

## How do I request an exception to the CareMore Health Plan's Formulary?

You can ask CareMore Health Plan to make an exception to our coverage rules. There are several types of exceptions that you can ask us to make.

- You can ask us to cover your drug even if it is not on our formulary.
- You can ask us to waive coverage restrictions or limits on your drug. For example, for certain drugs, CareMore Health Plan limits the amount of the drug that we will cover. If your drug has a quantity limit, you can ask us to waive the limit and cover more.
- You can ask us to provide a higher level of coverage for your drug. If your drug is contained in our non-preferred tier, you can ask us to cover it at the cost-sharing amount that applies to drugs in the preferred tier instead. This would lower the amount you must pay for your drug. Please note, if we grant your request to cover a drug that is not on our formulary, you may not ask us to provide a higher level of coverage for the drug. "Also, you may not ask us to provide a higher level of coverage for drugs that are in the specialty tier."

Generally, CareMore Health Plan will only approve your request for an exception if the alternative drugs included on the plan's formulary, the lower-tiered drug or additional utilization restrictions would not be as effective in treating your condition and/or would cause you to have adverse medical effects.

You should contact us to ask us for an initial coverage decision for a formulary, tiering or utilization restriction exception. **When you are requesting a formulary, tiering or utilization restriction exception you should submit a statement from your physician supporting your request.** Generally, we must make our decision within 72 hours of getting your prescribing physician's supporting statement. You can request an expedited (fast) exception if you or your doctor believe that your health could be seriously harmed by waiting up to 72 hours for a decision. If your request to expedite is granted, we must give you a decision no later than 24 hours after we get your prescribing physician's supporting statement.

**Your physician must submit a statement supporting your coverage determination or exception request. In order to help us make a decision more quickly, you should include supporting medical information from your doctor when you submit your exception request.**

### What if I have additional questions?

You can call us at: 1-800-546-5677 (seven days a week, 24 hours a day) if you have any additional questions. If you have a hearing or speech impairment, please call us at TTY 1-866-706-4757.

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient has a diagnosis of severe, recalcitrant, disabling psoriasis, repigmentation of idiopathic vitiligo or a diagnosis of cutaneous T-Cell lymphoma which has been unresponsive to other forms of treatment Pt. has a diagnosis of psoriasis. Not first line therapy. (10-70mg based on weight approx. 0.6mg/kg ORALLY)

**EXCLUSION CRITERIA:** 1) Patients exhibiting idiosyncratic reactions to psoralen compounds. 2) Patients possessing a specific history of light sensitive disease states should not initiate methoxsalen therapy except under special circumstances. Diseases associated with photosensitivity include lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum, and albinism. 3) Patients with melanoma or with a history of melanoma. 4) Patients with invasive squamous cell carcinomas. 5) Patients with aphakia, because of the significantly increased risk of retinal damage due to the absence of lenses.

**REQUIRED INFO:** 1) The patient has had a biopsy to verify diagnosis. 2) The patient has not adequately responded to other forms of therapy (topical, oral, etc.) 3). This medication is being used in conjunction with a schedule of controlled doses of long wave ultraviolet radiation.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# ABELCET

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Aspergillosis, Blastomycosis, Candidiasis, Cryptococcal meningitis, Leishmaniasis and Systemic mycosis.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** \*\*Note: THIS FORMULATION IS NOT INTERCHANGEABLE WITH OTHER FORMULATIONS, SUCH AS CONVENTIONAL AMPHOTERICIN B, AMPHOTERICIN B CHOLESTERYL SULFATE COMPLEX, OR AMPHOTERICIN B LIPOSOME

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**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Breakthrough cancer pain in opioid tolerant patients with malignancies currently taking chronic pain medications

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Adagen® is indicated for enzyme replacement therapy for adenosine deaminase (ADA) deficiency in patients with severe combined immunodeficiency disease (SCID) who are not suitable candidates for or who have failed bone marrow transplantation. Adagen® is not intended as a replacement for HLA identical bone marrow transplant therapy

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** ADAGEN® (pegademase bovine) Injection is recommended for use in infants from birth or in children of any age at the time of diagnosis. Pregnancy category C.

**AGE RESTRICTIONS:****MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

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<b>COVERED USES:</b>	All FDA-Approved indications not otherwise excluded from Part D. A diagnosis of pulmonary arterial hypertension with World Health Organization (WHO) function Class I.
<b>EXCLUSION CRITERIA:</b>	Patient is not on a nitrate or nitrate therapy on a regular in intermittent basis.
<b>REQUIRED INFO:</b>	
<b>AGE RESTRICTIONS:</b>	Patient must be 18 years of age or older.
<b>MD RESTRICTIONS:</b>	
<b>COVERAGE DURATION</b>	End of plan year
<b>OTHER CRITERIA:</b>	NA

# ALDURAZYME

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Mucopolysaccharidosis Type I

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Pregnancy Category: B--Patients should receive antipyretics and/or antihistamines prior to infusion

**AGE RESTRICTIONS:** Patient Must Be At Least 5 Years Of Age

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# APOKYN

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of Parkinson's disease, Acute, intermittent treatment of hypomobility "off" episodes

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Apomorphine is used to treat "off" episodes when they occur. It is not used to prevent "off" episodes. The safety and efficacy has not been established for use in pediatrics. Pregnancy category is C.

**AGE RESTRICTIONS:** Patient must be at least 18 years old

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# ARALAST

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Alpha-1-antitrypsin deficiency

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Patients must be immunized against Hepatitis B prior to receiving Prolastin®

**AGE RESTRICTIONS:** Patient must be at least 12 years old.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
1. Treatment of symptomatic anemia associated with chronic renal failure, including patients on dialysis (end-stage renal disease) and patients not on dialysis with a pretreatment HCT -Less Than-33% or HGB 10-12g/dl or Anemia in cancer patients receiving chemotherapy.

**EXCLUSION CRITERIA:** Treatment of patients who require immediate correction of severe anemia - Treatment of anemia in cancer or HIV-infected patients caused by other factors such as iron or folate deficiencies, hemolysis or GI bleeding. In these cases the underlying cause of the anemia should be managed appropriately - Treatment of anemia in rheumatoid arthritis - Treatment of pruritis associated with renal failure - Treatment of anemia in Gaucher's disease - Treatment of anemia in Castleman's disease - Treatment of anemia in paroxysmal nocturnal hemoglobinuria (PNH) - Treatment of sickle cell anemia - Treatment of symptomatic anemia related to zidovudine therapy in HIV-infected patients where the dose of zidovudine is -Less Than- 4200 mg/week - Treatment of anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery or patients at high risk for perioperative transfusions with significant, anticipated blood loss - Myelodysplastic syndrome in patients whose pre-treatment endogenous erythropoietin level is - Less Than- 500 mU/ml - Anemia of prematurity, when the patient has either a birthweight -Less Than- 1500 grams or a gestational age of -Less Than- 33 weeks - Special circumstance patients (such as Jehovah Witness) who will not/cannot receive whole blood or components as replacement for traumatic or surgical loss. Uncontrolled hypertension.

**REQUIRED INFO:** This medication must not meet the criteria for coverage under Medicare Part A or B

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# ARCALYST

**COVERED USES:** All FDA-Approved and compendia indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Arthroplasty of knee, Total - Postoperative deep vein thrombosis - Prophylaxis. Deep venous thrombosis, acute, In conjunction with warfarin sodium. Postoperative deep vein thrombosis - Prophylaxis - Repair of hiP. Postoperative deep vein thrombosis - Prophylaxis - Total replacement of hip. Pulmonary embolism, acute, In conjunction with warfarin sodium when initial therapy is administered in a hospital.

**EXCLUSION CRITERIA:** Active major bleeding - risk of uncontrollable hemorrhage--Bacterial endocarditis--Body weight less than 50 kg for prophylactic therapy of hip fracture, hip replacement or knee replacement surgery, or abdominal surgery - increased risk for major bleeding episodes--Fondaparinux-related thrombocytopenia--Hypersensitivity to fondaparinux--Severe renal impairment (creatinine clearance less than 30 milliliters/minute) - increased risk for major bleeding episodes

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Patient must be at least 18 years old

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

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**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of or Multiple Sclerosis (MS), Relapsing Multiple Sclerosis, Relapsing-Remitting Multiple Sclerosis (RRMS) and Progressive - Relapsing Multiple Sclerosis.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Have had at least two acute exacerbations during the previous two years, which consisting of new symptoms or aggravation of old symptoms lasting at least 24 hours in absence of fever, and preceded by stability or improvement for at least 30 days

**AGE RESTRICTIONS:** Patient must be at least 18 years old.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# BARACLUDE

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Active type B viral hepatitis, chronic

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** LFTs must be monitored

**AGE RESTRICTIONS:** Patient must be at least 16 years old

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Beta-lactam agents, other will be covered for: Endometritis (Azactam), Female genital infection (Azactam, Primaxin), Infection of skin and/or subcutaneous tissue (Azactam, Invanz, Merrem, Primaxin), Infection of abdomen (Azactam, Invanz, Merrem, Primaxin, Doribax), Lower respiratory tract infection (Azactam, Primaxin), Septicemia (Azactam, Primaxin), Urinary tract infection disease (Azactam, Invanz, Primaxin, Doribax), Community acquired pneumonia (Invanz), Diabetic foot infection, without osteomyelitis (Invanz), Operation of intestine, Prophylaxis or postoperative wound infection (Invanz), Pelvic Infection, acute (Invanz), Bacterial meningitis (Merrem), Bacterial endocarditis (Primaxin), Infection of bone—Infectious disorder of the joint (Primaxin), Polynephritis (Doribax), Primaxin - UTI and polymicrobial infections. Invanz, Community Acquired Pneumonia, Doribax, complicated UTI.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# BETASERON

- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of or Multiple Sclerosis (MS) or Relapsing-Remitting Multiple Sclerosis (RRMS).
- EXCLUSION CRITERIA:** The indication of the medication is for Hepatits-C (off-label)--The patient has concurrent illness that is likely to alter compliance or substantially reduce life expectancy (dementia, alcoholism, malignancy, or other chronic illnesses)--Pregnancy
- REQUIRED INFO:** Have had at least two acute exacerbations during the previous two years, which consisting of new symptoms or aggravation of old symptoms lasting at least 24 hours in absence of fever, and preceded by stability or improvement for at least 30 days
- AGE RESTRICTIONS:** Patient must be at least 18 years old
- MD RESTRICTIONS:**
- COVERAGE DURATION** End of plan year
- OTHER CRITERIA:** NA

# CEREDASE

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of Gaucher's Disease, Type 1, symptomatic

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# CEREZYME

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Non-neuropathic Gaucher's disease, chronic

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# CHANTIX

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Aid to smoking cessation

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Chantix should be started one week before the target date to quit smoking. Patient must also be enrolled in a plan approved smoking cessation program.

**AGE RESTRICTIONS:** The patient must be at least 18 years of age.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** Treatment should last for 12 weeks.

# CIMZIA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# COPAXONE

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of Relapsing-Remitting Multiple Sclerosis (RRMS).

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** The patient must have had an inadequate response or a documented failure due to lack of efficacy to interferon beta 1.

**AGE RESTRICTIONS:** Patient must be at least 18 years old

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# DIFFERIN

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Acne vulgaris: after washing, apply a thin film TOPICALLY to affected area(s) once daily at bedtime

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Safety and efficacy have not been established in children less than 12 years of age

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# ELAPRASE

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of Mucopolysaccharidosis, MPS-II.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Pregnancy category is C.

**AGE RESTRICTIONS:** Patient must be at least 5 years old.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
The patient has a diagnosis of mild to moderate atopic dermatitis.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** The patient is not immunocompromised. The patient has a documented failure or inadequate response with at least two topical corticosteroids, or a contraindication to topical corticosteroids.

**AGE RESTRICTIONS:** The patient is two years of age or older.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

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- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Psoriatic arthritis. Rheumatoid arthritis (RA). Juvenile rheumatoid arthritis (JRA). Ankylosing spondylitis (AS), Adult plaque psoriasis, as defined by the American College of Rheumatology (ACR).
- EXCLUSION CRITERIA:** shall not be granted for use Wegener's granulomatosis.
- REQUIRED INFO:** patient with a diagnosis of plaque psoriasis must have had an inadequate response or a documented failure due to lack of efficacy to one or more of the following, Topical corticosteroid, Tazarotene, Anthralin. Patient with a diagnosis of either rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis or psoriatic arthritis must have had an inadequate response or a documented failure due to lack of efficacy to one or more of the following disease modifying antirheumatic drugs (DMARDs), Methotrexate, Hydroxychloroquine, D-penicillamine, Sulfasalazine, Leflunomide, Azathioprine, Oral/Injectable Gold Compounds.
- AGE RESTRICTIONS:**
- MD RESTRICTIONS:**
- COVERAGE DURATION** End of plan year
- OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of Candidemia, Candidiasis of the esophagus, disseminated candidiasis, intra-abdominal and peritonitis.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Safety and efficacy in pediatric patients have not been established.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
1. Treatment of symptomatic anemia associated with chronic renal failure, including patients on dialysis (end-stage renal disease) and patients not on dialysis. 2. Treatment of symptomatic anemia where erythropoietin level is -Less Than- 500 mU/ml, related to zidovudine therapy in HIV-infected patients where the dose of zidovudine is -Less Than- 4200 mg/week. 3. Treatment of symptomatic anemia in patients with non-myeloid malignancies and anemia is caused by the effect of administered chemotherapy and the patient must be on chemotherapy concomitantly for a minimum of 2 months. 4. Treatment of anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery.

**EXCLUSION CRITERIA:** 1. Treatment of patients who require immediate correction of severe anemia -

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** \*\*\*Special circumstance patients (such as Jehovah Witness) who will not/cannot receive whole blood or components as replacement for traumatic or surgical loss will be taken into consideration.

# EXJADE

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. 1. Chronic iron toxicity. 2. Chronic iron toxicity secondary to transfusional iron overload.

**EXCLUSION CRITERIA:** §Exjade will NOT be covered for a diagnosis of hemochromatosis or when phlebotomy is an appropriate treatment

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# FABRAZYME

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Fabry's disease

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Patient must be at least 8 years old

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# FUNGIZONE

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. FUNGIZONE INTRAVENOUS (Amphotericin B for injection) will be covered for: Patient has a potentially life-threatening fungal infection such as one of the following: ASPERGILLOSIS, BLASTOMYCOSIS, SYSTEMIC CANDIDIASIS, COCCIDIOIDOMYCOSIS, CRYPTOCOCCOSIS, HISTOPLASMOSIS, ZYGOMYCOSIS, LEISHMANIASIS, SPOROTRICHOSIS

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Fungizone Intravenous should not be used to treat noninvasive fungal infections such as oral thrush, vaginal candidiasis, and esophageal candidiasis in patients with normal neutrophil counts

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** This medication does not meet coverage criteria under Medicare Part B

# GARDASIL

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Gardasil vaccine is indicated for the prevention of the following diseases in patients with the above mentioned diagnosis: Cervical cancer, Genital warts (condyloma acuminata) and the following precancerous or dysplastic lesions: Cervical adenocarcinoma in situ (AIS), Cervical intraepithelial neoplasia (CIN) grade 2 and grade 3, Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3, Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3, Cervical intraepithelial neoplasia (CIN) grade 1, vulvar and vaginal cancer caused by HPV types 16 and 18.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Indicated for female patients 9-26 years of age

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# GILENYA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Adolescent Growth Failure (783.43). Growth Failure. Adult patients with documented GHD (253.2, 253.3, 253.7) secondary to destructive lesions of the pituitary or the peripituitary area (e.g., pituitary adenoma), or as a result of treatment (e.g., cranial irradiation) or surgery. Adult patients with idiopathic growth hormone deficiency (783.43), Growth retardation in children with chronic renal insufficiency (593.9, 585.2-585.9), Patients with Turner's syndrome (758.6). GH therapy for patients with Turner's syndrome, Patients with AIDS (042) related wasting with involuntary weight loss of -Greater Than-10% of pre-illness baseline body weight or body mass index (BMI) less than 20, Children with Russel – Silver syndrome (759.89), Short Stature in Children with Noonan's syndrome—Norditropin® (759.89), Children with Prader – Willi syndrome.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# HRM AMPHETAMINES

**COVERED USES:** All FDA-approved indications not otherwise excluded from Part D

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** For patients over 65 years of age amphetamines are considered High Risk Medications (HRM) and patients should have a documented failure or intolerance to at least two of the following therapies for depression: tricyclic antidepressants without active metabolites (nortriptyline, desipramine), Selective Serotonin Reuptake Inhibitors, Selective Serotonin and Norepinephrine Reuptake Inhibitors.

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Juvenile Idiopathic Arthritis Crohn's Disease (555)—Humira® is indicated for the reduction of signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Humira® is also indicated for reducing the signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab (Remicade). The patient has a diagnosis of moderate to severe rheumatoid arthritis. (714.0) (Humira is now a first line therapy for moderate to severe RA as of 10-4-2005). Ankylosing spondylitis (720.0). Plaque Psoriasis (696.1): chronic (Moderate to Severe): initial, 80 mg SUBQ, followed by 40 mg SUBQ every other week starting one week after the initial dose. Psoriatic arthritis (696.0)

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Patient must not have an active infection (chronic or acute). The patient has a negative TB test result prior to therapy. The patient is not receiving anakinra (Kineret), etanercept (Enbrel), or infliximab (Remicade) in combination with Humira<sub>z</sub> (adalimumab). The patient must have a diagnosis rheumatoid arthritis, psoriatic arthritis, or psoriasis who has had an inadequate response to one or more DMARDs (disease modifying antirheumatic drugs) or a documented failure due to lack of efficacy to one or more of the following: Methotrexate, Hydroxychloroquine, D-penicillamine, Sulfasalazine, Leflunomide, Azathioprine, Oral/Injectable Gold Compounds (auranofin, aurothioglucose, gold sodium thiomalate). Patient has a diagnosis of plaque psoriasis who has had an inadequate response or a documented failure due to lack of efficacy to one or more of the following: topical corticosteroid, calcipotriene, tazarotene, anthralin. Patient has a diagnosis of ankylosing spondylitis who has had an inadequate response or a documented failure due to lack of efficacy to one or more of the following: NSAIDs, COX-2 inhibitors. Patient has a diagnosis of crohn's disease who has had an inadequate response or a documented failure due to lack of efficacy to one or more of the following: corticosteroids.

**AGE RESTRICTIONS:** Patient must be at least 4 years old.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA



**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
1. Long term treatment of growth failure in children with primary IGF-1 deficiency or with growth hormone gene deletion who have developed neutralizing antibodies to GH.

**EXCLUSION CRITERIA:** Patients -Less Than- 2 years old and/or -Greater Than-65 years old. Patients with closed epiphyses. Active or suspected neoplasia, and therapy should be discontinued if neoplasia develops, GH deficiency, Malnutrition, Hypothyroidism, Chronic anti-inflammatory steroids

**REQUIRED INFO:** Severe Primary IGFD is define with the following criteria: Height standard deviation score -Less Than- -3.0 AND Basal IGF-1 standard deviation score -Less Than- -3.0 AND Normal or elevated Growth Hormone GH OR Mutations in the GH receptor Post GHR signaling pathway mutations IGF-1 gene defects 0.12mg/kg twice daily is maximum dose—doses higher than this have not been evaluated for safety

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# INFERGEN

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Hepatitis C, chronic, in adult patients with compensated liver disease who have anti-HCV serum antibodies: 9 mcg SC 3 times weekly for 24 wks, at least 48 hr between injections - range 7.5-15 mcg/dose for up to 6 months

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Patient must have a baseline CBC at provider's office.

**AGE RESTRICTIONS:** Patient must be at least 18 years old.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

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**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of acute symptomatic deep vein thrombosis with or without pulmonary embolism.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Must be administered in conjunction with warfarin sodium. Innohep should not be used in patients with a history of heparin-induced thrombocytopenia. Pregnancy category B.

**AGE RESTRICTIONS:** Safety and efficacy in children have not been established. Patient should be at least 12 years of age.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** \*\*May be covered under Medicare Part B

- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of moderately to severely active rheumatoid arthritis (RA) as defined by the American College of Rheumatology (ACR).
- EXCLUSION CRITERIA:** Prior authorization requests shall not be granted for use in multiple sclerosis, lupus erythematosus, juvenile rheumatoid arthritis, inflammatory bowel diseases, sepsis syndrome or graft-versus-host disease. Kineret should not be used in combination with Tumor Necrosis Factor (TNF) blocking agents (Enbrel, Remicade). Kineret should also not be used in patients with active infections.
- REQUIRED INFO:** The patient must have had an inadequate response or a documented failure due to lack of efficacy to one or more of the following disease modifying antirheumatic drugs (DMARDs), such as: Methotrexate--Hydroxychloroquine--D-penicillamine--Sulfasalazine--Leflunomide--Azathioprine--Oral/Injectable Gold Compounds (auranofin, aurothioglucose, gold sodium thiomalate). The patient must not be using Kineret in combination with Enbrel, Remicade, or Humira.
- AGE RESTRICTIONS:** The patient must be -Greater Than- 18 years of age.
- MD RESTRICTIONS:**
- COVERAGE DURATION** End of plan year
- OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved and compendia indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Available only through the Letairis Education Access Program (LEAP) by calling 1-866-664-LEAP (5327) or by logging on to [www.letairis.com](http://www.letairis.com). Pulmonary hypertensive arterial disease, WHO functional class II or III

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Safety and effectiveness not established in pediatric patients

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# LEUKINE

- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Acute myeloid leukemia, Following chemotherapy. Bone marrow transplant, Myeloid reconstitution. Bone marrow transplant failure - Graft acceptance. Peripheral blood stem cell harvest, Mobilization, Febrile Neutropenia.
- EXCLUSION CRITERIA:** Concomitant chemo- or radiotherapy (or within 24 hours before or after). Excess leukemic myeloid blasts in the blood/bone marrow (greater than 10%). Hypersensitivity to GM-CSF or yeast-derived products
- REQUIRED INFO:** Patient must have biweekly CBC with differential
- AGE RESTRICTIONS:** Patient must be at least 18 years old.
- MD RESTRICTIONS:**
- COVERAGE DURATION** End of plan year
- OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of ANY of the following: acute deep venous thrombosis (DVT), pulmonary embolism (PE), venous thromboembolism (VTE) prophylaxis, unstable angina (UA), non-ST-segment elevation myocardial infarction (NSTEMI), or non-Q-wave myocardial infarction, acute myocardial infarction with ST-segment elevation (STEMI).

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Pediatric patients 2 months of age or older

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# MEPRON

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Pneumocystis pneumonia - prophylaxis, Pneumocystis pneumonia, Babesiosis, Malaria, Toxoplasmosis.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Patient with a diagnosis of pneumocystis pneumonia must have a documented allergy or intolerance to Sulfamethoxazole-Trimethoprim. Patient needing prophylaxis for pneumocystis pneumonia must have a documented failure, allergy, or intolerance to one of more of the following, Sulfamethoxazole-Trimethoprim, Dapsone, Aerosolized pentamidine.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# MYOZYME

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Glycogen storage disease, type II

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Caution must be used because of the potential for severe infusion reactions - appropriate medical support measures should be readily available when alglucosidase alfa is administered.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# NAGLAZYME

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Maroteaux-Lamy syndrome

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Safety and efficacy in patients younger than 5 years of age have not been evaluated.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs. 6mg subcutaneous injection once per chemotherapy cycle.
- EXCLUSION CRITERIA:** Prior Authorization request shall not be granted for use in patient receiving chemotherapy associated with delayed myelosuppression. Prior Authorization request shall not be granted for use in patient with neutropenia other than chemotherapy-related.
- REQUIRED INFO:** The patient must have had an inadequate response or a documented failure due to lack of efficacy to one or more of the following colony stimulating factors. Such as: Filgrastim, Neulasta® must not be administered in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
- AGE RESTRICTIONS:** Neulasta® 6mg fixed-dose formulation must not be used in infants, children, and adolescents weighing less than 45 kg.
- MD RESTRICTIONS:**
- COVERAGE DURATION** End of plan year
- OTHER CRITERIA:** NA

# NEUMEGA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Prevention of severe thrombocytopenia and the reduction of the need for platelet transfusions following myelosuppressive therapy in adult patients at high risk of severe thrombocytopenia.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Baseline and periodic CBC. Platelet counts at the time of expected nadir and until post-nadir counts are greater than or equal to 50,000/microliter.

**AGE RESTRICTIONS:** Safety and efficacy not established in pediatric patients - dose-limiting papilledema has occurred

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# NEUPOGEN

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Neutropenia secondary to chemotherapy--Bone marrow transplantation--Idiopathic, cyclic, or congenital neutropenia, Peripheral blood progenitor cell (PBPC) mobilization or Post-PBPC transplantation, AIDS-associated neutropenia, Drug-induced neutropenia, Myelodysplastic syndromes complicated with infection

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Prior authorizations will only be approved for patients who will be self-administering filgrastim. Patients that receive their injections in the provider's office or from home health care should have the filgrastim covered under their medical benefit. Appropriate lab tests - CBC and platelet count, must be conducted to necessitate the continuation of therapy.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# ORENCIA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
With a diagnosis of moderate to severe rheumatoid arthritis,  
Juvenile Idiopathic Arthritis.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** May use drug as monotherapy or concomitantly with DMARD except  
TNF antagonist (eg. Anakinra)

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# ORFADIN

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of hereditary tyrosinemia type 1. The patient is also undergoing dietary restriction of tyrosine and phenylalanine. The patient has had a slit-lamp examination of his/her eyes and serum phosphate should be measured as a screening test for patients with renal involvement at risk of secondary hypophosphatemia and rickets, prior to the initiation of therapy with Orfadin®.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** The patient is also undergoing dietary restriction of tyrosine and phenylalanine. The patient has had a slit-lamp examination of his/her eyes and serum phosphate should be measured as a screening test for patients with renal involvement at risk of secondary hypophosphatemia and rickets, prior to the initiation of therapy with Orfadin®.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient has a diagnosis of severe, recalcitrant, disabling psoriasis. Cutaneous/peripheral T-cell lymphoma. Vitiligo.
- EXCLUSION CRITERIA:** Patients with the following should not use Oxsoreslan: Patients exhibiting idiosyncratic reactions to psoralen compounds. Patients possessing a specific history of light sensitive disease states should not initiate methoxsalen therapy except under special circumstances. Diseases associated with photosensitivity include lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum, and albinism. Patients with melanoma or with a history of melanoma. Patients with invasive squamous cell carcinomas. Patients with aphakia, because of the significantly increased risk of retinal damage due to the absence of lenses.
- REQUIRED INFO:** The patient has not adequately responded to one or more topical corticosteroid therapies. This medication is being used in conjunction with a schedule of controlled doses of long wave ultraviolet radiation.
- AGE RESTRICTIONS:** Patients must be at least 18 years old.
- MD RESTRICTIONS:**
- COVERAGE DURATION** End of plan year
- OTHER CRITERIA:** NA

# PEG INTRON AND PEGASYS

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of one of the following: Chronic Hepatitis B, Chronic Hepatitis C, Chronic Hepatitis C, in patients with compensated liver disease--HIV infection.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Patients with genotype 2 or 3 on combination therapy should be treated for 24 weeks total. If the HCV RNA level has not decreased by at least two log<sub>10</sub> units by week 12, therapy should be discontinued.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# PENTAM

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Pneumocystis carinii pneumonia. Pneumocystis carinii pneumonia, high-risk, HIV patients - prophylaxis

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Pregnancy category C. Contraindications: hypersensitivity to pentamidine or diamidine compounds. Monitoring of the following is necessary prior to and during treatment: CBC, platelet counts, serum calcium concentrations, hepatic function, and ECG. Daily BUN, serum creatinine, and blood glucose levels

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# PROMACTA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# PROTOPIC

- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient has a diagnosis of moderate to severe atopic dermatitis.
- EXCLUSION CRITERIA:** Prior authorizations will not be approved if: Patient is under the age of 2. Patient has a compromised immune function. Patients diagnosed with Netherton's Syndrome. Patient has an infection at the site of application.
- REQUIRED INFO:** The patient is not immunocompromised. The patient has a documented failure or inadequate response with at least two topical corticosteroids, or a contraindication to topical corticosteroids
- AGE RESTRICTIONS:** The patient is two years of age or older
- MD RESTRICTIONS:**
- COVERAGE DURATION** End of plan year
- OTHER CRITERIA:** NA

# PULMOZYME

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

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<b>COVERED USES:</b>	All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of Relapsing-Remitting Multiple Sclerosis (RRMS).
<b>EXCLUSION CRITERIA:</b>	Prior authorizations will not be granted in cases of: The indication of the medication is for Hepatitis-C (off-label), The patient has concurrent illness that is likely to alter compliance or substantially reduce life expectancy (dementia, alcoholism, malignancy, or other chronic illnesses). Pregnancy (Category C, but not recommended). History of depression that is not well managed or controlled.
<b>REQUIRED INFO:</b>	The patient must be ambulatory and have the ability to self-administer the medication. Have had at least two acute exacerbations during the previous two years, which consisting of new symptoms or aggravation of old symptoms lasting at least 24 hours in absence of fever, and proceeded by stability or improvement for at least 30 days. Has had baseline CBC and LFT lab tests.
<b>AGE RESTRICTIONS:</b>	
<b>MD RESTRICTIONS:</b>	
<b>COVERAGE DURATION</b>	End of plan year
<b>OTHER CRITERIA:</b>	NA

- 
- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of a lower extremity diabetic neuropathic ulcer.
- EXCLUSION CRITERIA:** Prior authorization requests shall not be granted for use in pressure ulcers.
- REQUIRED INFO:** The ulcer must extend into the subcutaneous tissue or beyond. (Stage III or IV as defined by the International Association of Enterostomal Therapy for staging chronic wounds). The patient must have failed standard therapy for at least two months (careful and frequent debridement, moist dressing changes, and non-weight bearing). The ulcer must have an adequate blood supply.
- AGE RESTRICTIONS:**
- MD RESTRICTIONS:**
- COVERAGE DURATION** End of plan year
- OTHER CRITERIA:** NA

# RELISTOR

**COVERED USES:** All FDA-Approved and compendia indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# REVATIO

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The member must have a diagnosis of pulmonary hypertension.

**EXCLUSION CRITERIA:** 1.NPS will not grant any PAs for Revatio™ if the diagnosis is for erectile dysfunction.

**REQUIRED INFO:** If the member is requesting a PA for Revatio™ the following criteria must be met: Patient must have a blood pressure -Greater Than- 90/50 mm hg. Documentation must be provided that the member is not concurrently taking a nitrate. Documentation must be provided that the member is not concurrently taking ritonavir. Documentation must be provided that the member is not concurrently taking an alpha adrenergic blocker (i.e. doxazosin, prazosin, terazosin, phenoxybenzamine, tamsulosin)

**AGE RESTRICTIONS:** Patient must be at least 18 years old.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** A caution was issued for Revatio™ use with any alpha blocker.

# RILUTEK

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. RILUTEK is indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS).

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:** The safety and the effectiveness of RILUTEK in pediatric patients have not been established.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# SANDOSTATIN LAR DEPOT, SANDOSTATIN IN

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Acromegaly, Carcinoid tumors, Vasoactive Intestinal Peptide Tumors (VIPomas).

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** The patient must tolerate an initial treatment of Sandostatin® Injectable for a minimum of 2 weeks.

**AGE RESTRICTIONS:** The patient must be at least 18 years old.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

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**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. A diagnosis of secondary hyperparathyroidism in patients with Chronic Kidney Disease on dialysis. The patient has a diagnosis of hypercalcemia in patients with parathyroid carcinoma.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Patient with hyperparathyroidism and chronic kidney disease with dialysis they should have a documented failure of one or more of the following, Calcitriol, Paricalcitol or Phosphate binder - calcium carbonate, calcium acetate, aluminum hydroxide, aluminum carbonate, or sevelamer.

**AGE RESTRICTIONS:** The patient is at least 18 years old.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# SIMPONI

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Rheumatoid arthritis in combination with methotrexate, psoriatic arthritis alone or in combination with methotrexate, and ankylosing spondylitis.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Patient must be 18 years of age or older.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# SOLARAZE

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
The patient has a diagnosis of actinic keratoses.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** Complete healing of the lesion may not be evident for 30 days following the discontinuation of treatment. Lesions that do not respond to treatment should be carefully reevaluated and management reconsidered.

# SOMATULINE

**COVERED USES:** All FDA-Approved and compendia indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# SOMAVERT

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Diagnosis of acromegaly documented by elevated GH levels (GH level -Greater Than- 5ng/mL)

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Patients have had a documented inadequate response to surgery and/or radiation therapy. Patient must have baseline LFTs (AST and ALT less than 3 times upper limit). Patients must have failed ONE or MORE of the following treatments: Transsphenoidal surgery, Radiation therapy, Octreotide, Lanreotide, Vapreotide, Bromocriptine, Pergolide

**AGE RESTRICTIONS:** Patient must be at least 18 years old

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# STRIANT

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of Primary Hypogonadism (congenital or acquired). The patient must have a diagnosis of Hypogonadotropic Hypogonadism (congenital or acquired)

**EXCLUSION CRITERIA:** •Patient must not have a diagnosis of breast or prostate cancer

**REQUIRED INFO:** Patient must be a male (Striant is contraindicated in women)

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# SYNAREL

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Central Precocious Puberty In Children of Both Sexes,  
Endometriosis

**EXCLUSION CRITERIA:** Patient must not be pregnant (cat. X)

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Patient must be at least 18 years old for diagnosis of endometriosis.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

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**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Indication for the management of cystic fibrosis patients with  
Pseudomonas Aeruginosa.

**EXCLUSION CRITERIA:** •Patient must not be pregnant. (CATEGORY 'D').

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Patient must be 6 years of age or older.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

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**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. A diagnosis of pulmonary arterial hypertension with World Health Organization (WHO) Class II to IV symptoms.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** The patient is not currently taking glyburide or cyclosporine. The patient has had baseline liver function tests (ALT, AST) performed prior to the initiation of therapy. For female patients of childbearing potential (12-50 years of age), a baseline negative pregnancy test is performed prior to the initiation of therapy.

**AGE RESTRICTIONS:** Patients must be at least 18 years old.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. A complicated skin infection by one of the following: *E. coli*, *Enterococcus faecalis* (vancomycin-susceptible only), *Staphylococcus aureus* (methicillin-susceptible and methicillin-resistant), *Streptococcus agalactiae*, *Streptococcus anginosus* (including *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Streptococcus pyogenes* and *Bacteroides fragilis*. A complicated intra-abdominal infection as a result from one of the following: *Citrobacter freundii*, *Enterobacter cloacae*, *E. coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Enterococcus faecalis* (vancomycin-susceptible only), *Staphylococcus aureus* (methicillin-susceptible only), *Streptococcus anginosus* (including *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Bacteroides fragilis*, *Bacteroides thetaiotaomicron*, *Bacteroides uniformis*, *Bacteroides vulgatus*, *Clostridium perfringens*, and *Peptostreptococcus micros*.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** If the patient has severe hepatic impairment (Child Pugh C), an initial dose of 100 mg of Tygacil™ should be given followed by a maintenance dose of 25 mg every 12 hours. The patient should be closely monitored for treatment response.

**AGE RESTRICTIONS:** The patient must be at least 18 years old

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# TYSABRI

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Relapsing Multiple Sclerosis, Crohn's Disease.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Pregnancy Category: C.

**AGE RESTRICTIONS:** Patient Must Be At Least 18 Years Old.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** \*\*NOTE: Marketing of the drug was voluntarily suspended in March 2005. However, the clinical hold on natalizumab was lifted under specific circumstances on February 15, 2006. Natalizumab may be resumed in patients who had previously been receiving the drug within an investigational new drug (IND) study. Tysabri is available only through a special restricted distribution program called the TOUCH Prescribing Program and must be administered only to patients enrolled in this program.

# VANCOCIN

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** This medication does not meet coverage criteria under Medicare Part B. \*Note that the oral formulation is not absorbed systemically and cannot be used to treat systemic infections.

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Aspergillosis, Invasive, Candidemia, Candidiasis of the esophagus, Disseminated candidiasis, of the skin and infections in abdomen, kidney, bladder wall, and wounds, Mycosis, Serious infections due to *Scedosporium apiospermum* and *Fusarium* species.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Patient must be at least 12 years old.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# XENAZINE

**COVERED USES:** All FDA-Approved and compendia indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Cataplexy associated with narcolepsy

**EXCLUSION CRITERIA:** The patient is not concurrently taking any sedative hypnotic agents  
at the time of the prior authorization review

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Patient must be at least 16 years old.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

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**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. A diagnosis of secondary hyperparathyroidism associated with chronic kidney disease (CKD) stage 3 or 4.

**EXCLUSION CRITERIA:** Vitamin D toxicity. Hypercalcemia

**REQUIRED INFO:**

**AGE RESTRICTIONS:** Injectable formulation is indicated for children 5 years and older.

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

# ZORBTIVE

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.  
Cachexia associated with AIDS, Growth hormone deficiency, Short Bowel Syndrome

**EXCLUSION CRITERIA:**

**REQUIRED INFO:**

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Appendicitis, Complicated by rupture or abscess, Community acquired pneumonia, Infection of skin and subcutaneous tissue, including diabetic foot infections, Nosocomial pneumonia, Pelvic inflammatory disease, Peritonitis, Puerperal endometritis.

**EXCLUSION CRITERIA:** •Zosyn is contraindicated in patients with a history of allergic reactions to any of the penicillins, cephalosporins, or (beta)-lactamase inhibitors.

**REQUIRED INFO:** To reduce the development of drug-resistant bacteria and maintain the effectiveness of Zosyn (piperacillin and tazobactam) injection and other antibacterial drugs, Zosyn (piperacillin and tazobactam) should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA

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**COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Patient has Vancomycin-resistant Enterococcus faecium infection including patients with concurrent bacteremia. Patient has nosocomial pneumonia caused by Staphylococcus aureus (methicillin-resistant or methicillin-sensitive strains) or Streptococcus pneumoniae (including multi-drug resistant strains: ie penicillin, second-generation cephalosporins, macrolides, tetracycline, and trimethoprim/sulfamethoxazole.) Patient has a complicated skin and skin structure infection caused by Staphylococcus aureus (methicillin-resistant or methicillin-sensitive strains), Streptococcus pyogenes, or streptococcus agalactiae (including diabetic foot infections without concomitant osteomyelitis).

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Patient requires a weekly CBC.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION** End of plan year

**OTHER CRITERIA:** NA