/need for oral steroids and sustained clinical improvement from baseline.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Pulmonologist or Immunologist.

### **Coverage Duration**

Initial: 12 weeks Renewal: 6 months.

### **Other Criteria**

1) Documentation of maximal non-pharmacologic management of environmental allergens and triggers (tobacco smoke, dust mites, pets, molds, occupational exposure and GERD [Gastroesophageal Reflux Disease]), 2) Failure of or contraindications to allergen immunotherapy, and 3) Failure of a high-dose inhaled corticosteroid and a long-acting beta agonist and history of compliance with asthma medications evident from pharmacy claims data.

**XYREM****Affected Drugs**

XYREM®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

N/A

**Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

3 months.

**Other Criteria**

Failure of or contraindications to the following: 1) methylphenidate or dextroamphetamine and 2) Provigil.

**XYZAL****Affected Drugs**

XYZAL®

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

**Exclusion Criteria**

N/A

**Required Medical Information**

N/A

**Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

12 months.

**Other Criteria**

Failure of or contraindication to OTC cetirizine and fexofenadine.

## **ZEMPLAR**

### **Affected Drugs**

ZEMPLAR®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

1) Stage 3 Chronic Kidney Disease (CKD): a) GFR 30-59, b) iPTH at least 70 pg/mL, c) serum calcium less than 9.5 mg/dL, d) serum phosphorus less than or equal to 4.6 mg/dL. 2) Stage 4 CKD [Chronic Kidney Disease]: a) GFR 15-29, b) iPTH greater than 110 pg/mL, c) serum calcium less than 9.5 mg/dL, d) serum phosphorus less than or equal to 4.6 mg/dL.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Lifetime.

### **Other Criteria**

Failure of or contraindication to calcitriol.

## **ZOSTAVAX**

### **Affected Drugs**

ZOSTAVAX®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

1) Primary or acquired immunodeficiency states including leukemia, lymphoma, or other malignancies affecting the bone marrow or lymphatic system AIDS/HIV or other unspecified cellular immunodeficiency. 2) Concurrent immunosuppressive therapy including high-dose steroids (greater than or equal to 20mg/d of prednisone) for more than 2 weeks radiation and immune modulators/mediators such as the anti-TNF [Tumor necrosis factor] agents including adalimumab, infliximab, and etanercept. 3) Patients receiving hematopoietic stem cell transplant. 4) Active, untreated tuberculosis. 5) Pregnancy.

### **Required Medical Information**

N/A

### **Age Restrictions**

Age at least 60 years.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

1 dose.

### **Other Criteria**

N/A

## ZYVOX

### Affected Drugs

ZYVOX®

### Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

### Exclusion Criteria

N/A

### Required Medical Information

1) Vancomycin-resistant enterococcus faecalis: clinical evidence of infection and culture and sensitivity indicates resistance to or failure of or contraindication to ampicillin. 2) Skin and skin-structure infection, including diabetic foot infections without concomitant osteomyelitis, due to *S. aureus* (including MRSA), *S. pyogenes*, or *S. agalactiae*: culture and sensitivity indicates resistance to or contraindication to ALL of the following: oral TMP/SMX, tetracyclines, clindamycin, fluoroquinolones and vancomycin resistance. 3) Community acquired pneumonia or nosocomial pneumonia caused by *S. aureus* (including MRSA) or *S. pneumoniae*, including multidrug-resistant strains (MDRSP): culture and sensitivity indicates resistance to or contraindication to clindamycin, TMP/SMX, doxycycline and minocycline.

### Age Restrictions

N/A

### Prescriber Restrictions

Infectious disease specialist.

### Coverage Duration

VRE [Vancomycin resistant enterococcus]: 1 month Others: 14 days.

### Other Criteria

N/A

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