



# PRIOR AUTHORIZATION CRITERIA

## TABLE OF CONTENTS

ADAGEN .....	4
ALDURAZYME .....	5
ALIMTA .....	6
AMEVIVE.....	7
AMINOSYN .....	8
ANADROL-50.....	9
ANCOBON .....	10
ANDROGEL .....	11
ANDROID .....	12
ANDROXY .....	13
APOKYN .....	14
ARALAST.....	15
ARANESP .....	16
ARCALYST .....	17
AVASTIN .....	18
AVONEX.....	19
AZACTAM.....	20
BETASERON .....	21
BLEOMYCIN SULFATE .....	22
BOTOX .....	23
BUPHENYL.....	24
CAMPATH.....	25
CANCIDAS.....	26
CELLCEPT.....	27
CEREDASE.....	28
CEREZYME.....	29
CHANTIX.....	30
CIMZIA .....	31
COPAXONE .....	32
CYSTADANE .....	33
DACOGEN .....	34
DRONABINOL .....	35
ELAPRASE .....	36
ELIGARD.....	37
ELITEK .....	38
EMSAM .....	39
ENBREL .....	40
EPOGEN .....	41
ERAXIS .....	42
EXJADE .....	43
FABRAZYME .....	44
FASLODEX .....	45
FENTANYL CITRATE ORAL TRANSMUCOSAL.....	46
FENTORA .....	47
FLEBOGAMMA .....	48
FOMEPIZOLE .....	49
FORTEO.....	50
FOSCARNET SODIUM.....	51
GAMASTAN S/D.....	52



GAMMAGARD .....	53
GAMUNEX .....	54
GEMZAR .....	55
GLEEVEC.....	56
HERCEPTIN.....	57
HUMIRA .....	58
HYCAMTIN.....	59
INCRELEX.....	60
INFERGEN .....	61
INNOHEP .....	62
INTRON-A .....	63
IPLEX .....	64
ITRACONAZOLE .....	65
IVEEGAM EN .....	66
IXEMPRA .....	67
KINERET .....	68
KUVAN .....	69
LETAIRIS .....	70
LEUKINE .....	71
LEUPROLIDE.....	72
LUPRON.....	73
LYSODREN.....	74
MEPRON .....	75
MESNEX.....	76
MYCAMINE .....	77
MYOBLOC .....	78
NAGLAZYME.....	79
NEULASTA .....	80
NEUMEGA .....	81
NEUPOGEN .....	82
NEUTREXIN.....	83
NEXAVAR .....	84
NORDITROPIN .....	85
NOXAFIL .....	86
OCTAGAM .....	87
OCTREOTIDE ACETATE.....	88
ONTAK .....	89
ORENCIA .....	90
ORFADIN .....	91
OXANDROLONE .....	92
OXYCONTIN .....	93
PACLITAXEL .....	94
PAMIDRONATE DISODIUM.....	95
PEGASYS .....	96
PEG-INTRON .....	97
PERFOROMIST .....	98
POLYGAM.....	99
PROCRIT.....	100
PROLASTIN .....	101
PROLEUKIN.....	102
PROTONIX IV.....	103
PULMOZYME.....	104
QUALAQUIN.....	105
RAPTIVA .....	106
REBETOL.....	107
REBIF .....	108



REGRANEX .....	109
REMICADE.....	110
REVATIO.....	111
REVLIMID.....	112
RIBASPHERE .....	113
RILUTEK .....	114
RITUXAN.....	115
SANDOSTATIN LAR DEPOT .....	116
SEROSTIM.....	117
SOMATULINE DEPOT .....	118
SOMAVERT .....	119
SPORANOX .....	120
SPRYCEL.....	121
SUCRAID .....	122
SUTENT .....	123
SYMLIN .....	124
SYNAREL.....	125
SYNERCID.....	126
TARCEVA .....	127
TARGRETIN.....	128
TASIGNA.....	129
TAXOTERE .....	130
TESTIM.....	131
TESTRED .....	132
TEV-TROPIN.....	133
THALOMID.....	134
THIOTEPA.....	135
THYMOGLOBULIN.....	136
TOBI .....	137
TORISEL .....	138
TRACLEER .....	139
TREANDA .....	140
TRETINOIN .....	141
TRISENOX .....	142
TYGACIL .....	143
TYKERB .....	144
TYSABRI.....	145
VANCOCIN HCL .....	146
VELCADE.....	147
VENTAVIS.....	148
VFEND.....	149
VIDAZA .....	150
VIRAZOLE.....	151
XOLAIR .....	152
ZAVESCA.....	153
ZOLINZA .....	154
ZOMETA.....	155
ZORBTIVE.....	156
ZYVOX.....	157



Drug Name:

**ADAGEN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit it would be covered by Medicare Part B

***Required Medical Information:***

Diagnosis for use. Adenosine deaminase deficiency - Severe combined immunodeficiency disease.

***Age Restrictions:*** not approved for use in adults

***Prescriber Restrictions:***

***Coverage Duration:*** 6 mos

***Other Criteria:***



***Drug Name:***

**ALDURAZYME**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit it would be covered by Medicare Part B. Not covered for mildly affected patients with the Scheie form.

***Required Medical Information:***

Diagnosis for use. Mucopolysaccharidosis, Type I (Hurler and Hurler-Scheie forms) and Scheie form with moderate to severe symptoms.

***Age Restrictions:*** less than 5yrs old

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**ALIMTA**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit it would be covered by Medicare Part B

***Required Medical Information:***

For the following diagnosis: Malignant mesothelioma of pleura, In combination with cisplatin in patients who are not candidates for surgical resection, OR for Non-small cell lung cancer, locally advanced or metastatic, after prior chemotherapy.

***Age Restrictions:*** Not indicated for use in pediatrics.

***Prescriber Restrictions:***

***Coverage Duration:*** Length of approval as determined by diagnosis and course of treatment.

***Other Criteria:***



**Drug Name:**

**AMEVIVE**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

If this medication is administered by a physician incident to a physician's visit it would be covered by Medicare Part B. Amevive should not be administered to patients: with a CD4+ T lymphocyte count below normal (250 cells/mL); with a history of systemic malignancy; with clinically important infections

**Required Medical Information:**

Amevive is an immunosuppressive dimeric fusion protein that is indicated for the treatment of moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. It is available in as both an intra-muscular and an intravenous injection to be administered once-weekly and should only be used under the guidance and supervision of a physician. Coventry Health Care will cover Amevive when meeting all the following criteria: Amevive is prescribed by a licensed dermatologist or other prescriber for treatment of chronic moderate to severe (greater than 1 year) plaque psoriasis, AND the body surface area (BSA) involvement is equal to or greater than 10% OR for patients with severe psoriasis in vulnerable areas (such as hands, soles, palms, face and genital areas), BSA involvement of equal to or greater than 1-3%, AND failure of at least two (2) non-biologic therapies, such as phototherapy or systemic therapies. Failure for this policy is defined as either no improvement or worsening of plaque psoriasis. Amevive should only be used under the guidance and supervision of a physician. The recommended dose of Amevive is 7.5 mg given once weekly as an IV bolus or 15 mg given once weekly as an IM injection. The CD4+ T lymphocyte counts of patients receiving Amevive should be monitored before initiating dosing and then weekly throughout the course of the 12-week dosing regimen. Dosing should be withheld if CD4+ T lymphocyte counts are below 250 cells/ $\mu$ L. The drug should be discontinued if the counts remain below 250 cells/ $\mu$ L for one month. Patients meeting criteria for approval are allowed an initial course of 12-weeks. Quantities are limited to 4-vials per month. Retreatment with an additional 12-week course may be initiated provided that CD4+ T lymphocyte counts are within the normal range, and a minimum of a 12-week interval has passed since the previous course of treatment. Data on retreatment beyond two cycles are limited.

**Age Restrictions:** Adults: 18 years and older.

**Prescriber Restrictions:**

**Coverage Duration:** Up to 24 weeks

**Other Criteria:**



***Drug Name:***

**AMINOSYN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

This is covered under Part B when the following exists: specific diagnosis to include a non-functioning GI tract: Sole source of nutrition:  
Use of TPN for a minimum of 90 days

***Required Medical Information:***

Diagnosis for use. Aminosyn infused with dextrose by peripheral vein infusion is indicated as a source of nitrogen in the nutritional support in patients documented to have adequate stores of body fat, in whom, for short periods of time, oral nutrition cannot be tolerated, is undesirable, or inadequate.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 6 months

***Other Criteria:***



***Drug Name:***

**ANADROL-50**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D: such as the following FDA approved indications: anemias caused by deficient red cell production. Acquired or congenital aplastic anemias, myelofibrosis, and/or hypoplastic anemias caused by the administration of myelotoxic drugs.

***Exclusion Criteria:***

***Required Medical Information:***

Diagnosis for use. CBC with differential.

***Age Restrictions:*** For both male and female patients, all ages

***Prescriber Restrictions:***

***Coverage Duration:*** 3 months

***Other Criteria:***



***Drug Name:***

**ANCOBON**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D: such as the following FDA approved indication: septicemia, endocarditis, urinary tract infections, pulmonary infections secondary to Candidiasis: AND meningitis, pulmonary infections, septicemia, urinary tract infections secondary to Cryptococcosis.

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit it would be covered by Medicare Part B

***Required Medical Information:***

Diagnosis for treatment. Use with extreme caution in patients with impaired renal function. Close monitoring of hematologic, renal, and hepatic status of all patients is essential.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 2 months

***Other Criteria:***



***Drug Name:***

**ANDROGEL**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Testosterone levels within normal range (range for the lab doing the testing): Female patients: Men with carcinoma of the breast or suspected carcinoma of the prostate: Use for muscle building purposes.

***Required Medical Information:***

Diagnosis for use: Testosterone levels- total and free: LH and FSH levels

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initial for 3 months: then 1 year

***Other Criteria:***

Higher quantities will require failure of recommended doses per day.: Retreatment will be initiated for an additional one-year course of therapy provided that topical testosterone therapy is maintaining normal testosterone levels. Androgel is preferred agent



***Drug Name:***

**ANDROID**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Diagnosis for use: Indicated for delay in sexual development AND/OR puberty, and hypogonadotropic hypogonadism and metastasis from malignant tumor of breast inoperable metastatic disease (skeletal) in women 1 to 5 years postmenopausal and primary hypogonadism. Testosterone levels- total and free: LH and FSH levels

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 3 months then 1 year if response noted.

***Other Criteria:***



***Drug Name:***

**ANDROXY**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Diagnosis for use: Indicated for delay in sexual development AND/OR puberty, and hypogonadotropic hypogonadism and I and primary hypogonadism and for adjunct palliative treatment of Breast cancer. Testosterone levels- total and free: LH and FSH levels

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initially - 3 months

***Other Criteria:***



***Drug Name:***

**APOKYN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Diagnosis for use: Medical HX that documents patient experiences motor fluctuations despite an optimized oral drug regime which includes levodopa; and the patient is compliant with current Parkinson's disease drug therapy (taking at least 75% of medication doses)..

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initial approval -12 weeks: Renewal Improvement in motor function for extended approval of 1 year

***Other Criteria:***



***Drug Name:***

**ARALAST**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Aralast is not indicated as therapy for lung disease patients in whom congenital (alpha) 1-PI deficiency has not been established. Aralast is the preferred agent for this indication.

***Required Medical Information:***

Diagnosis for use: For chronic augmentation therapy in patients having congenital deficiency of (alpha) 1-PI with clinically evident emphysema. Clinical and biochemical studies have demonstrated that with such therapy, Aralast™ is effective in maintaining target serum (alpha) 1 -PI trough levels and increasing (alpha) 1 -PI levels in epithelial lining fluid (ELF)

***Age Restrictions:*** Adults: Pediatric: Safety and efficacy not established in children

***Prescriber Restrictions:***

***Coverage Duration:*** Initial approval: 6 months: Extended approval: Annual review will be based on response to therapy

***Other Criteria:***

Diagnosis is documented as congenital deficiency of alpha 1-antitrypsin with clinically evident emphysema.



**Drug Name:**

**ARANESP**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

For patients receiving hemodialysis at a dialysis center the ESA drug would be paid for by the Part B benefit. Aranesp is covered only after documented failure of Procrit (target levels not reached after 8 weeks of therapy), or significant side effects from its use. HG or Hct at or above 12g/dl or 36%. ESA is not indicated for patients with an endogenous serum erythropoietin level of above 500 mU/mL or treatment of anemia in HIV-infected patients caused by other factors such as iron or folate deficiencies, hemolysis or GI bleeding . Initiation of therapy is warranted when the hematocrit is below 30% or hemoglobin is below 10 g/dL. ESA therapy is restricted to anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma and lymphocytic leukemia.

**Required Medical Information:**

Diagnosis for use: Treatment of anemia associated with CKF, including patients on dialysis (end-stage renal disease) and patients not on dialysis, to elevate or maintain the red blood cell level (as manifested by the hemoglobin or hematocrit determinations) and to decrease the need for transfusions. Not intended for patients who require immediate correction of severe anemia. ESA may obviate the need for maintenance transfusions but is not a substitute for emergency transfusions. Treatment of anemia related to zidovudine therapy in HIV-infected patients: To elevate or maintain the red blood cell level (as manifested by the hemoglobin or hematocrit determinations) and to decrease the need for transfusions. Treatment of anemia in cancer patients on chemotherapy: Treatment of anemia in patients with malignancies where anemia is caused by the effect of concomitantly administered chemotherapy. It is intended to decrease the need for transfusions in patients who will receive chemotherapy for a minimum of 2 months. ESA therapy is restricted to anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma and lymphocytic leukemia. Reduction in allogeneic blood transfusions in surgery patients: Myelodysplastic Syndrome (MDS). Use of ESA is indicated in states of anemia where there is presumed to be inadequate EPO production. Laboratory evidence: depending on diagnosis hemoglobin (g/dL) and/or hematocrit (%) : GFR: Percent transferrin saturation (TSAT): Serum ferritin: Vitamin B12 levels: folate levels: EPO level: marrow blasts %: recent transfusion HX: Exclusion of other causes of anemia: Patient has symptomatic anemia, with symptoms including, but not limited to, weakness, syncope, tiredness, dyspnea, chest pain, postural hypotension, tachycardia or a marked reduction in activities of daily living.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initial approval: chemotherapy-related anemia-4 weeks: MDS-6 months: all other indications-8 weeks

**Other Criteria:**



***Drug Name:***

**ARCALYST**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit, this would be covered by Medicare Part B. Participation in a non-approved clinical trial using ARCALYST as part of the drug therapy. Investigational uses not recognized as an FDA approved indication or use not recognized in one of the following compendia: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, DRUGDEX Information System.

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initial approval for 6 months

***Other Criteria:***

Loading dose of 320mg delivered as two, 2ml SQ injections of 160mg each. Dosing continued with a once-weekly injection of 160mg administered as a single 2ml SQ injection. The first injection of ARCALYST should be performed under the supervision of a qualified healthcare professional. If a patient or caregiver is to administer ARCALYST, he/she should be instructed on aseptic and reconstitution of ARCALYST for proper administration. ARCALYST should not be given more often than once weekly. Dosage modification not required for advanced age or gender.



**Drug Name:**

**AVASTIN**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Participation in a non-approved clinical trial using Avastin as part of the drug therapy. Investigational uses not recognized as an FDA approved indication or use not recognized in one of the following compendia: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, DRUGDEX Information System. If this medication is administered by a physician incident to a physician's visit, this would be covered by Medicare Part B

**Required Medical Information:**

Diagnosis for use: Non-Small Cell Lung Cancer: Metastatic Colorectal Cancer: Metastatic Breast Cancer:

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initial approval for 6 months. Extended approval based on continued response to therapy.

**Other Criteria:**

Avastin, in combination with intravenous 5-fluorouracil-based chemotherapy, is indicated for first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum. Avastin®, used in combination with intravenous 5-FU-based chemotherapy, is administered as an intravenous infusion (5 mg/kg or 10 mg/kg) every 14 days. The recommended dose of Avastin®, when used in combination with bolus-IFL, is 5 mg/kg. The recommended dose of Avastin®, when used in combination with FOLFOX4, is 10 mg/kg. Avastin®, in combination with carboplatin and paclitaxel, is indicated for first line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous, non-small cell lung cancer. The recommended dose of Avastin® is 15 mg/kg, as an IV infusion every 3 weeks. Note: Avastin® should not be initiated until at least 28 days following major surgery. The surgical incision should be fully healed prior to initiation of Avastin®



**Drug Name:**

**AVONEX**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

**Required Medical Information:**

Diagnosis of definite or probable relapsing-remitting MS, secondary progressive MS with relapses, or progressive relapsing MS. Direct statement from a neurologist that diagnosis is a relapsing form of MS, or a first MS attack with documented MRI scan abnormalities characteristic of MS. OR Evaluation documenting EITHER: history of at least two focal neurological deficits (e.g. loss of vision, double vision, localized numbness or weakness), in which the first resolved and the second followed after a period of at least 6 months, OR History of one focal neurological deficit which has resolved, and an MRI suggestive of MS: At least 3 total lesions, each at least 5mm: At least one lesion with contrast enhancement: At least 2 out of 3 lesions in either, Periventricular white matter OR Brain stem (e.g., cerebellar peduncle, pons) OR (3) Spinal cord. Lack of statement that lesions are consistent with ischemic disease: AND Functional status is ambulatory (with or without assistive devices).

**Age Restrictions:**

**Prescriber Restrictions:** Neurologist

**Coverage Duration:** 1 year

**Other Criteria:**

For patients treated greater than 1 yr, annual certification from a neurologist that therapy has been effective, i.e. treatment has decreased relapses or diminished number of lesions on MRI AND for patients previously treated with mitoxantrone, documentation that prior treatment with requested drug was successful in decreasing relapses or diminishing the number of lesions on MRI AND dosage does not exceed the FDA approved dose



***Drug Name:***

**AZACTAM**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit, this would be covered by Medicare Part B.

***Required Medical Information:***

Diagnosis for use and results of a culture and sensitivity indicating sensitivity to Azactam and bacterial resistant to aminopenicillins, first or second generation cephalosporins, and/or aminoglycosides or other medical information indicating Azactam is the antibiotic of choice.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** As required by diagnosis..

***Other Criteria:***



***Drug Name:***

**BETASERON**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Diagnosis of definite or probable relapsing-remitting MS, secondary progressive MS with relapses, or progressive relapsing MS. Direct statement from a neurologist that diagnosis is a relapsing form of MS, or a first MS attack with documented MRI scan abnormalities characteristic of MS. OR Evaluation documenting EITHER: history of at least two focal neurological deficits (e.g. loss of vision, double vision, localized numbness or weakness), in which the first resolved and the second followed after a period of at least 6 months, OR History of one focal neurological deficit which has resolved, and an MRI suggestive of MS: At least 3 total lesions, each at least 5mm: At least one lesion with contrast enhancement: At least 2 out of 3 lesions in either, Periventricular white matter OR Brain stem (e.g., cerebellar peduncle, pons) OR (3) Spinal cord. Lack of statement that lesions are consistent with ischemic disease: AND Functional status is ambulatory (with or without assistive devices).

***Age Restrictions:***

***Prescriber Restrictions:*** Neurologist

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**BLEOMYCIN SULFATE**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit it would be covered by Medicare Part B

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 6 months up to a maximum of 400 units

***Other Criteria:***



***Drug Name:***

**BOTOX**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

NOT approvable for cosmetic use. If this medication is administered by a physician incident to a physician's visit it would be covered by Medicare Part B.

***Required Medical Information:***

For the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia. For the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents. For the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above. Also approvable for Cerebral Palsy and Spastic hemiplegia

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 12 months

***Other Criteria:***

The efficacy of Botox® treatment in deviations over 50 prism diopters, in restrictive strabismus, in Duane's syndrome with lateral rectus weakness, and in secondary strabismus caused by prior surgical over-recession of the antagonist has not been established. Botox® is ineffective in chronic paralytic strabismus except when used in conjunction with surgical repair to reduce antagonist contracture.



***Drug Name:***

**BUPHENYL**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Cycle disorders: As adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamoylase (OTC) or argininosuccinic acid synthetase (AAS). In all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life). In patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemic encephalopathy. It is important that the diagnosis is made early and treatment initiated immediately to improve survival. Any episode of acute hyperammonemia should be treated as a life-threatening emergency.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



**Drug Name:**

**CAMPATH**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B.

**Required Medical Information:**

Diagnosis of B-cell chronic lymphocytic leukemia (B-CLL)

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** 6 months

**Other Criteria:**

Dosing Schedule and Administration Administer as an IV infusion over 2 hours. Do not administer as intravenous push or bolus. Recommended Dosing Regimen. Gradually escalate to the maximum recommended single dose of 30 mg. Escalation is required at initiation of dosing or if dosing is held longer than 7 days during treatment. Escalation to 30 mg ordinarily can be accomplished in 3-7 days. Escalation Strategy: Administer 3 mg daily until infusion reactions are less than or equal to grade 2. Then administer 10 mg daily until infusion reactions are less than grade 2. Then administer 30 mg/day three times per week on alternate days (e.g., Mon-Wed-Fri). The total duration of therapy, including dose escalation, is 12 weeks. Single doses of greater than 30 mg or cumulative doses greater than 90 mg per week increase the incidence of pancytopenia. Recommended Concomitant Medications Premedicate with diphenhydramine (50 mg) and acetaminophen (500-1000 mg) 30 minutes prior to first infusion and each dose escalation. Institute appropriate medical management (e.g. steroids, epinephrine, meperidine) for infusion reactions as needed. Administer trimethoprim/sulfamethoxazole DS twice daily (BID) three times per week (or equivalent) as Pneumocystis jiroveci pneumonia (PCP) prophylaxis. Administer famciclovir 250 mg BID or equivalent as herpetic prophylaxis. Continue PCP and herpes viral prophylaxis for a minimum of 2 months after completion of Campath or until the CD4+ count is greater than or equal to 200 cells/ $\mu$ L, whichever occurs later.



***Drug Name:***

**CANCIDAS**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B.

***Required Medical Information:***

Empirical therapy for presumed fungal infections in febrile, neutropenic patients. Treatment of Candidemia and the following Candida infections: intra-abdominal abscesses, peritonitis and pleural space infections. Cancidas has not been studied in endocarditis, osteomyelitis, and meningitis due to Candida. Treatment of Esophageal Candidiasis Treatment of Invasive Aspergillosis in patients who are refractory to or intolerant of other therapies (i.e., amphotericin B, lipid formulations of amphotericin B, and/or itraconazole). Cancidas has not been studied as initial therapy for invasive aspergillosis. Extended approvals will depend on severity of infection and response to initial course of therapy.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initially-21 days

***Other Criteria:***

Prior authorization requests will be approved for current FDA approved indications, when used within manufacturer's recommended dosing guidelines or for indications as recognized in the follow compendia: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, DRUGDEX Information System



***Drug Name:***

**CELLCEPT**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

When used for a Medicare covered transplant for a patient enrolled in Medicare Part A at the time of the transplant it is covered under Medicare Part B. When the indication is not for a covered transplant (Part B), the patient must have tried and failed therapy with Myfortic OR have a documented medical reason why this medication is medically/therapeutically inappropriate.

***Required Medical Information:***

For the prophylaxis of organ rejection in patients receiving allogenic renal, hepatic, or cardiac transplants. Use mycophenolate concomitantly with cyclosporine and corticosteroids.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**CEREDASE**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B.

***Required Medical Information:***

Alglucerase is effective for long-term enzyme replacement therapy in patients with confirmed TYPE 1 GAUCHER DISEASE, who exhibit one or more of the following conditions. a) moderate-to-severe anemia b) thrombocytopenia and bleeding tendencies c) bone disease (eg osteopenia and osteonecrosis) d) significant hepatomegaly or splenomegaly.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 6 months

***Other Criteria:***



***Drug Name:***

**CEREZYME**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B.

***Required Medical Information:***

Gaucher disease: Long-term enzyme replacement therapy for patients with a confirmed diagnosis of Type 1 Gaucher disease that results in one or more of the following conditions: anemia thrombocytopenia bone disease hepatomegaly splenomegaly.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 7 months

***Other Criteria:***



**Drug Name:**

**CHANTIX**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

CHANTIX will be approved for smoking cessation treatment in patients who have documented failure with nicotine replacement therapy, AND who have had failure on a therapeutic course of Bupropion (7-9 weeks), or have a contraindication to its use

**Required Medical Information:**

CHANTIX is indicated as an aid to smoking cessation treatment Extended authorization - may be renewed for one additional 3 month period per year for beneficiaries who have stopped smoking after the initial 3 month treatment period. A maximum of 6 months will be allowed per patient per year.

**Age Restrictions:** 18 years an older

**Prescriber Restrictions:**

**Coverage Duration:** 3 months

**Other Criteria:**

Patients should be treated with CHANTIX for 12 weeks. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment with CHANTIX is recommended to further increase the likelihood of long-term abstinence. Patients who do not succeed in stopping smoking during 12 weeks of initial therapy, or who relapse after treatment, should be encouraged to make another attempt once factors contributing to the failed attempt have been identified and addressed



**Drug Name:**

**CIMZIA**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Cimzia® (certolizumab pegol) is not covered for patients with active infections because its safety in active infections has not been established. Treatment of inflammatory conditions, other than FDA approved indications or indications supported in Medicare approved compendia, is considered investigational and therefore not covered. If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

**Required Medical Information:**

Diagnosis for use: moderate to severely active Crohn's disease. Extended Approval: 1 year: Annual review based on submitted documentation of therapeutic response.

**Age Restrictions:** 18yrs or older

**Prescriber Restrictions:**

**Coverage Duration:** 6 months

**Other Criteria:**

The recommended initial dose of Cimzia® is 400 mg given as two subcutaneous injections (200 mg each) at weeks 0, 2, and 4. The recommended maintenance regimen in patients who obtain a clinical response is 400 mg every four weeks. Cimzia® is available as a vial containing 200 mg of certolizumab powder for reconstitution.



***Drug Name:***

**COPAXONE**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Diagnosis of definite or probable relapsing-remitting MS, secondary progressive MS with relapses, or progressive relapsing MS. Direct statement from a neurologist that diagnosis is a relapsing form of MS, or a first MS attack with documented MRI scan abnormalities characteristic of MS.

***Age Restrictions:***

***Prescriber Restrictions:*** Neurologist

***Coverage Duration:*** 1 year

***Other Criteria:***

For patients treated greater than 1 yr, annual certification from a neurologist that therapy has been effective, i.e. treatment has decreased relapses or diminished number of lesions on MRI AND for patients previously treated with mitoxantrone, documentation that prior treatment with requested drug was successful in decreasing relapses or diminishing the number of lesions on MRI AND dosage does not exceed the FDA approved dose



***Drug Name:***

**CYSTADANE**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Homocystinuria: The treatment of homocystinuria to decrease elevated homocysteine blood levels. Included within the category of homocystinuria are deficiencies or defects in: Cystathionine beta-synthase (CBS) 5,10-methylenetetrahydrofolate reductase (MTHFR) and cobalamin cofactor metabolism (cbl).

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



**Drug Name:**

**DACOGEN**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B.

**Required Medical Information:**

Dacogen is indicated for treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and Intermediate-1, Intermediate-2, and High-Risk International Prognostic Scoring System groups

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initial approval: 3 months Extended approval: 6 months if benefit is demonstrated

**Other Criteria:**

MDS and secondary MDS of all subtypes and Intermediate-1, Intermediate-2, and High-Risk International Prognostic Scoring System groups. **DOSAGE AND ADMINISTRATION:** First Treatment Cycle The recommended Dacogen dose is 15 mg/m<sup>2</sup> administered by continuous intravenous infusion over 3 hours repeated every 8 hours for 3 days. Patients may be premedicated with standard anti-emetic therapy. Subsequent Treatment Cycles The cycle should be repeated every 6 weeks. It is recommended that patients be treated for a minimum of 4 cycles however, a complete or partial response may take longer than 4 cycles. Treatment may be continued as long as the patient continues to benefit



***Drug Name:***

**DRONABINOL**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Not covered as first line agent for loss of appetite in AIDS or for first line agent in chemo induced nausea and vomiting

***Required Medical Information:***

Diagnosis for use: AIDS - Loss of appetite or Chemotherapy-induced nausea and vomiting, Prophylaxis

***Age Restrictions:*** Adults - AIDS-Loss of appetite

***Prescriber Restrictions:***

***Coverage Duration:*** Aids-loss of appetite: Initial 3 months.Chemo induced N and V: duration of chemo therapy.

***Other Criteria:***



***Drug Name:***

**ELAPRASE**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

***Required Medical Information:***

The intravenous administration of Elaprase is indicated for the treatment of Hunter Syndrome (Mucopolysaccharidosis II) in adults, adolescents, and children at least 5 years of age.

***Age Restrictions:*** at least 5 years and older.

***Prescriber Restrictions:***

***Coverage Duration:*** Initial approval: 6 months Extended approval: Annual review will be based on response to therapy

***Other Criteria:***

Elaprase is dosed at 0.5mg/kg and administered over 1 hour every week as an intravenous infusion. Note: Because of the potential for severe infusion reactions, appropriate medical support should be readily available when Elaprase is administered



***Drug Name:***

**ELIGARD**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 6 months

***Other Criteria:***



**Drug Name:**

**ELITEK**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

**Required Medical Information:**

Rasburicase is indicated for the initial management of plasma uric acid levels in pediatric patients with leukemia, lymphoma, and solid tumor malignancies who are receiving chemotherapy expected to cause tumor lysis and subsequent increased plasma uric acid levels, OR in adults as prophylaxis and treatment of hyperuricemia with hematologic malignancies or high-risk solid tumors who had or were at high risk of developing tumor lysis syndrome, AND pretreatment screening has been performed for patients at a higher risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency (eg, patients of African or Mediterranean ancestry) Monitor plasma uric acid levels: Obtain other markers/assessments of tumor lysis syndrome (eg, serum creatinine, serum electrolytes): Monitor for signs and symptoms of a severe allergic reaction (eg, bronchospasm, chest pain and tightness, dyspnea, hypoxia, hypotension, shock, and/or urticaria)

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** One time for course of therapy (1 to 7 days).

**Other Criteria:**

Lyophilized rasburicase (unreconstituted vials) and the diluent for reconstitution should be stored at 2 to 8 degrees C (36 to 46 degrees F) and protected from light. Freezing should be avoided. Reconstituted vials of rasburicase must be used within 24 hours. Reconstituted or diluted solutions can be stored for up to 24 hours at 2 to 8 degrees C



**Drug Name:**

**EMSAM**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

The recipient will need to have failed or be intolerant to at least two antidepressants of different mechanisms from any of the following classes:SSRIs, SNRIs, OR the new generation antidepressants (i.e. Bupropion, Mirtazapine)

**Required Medical Information:**

Treatment of major depressive disorder

**Age Restrictions:** 18 years or older

**Prescriber Restrictions:** psychiatrist (or prescribed upon the recommendation of a psychiatric consult)

**Coverage Duration:** 1 year

**Other Criteria:**

Selegiline is contraindicated with the following medications and should not be approved if the patient is currently taking any of the following: selective serotonin reuptake inhibitors (SSRIs, e.g., fluoxetine, sertraline, and paroxetine), dual serotonin and norepinephrine reuptake inhibitors (SNRIs, e.g., venlafaxine and duloxetine), tricyclic antidepressants (TCAs, e.g., imipramine and amitriptyline), bupropion hydrochloride meperidine and analgesic agents such as tramadol, methadone and propoxyphene cyclobenzaprine, oral selegiline or other MAO inhibitors (MAOIs e.g., isocarboxazid, phenelzine, and tranylcypromine)



***Drug Name:***

**ENBREL**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Diagnosis for use. For moderately to severely active polyarticular-course juvenile rheumatoid arthritis: Require documentation of an inadequate response to methotrexate (MTX) alone for the appropriate treatment period unless MTX is contraindicated. For moderately to severely active rheumatoid arthritis: Require documentation of an inadequate response to MTX and at least one (1) other disease-modifying anti-rheumatic drug (DMARD) or tumor necrosis factor inhibitor (TNF-I) for the appropriate treatment period, unless MTX is contraindicated, then Enbrel is covered after failure to respond to at least two (2) other DMARDs. For psoriatic arthritis: Require documentation of an inadequate response to either MTX or other DMARD for the appropriate treatment period. For moderate to severe chronic (greater than one year in duration) plaque psoriasis: Require the body surface area (BSA) involvement equal to or greater than 10%, AND documentation of at least two (2) non-biologic therapies, such as phototherapy or systemic therapies. For ankylosing spondylitis: Require documentation of inadequate response to maximum tolerated doses of at least (2) non-steroidal anti-inflammatory drugs (NSAIDs).

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 12 weeks for plaque psoriasis and 6 months for other indications. Then annual review.

***Other Criteria:***



**Drug Name:**

**EPOGEN**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

For patients receiving hemodialysis at a dialysis center the ESA drug would be paid for by the Part B benefit. Aranesp is covered only after documented failure of Procrit (target levels not reached after 8 weeks of therapy), or significant side effects from its use. HG or Hct at or above 12g/dl or 36%. ESA is not indicated for patients with an endogenous serum erythropoietin level of above 500 mU/mL or treatment of anemia in HIV-infected patients caused by other factors such as iron or folate deficiencies, hemolysis or GI bleeding . Initiation of therapy is warranted when the hematocrit is below 30% or hemoglobin is below 10 g/dL. ESA therapy is restricted to anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma and lymphocytic leukemia.

**Required Medical Information:**

Diagnosis for use: Treatment of anemia associated with CKF, including patients on dialysis (end-stage renal disease) and patients not on dialysis, to elevate or maintain the red blood cell level (as manifested by the hemoglobin or hematocrit determinations) and to decrease the need for transfusions. Not intended for patients who require immediate correction of severe anemia. ESA may obviate the need for maintenance transfusions but is not a substitute for emergency transfusions. Treatment of anemia related to zidovudine therapy in HIV-infected patients: To elevate or maintain the red blood cell level (as manifested by the hemoglobin or hematocrit determinations) and to decrease the need for transfusions. Treatment of anemia in cancer patients on chemotherapy: Treatment of anemia in patients with malignancies where anemia is caused by the effect of concomitantly administered chemotherapy. It is intended to decrease the need for transfusions in patients who will receive chemotherapy for a minimum of 2 months. ESA therapy is restricted to anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma and lymphocytic leukemia.Reduction in allogeneic blood transfusions in surgery patients:Myelodysplastic Syndrome (MDS).Use of ESA is indicated in states of anemia where there is presumed to be inadequate EPO production Laboratory evidence:depending on diagnosis hemoglobin (g/dL) and/or hematocrit (%) : GFR: Percent transferrin saturation (TSAT):) Serum ferritin: Vitamin B12 levels: folate levels: EPO level: marrow blasts %: recent transfusion HX: Exclusion of other causes of anemia: Patient has symptomatic anemia, with symptoms including, but not limited to, weakness, syncope, tiredness, dyspnea, chest pain, postural hypotension, tachycardia or a marked reduction in activities of daily living.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initial approval: chemotherapy-related anemia-4 weeks:MDS-6 months: all other indications-8 weeks

**Other Criteria:**



***Drug Name:***

**ERAXIS**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

The patient will need to have tried and failed fluconazole and oral Vfend®. Eraxis® has not been studied in endocarditis, osteomyelitis, and meningitis due to Candida, and has not been studied in sufficient numbers of neutropenic patients to determine efficacy in this group

***Required Medical Information:***

Eraxis is approvable for the treatment of: Candidemia and other forms of Candida infections (intra-abdominal abscess, and peritonitis) Esophageal candidiasis in patients who are immunocompromised or have had failure on fluconazole and oral Vfend. A culture must be performed - Specimens for fungal culture and other relevant laboratory studies (including histopathology) should be obtained prior to therapy to isolate and identify causative organism(s). Therapy may be instituted before the results of the cultures and other laboratory studies are known. However, once these results become available, antifungal therapy should be adjusted accordingly

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 week until culture/histopathology received. Confirmed DX –approve to cover course of therapy.

***Other Criteria:***



**Drug Name:**

**EXJADE**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Usage in non-FDA approved indications is considered experimental/ investigational, and therefore NOT covered.

**Required Medical Information:**

Exjade will be covered when a patient has evidence of chronic iron overload, such as the transfusion of approximately 100 mL/kg of packed red blood cells (approximately 20 units for a 40 kg patient) and a serum ferritin consistently above 1000 mcg/L. Doses of Exjade® exceeding 30 mg/kg per day are not covered since there is limited experience with doses above this level. After commencing therapy, it is recommended that serum ferritin be monitored every month and the dose adjusted if necessary every 3 to 6 months based on serum ferritin trends. If the serum ferritin falls consistently below 500 mcg/L, consideration should be given to temporarily interrupt therapy with Exjade®.

**Age Restrictions:** Covered for members 2 years of age and older with chronic iron overload due to blood transfusions.

**Prescriber Restrictions:**

**Coverage Duration:** Initial- 3 months. Can be extended in three month increments if benefit is demonstrated

**Other Criteria:**



***Drug Name:***

**FABRAZYME**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B.

***Required Medical Information:***

Fabry disease: For use in patients with Fabry disease. Agalsidase beta reduces globotriaosylceramide (GL-3) deposition in capillary endothelium of the kidney and certain other cell types.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 12 months

***Other Criteria:***



***Drug Name:***

**FASLODEX**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B.

***Required Medical Information:***

Breast cancer: Treatment of hormone receptor-positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



**Drug Name:**

**FENTANYL CITRATE ORAL TRANSMUCOSAL**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

The drug is not indicated in the management of acute or post-operative pain. This medication must not be used in opioid non-tolerant patients. The patient must not have any of the following contraindications: Hypersensitivity to opiates: Hypoxia/hypercarbia: Severe asthma or chronic obstructive pulmonary disease (COPD): Paralytic ileus. Pain not associated with cancer.

**Required Medical Information:**

For the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying cancer pain.

**Age Restrictions:** the patient must be 16 years old or older

**Prescriber Restrictions:** oncologists and pain specialists who are experienced in the use of Schedule II opioids to treat cancer pain.

**Coverage Duration:** 2 year

**Other Criteria:**

The requested quantity should be less than or equal to 120 per month. Once a successful dose has been found (i.e., an average episode is treated with a single unit), patients should limit consumption to four or fewer units per day. If consumption increases above four units/day, the dose of the long-acting opioid used for persistent cancer pain should be re-evaluated.



**Drug Name:**

**FENTORA**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

The drug is not indicated in the management of acute or post-operative pain. This medication must not be used in opioid non-tolerant patients. The patient must not have any of the following contraindications: Hypersensitivity to opiates: Hypoxia/hypercarbia: Severe asthma or chronic obstructive pulmonary disease (COPD): Paralytic ileus. Pain not associated with cancer.

**Required Medical Information:**

For the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying cancer pain.

**Age Restrictions:** the patient must be 18 years old or older

**Prescriber Restrictions:** oncologists and pain specialists who are experienced in the use of Schedule II opioids to treat cancer pain.

**Coverage Duration:** 3 year

**Other Criteria:**

The requested quantity should be less than or equal to 120 per month. Once a successful dose has been found (i.e., an average episode is treated with a single unit), patients should limit consumption to four or fewer units per day. If consumption increases above four units/day, the dose of the long-acting opioid used for persistent cancer pain should be re-evaluated.



***Drug Name:***

**FLEBOGAMMA**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Covered under Part B when used for the treatment of primary immune deficiency diseases (ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, 279.2). All other indications are covered under Part D.

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**FOMEPIZOLE**

***Covered Uses:***

All FDA-approved indications, such as an antidote for ethylene glycol poisoning or suspected ingestion in adults, or indicated as an antidote for methanol intoxication or suspected ingestion and not otherwise excluded from Part D

***Exclusion Criteria:***

Fomepizole is administered in an ER or hospital and would be covered by Medicare Part B

***Required Medical Information:***

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** As determined by the course of treatment.

***Other Criteria:***



**Drug Name:**

**FORTEO**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Coverage of Forteo treatment may not be considered medically necessary when: The patient is not a postmenopausal woman with osteoporosis who is at high risk for fracture, OR the patient is not a man with primary or hypogonadal osteoporosis who is at high risk for fracture AND if the patient has not failed to have an adequate response to treatment with at least ONE first-line pharmacologic therapy of adequate treatment duration ( 2 years or longer), OR the patient is intolerant to at least TWO first line pharmacologic agents or has a contraindication to the use, including one IV biphosphonate.

**Required Medical Information:**

Coverage of Forteo treatment may be considered medically necessary for a patient who is a postmenopausal woman with osteoporosis who is at high risk for fracture, OR the patient is a man with primary or hypogonadal osteoporosis who is at high risk for fracture AND the patient fails to have an adequate response to treatment with at least ONE first-line pharmacologic therapy of adequate treatment duration ( 2 years or longer), OR the patient is intolerant to at least TWO first line pharmacologic agents or has a contraindication to the use, including one IV biphosphonate. Patient must have prior fragility fracture\*\* OR two of the following risk factors: Low BMD\* (T-score less than or equal to -2.5 at the spine or hip or both), or Advanced Age (greater than 70 years ), or Family History of Osteoporosis (1st degree relative).

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** 1 year for a maximum of 2 years

**Other Criteria:**

Reasons for Therapeutic Failure of First-Line Osteoporosis Medications: Loss of BMD on serial studies over a two-year period, OR Has fragility fracture(s) after a treatment duration of two-years First-Line Pharmacologic Treatment Options for Osteoporosis: Bisphosphonates, Selective Estrogen-Receptor Modulator (SERM), Fosamax (Alendronate) - oral, Evista (Raloxifene) – oral, Actonel (Risedronate) – oral, Boniva (Ibandronate) –oral, IV, and Reclast (Zoledronic acid) - IV



***Drug Name:***

**FOSCARNET SODIUM**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B. Foscarnet is NOT indicated for patients who are immunocompetent.

***Required Medical Information:***

Foscarnet sodium is indicated for the treatment of cytomegaloviral retinitis in adult patients with AIDS either as monotherapy or in combination with ganciclovir in patients who have relapsed on monotherapy with either drug. Maintenance- If patient shows response can be approved for 6 months.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** CMV retinitis-Initially-3 weeks.

***Other Criteria:***



***Drug Name:***

**GAMASTAN S/D**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Part B for these indications – all other indications are Part D. For the treatment of primary immune deficiency diseases (ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, 279.2)

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**GAMMAGARD**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Part B for these indications – all other indications are Part D. For the treatment of primary immune deficiency diseases (ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, 279.2)

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**GAMUNEX**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Part B for these indications – all other indications are Part D. For the treatment of primary immune deficiency diseases (ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, 279.2)

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**GEMZAR**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B.

***Required Medical Information:***

Documentation that Gemzar is being used for the following: As first line therapy in locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) carcinoma of pancreas, or for patients previously treated with 5-fluorouracil: As first-line therapy for metastatic breast cancer in patients previously treated with anthracycline-containing adjuvant chemotherapy or in whom anthracyclines are clinically contraindicated: As first line therapy in combination with cisplatin for non-small cell lung cancer in patients with inoperable, locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) disease. Advanced ovarian cancer, in combination with carboplatin for patients who relapsed at least 6 months after platinum-based therapy.

***Age Restrictions:*** safety and effectiveness in children have not been established

***Prescriber Restrictions:***

***Coverage Duration:*** 6 months

***Other Criteria:***



**Drug Name:**

**GLEEVEC**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

**Required Medical Information:**

Indicated for treatment of patients diagnosed with Kit Positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST). Indicated for treatment of newly diagnosed adult patients with Philadelphia chromosome positive (Ph+) Chronic Myeloid Leukemia (CML) in chronic phase. Indicated for treatment of patients with Philadelphia chromosome positive chronic myeloid leukemia (CML) in blast phase, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. Indicated for treatment of pediatric patients with Ph+ chronic phase CML whose disease has recurred after stem cell transplant or who are resistant to interferon alpha therapy. Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown

**Age Restrictions:** Adult patients with: Philadelphia chromosome positive (Ph+) Chronic Myeloid Leukemia (CML) in chronic phase and aggressive systemic mastocytosis. Pediatrics with Ph+ chronic phase CML whose disease has recurred after stem cell transplant or who are resistant to interferon alpha therapy.

**Prescriber Restrictions:**

**Coverage Duration:** Initial approval is 3 months and renewal is 6 months if improvement is seen

**Other Criteria:**



***Drug Name:***

**HERCEPTIN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

This medication is administered by a physician incident to a physician's visit and would be covered by Medicare Part B. Herceptin should only be used in patients whose tumors have HER2 protein overexpression, ie. positive or equivocal HER2 protein expression

***Required Medical Information:***

Herceptin is indicated: As part of a treatment regimen containing doxorubicin, cyclophosphamide, and paclitaxel for the adjuvant treatment of HER2-overexpressing, breast cancer. As a single agent, for the adjuvant treatment of HER2-overexpressing node-negative (ER/PR negative or with one high-risk feature) or node positive breast cancer, following multi-modality anthracycline based therapy. Left ventricular function should be evaluated in all patients prior to and during treatment. (Discontinuation of Herceptin treatment should be strongly considered in patients who develop a clinically significant decrease in left ventricular function.)

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 52 weeks

***Other Criteria:***



**Drug Name:**

**HUMIRA**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

**Required Medical Information:**

Rheumatoid Arthritis and Psoriatic Arthritis: Initial approval for 6 months. If the patient demonstrates disease stability or improvement as documented by the assessment components of the ACR 20 criteria, or equivalent documentation of improvement, then Humira may be approved for 1 year. Ankylosing Spondylitis: Initial approval for 6 months. If the patient demonstrates disease stability or improvement as documented by the assessment components of the NY criteria (Table 3), or equivalent documentation of improvement, then Humira may be approved for 1 year. Crohn's Disease and Plaque Psoriasis: Initial approval for 12 weeks. If the patient demonstrates disease stability or improvement, Humira may be approved for 1 year. Juvenile Rheumatoid Arthritis: Initial approval for 6 months. If patient demonstrates disease stability or improvement as documented by the assessment components of the Pediatric ACR 30 criteria, or equivalent documentation of improvement, then Humira may be approved for 1 year.

**Age Restrictions:**

**Prescriber Restrictions:**

Rheumatologist, Dermatologist, Gastroenterologist

**Coverage Duration:**

Dependent on diagnosis

**Other Criteria:**

Rheumatoid arthritis: Treatment of moderately to severely active rheumatoid arthritis in adult patients who have had an inadequate response to methotrexate and at least one other DMARD or BRM for the appropriate treatment period: either as monotherapy or in combination, OR if methotrexate use is contraindicated, after failure to respond to maximum tolerated doses or experienced unacceptable toxicity to the treatment of at least two (2) other DMARDs or BRMs. Juvenile Idiopathic Arthritis: for moderately to severely active polyarticular juvenile idiopathic arthritis, AND the patient has an inadequate response to methotrexate alone for the appropriate treatment period, or if methotrexate is contraindicated. Psoriatic Arthritis: Indicated for reducing signs and symptoms of active arthritis in patients with psoriatic arthritis. Humira can be used alone or in combination with DMARDs, AND the patient has an inadequate response to methotrexate OR at least one other orally administered DMARD for the appropriate treatment period, either as monotherapy or in combination. Ankylosing Spondylitis: Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis, AND member has not responded to maximum tolerated doses of at least two (2) non-steroidal anti-inflammatory drugs (NSAIDs). Crohn's Disease: Indicated for reducing 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: and reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab, AND patient has failed to respond to at least ONE conventional therapy for an appropriate trial period, OR patient has lost response to or is intolerant to infliximab (Remicade) therapy. Plaque Psoriasis: Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate, AND the body surface area (BSA) involvement is greater than 10% OR for patients with severe psoriasis in vulnerable areas (such as hands, soles, palms, face and genital areas), BSA involvement of greater than 1-3%, AND failure of at least two (2) non-biologic therapies, such as phototherapy or systemic therapies. Failure for this policy is defined as either no improvement or worsening of plaque psoriasis



***Drug Name:***

**HYCANTIN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

***Required Medical Information:***

Carcinoma of cervix, in combination with cisplatin for Stage IVB, recurrent, or persistent Metastatic ovarian tumor, After failure of initial or subsequent chemotherapy Small cell carcinoma of lung, After failure of first-line therapy Topotecan should not be given to patients with baseline neutrophil counts of less than 1,500 cells/mm<sup>3</sup>. In order to monitor the occurrence of bone marrow suppression, primarily neutropenia, which may be severe and result in infection and death, frequent peripheral blood cell counts should be performed on all patients receiving topotecan

***Age Restrictions:*** safety and effectiveness not established in pediatric patients

***Prescriber Restrictions:***

***Coverage Duration:*** 12 weeks. Additional approvals if response is documented.

***Other Criteria:***



**Drug Name:**

**INCRELEX**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Increlex is contraindicated in patients with allergies to mecasermin or any component of the Increlex formulation, for growth promotion in patients with closed epiphyses, for IV administration, in patients with active or suspected neoplasia. Increlex should be discontinued if neoplasia develops while on therapy.

**Required Medical Information:**

Increlex (mecasermin [rDNA origin] injection) is indicated for the long-term treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. Child has one of the following conditions: Severe primary IGF-1 deficiency (see Table 1 for definition of this diagnosis), OR Growth hormone gene deletion with developed neutralizing antibodies to growth hormone, OR Genetic mutation of GH receptor (i.e. Laron Syndrome), AND Child has severe growth retardation with height standard deviation score (SDS) more than 3 SDS below the mean for chronological age and sex, AND Child with IGF-1 level greater than or equal to 3 standard deviations below normal based on lab reference range for age and sex, AND Child with normal or elevated growth hormone (GH) levels based on at least one growth hormone stimulation test, AND Evidence of open epiphyses. Extended Approval: Annual review is required to determine if Increlex therapy continues to be medically necessary.

**Age Restrictions:** Children less than two (2) years of age Adults (defined as 18 years and older)

**Prescriber Restrictions:** pediatric endocrinologist

**Coverage Duration:** Initial-6 months.

**Other Criteria:**



***Drug Name:***

**INFERGEN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Patient is a candidate for either pegylated interferon (Pegasys or Peg-Intron) or interferon alfa-2b (Intron-A or Roferon-A), AND has been previously treated with a cycle of interferon alfa-2b, pegylated interferon, or interferon alfacon-1

***Required Medical Information:***

For the treatment of chronic hepatitis C virus (HCV) infection in patients 18 years of age or older with compensated liver disease who have anti-HCV serum antibodies or the presence of HCV RNA.

***Age Restrictions:*** Patient is 18 years of age

***Prescriber Restrictions:***

***Coverage Duration:*** 24 weeks

***Other Criteria:***



**Drug Name:**

**INNOHEP**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

**Required Medical Information:**

Diagnosis for use:

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** from 5 days to 6 months depending on diagnosis

**Other Criteria:**

Patients at intermediate risk of thromboembolism, use low dose unfractionated heparin or a prophylactic dose of LMWH 2 days pre-operatively and post-operatively (5-7 days) OR Patients at high risk of thromboembolism, use full-dose unfractionated heparin or full-dose LMWH approximately 2 day preoperatively then commence low-dose UFH or LMWH and warfarin therapy postoperatively (5-7 days): Prevention of venous thromboembolism:Patients undergoing major gynecologic procedures and general surgery patients, and who are at high risk of developing a thromboembolism:Cancer surgery and over 60 years of age OR have previously experienced a VTE.Approval for therapy up to 28 days post-hospital discharge.Patients undergoing orthopedic procedures:Elective hip arthroplasty, LMWH (high-risk dose) or fondaparinux (2.5 mg), up to 35 days post-op OR Elective knee arthroplasty, LMWH (high-risk dose) or fondaparinux, at least 10 days OR Knee arthroscopy, high risk patients only (based on preexisting VTE risk factors or following a prolonged or complicated procedure, LMWH (high-risk dose), 10 days OR Hip fracture surgery, LMWH (high-risk dose) or fondaparinux, up to 35 days post- surgery OR Elective spine surgery, high risk patients only (advanced age (over 65 years old), known malignancy, presence of a neurologic deficit, previous VTE, or an anterior surgical approach), unfractionated heparin, or LMWH, up to 14 days.Treatment of venous thromboembolic disease:Initial treatment of acute, objectively confirmed deep vein thrombosis and/or acute nonmassive pulmonary embolism, initial treatment using body-adjusted doses of LMWH for at least 5 days, or until warfarin therapy is in the therapeutic range OR for patients with cancer and DVT and/or pulmonary embolism, treatment with LMWH for up to 6 months (followed by long-term warfarin therapy): OR for patients affected by spontaneous superficial thrombophlebitis, intermediate doses of UFH or LMWH for 4 weeks



**Drug Name:**

**INTRON-A**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

**Required Medical Information:**

Hairy-cell leukemia: Malignant melanoma: Adjuvant to surgical treatment with malignant melanoma who are free of disease but are at high risk for systemic recurrence within 56 days of surgery. Initial treatment of clinically aggressive follicular non-Hodgkin lymphoma in conjunction with anthracycline-containing combination chemotherapy. Intralesional treatment of external genital or perianal warts: AIDS-related Kaposi sarcoma: Chronic hepatitis C: In patients with compensated liver disease who have a history of blood or blood product exposure and/or patients who are hepatitis C virus (HCV)-antibody-positive. (Interferon alfa-2b also is indicated for hepatitis C in combination with ribavirin capsules. Chronic hepatitis B: In patients 1 year of age or older with compensated liver disease and hepatitis B virus (HBV) replication. Patients must be serum HBsAg-positive for at least 6 months and have HBV replication (serum HBeAg-positive) with elevated serum ALT.

**Age Restrictions:** In patients 18 years or older with: Hairy-cell leukemia: Malignant melanoma: Follicular lymphoma: Condylomata acuminata: AIDS-related Kaposi sarcoma: Chronic hepatitis C: In patients 1 year of age or older with Chronic hepatitis B.

**Prescriber Restrictions:**

**Coverage Duration:** 1 year

**Other Criteria:**



**Drug Name:**

**IPLEX**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

**Required Medical Information:**

Iplex (mecasermin [rDNA origin] injection) is indicated for the long-term treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. Child has one of the following conditions: Severe primary IGF-1 deficiency (see Table 1 for definition of this diagnosis), OR Growth hormone gene deletion with developed neutralizing antibodies to growth hormone, OR Genetic mutation of GH receptor (i.e. Laron Syndrome), AND Child has severe growth retardation with height standard deviation score (SDS) more than 3 SDS below the mean for chronological age and sex, AND Child with IGF-1 level greater than or equal to 3 standard deviations below normal based on lab reference range for age and sex, AND Child with normal or elevated growth hormone (GH) levels based on at least one growth hormone stimulation test, AND Evidence of open epiphyses

**Age Restrictions:** Children less than three (3) years of age Adults (defined as 18 years and older)

**Prescriber Restrictions:** pediatric endocrinologist

**Coverage Duration:** 6 months

**Other Criteria:**



**Drug Name:**

**ITRACONAZOLE**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Not covered for cosmetic use.

**Required Medical Information:**

Aspergillosis Blastomycosis Febrile neutropenia, empiric For empiric therapy of febrile neutropenic (ETFN) patients with suspected fungal infections. Histoplasmosis Treatment of histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis in non-immunocompromised or immunocompromised patients. Onychomycosis Treatment of onychomycosis of the toenail with or without fingernail involvement and onychomycosis of the fingernail because of dermatophytes (*Tinea unguium*) in non-immunocompromised patients. Oropharyngeal/esophageal candidiasis Treatment of oropharyngeal or esophageal candidiasis. Documented pain or impairment and a positive onychomycosis susceptible pathogen culture. Covered for onychomycosis in immunocompromised, diabetic patients or patients with peripheral vascular disease and a positive onychomycosis susceptible pathogen culture. Limit authorization to 12 weeks (toe) and 6 weeks (finger) per year

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Fingernail infection approve for 6 weeks. Toenail infection approve for 12 weeks.

**Other Criteria:**



***Drug Name:***

**IVEEGAM EN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

For the treatment of primary immune deficiency diseases (ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, 279.2)

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



**Drug Name:**

**IXEMPRA**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Not covered as first line therapy. Ixemptra is not covered for patients with the following criteria: Use in cancers other than advanced breast cancer (i.e. investigational use) Use in combination with other chemotherapy agents where data is not available or insufficient to support the combination use. If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

**Required Medical Information:**

Ixemptra is indicated for use in combination with capecitabine in the treatment of metastatic or locally advanced breast cancer in patients that have not responded to an anthracycline and taxane chemotherapy agent. Ixemptra® is also indicated as monotherapy in patients with metastatic or locally advanced breast cancer in which the tumor is resistant or refractory to anthracyclines, taxanes and capecitabine.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initially-12 weeks. Extended Approval: 1 year in persons with stable disease

**Other Criteria:**



**Drug Name:**

**KINERET**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Not a first line agent: patient must have failed 1 or more disease modifying antirheumatic drugs (DMARDs) before approving Kineret.

**Required Medical Information:**

Rheumatoid Arthritis: for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis. The patient has an inadequate response to methotrexate and at least one other DMARD or BRM for the appropriate treatment period, either as monotherapy or in combination, OR methotrexate use is contraindicated, after failure to respond to maximum tolerated doses or experienced unacceptable toxicity to the treatment of at least two (2) other DMARDs or BRMs,

**Age Restrictions:** patients 18 years of age or older

**Prescriber Restrictions:** rheumatologist

**Coverage Duration:** Initially-6 months. Renewal-6 months if patient demonstrates disease stability or improvement

**Other Criteria:**



**Drug Name:**

**KUVAN**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Kuvan therapy is considered experimental/investigational and is NOT covered for: Treatment of conditions other than those listed under FDA-approved indication(s): Treatment of PKU during pregnancy: Treatment of PKU in members less than 4 years of age

**Required Medical Information:**

Kuvan is indicated to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4-) responsive Phenylketonuria (PKU). Kuvan is to be used in conjunction with a Phe-restricted diet. There are currently no pharmacogenomic tests to identify patients most likely to respond to Kuvan. No consensus exists regarding the optimal levels of blood Phe. However, based on data regarding the relationship between Phe level and brain function, the National Institutes of Health (NIH) consensus panel recommends that Phe levels be maintained between: 2-6 mg/dL (120-360 micromol/L) if less than 12 years of age, 2-10 mg/dL (120-600 micromol/L) if greater than 12 and less than 18 years of age, and 2-15 mg/dL (120-900 micromol/L) if greater than 18 years of age. Initial extension will ONLY be granted for members who meet ALL of the following criteria: Documented response to therapy as defined by a  $\geq 30\%$  reduction in baseline Phe level, AND Documented compliance with Kuvan, AND Documented compliance with a Phe-restricted diet, AND Still under the appropriate care and re-evaluations of a specialist knowledgeable in the management of PKU. Extended Approval: 6 month intervals, based on documentation of ALL of the following: Maintenance of a  $\geq 30\%$  reduction in baseline Phe level, AND Documented compliance with Kuvan, AND Documented compliance with a Phe-restricted diet, AND Still under the appropriate care and re-evaluations of a specialist knowledgeable in the management of PKU

**Age Restrictions:**

**Prescriber Restrictions:** specialist knowledgeable in the management of PKU

**Coverage Duration:** Initial Approval: 2 months. Extended Approval: 6 month intervals

**Other Criteria:**

Kuvan is ONLY covered for members who meet ALL of the following criteria: Documented diagnosis of Phenylketonuria (PKU), AND Treated by a specialist knowledgeable in the management of PKU, AND Documented compliance with a strict Phe-restrictive diet for at least 6 months prior to request, AND Age equal or greater than 4 years at the time of the request, AND Documented baseline Phe level: Greater than 6 mg/dL (360 micromol/L) if 12 years of age or younger, OR Greater than 10 mg/dL (600 micromol/L) if older than 12 and 18 years of age or younger, OR Greater than 15 mg/dL (900 micromol/L) if 18 years of age or older, AND Kuvan is to be used in conjunction with a Phe-restrictive diet. DOSE The recommended starting dose of Kuvan is 10 mg/kg/day taken orally with food once daily (preferably at the same time each day). Tablets should be administered either as a whole tablet or thoroughly dissolved in 4 to 8 oz. (120 to 240 mL) of water or apple juice and taken within 15 minutes of dissolution. If blood Phe levels have not decreased from baseline after up to 1 month at 10 mg/kg/day, the dose may be increased to 20 mg/kg/day. Patients whose blood Phe does not decrease after 1 month of treatment at 20 mg/kg/day are considered "non-responders, and treatment with Kuvan should be discontinued in these patients. For patients who respond to Kuvan treatment, the dosage may be adjusted within the range of 5 to 20 mg/kg/day according to the response to therapy.



**Drug Name:**

**LETAIRIS**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Covered with a designation of WHO Group I, AND WHO functional class II, or WHO functional class III and has tried and failed, or is not a candidate for Tracleer®, AND Have received treatment trials with currently accepted therapies (eg. anticoagulants, diuretics, calcium channel blockers) for at least one month without adequate relief

**Required Medical Information:**

Diagnosis for use: primary pulmonary hypertension, or secondary pulmonary hypertension due to scleroderma, sclerosis or autoimmune disease. Serum aminotransferase levels drawn prior to initiation of therapy and at least monthly thereafter. Must be enrolled in, and meet all conditions of the Letairis® Education and Access Program (LEAP). EXTENDED AUTHORIZATION: Requires documentation of clinical response characterized by: stabilization or improvement in functional status (NYHA functional class), OR improvement in PAP or other measures of pulmonary hypertension

**Age Restrictions:**

**Prescriber Restrictions:** Pulmonologist or Cardiologist

**Coverage Duration:** 4 months

**Other Criteria:**



**Drug Name:**

**LEUKINE**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Neutropenia due to Hepatitis C therapy is not an approvable diagnosis.

**Required Medical Information:**

Primary prophylaxis in conjunction with chemotherapy: in previously untreated adult and pediatric members with non-myeloid malignancies receiving established myelosuppressive chemotherapy that is expected to result in a greater than 40% incidence of febrile neutropenia OR members receiving chemotherapy who are at increased risk for chemotherapy-induced infectious complications because of bone marrow compromise or comorbidity. Febrile neutropenia\*: Adjunctive use with antibiotics in high-risk, febrile, neutropenic members who have one or more prognostic factors that are predictive of clinical deterioration: Documented neutropenia with absolute neutrophil count (ANC) under 1000/m, or uncontrolled primary disease, or Pneumonia, or Hypotension, or Multi-organ dysfunction (sepsis syndrome); or Invasive fungal infection. Dose-intensive chemotherapy: Use in settings where clinical research demonstrates that dose-intensive therapy produces improvement in disease control, when these therapies are expected to produce significant rates of febrile neutropenia. This include: Dose dense treatment given at every 2 weeks for early-stage breast cancer, or CHOP regimen for non-Hodgkin's lymphoma. Acute myeloid leukemia: For administration shortly after the completion of induction AML therapy in members 55 years of age or older, to achieve modest decreases in the duration of neutropenia, OR for administration to members of any age, after the completion of consolidation chemotherapy for AML, to shorten the duration of neutropenia profoundly. Acute lymphoblastic leukemia (ALL)\*\*: For administration after completion of the first few days of chemotherapy of the initial induction or first post-remission course. Myelodysplastic Syndromes: Intermittent use only in member with myelodysplastic syndromes who has less than 15% blasts in their bone marrow, AND has severe neutropenia (ANC less then 500/mL) and recurrent infections.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initially-3 months. Extended approval:if therapy continues to be medically necessary

**Other Criteria:**

Adjuncts to progenitor-cell transplantation: Mobilization of autologous or donor hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis in order to increase the number of circulating peripheral-blood progenitor-cells (PBPC) collected for engraftment for allogenic peripheral stem cell transplantation: OR reduction in the duration of neutropenia and neutropenia-related infectious complications in members with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplantation (BMT): OR assisting in the recovery of members who experience delayed or inadequate neutrophil engraftment following progenitor-cell transplantation by speeding hematopoietic reconstitution following BMT or PBPC transplantation. Severe chronic neutropenia (with ANC less then 500/ml): Chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g. fever, infections, oropharyngeal ulcers) in symptomatic members with congenital neutropenia, cyclic neutropenia or idiopathic neutropenia. Advanced HIV: Members with advanced HIV and neutropenia (ANC less than 1000/mL) to allow scheduled dosing of myelosuppressive anti-retroviral medication (e.g. zidovudine and ganciclovir)



***Drug Name:***

**LEUPROLIDE**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 6 months

***Other Criteria:***



***Drug Name:***

**LUPRON**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B. B vs. D

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 6 months

***Other Criteria:***



***Drug Name:***

**LYSODREN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Adrenal carcinoma, Inoperable. Patients should be started at a dose of 1 gram (g) daily with weekly incremental increases up to 3 g daily or the highest tolerable dose. When serum concentrations of mitotane reach 14 to 20 mcg/mL (in 3 to 5 months, 283 to 387-g cumulative dose), patients should tapered to 1 to 2 g daily. Dose adjustments were made thereafter based on serum monitoring at 3-month intervals

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 3 months

***Other Criteria:***



***Drug Name:***

**MEPRON**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

When used for Pneumocystis pneumonia patient must have failed or been intolerant to SMP/TMX.

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



**Drug Name:**

**MESNEX**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

**Required Medical Information:**

For the prophylaxis of ifosfamide induced hemorrhagic cystitis, Mesnex may be given on a fractionated dosing schedule of three bolus intravenous injections or a single bolus injection followed by two oral administrations of Mesnex® tablets as outlined below.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Duration of ifosfamide therapy

**Other Criteria:**

Intravenous Schedule: Mesnex is given as intravenous bolus injections in a dosage equal to 20% of the ifosfamide dosage (w/w) at the time of ifosfamide administration and 4 and 8 hours after each dose of ifosfamide. The total daily dose of mesna is 60% of the ifosfamide dose. Intravenous and Oral Dosing: Mesnex injection is given as intravenous bolus injections in a dosage equal to 20% of the ifosfamide dosage (w/w) at the time of ifosfamide administration. Mesnex tablets are given orally in a dosage equal to 40% of the ifosfamide dose 2 and 6 hours after each dose of ifosfamide. The total daily dose of mesna is 100% of the ifosfamide dose. Patients who vomit within two hours of taking oral mesna should repeat the dose or receive intravenous mesna. The efficacy and safety of this ratio of I.V. and PO mesna has not been established as being effective for daily doses of Ifex higher than 2.0 g/m<sup>2</sup>. The dosing schedule should be repeated on each day that ifosfamide is administered. When the dosage of ifosfamide is adjusted (either increased or decreased), the ratio of Mesnex to Ifex should be maintained



***Drug Name:***

**MYCAMINE**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Diagnosis for use indicating the following: In treatment of esophageal candidiasis, documentation of other drugs tried. Date of proposed stem cell transplant when used being for prophylaxis.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:***      Duration of Therapy

***Other Criteria:***



***Drug Name:***

**MYOBLOC**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

MyoBloc is not covered for cosmetic uses (hyperkinetic facial lines).

***Required Medical Information:***

MyoBloc is indicated for the treatment of patients with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

***Age Restrictions:***

***Prescriber Restrictions:***

MyoBloc should be administered by physicians familiar and experienced in the assessment and management of patients with cervical dystonia.

***Coverage Duration:*** 6 months

***Other Criteria:***



***Drug Name:***

**NAGLAZYME**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B.

***Required Medical Information:***

Diagnosis for use: The intravenous administration of Naglazyme is indicated for patients with Maroteaux-Lamy syndrome (Mucopolysaccharidosis IV).

***Age Restrictions:*** not indicated in patients under 5 years old

***Prescriber Restrictions:***

***Coverage Duration:*** Initial approval: 6 months Extended approval: Annual review will be based on response to therapy.

***Other Criteria:***



**Drug Name:**

**NEULASTA**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Neutropenia due to Hepatitis C therapy is not an approvable diagnosis.

**Required Medical Information:**

Febrile neutropenia: Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Adjunctive use with antibiotics in high-risk, febrile, neutropenic members who have one or more of the following prognostic factors that are predictive of clinical deterioration: documented neutropenia with absolute neutrophil count (ANC) below 1000/mL, or uncontrolled primary disease, or pneumonia, or hypotension, or multi-organ dysfunction (sepsis syndrome), or Invasive fungal infection

**Age Restrictions:**

**Prescriber Restrictions:** certified hematologist and/or oncologist

**Coverage Duration:** Initially-3 months. Extended approval:if therapy continues to be medically necessary

**Other Criteria:**



***Drug Name:***

**NEUMEGA**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Thrombocytopenia, Severe, reduction of the need for platelet transfusions following myelosuppressive chemotherapy in adult patients with non-myeloid malignancies who are at high risk for severe thrombocytopenia, Prophylaxis

***Age Restrictions:***

***Prescriber Restrictions:*** certified hematologist and/or oncologist

***Coverage Duration:*** Duration of chemo therapy

***Other Criteria:***



**Drug Name:**

**NEUPOGEN**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Neutropenia due to Hepatitis C therapy is not an approvable diagnosis.

**Required Medical Information:**

Myelosuppressive chemotherapy: To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever. Acute myeloid leukemia (AML): To reduce the time to neutrophil recovery and the duration of fever following induction or consolidation chemotherapy treatment of adults with AML. Bone marrow transplant (BMT): To reduce the duration of neutropenia and neutropenia-related clinical sequelae (e.g., febrile neutropenia) in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by BMT. Peripheral Blood Progenitor Cell (PBPC) Collection: For the mobilization of hematopoietic progenitor cells into the peripheral blood for leukapheresis collection. Mobilization allows for collection of increased progenitor cell numbers capable of engraftment compared with collection by leukapheresis without mobilization or bone marrow harvest. After myeloablative chemotherapy, the transplantation of an increased number of progenitor cells can lead to more rapid engraftment, decreasing the need for supportive care. Severe chronic neutropenia (SCN): Chronic administration to reduce the incidence and duration of sequelae of neutropenia in symptomatic patients with congenital, cyclic or idiopathic neutropenia.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initially-3 months. Extended approval: if therapy continues to be medically necessary

**Other Criteria:**

Adjuncts to progenitor-cell transplantation: Mobilization of autologous or donor hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis in order to increase the number of circulating peripheral-blood progenitor-cells (PBPC) collected for engraftment for allogeneic peripheral stem cell transplantation: OR reduction in the duration of neutropenia and neutropenia-related infectious complications in members with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplantation (BMT): OR assisting in the recovery of members who experience delayed or inadequate neutrophil engraftment following progenitor-cell transplantation by speeding hematopoietic reconstitution following BMT or PBPC transplantation. Severe chronic neutropenia (with ANC less than 500/ml): Chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g. fever, infections, oropharyngeal ulcers) in symptomatic members with congenital neutropenia, cyclic neutropenia or idiopathic neutropenia. Advanced HIV: Members with advanced HIV and neutropenia (ANC under 1000/mL) to allow scheduled dosing of myelosuppressive anti-retroviral medication (e.g. zidovudine and ganciclovir).



***Drug Name:***

**NEUTREXIN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

2nd line therapy for moderate-to-severe PCP (Pneumocystis carinii pneumonia) in immunocompromised patients, including AIDS patients who have failed or are intolerant to co-trimoxazole (TMP/SMX).

***Required Medical Information:***

Indicated as alternative therapy for treatment of moderate-to-severe Pneumocystis Carinii pneumonia (PCP) in immunocompromised patients, including patients with AIDS. Leucovorin must be given during treatment with trimetrexate and for 3 days after trimetrexate is finished.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Trimetrexate for 21 days; Leucovorin for 24 days.

***Other Criteria:***



***Drug Name:***

**NEXAVAR**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Not covered in patients with advanced cardiac conditions or for use in combination with other cytotoxic therapy, or for use in cancers other than advanced renal cell carcinoma such as advanced primary liver cancer, metastatic melanoma, non-small cell lung cancer, ovarian cancer, head and neck cancer and others, or in patients with an ECOG performance standard greater than 1, or in patients who have high prognostic risk category

***Required Medical Information:***

Coventry Health Care covers Nexavar for patients with a diagnosis of advanced (unresectable or metastatic) renal cell carcinoma, and patients with ECOG performance status 0 or 1, and patients with low or intermediate prognostic risk category (MSKCC prognostic risk category). OR patients with advanced hepatocellular carcinoma (HCC), previously untreated and inoperable. Cardiac evaluation to determine if patient has any advanced cardiac condition.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 8 months

***Other Criteria:***



**Drug Name:**

**NORDITROPIN**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

**Required Medical Information:**

Growth Hormone Deficiency in Children and Adolescents: Patient has failed to respond to at least 2 standard GH stimulation tests. One abnormal GH test is sufficient for children with brain tumors and irradiation with documented multiple pituitary hormone deficiency (MPHD) AND Appropriate imaging (MRI or CT) of the brain to exclude tumor on hypothalamic-pituitary region One of the following criteria are met: Child has severe growth retardation with height standard deviation score (SDS) more than 3 SDS below the mean for chronological age and sex, OR Child has moderate growth retardation with height SDS -2 and -3 SDS below the mean chronological age and sex and decreased growth rate (growth velocity measured over one year below 25th percentile for age and sex), OR Child exhibits severe deceleration in growth rate (growth velocity measured over 1 year -2 SDS below the mean for age and sex), OR Child has decreasing growth rate combined with a predisposing condition such as previous cranial irradiation or tumor, OR Child exhibits evidence of other pituitary hormone deficiencies or signs of congenital GHD (hypoglycemia, microphallus).

**Age Restrictions:**

**Prescriber Restrictions:** certified endocrinologis

**Coverage Duration:** Initial- 6 months. Extended approval: determine if therapy continues to be medically necessary.

**Other Criteria:**

Growth Hormone Deficiency in Adults: Covered for replacement of endogenous growth hormone in patients with adult GH deficiency who meet ALL the following criteria: Adult onset: Patients who have growth hormone deficiency either alone or with multiple hormone deficiencies (hypopituitarism), as a result of EITHER, disease of the pituitary or hypothalamus, OR injury to either the pituitary or hypothalamus from surgery, radiation therapy, or trauma, OR Childhood onset: Patients who were growth-hormone deficient during childhood who have GH deficiency confirmed as adult before replacement therapy is started., AND Biochemical diagnosis of GH deficiency, by means of a negative response to two standard GH stimulation test [maximum peak less than 5 ng/ml when measured by RIA (polyclonal antibody) or less than 2.5 ng/ml when measured by IRMA (monoclonal antibody)], AND Patients already receiving full supplementation of other deficient hormones as required AND Objective measurement of clinical features of growth hormone deficiency. Severely decreased QOL (defined as score of at least 11 out of 25) as assessed using the Adult growth hormone deficiency assessment (AGHDA) questionnaire: AND EITHER, Reduced bone density of more than 1 SD below the age and gender-specific mean, (which by WHO criteria would predict a relative fracture risk of more than 2.5) provided that other etiologies have been ruled out or maximally treated, OR, Evidence of cardiac decompensation defined as reduced ejection fraction of below 50% provided that other etiologies have been ruled out or maximally treated: AND Growth hormone is initiated at a low dose and titrated slowly upward at monthly interval:



***Drug Name:***

**NOXAFIL**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Approvable for Prevention of invasive Aspergillus and Candida infections in immunosuppressed patients with disease that is refractory to, itraconazole for aspergillus or fluconazole for Candida or in patients who are intolerant of these products. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy.

***Age Restrictions:*** npt approved for under 13 years old

***Prescriber Restrictions:***

***Coverage Duration:*** 6 months

***Other Criteria:***



***Drug Name:***

**OCTAGAM**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Part B for these indications – all other indications are Part D. For the treatment of primary immune deficiency diseases (ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, 279.2)

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**OCTREOTIDE ACETATE**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Acromegaly: To reduce blood levels of growth hormone and IGF-I in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation and bromocriptine at maximally tolerated doses. The goal is to achieve normalization of growth hormone and IGF-I levels. Carcinoid tumors: Symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits associated severe diarrhea and flushing episodes. Vasoactive intestinal peptide tumors (VIPomas): Treatment of the profuse watery diarrhea associated with VIP-secreting tumors.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 6 months

***Other Criteria:***



***Drug Name:***

**ONTAK**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

This medication is administered by a physician incident to a physician's visit and would be covered by Medicare Part B.

***Required Medical Information:***

Ontak is indicated for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor. The safety and efficacy of denileukin diftitox in patients with CTCL whose malignant cells do not express the CD25 component of the IL-2 receptor have not been examined.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 6 months. Extended - dependent on response.

***Other Criteria:***

Patients treated with denileukin diftitox must be managed in a facility equipped and staffed for cardiopulmonary resuscitation and where the patient can be closely monitored for an appropriate period based on his or her health status



***Drug Name:***

**ORENCIA**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B. Orenzia (abatacept) is not covered for patients with active infections because its safety in active infections has not been established. The treatment of inflammatory conditions, other than (adult) rheumatoid arthritis or Juvenile Idiopathic Arthritis, is considered investigational and therefore not covered. .Not covered when used in combination with another TNF antagonists and anakinra

***Required Medical Information:***

Diagnosis for use: Orenzia (abatacept) is covered as monotherapy or as adjunct therapy for the treatment of moderately to severely active rheumatoid arthritis when: the patient has had an inadequate response to maximum tolerated doses or experienced unacceptable toxicity to the treatment with at least one DMARD AND Remicade, for the appropriate treatment period, either as monotherapy or in combination with methotrexate.

***Age Restrictions:*** 6 yrs and older

***Prescriber Restrictions:*** Rheumatologist

***Coverage Duration:*** Initial approval: 6 months Extended approval: 1 year

***Other Criteria:***



***Drug Name:***

**ORFADIN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Orfadin capsules (nitisinone) are indicated as an adjunct to dietary restriction of tyrosine and phenylalanine in the treatment of hereditary tyrosinemia type 1.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initial approval: 6 months. Extended approval: based on response to therapy

***Other Criteria:***



***Drug Name:***

**OXANDROLONE**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Not Covered for the indication of weight gain

***Required Medical Information:***

Documentation to support diagnosis for use as follows: Bone pain: For the relief of the bone pain frequently accompanying osteoporosis.  
Protein catabolism: To offset the protein catabolism associated with prolonged administration of corticosteroids. For male and female, all ages

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 month, renewals for return of symptoms

***Other Criteria:***



***Drug Name:***

**OXYCONTIN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Oxycontin will only be approved for payment if the following criteria is met: members with chronic non-malignant pain will be required to use two (2) alternative formulary long acting opioids. Alternatives include methadone (Dolophine), controlled-release morphine (MS Contin, Kadian, Avinza), Opana ER or Fentanyl patches

***Required Medical Information:***

Documentation of chronic pain due to a malignant or a non-malignant painful condition. For the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. Treatment with doses of 80mg or greater of Oxycontin should only be initiated in patients who have demonstrated opioid tolerance. Oxycontin is NOT intended for use as a PRN analgesic.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**PACLITAXEL**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

This medication is administered by a physician incident to a physician's visit and would be covered by Medicare Part B.

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:*** safety and efficacy not established in pediatric patients

***Prescriber Restrictions:***

***Coverage Duration:*** Duration of treatment plan

***Other Criteria:***



***Drug Name:***

**PAMIDRONATE DISODIUM**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B. Patients who receive Pamidronate should have their serum creatinine assessed prior to each treatment. Treatment should be withheld for renal deterioration. In clinical studies, renal deterioration was as follows: For patients with normal baseline creatinine, increase of 0.5 mg/dL. For patients with abnormal baseline creatinine, increase of 1.0 mg/dL. Pamidronate treatment was resumed when creatinine returned to within 10% of baseline value.

***Required Medical Information:***

Diagnosis: Hypercalcemia of Malignancy (HCM); Paget's Disease; Osteolytic Bone Lesions of Multiple Myeloma; Osteolytic Bone Metastasis of Breast Cancer. Calcium levels and renal function tests.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 12 months

***Other Criteria:***



***Drug Name:***

**PEGASYS**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Chronic hepatitis C: For the treatment of adults with chronic hepatitis C who have compensated liver disease and have not been previously treated with interferon alfa. Patients in whom efficacy was demonstrated included patients with compensated liver disease and histological evidence of cirrhosis. Patients with hepatitis C virus (HCV) and elevated ALT should undergo HCV genotyping. Those with genotype 1 or 4 should receive 48 weeks of peginterferon + ribavirin and those with genotype 2 or 3 should undergo 24 weeks of treatment. If there is less than a 2-log decline in HCV-RNA titer after 12 weeks of treatment further treatment is not indicated no matter what genotype. If any viral load is still detectable in genotypes 1 or 4 after 24 weeks of treatment, further treatment is not indicated. Treatment duration longer than 24 weeks has not been shown to improve response in genotypes 2 or 3. Initial approval: 16 weeks and viral titer should be obtained at week 12 of therapy. Therapy is approvable for a maximum of 24 weeks in patients that are HCV genotypes 2 or 3 who have achieved a virologic response (either undetectable HCV RNA [less than 50 IU/mL] or at least a 2-log drop in HCV RNA titer from baseline) at 12 weeks of treatment. Therapy is approvable for up to 48 weeks in HCV genotype 1 or 4 patients who have achieved a virologic response (either undetectable HCV RNA [less than 50 IU/mL] or at least a 2-log drop in HCV RNA titer from baseline) at 12 weeks of treatment. If patients fail to achieve a virologic response by 12 weeks, further treatment is not indicated.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initially-12 weeks: Extended-based on response and genotype.

***Other Criteria:***



**Drug Name:**

**PEG-INTRON**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Pegasys (pegylated interferon alfa-2a) and Ribasphere/Ribavirin (generic Rebetol) are the CHC preferred pegylated interferon/ribavirin products. Patient must have tried and failed therapy with Pegasys/Ribavirin OR have a documented medical reason why this medication is medically/therapeutically inappropriate.

**Required Medical Information:**

Diagnosis for use and documentation of labs to support diagnosis as follows: Chronic hepatitis C: For the treatment of chronic hepatitis C (alone or in combination with Rebetol (ribavirin)) in patients with compensated liver disease without hepatic coma who have not completed the first 24 weeks of therapy and who are not non-responders to any previous interferon therapy. Patients with hepatitis C virus (HCV) and elevated ALT should undergo HCV genotyping. Those with genotype 1 or 4 should receive 48 weeks of peginterferon + ribavirin and those with genotype 2 or 3 should undergo 24 weeks of treatment. In Genotypes 1, and 4, if there is less than a 2-log decline in HCV-RNA titer after 12 weeks of treatment further treatment is not indicated.. Treatment duration longer than 24 weeks has not been shown to improve response in genotypes 2 or 3. In Genotypes 1 and 4: Initial approval 16 weeks and viral titer should be obtained at week 12 of therapy. Therapy is approvable for a maximum of 24 weeks in patients that are HCV genotypes 2 or 3. Therapy is approvable for up to 48 weeks in HCV genotype 1 or 4 patients who have achieved a virologic response (either undetectable HCV RNA [less than 50 IU/mL] or at least a 2-log drop in HCV RNA titer from baseline) at 12 weeks of treatment. If patients with Genotypes 1 and 4 fail to achieve a virologic response by 12 weeks, further treatment is not indicated.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initially: Genotypes 1 and 4 for 16 weeks.: Genotypes 2 and 3 for 24 weeks.

**Other Criteria:**



***Drug Name:***

**PERFOROMIST**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Not covered for the following: For the treatment of asthma For patients not in the institutionalized setting. They will be referred to the Part B benefit. For use with other medications containing long-acting beta2-agonists Requests for doses more frequent than one nebulizer twice daily, AND for patients who have not tried and failed or cannot use preferred inhaled lower tier meter dosed (dry powder or HFA) long-acting beta2-agonists

***Required Medical Information:***

PERFOROMIST Inhalation Solution is indicated for the long-term, twice-daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema. PERFOROMIST Inhalation Solution will be approved for beneficiaries with COPD who are not controlled by inhaled anticholinergics and/or inhaled steroids, with short acting rescue agents

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**POLYGAM**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Part B for these indications – all other indications are Part D. For the treatment of primary immune deficiency diseases (ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, 279.2)

***Required Medical Information:***

Diagnosis for use.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



**Drug Name:**

**PROCRIT**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

For patients receiving hemodialysis at a dialysis center the ESA drug would be paid for by the Part B benefit. Aranesp is covered only after documented failure of Procrit (target levels not reached after 8 weeks of therapy), or significant side effects from its use. HG or Hct at or above 12g/dl or 36%. ESA is not indicated for patients with an endogenous serum erythropoietin level of above 500 mU/mL or treatment of anemia in HIV-infected patients caused by other factors such as iron or folate deficiencies, hemolysis or GI bleeding . Initiation of therapy is warranted when the hematocrit is below 30% or hemoglobin is below 10 g/dL. ESA therapy is restricted to anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma and lymphocytic leukemia.

**Required Medical Information:**

Diagnosis for use: Treatment of anemia associated with CKF, including patients on dialysis (end-stage renal disease) and patients not on dialysis, to elevate or maintain the red blood cell level (as manifested by the hemoglobin or hematocrit determinations) and to decrease the need for transfusions. Not intended for patients who require immediate correction of severe anemia. ESA may obviate the need for maintenance transfusions but is not a substitute for emergency transfusions. Treatment of anemia related to zidovudine therapy in HIV-infected patients: To elevate or maintain the red blood cell level (as manifested by the hemoglobin or hematocrit determinations) and to decrease the need for transfusions. Treatment of anemia in cancer patients on chemotherapy: Treatment of anemia in patients with malignancies where anemia is caused by the effect of concomitantly administered chemotherapy. It is intended to decrease the need for transfusions in patients who will receive chemotherapy for a minimum of 2 months. ESA therapy is restricted to anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma and lymphocytic leukemia. Reduction in allogeneic blood transfusions in surgery patients: Myelodysplastic Syndrome (MDS). Use of ESA is indicated in states of anemia where there is presumed to be inadequate EPO production. Laboratory evidence: depending on diagnosis hemoglobin (g/dL) and/or hematocrit (%) : GFR: Percent transferrin saturation (TSAT): Serum ferritin: Vitamin B12 levels: folate levels: EPO level: marrow blasts %: recent transfusion HX: Exclusion of other causes of anemia: Patient has symptomatic anemia, with symptoms including, but not limited to, weakness, syncope, tiredness, dyspnea, chest pain, postural hypotension, tachycardia or a marked reduction in activities of daily living

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initial approval: chemotherapy-related anemia-4 weeks:MDS-6 months: all other indications-8 weeks

**Other Criteria:**



**Drug Name:**

**PROLASTIN**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Not covered for patients who DO NOT have a diagnosis of Alpha 1 Antitrypsin Deficiency with PiZZ, PiZ(null) or Pi(null)(null) phenotypes: OR have a contraindications to use of Prolastin. Aralast is the preferred agent for this indication.

**Required Medical Information:**

Alpha 1 Antitrypsin Deficiency: For chronic replacement therapy of individuals having congenital deficiency of alpha 1 -PI (alpha 1 -antitrypsin deficiency) with clinically demonstrable panacinar emphysema. Clinical and biochemical studies have demonstrated that with such therapy, it is possible to increase plasma levels of alpha 1 -PI, and that levels of functionally active alpha 1 -PI in the lung epithelial lining fluid are increased proportionately. As some individuals with alpha 1 -antitrypsin deficiency will not go on to develop panacinar emphysema, only those with evidence of such disease should be considered for chronic replacement therapy with Prolastin. Subjects with the PiMZ or PiMS phenotypes of alpha 1 -antitrypsin deficiency should not be considered for such treatment as they appear to be at small risk for panacinar emphysema.

**Age Restrictions:** Coverage is limited to adults

**Prescriber Restrictions:**

**Coverage Duration:** 1 year

**Other Criteria:**



**Drug Name:**

**PROLEUKIN**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Restrict therapy to patients with normal cardiac and pulmonary functions as defined by thallium stress testing and formal pulmonary function testing. Use extreme caution in patients with normal thallium stress tests and pulmonary function tests who have a history of prior cardiac or pulmonary disease. If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

**Required Medical Information:**

Metastatic renal-cell carcinoma: Dose: 600,000 IU/kg (0.037 mg/kg) every 8 hours for maximum of 14 doses, repeat after 9 days for maximum total of 28 doses. Metastatic Melanoma: Dose 600,000 IU/kg (0.037 mg/kg) every 8 hours for maximum of 14 doses, repeat after 9 days for maximum total of 28 doses.

**Age Restrictions:** adults over 18 years of age.

**Prescriber Restrictions:**

**Coverage Duration:** 6months

**Other Criteria:**



***Drug Name:***

**PROTONIX IV**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Prior to a patient receiving a non-preferred PPI, a patient must first have a therapeutic failure on one of the following Omeprazole products: Omeprazole, or Zegerid or Prilosec OTC. Coverage of High Dose Formulary PPI: Definition: High dose formulary PPI is defined as Nexium, Protonix or Prilosec OTC/Omperazole/Zegerid at 80mg per day. Diagnosis of Zollinger-Ellison Syndrome: Uncomplicated GERD - covered when there is breakthrough symptoms on standard once daily PPI, AND Failure of once daily PPI PLUS add-on H2-Blocker, OR Failure of Prilosec OTC/generic omeprazole 20mg twice daily. Complicated GERD and other higher risk conditions - reflux-associated laryngitis, recent GI bleed, grade 3 or 4 erosive esophagitis (or Los Angeles Grade C or D), or GERD exacerbated asthma, a short term course (3 to 6 months) of twice daily formulary PPI may be authorized to treat an acute or exacerbated condition. To receive long-term high dose PPI therapy, then the following condition must be met: Failure to step-down to standard once daily doses of following the initial high dose therapy. Failure is defined as a return of symptoms. The IV formulation of Protonix may be approved when the patient has met the criteria for oral therapy and there is a significant clinical reason the patient cannot use the oral form.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**PULMOZYME**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

For patients not in the institutionalized setting. They will be referred to the Part B benefit.

***Required Medical Information:***

Cystic fibrosis (CF): Daily administration in conjunction with standard therapies in the management of CF patients to reduce the frequency of respiratory infections requiring parenteral antibiotics and to improve pulmonary function

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**QUALAQUIN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Not approved for treatment or prevention of leg cramps, prevention of malaria, or in pts with complicated *P. falciparum*

***Required Medical Information:***

Indicated only for the treatment of uncomplicated *Plasmodium falciparum* malaria. Quinine sulfate has been shown to be effective in geographical regions where resistance to chloroquine has been documented.

***Age Restrictions:*** 16 years of age and older

***Prescriber Restrictions:***

***Coverage Duration:*** 7 days (2 capsules every 8 hours)

***Other Criteria:***



***Drug Name:***

**RAPTIVA**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

For the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Patients meeting criteria for approval are allowed an initial course of 12 weeks. Dosing is limited to 1 mg/kg weekly SC injection. Additional clinical information showing efficacy is needed for extended approval up to 1 year of treatment. The safety and efficacy of Raptiva therapy beyond 1 year have not been established. For the treatment of chronic moderate to severe (1 year) plaque psoriasis in adult patients 18 years of age when: The body surface area (BSA) involvement is 10%, AND previous phototherapy AND at least ONE other systemic therapy results in either no improvement or worsening of plaque psoriasis

***Age Restrictions:*** adults 18 years or older

***Prescriber Restrictions:***

***Coverage Duration:*** Initial course of therapy 12 weeks

***Other Criteria:***



**Drug Name:**

**REBETOL**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Ribasphere/Ribavirin (generic Rebetol) are the CHC preferred ribavirin products. Ribavirin 200mg caps/tabs strength and dosage forms must be used.

**Required Medical Information:**

Must be administered in combination with alpha interferon injection for the treatment of chronic hepatitis C in patients with compensated liver disease previously untreated with alpha interferon or who have relapsed following alpha interferon therapy. Patients with hepatitis C virus (HCV) and elevated ALT should undergo HCV genotyping. Those with genotype 1 or 4 should receive 48 weeks of peg interferon + ribavirin and those with genotype 2 or 3 should undergo 24 weeks of treatment. If there is less than a 2-log decline in HCV-RNA titer after 12 weeks of treatment further treatment is not indicated no matter what genotype. If any viral load is still detectable in genotypes 1 or 4 after 24 weeks of treatment, further treatment is not indicated. Treatment duration longer than 24 weeks has not been shown to improve response in genotypes 2 or 3. Initial approval for 16 weeks and viral titer should be obtained at week 12 of therapy. Therapy is approvable for a maximum of 24 weeks in patients that are HCV genotypes 2 or 3 who have achieved a virologic response (either undetectable HCV RNA [less than 50 IU/mL] or at least a 2-log drop in HCV RNA titer from baseline) at 12 weeks of treatment. Therapy is approvable for up to 48 weeks in HCV genotype 1 or 4 patients who have achieved a virologic response (either undetectable HCV RNA [less than 50 IU/mL] or at least a 2-log drop in HCV RNA titer from baseline) at 12 weeks of treatment. If patients fail to achieve a virologic response by 12 weeks, further treatment is not indicated

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initially-12 weeks: Extended-based on response and genotype.

**Other Criteria:**



**Drug Name:**

**REBIF**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Must have a trial and failure with Betaseron, or have a contraindication to its use.

**Required Medical Information:**

Diagnosis of definite or probable relapsing-remitting MS, secondary progressive MS with relapses, or progressive relapsing MS. Direct statement from a neurologist that diagnosis is a relapsing form of MS, or a first MS attack with documented MRI scan abnormalities characteristic of MS. OR Evaluation documenting EITHER: history of at least two focal neurological deficits (e.g. loss of vision, double vision, localized numbness or weakness), in which the first resolved and the second followed after a period of at least 6 months, OR History of one focal neurological deficit which has resolved, and an MRI suggestive of MS: At least 3 total lesions, each at least 5mm: At least one lesion with contrast enhancement: At least 2 out of 3 lesions in either, Periventricular white matter OR Brain stem (e.g., cerebellar peduncle, pons) OR (3) Spinal cord. Lack of statement that lesions are consistent with ischemic disease: AND Functional status is ambulatory (with or without assistive devices).

**Age Restrictions:**

**Prescriber Restrictions:** Neurologist

**Coverage Duration:** 1 year

**Other Criteria:**

For patients treated greater than 1 yr, annual certification from a neurologist that therapy has been effective, i.e. treatment has decreased relapses or diminished number of lesions on MRI, AND for patients previously treated with mitoxantrone, documentation that prior treatment with requested drug was successful in decreasing relapses or diminishing the number of lesions on MR, AND dosage does not exceed the FDA approved dose



***Drug Name:***

**REGRANEX**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Treatment of lower-extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply. To be used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control. Confirmed underlying diagnosis/status of diabetes either by history of current diabetic medical treatment or labs provided by the prescriber. Patient must have a wound care treatment plan. The ulcer has the following characteristics: located on the lower extremity, extends into the subcutaneous tissue or beyond, and has adequate blood supply. Reapproval requires 30% decrease in the ulcer size by the 10th week of therapy. Approval may be given for another 10 weeks. Patient had failure on another wound care product.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 10 weeks

***Other Criteria:***



**Drug Name:**

**REMICADE**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

**Required Medical Information:**

Diagnosis for use. For rheumatoid arthritis: Require documentation of an inadequate response to methotrexate (MTX) and at least one (1) disease-modifying anti-rheumatic drug (DMARD) or tumor necrosis factor inhibitor (TNF), if MTX is contraindicated, require inadequate response to at least two (2) other DMARDs or TNFs for the appropriate treatment period. For psoriatic arthritis: Require documentation of an inadequate response to MTX or at least one (1) other orally administered DMARD for the appropriate treatment period. For ankylosing spondylitis: Require documentation of inadequate responses to at least two (2) non-steroidal anti-inflammatory drugs (NSAIDs) at maximum tolerated doses. For plaque psoriasis: Require documentation of body surface area (BSA) involvement greater than 10% and inadequate response to at least two (2) non-biologic therapies, such as phototherapy or systemic therapies. For ulcerative colitis: Require documentation of an inadequate response or intolerance to at least two (2) drugs, each from a different therapeutic class, 5-aminosalicylic acid compounds (5-ASA) or immunosuppressants, for the appropriate treatment period. For moderate-severe Crohn's disease: Require diagnosis of disease. For fistulizing Crohn's disease: Require diagnosis of fistulizing disease.

**Age Restrictions:** Pediatric Crohn's Disease: children 6 years of age and older Chronic moderate to severe plaque psoriasis in adult patients over 18 years of age

**Prescriber Restrictions:**

**Coverage Duration:** Initially—6 months: Extended authorization Annually based on documented therapeutic response.

**Other Criteria:**

Remicade should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.



**Drug Name:**

**REVATIO**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Safety and efficacy of Revatio has not been established in: patients with a history of MI, stroke or life-threatening arrhythmia in the last 6 months; patients with a coronary artery disease causing unstable angina; patients with hypertension; patients with retinitis pigmentosa; patients currently treated with prostacyclin (Flolan, Ventavis, Remodulin) or endothelin antagonists (Tracleer) (Use has not been studied); patients with PAH secondary to sickle cell disease. Revatio is not covered for the diagnosis of ED/impotence

**Required Medical Information:**

Covered for patients with pulmonary arterial hypertension (PAH) who meet the following criteria: Patient has been diagnosed with pulmonary arterial hypertension by a Pulmonologist or Cardiologist, and WHO Group I, and patient is not a candidate for therapy with a calcium channel blocker. Initial authorization will be for a 4 month period. Therapy beyond 4 months requires documentation of patient clinical response, characterized by: Stabilization or improvement in functional status (NYHA functional class), or Improvement in PAP or other measures of pulmonary hypertension Revatio is only approved for 20 mg TID.

**Age Restrictions:** Not covered for pediatric patients under 18 years of age

**Prescriber Restrictions:** Cardiologist or Pulmonologist

**Coverage Duration:** Initially- 4 months: Longer if patient responds.

**Other Criteria:**



***Drug Name:***

**REVLIMID**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Revlimid is only available under a restricted distribution program called RevAssist.

***Required Medical Information:***

Myelodysplastic Syndromes: The approval can be extended for six months if benefit is demonstrated, as evidenced by transfusion independence within the past two months. Multiple Myeloma: Initial approval 3 months. The approval can be extended another three months if benefit is demonstrated, as evidenced by absence of disease progression. Covered for patients with transfusion-dependent anemia in low- or intermediate-1 risk MDS with a 5q (q31-33) cytogenetic abnormality. Transfusion dependence is defined as having greater than 2 units of red blood cells within 8 weeks of treatment. Low- or intermediate-1 risk MDS is defined as having an International Prognostic Scoring System (IPSS) Score for MDS of 0 to 1, OR Coventry Health Care covers the cost of Revlimid for members with refractory multiple myeloma who have failed to respond to at least 1 prior therapy.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initially - 3 to 5 months dependent on diagnosis.

***Other Criteria:***



**Drug Name:**

**RIBASPHERE**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Ribasphere/Ribavirin (generic Rebetol) are the CHC preferred ribavirin products. Ribavirin 200mg caps/tabs are the preferred strength and dosage forms AND must be used. Ribapak is not preferred and cannot be used unless there is a documented medical/therapeutic reason.

**Required Medical Information:**

Must be administered in combination with alpha interferon injection for the treatment of chronic hepatitis C in patients with compensated liver disease previously untreated with alpha interferon or who have relapsed following alpha interferon therapy. Patients with hepatitis C virus (HCV) and elevated ALT should undergo HCV genotyping. Those with genotype 1 or 4 should receive 48 weeks of peg interferon + ribavirin and those with genotype 2 or 3 should undergo 24 weeks of treatment. If there is less than a 2-log decline in HCV-RNA titer after 12 weeks of treatment further treatment is not indicated no matter what genotype. If any viral load is still detectable in genotypes 1 or 4 after 24 weeks of treatment, further treatment is not indicated. Treatment duration longer than 24 weeks has not been shown to improve response in genotypes 2 or 3. Initial approval for 16 weeks and viral titer should be obtained at week 12 of therapy. Therapy is approvable for a maximum of 24 weeks in patients that are HCV genotypes 2 or 3 who have achieved a virologic response (either undetectable HCV RNA [less than 50 IU/mL] or at least a 2-log drop in HCV RNA titer from baseline) at 12 weeks of treatment. Therapy is approvable for up to 48 weeks in HCV genotype 1 or 4 patients who have achieved a virologic response (either undetectable HCV RNA [less than 50 IU/mL] or at least a 2-log drop in HCV RNA titer from baseline) at 12 weeks of treatment. If patients fail to achieve a virologic response by 12 weeks, further treatment is not indicated.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initially-12 weeks: Extended-based on response and genotype.

**Other Criteria:**



***Drug Name:***

**RILUTEK**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Diagnosis for use of Amyotrophic lateral sclerosis (ALS).

***Age Restrictions:*** safety and efficacy have not been established in pediatric patients

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



**Drug Name:**

**RITUXAN**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B Reasons for Non-Coverage: Combination treatment of Orencia or an anti-TNF or a biologic response modifier

**Required Medical Information:**

Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma, OR Diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma in combination with CHOP or other anthracycline-based chemotherapy regimens, OR Relapsing or refractory hairy cell leukemia after purine analog therapy, OR Chronic lymphocytic leukemia, OR Aggressive B-Cell lymphoma. For the above indications the following conditions must be met: The prescribing physician is an oncologist or hematologist, AND The patient is 18 years of age or older. Adult patients with moderately- to severely- active rheumatoid arthritis in combination with methotrexate, who have had an inadequate response to one or more Tumor Necrosis Factor (TNF) antagonist therapies. Idiopathic thrombocytopenic purpura: the following conditions must be met: The prescribing physician is a rheumatologist, AND The patient is 18 years of age or older, AND The patient has an inadequate response to methotrexate AND at least one other DMARD AND at least one BRM, including Remicade, for the appropriate treatment period, AND Rituxan must be used in combination with methotrexate.

**Age Restrictions:** 18 years of age or older.

**Prescriber Restrictions:** oncologist/rheumatologist

**Coverage Duration:** Initial course - Extended approval: Annual review

**Other Criteria:**

Patients meeting criteria for approval are allowed an initial course of Rituxan at the dose and schedule mentioned below. Relapsed or Refractory, Low-Grade or Follicular, CD20-Positive, B-Cell, Non-Hodgkin's Lymphoma: 375 mg/m<sup>2</sup> IV infusion once weekly for 4 or 8 doses. Responding patients requiring additional therapy: 375 mg/m<sup>2</sup> IV infusion once weekly for 4 doses. Diffuse Large B-Cell NHL: 375 mg/m<sup>2</sup> IV per infusion given on Day 1 of each cycle of chemotherapy for up to 8 infusions. Rheumatoid Arthritis: Two- 1000 mg IV infusions separated by two weeks. Chronic Lymphocytic Leukemia 375 mg/m<sup>2</sup> weekly for 4 weeks. Hairy Cell Leukemia, Relapsed or Refractory: Initial: 375 mg/m<sup>2</sup> weekly for 8 weeks. Additional 4 doses if complete response not achieved. Aggressive B-Cell Lymphoma: 375 mg/m<sup>2</sup> IV per infusion given on Day 1 of each cycle of chemotherapy for up to 8 infusions. Idiopathic thrombocytopenic purpura: 375 mg/m<sup>2</sup> weekly for 4 weeks. For patient's being treated for moderately- severe rheumatoid arthritis: Initial approval – 1 cycle (2 doses). Extended approval: Annual review by rheumatologist based on disease stability or improvement as documented by the assessment components of the ACR 20 criteria (Table 3), or equivalent documentation of improvement. If no improvement occurs then Coventry Health Care will not cover continued treatment. ACR among patients who received one dose remained the same at weeks 24 and 48.



***Drug Name:***

**SANDOSTATIN LAR DEPOT**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Patient must have tried and failed therapy with generic Octreotide OR have a documented medical reason why this medication is medically/therapeutically inappropriate.

***Required Medical Information:***

Acromegaly: To reduce blood levels of growth hormone and IGF-I in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation and bromocriptine at maximally tolerated doses. The goal is to achieve normalization of growth hormone and IGF-I levels. Carcinoid tumors: Symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits associated severe diarrhea and flushing episodes. Vasoactive intestinal peptide tumors (VIPomas): Treatment of the profuse watery diarrhea associated with VIP-secreting tumors.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 6 months

***Other Criteria:***



***Drug Name:***

**SEROSTIM**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Serostim may be approved when prescribed for the diagnosis of AIDS wasting by a physician who has training and experience in treating those with AIDS and AIDS wasting. The following information may be used as a guide to confirm the medical necessity for Serostim: Patient must have the diagnosis of AIDS wasting and/or cachexia. The patient must be on anti-viral therapy and compliant with their regimen. The patient must be evaluated for inadequate nutritional intake, malabsorption, opportunistic infections, and/or hypogonadism as a potential cause for weight loss. Has the patient had progressive weight loss of greater than 10% of body weight from pre-illness? Does the patient have a BMI less than 20? Has the patient failed a trial of appetite stimulation (megestrol)? How many weeks has the patient received Serostim therapy (48 weeks maximum per manufacturer)? Is the request for more than one injection per day? If this is request for a re-approval: Has the patient lost weight since the last approval? Has the patient been compliant with Serostim therapy? Has the patient been compliant with their antiviral therapy?

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initially-12 weeks: Subsequent approvals-3 month periods: Max- 48 weeks

***Other Criteria:***



**Drug Name:**

**SOMATULINE DEPOT**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

**Required Medical Information:**

Acromegaly – in patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option., OR have failed an adequate trial of octreotide. DOSING : (initial) 90 mg deep SUBQ injection every 4 weeks for 3 months (maintenance) after 3 months, for GH levels greater than 1 ng/mL but less than or equal to 2.5ng/mL, normal insulin-like growth factor-1 (IGF-1), and controlled symptoms, continue 90 mg every 4 weeks: for GH greater than 2.5 ng/mL, elevated IGF-1, and/or uncontrolled symptoms, increase to 120 mg every 4 weeks: for GH of 1 ng/mL or less, normal IGF-1, and controlled symptoms, reduce dose to 60 mg every 4 weeks: thereafter, adjust dose according to response.

**Age Restrictions:** safety and effectiveness in pediatric patients have not been established

**Prescriber Restrictions:**

**Coverage Duration:** Initially-3 months. Maintenance-3 months with dose adjusted according to response.

**Other Criteria:**



***Drug Name:***

**SOMAVERT**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Acromegaly: For the treatment of acromegaly in patients who have had an inadequate response to surgery and/or radiation therapy and/or other medical therapies, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum insulin-like growth factor-I (IGF-I) levels. Annual reauthorization is based upon patient's response to therapy as evidenced by normalization of IGF-I levels and liver function tests that are less than 5 times upper limit of normal, without signs/symptoms of hepatitis or other liver injury, or increase in serum TBIL.

***Age Restrictions:*** safety and effectiveness in pediatric patients have not been established

***Prescriber Restrictions:***

***Coverage Duration:*** Initial therapy may be authorized for a period of 1 year

***Other Criteria:***



**Drug Name:**

**SPORANOX**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Not covered for cosmetic use. Patient must have tried and failed therapy with Itraconazole capsules OR have a documented medical reason why this medication is medically/therapeutically inappropriate.

**Required Medical Information:**

Aspergillosis Blastomycosis Febrile neutropenia, empiric For empiric therapy of febrile neutropenic (ETFN) patients with suspected fungal infections. Histoplasmosis Treatment of histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis in non-immunocompromised or immunocompromised patients. Onychomycosis Treatment of onychomycosis of the toenail with or without fingernail involvement and onychomycosis of the fingernail because of dermatophytes (Tinea unguium) in non-immunocompromised patients. Oropharyngeal/esophageal candidiasis Treatment of oropharyngeal or esophageal candidiasis. Documented pain or impairment and a positive onychomycosis susceptible pathogen culture. Covered for onychomycosis in immunocompromised, diabetic patients or patients with peripheral vascular disease and a positive onychomycosis susceptible pathogen culture. Limit authorization to 12 weeks (toe) and 6 weeks (finger) per year

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Fingernail infection approve for 6 weeks. Toenail infection approve for 12 weeks.

**Other Criteria:**



**Drug Name:**

**SPRYCEL**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

The treatment of conditions other than approved by FDA is considered investigational and is therefore not covered.

**Required Medical Information:**

For the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy including imatinib AND for the treatment of adults with Philadelphia chromosome positive acute lymphoblastic leukemia with resistance or intolerance to prior therapy. Use of Sprycel should continue for maintenance of major cytogenetic response (0-35% Ph+ metaphases) and until disease progression or death. Approved dose for CML and Ph+ ALL is 70mg twice daily. 100 mg ORALLY twice daily in accelerated or blast phase CML or Philadelphia chromosome-positive acute lymphoblastic leukemia (ALL) in patients who do not achieve a hematologic or cytogenetic response at the recommended dose .

**Age Restrictions:** Adults

**Prescriber Restrictions:**

**Coverage Duration:** Initial Period - 3 months. Extended Use: 3 months followed by cytogenetic analyses.

**Other Criteria:**

The patient is diagnosed with Chronic Myeloid Leukemia (CML), OR diagnosed with Philadelphia chromosome positive Acute Lymphoblastic Leukemia (Ph+ ALL) AND the patient has demonstrated either intolerance or resistance to prior imatinib (Gleevec) therapy. Intolerance to imatinib therapy defined as presence of adverse effects at 400-800mg daily of imatinib Resistance to imatinib therapy defined as loss of cytogenetic response determined by CML or Ph+ ALL patients experiencing a progression of disease post cytogenetic/hematologic response OR Chronic phase CML patients experiencing lack of cytogenetic response by month 12 of imatinib therapy OR Blast, accelerated phase CML or Ph+ ALL patients experiencing a failure to achieve complete hematologic response within 3-6 months of imatinib therapy



***Drug Name:***

**SUCRAID**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Not covered for patients known to be hypersensitive to yeast, yeast products, or glycerin (glycerol).

***Required Medical Information:***

Sucraid (sacrosidase) oral solution is indicated as oral replacement therapy of the genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency. (CSID)

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initial approval: 6 months. Extended approval: Annual review based on response to therapy.

***Other Criteria:***



***Drug Name:***

**SUTENT**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

For the treatment of gastrointestinal stromal tumor after disease progression on or intolerance to imatinib mesylate. AND for the treatment of advanced renal cell carcinoma. Approval for advanced renal cell carcinoma is based on partial response rates and duration of responses. Continuation of approval for 1 year in persons with stable disease (tumor size within 25% of baseline). Discontinuation when there is evidence of disease progression.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initial approval for 12 weeks. Continuation of approval for 1 year in persons with stable disease

***Other Criteria:***



**Drug Name:**

**SYMLIN**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Symlin is not covered for patients meeting any of the following criteria: Poor compliance with current insulin regimen Poor compliance with prescribed self-blood glucose monitoring An A1C less than 7% or greater than 9% Recurrent severe hypoglycemia requiring assistance during the previous 6 months Presence of hypoglycemia unawareness Confirmed diagnosis of gastroparesis Need for medications that stimulate GI motility Pediatric patients Concurrent use with other oral antidiabetic medications (except metformin and sulfonylureas) or drugs that alter gastrointestinal motility

**Required Medical Information:**

Type 2 diabetes, as an adjunct treatment in patients who use mealtime insulin therapy and have failed to achieve desired glucose control despite optimal insulin therapy, with or without a concurrent sulfonylurea agent and/or metformin. Type 1 diabetes, as an adjunct treatment in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy. Continued approval: 1 year based on response to therapy (improved glycemic control as evidenced by A1C lowering from baseline).

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initial approval period of 6 months. Annual review will be based on response to therapy

**Other Criteria:**

CRITERIA: Type 1 diabetics: Using both basal insulin and short-acting insulin, and requires three or more insulin injections daily, OR 3. Using an insulin pump. Type 2 diabetics: Using both basal insulin and short-acting insulin, AND requires three or more insulin injections daily, OR using an insulin pump, AND receiving maximum tolerated doses of metformin, unless the patient is not a candidate for metformin therapy. Failure to achieve adequate glycemic control despite individualized insulin management defined as: A1C level is greater than 7% and less than 9%, and marked day-to-day variability in glucose levels (based on review of self-monitoring blood glucose levels) Home blood glucose monitoring is carried out three or more times per day Currently receiving individualized medical nutrition therapy by a registered dietician Require monitoring total daily carbohydrate intake Currently receiving ongoing care under the guidance of a healthcare professional skilled in the use of insulin and supported by the services of diabetes educators



***Drug Name:***

**SYNAREL**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

SYNAREL should not be administered to patients who: are hypersensitive to GnRH, GnRH agonist analogues or any of the excipients of SYNAREL: have undiagnosed vaginal bleeding: are pregnant or may become pregnant as major foetal abnormalities were observed in rats (not applicable when used in in vitro fertilization programmes): are breast feeding.

***Required Medical Information:***

Documentation of the following use: for the hormonal management of endometriosis, including pain relief and reduction of endometrial lesions for a period of six months.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**SYNERCID**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Vancomycin resistance not documented with a Culture and sensitivity report or failure of trial on Vancomycin. Not a first line agent. If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

***Required Medical Information:***

Bacteremia - Vancomycin-resistant Enterococcus faecium infection Infection of skin AND/OR subcutaneous tissue, Complicated, caused by Staphylococcus aureus and Streptococcus pyogenes. Culture and sensitivity report.

***Age Restrictions:*** 16 years of age and older

***Prescriber Restrictions:***

***Coverage Duration:*** As indicated by course of treatment.

***Other Criteria:***



***Drug Name:***

**TARCEVA**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Tarceva is NOT indicated for first line treatment, with or without platinum-based chemotherapy.

***Required Medical Information:***

Covered for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen. Initial approval is for 3 months. The approval will be extended for an additional 6 months, if benefit is demonstrated by: control of tumor growth: No evidence of increase in tumor size relative to pre-treatment report as shown by radiologic study or direct evaluation, or disease-related symptom improvement: Evidence of substantial improvement in symptoms such as (but not limited to) exercise tolerance, weight loss, oxygenation, respiratory rate, CO<sub>2</sub> retention, cough, dyspnea, fever and pleural fluid accumulation, or reduction in paraneoplastic syndromes. OR Covered in combination with gemcitabine (Gemzar) for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer. Initial approval is 3 months. The approval will be extended for an additional 6 months if benefit is demonstrated by: Control of tumor growth: No evidence of increase in tumor size relative to pre-treatment report as shown by radiologic study or direct evaluation, or disease-related symptom improvement: Evidence of substantial improvement in symptoms such as (but not limited to) jaundice, weight loss, appetite loss, ascites, mid-epigastric or back pain, or reduction in paraneoplastic syndromes.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initial approval is 3 months and renewal is 6 months

***Other Criteria:***



***Drug Name:***

**TARGRETIN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

This medication should not be administered to patients who are pregnant.

***Required Medical Information:***

Treatment of cutaneous manifestations of Cutaneous T-Cell Lymphoma (CTCL) Stage 1-A or Stage 1-B in patients who are refractory to at least one prior systemic therapy for the oral Targretin and those who have persistent or refractory disease or have not tolerated other topical therapies for the Targretin gel. The prescriber's office needs to communicate other therapies/ treatment failures for the patient's cutaneous lesions.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 4 months

***Other Criteria:***



**Drug Name:**

**TASIGNA**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

The treatment of conditions other than approved by FDA is considered investigational and is therefore not covered.

**Required Medical Information:**

Indicated for the treatment of chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (CML) in adult patients resistant to or intolerant to prior therapy that included imatinib. The patient is diagnosed with Philadelphia chromosome positive Chronic Myeloid Leukemia (CML), AND the patient has demonstrated either intolerance or resistance to prior imatinib (Gleevec) therapy. Intolerance to imatinib therapy defined as presence of adverse effects at 400-800mg daily of imatinib. Resistance to imatinib therapy defined as loss of cytogenetic response determined by CML patients experiencing a progression of disease post cytogenetic/hematologic response OR Chronic phase CML patients experiencing lack of cytogenetic response by month 12 of imatinib therapy OR Blast, accelerated phase CML patients experiencing a failure to achieve complete hematologic response within 3-6 months of imatinib therapy. Use of Tasigna should continue for maintenance of major cytogenetic response (0-35% Ph+ metaphases) and until disease progression or death.

**Age Restrictions:** safety and efficacy not established in pediatric patients

**Prescriber Restrictions:**

**Coverage Duration:** Initial Period: 3 months.

**Other Criteria:**

400 mg orally twice daily, approximately 12 hours apart and should not be taken with food. The capsules should be swallowed whole with water. No food should be consumed for at least 2 hours before the dose is taken and no food should be consumed for at least one hour after. Dose adjustment may be required for hematologic and non-hematologic toxicities, and drug interactions



**Drug Name:**

**TAXOTERE**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

This medication is administered by a physician incident to a physician's visit and would be covered by Medicare Part B. Docetaxel should generally not be given to patients with abnormal liver enzymes or elevated bilirubin levels. These patients are at increased risk for the development of grade 4 neutropenia, febrile neutropenia, infections, severe thrombocytopenia, severe stomatitis, severe skin toxicity, and toxic death. Docetaxel therapy should not be given to patients with neutrophil counts of less than 1500 cells/mm<sup>3</sup>. Severe hypersensitivity reactions characterized by generalized rash/erythema, hypotension and/or bronchospasm, or very rarely fatal anaphylaxis, have been reported with therapy

**Required Medical Information:**

Breast cancer, Adjuvant treatment in combination with doxorubicin and cyclophosphamide for patients. Breast cancer, Locally advanced/metastatic disease, after failure of prior chemotherapy Gastric cancer. Head and neck cancer, Locally advanced squamous cell disease, induction treatment in combination with cisplatin and fluorouracil. Metastatic prostate cancer, Androgen independent (hormone refractory), in combination with prednisone. Non-small cell lung cancer, Locally advanced/metastatic disease, as monotherapy after failure of prior platinum-based chemotherapy. Non-small cell lung cancer, Unresectable, locally advanced/metastatic disease, first-line therapy in combination with cisplatin.

**Age Restrictions:** safety and efficacy not established in patients below the age of 16 years

**Prescriber Restrictions:**

**Coverage Duration:** Initially-6 month. Further approvals dependent on response.

**Other Criteria:**



***Drug Name:***

**TESTIM**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Testosterone levels within normal range (range for the lab doing the testing): Female patients: Men with carcinoma of the breast or suspected carcinoma of the prostate: Use for muscle building purposes. Patient must have tried and failed therapy with Androgel OR have a documented medical reason why this medication is medically/therapeutically inappropriate

***Required Medical Information:***

Diagnosis for use: Testosterone levels- total and free: LH and FSH levels

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initial for 3 months: then 1 year

***Other Criteria:***

Higher quantities will require failure of recommended doses per day.: Retreatment will be initiated for an additional one-year course of therapy provided that topical testosterone therapy is maintaining normal testosterone levels. Androgel is preferred agent



***Drug Name:***

**TESTRED**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Diagnosis for use: Indicated for delay in sexual development AND/OR puberty, and hypogonadotropic hypogonadism and metastasis from malignant tumor of breast inoperable metastatic disease (skeletal) in women 1 to 5 years postmenopausal and primary hypogonadism. Testosterone levels- total and free: LH and FSH levels

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 3 months then 1 year if response noted.

***Other Criteria:***



**Drug Name:**

**TEV-TROPIN**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

The patient must try and fail on Norditropin prior to receiving Tev-Tropin (the other formulary growth hormone) or any other non-formulary growth hormone, unless a clinical contraindication exists.

**Required Medical Information:**

Growth Hormone Deficiency in Children and Adolescents: Patient has failed to respond to at least 2 standard GH stimulation tests. One abnormal GH test is sufficient for children with brain tumors and irradiation with documented multiple pituitary hormone deficiency (MPHD) AND Appropriate imaging (MRI or CT) of the brain to exclude tumor on hypothalamic-pituitary region One of the following criteria are met: Child has severe growth retardation with height standard deviation score (SDS) more than 3 SDS below the mean for chronological age and sex, OR Child has moderate growth retardation with height SDS -2 and -3 SDS below the mean chronological age and sex and decreased growth rate (growth velocity measured over one year below 25th percentile for age and sex). OR Child exhibits severe deceleration in growth rate (growth velocity measured over 1 year -2 SDS below the mean for age and sex), OR Child has decreasing growth rate combined with a predisposing condition such as previous cranial irradiation or tumor, OR Child exhibits evidence of other pituitary hormone deficiencies or signs of congenital GHD (hypoglycemia, microphallus).

**Age Restrictions:**

**Prescriber Restrictions:** certified endocrinologis

**Coverage Duration:** Initial- 6 months. Extended approval: determine if therapy continues to be medically necessary.

**Other Criteria:**

Growth Hormone Deficiency in Adults: Covered for replacement of endogenous growth hormone in patients with adult GH deficiency who meet ALL the following criteria: Adult onset: Patients who have growth hormone deficiency either alone or with multiple hormone deficiencies (hypopituitarism), as a result of EITHER, disease of the pituitary or hypothalamus, OR, injury to either the pituitary or hypothalamus from surgery, radiation therapy, or trauma, OR Childhood onset: Patients who were growth-hormone deficient during childhood who have GH deficiency confirmed as adult before replacement therapy is started., AND Biochemical diagnosis of GH deficiency, by means of a negative response to two standard GH stimulation test [maximum peak less than 5 ng/ml when measured by RIA (polyclonal antibody) or less than 2.5 ng/ml when measured by IRMA (monoclonal antibody)], AND Patients already receiving full supplementation of other deficient hormones as required AND Objective measurement of clinical features of growth hormone deficiency. Severely decreased QOL (defined as score of at least 11 out of 25) as assessed using the Adult growth hormone deficiency assessment (AGHDA) questionnaire, AND EITHER, Reduced bone density of more than 1 SD below the age and gender-specific mean, (which by WHO criteria would predict a relative fracture risk of more than 2.5) provided that other etiologies have been ruled out or maximally treated, OR, Evidence of cardiac decompensation defined as reduced ejection fraction of below 50% provided that other etiologies have been ruled out or maximally treated, AND Growth hormone is initiated at a low dose and titrated slowly upward at monthly interval:



***Drug Name:***

**THALOMID**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

The drug is available only under a special restricted distribution program called the S.T.E.P.S(TM) Program (System for Thalidomide Education and Prescribing Safety); only prescribers and pharmacists registered with this program may prescribe and dispense thalidomide.

***Required Medical Information:***

Indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). Indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. Covered for previously treated and untreated patients with multiple myeloma.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 YEAR

***Other Criteria:***



***Drug Name:***

**THIOTEPA**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Covered for the following indications: Breast adenocarcinoma: Carcinoma of bladder, Superficial papillary: Hodgkin's disease: Intracavitary malignant effusion: Adenocarcinoma ovarian cancer

***Age Restrictions:*** safety and efficacy in children have not been established

***Prescriber Restrictions:***

***Coverage Duration:*** Initially-4 weeks. Extended approval based on Diagnosis and response.

***Other Criteria:***



***Drug Name:***

**THYMOGLOBULIN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B. When used for a Medicare covered transplant for a patient eligible for Medicare Part A at the time of the transplant it is covered under Medicare Part B

***Required Medical Information:***

Indication for use include: Rabbit antithymocyte globulin (RATG) - Indicated for the treatment of renal transplant acute rejection in conjunction with concomitant immunosuppression, AND Equine antithymocyte globulin - Indicated for the treatment of moderate to severe aplastic anemia in patients who are unsuitable for bone marrow transplantation, AND for renal allograft rejection.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**TOBI**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

When used for chronic therapy in a nebulizer in other than a skilled nursing setting (LTCH) it is covered as a Part B drug.

***Required Medical Information:***

Cystic fibrosis: 300 mg (1 ampule) INHALED via nebulizer twice daily (28 days on, 28 days off): do not take less than 6 h apart

***Age Restrictions:*** for use in patients 6 years and older

***Prescriber Restrictions:***

***Coverage Duration:*** Duration of treatment

***Other Criteria:***



***Drug Name:***

**TORISEL**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit, this would be covered by Medicare Part B

***Required Medical Information:***

TORISEL is indicated for the treatment of advanced renal cell carcinoma. The recommended dose of TORISEL for advanced renal cell carcinoma is 25 mg infused over a 30-60 minute period once a week. TORISEL should be held for absolute neutrophil count (ANC) less than 1,000/mm<sup>3</sup>, platelet count less than 75,000/mm<sup>3</sup>, or NCI CTCAE grade 3 or greater adverse reactions. Once toxicities have resolved to grade 2 or less, TORISEL may be restarted with the dose reduced by 5 mg/week to a dose no lower than 15 mg/week. Continuation of approval for 1 year in persons with stable disease (tumor size within 25% of baseline). Discontinuation when there is evidence of disease progression.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initial approval for 12 weeks. Continuation of approval for 1 year in persons with stable disease

***Other Criteria:***

Patients should receive prophylactic intravenous diphenhydramine 25 to 50 mg (or similar antihistamine) approximately 30 minutes before the start of each dose of TORISEL.



***Drug Name:***

**TRACLEER**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Not covered for the following: concomitant administration with cyclosporine or glyburide, AND pregnancy (monthly pregnancy tests should be obtained while on therapy)

***Required Medical Information:***

Pulmonary Arterial Hypertension (PAH): Approval may be granted for the treatment of pulmonary hypertension in adult patients when: the patient has been diagnosed with primary pulmonary hypertension by a Pulmonologist or Cardiologist, OR the patient has been diagnosed with secondary pulmonary hypertension due to scleroderma, sclerosis or autoimmune disease by a Pulmonologist or Cardiologist, AND the patient is WHO functional class III or IV, AND the patient has received adequate treatment trials with currently accepted therapies. Authorization is limited to 60 tablets a month, for 4 months, due to a lack of demonstrated increased benefit, and an increased risk of liver toxicity from higher doses. Therapy beyond 4 months will require patient documentation of clinical response.

***Age Restrictions:***

***Prescriber Restrictions:*** Pulmonologist or Cardiologist

***Coverage Duration:*** 4 months

***Other Criteria:***



**Drug Name:**

**TREANDA**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

If this medication is administered by a physician incident to a physician's visit, this would be covered by Medicare Part B. Participation in a non-approved clinical trial using TREANDA as part of the drug therapy. Investigational uses not recognized as an FDA approved indication or use not recognized in one of the following compendia: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, DRUGDEX Information System. Renal impairment: Should not be used if CrCL is less than 40 mL/min. Use with caution in lesser degrees of renal impairment. (8.6). Hepatic impairment: Should not be used in moderate or severe hepatic impairment.

**Required Medical Information:**

Diagnosis for use: TREANDA® (bendamustine hydrochloride) for Injection is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL). Efficacy relative to first line therapies other than chlorambucil has not been established.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initial approval for 6 months

**Other Criteria:**

DOSAGE AND ADMINISTRATION: 100 mg/m<sup>2</sup> infused intravenously over 30 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles (2.1): Delay treatment for Grade 4 hematologic toxicity or clinically significant greater than or equal to Grade 2 non-hematologic toxicity (2.2): Dose modifications for hematologic toxicity: for Grade 3 or greater toxicity, reduce dose to 50 mg/m<sup>2</sup> on Days 1 and 2: if Grade 3 or greater toxicity recurs, reduce dose to 25 mg/m<sup>2</sup> on Days 1 and 2. (2.2): Dose modifications for non-hematologic toxicity: for clinically significant Grade 3 or greater toxicity, reduce the dose to 50 mg/m<sup>2</sup> on Days 1 and 2 of each cycle. (2.2): Dose re-escalation may be considered. (2.2)



***Drug Name:***

**TRETINOIN**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Acute Promyelocytic Leukemia (APL): for the induction of remission in patients with APL, French-American-British (FAB) classification M3 (including the M3 variant), characterized by the presence of the t(15,17) translocation and/or the presence of the PML/RAR $\alpha$  gene, who are refractory to, or who have relapsed from, anthracycline chemotherapy, or for whom anthracycline-based chemotherapy is contraindicated. Tretinoin is for the induction of remission only. Patients should receive an accepted form of remission consolidation and/or maintenance therapy for APL after completion of induction therapy with tretinoin.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initial approval is 3 months and renewal is 6 months if improvement is seen

***Other Criteria:***

If the patient meets the clinical criteria, failure on other lower tier medications is not required.



***Drug Name:***

**TRISENOX**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

***Required Medical Information:***

Indicated for induction and consolidation of acute promyelocytic leukemia (APL) characterized by t(15,17) translocation or PML/RAR-alpha gene expression, in patients who are refractory to or have relapsed from retinoid and anthracycline chemotherapy

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 3 months (60 doses for 60 days plus an additional 25 doses for 5 weeks)

***Other Criteria:***

Second-line therapy in acute promyelocytic leukemia (APL) characterized by t(15,17) translocation or PML/RAR-alpha gene expression. Specifically, this agent is useful in patients relapsing after or refractory to conventional regimens of Tretinoin plus chemotherapy (anthracycline).



**Drug Name:**

**TYGACIL**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

**Required Medical Information:**

Complicated skin and skin structure infections caused by *E. coli*, *E. faecalis* (vancomycin-susceptible isolates only), *S. aureus* (methicillin-susceptible and -resistant isolates), *S. agalactiae*, *S. anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *S. pyogenes*, and *B. fragilis*. Complicated intra-abdominal infections caused by *C. freundii*, *E. cloacae*, *E. coli*, *K. oxytoca*, *K. pneumoniae*, *E. faecalis* (vancomycin-susceptible isolates only), *S. aureus* (methicillin-susceptible isolates only), *S. anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *B. fragilis*, *B. thetaiotaomicron*, *B. uniformis*, *B. vulgatus*, *C. perfringens*, and *P. micros*. Culture and sensitivity report

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Course of treatment

**Other Criteria:**



**Drug Name:**

**TYKERB**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Tykerb is NOT covered for members with the following criteria: Patients who are HER2-negative. Hypersensitivity to 5-fluorouracil (due to combination with capecitabine). Patients with severe renal impairment (creatinine clearance less than 30 ml/min) (due to combination with capecitabine). Patients with known dihydropyrimidine dehydrogenase (DPD) deficiency (due to combination with capecitabine)

**Required Medical Information:**

Tykerb is indicated for use in combination with Xeloda (capecitabine) for the treatment of patients with advanced or metastatic breast cancer whose tumors over-express HER2 and who have received prior therapy including an anthracycline (doxorubicin, daunorubicin, epirubicin, idarubicin), a taxane (paclitaxel, docetaxel), and Herceptin® (trastuzumab).

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Initial Approval: 6 months Extended Approval: Based on therapeutic response.

**Other Criteria:**

Tykerb is covered for members who meet the following criteria: Only be used in patients with advanced or metastatic breast cancer with HER2 protein over-expression, ie. positive or equivocal HER2 protein expression, and in patients who have received prior therapy with an anthracycline, a taxane, and trastuzumab. The recommended dose of Tykerb is 1250 mg (5 x 250 mg tablets) given orally once daily on days 1-continuously in combination with capecitabine 2000 mg/m<sup>2</sup>/day (administered orally in two doses approximately 12 hours apart) on days 1-14 in a repeating 21 day cycle. Tykerb should be taken at least one hour before or after a meal. Capecitabine should be taken with food or within 30 minutes after food. Tykerb should be taken once daily. Do not divide doses. Modify dose for cardiac or other toxicities, severe hepatic impairments, and CYP 3A4 drug interactions. Note: Decreases in left ventricular ejection fraction have been reported. Confirm normal LVEF before initiating Tykerb therapy and continue evaluations throughout treatment.



**Drug Name:**

**TYSABRI**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Not covered as a first line agent for Multiple Sclerosis: Patient has tried and failed, or has contraindication to, or intolerable to the side effects of any ONE (1) interferon-beta (Avonex, Rebif or Betaseron) AND glatiramer acetate (Copaxone), with failure defined as meeting 2 of the following criteria: The patient continues to have clinical relapses, OR the patient continues to have CNS lesion progression as measured by MRI, OR the patient continues to have worsening disability, including, but not limited to, decreased mobility or decreased ability to perform activities of daily living due to disease progression, AND comply with TOUCH (TYSABRI Outreach: Unified Commitment to Health) Prescribing Program (mandated by FDA). Functional status that is no longer ambulatory (with or without assistive devices – dependent on another individual to provide all care.) Not covered in patients: with a diagnosis documented as chronic progressive multiple sclerosis: Combination therapy with any interferon-beta (Avonex, Betaseron, Rebif) or glatiramer acetate (Copaxone): any other non-FDA approved indications: concurrent use of Tysabri with chronic immunosuppressant, immunomodulatory therapies, antineoplastics and or TNF- $\alpha$  due to increased risk of PML: patients who are immunocompromised due to HIV, hematological malignancies, organ transplants or immunosuppressive therapies. Current or past history of PML.

**Required Medical Information:**

TYSABRI is indicated as monotherapy for the treatment of patients with relapsing forms of multiple sclerosis to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations. The safety and efficacy of TYSABRI beyond two years are unknown. Because TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability (see BOXED WARNING and WARNINGS, Progressive Multifocal Leukoencephalopathy), TYSABRI is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, alternate multiple sclerosis therapies. TYSABRI is indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate conventional CD therapies and inhibitors of TNF- $\alpha$ . TYSABRI should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF- $\alpha$ . Initial authorization for Crohn's Disease: 3 months (discontinue Tysabri if no therapeutic benefit seen 12 weeks after initiating treatment). Extended authorization: Annual basis (reassess therapeutic benefit/response annually)

**Age Restrictions:** safety and efficacy not established in pediatric patients

**Prescriber Restrictions:** Neurologist or gastroenterologist

**Coverage Duration:** Multiple Sclerosis: 1 year. Crohn's Disease: Initial authorization: 3 months

**Other Criteria:**

Because TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability TYSABRI is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, alternate multiple sclerosis therapies. TYSABRI is indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate conventional CD therapies and inhibitors of TNF- $\alpha$ . TYSABRI should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF- $\alpha$ . Initial authorization for Crohn's Disease: 3 months (discontinue Tysabri if no therapeutic benefit seen 12 weeks after initiating treatment). Extended authorization: Annual basis (reassess therapeutic benefit/response annually)



***Drug Name:***

**VANCOCIN HCL**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Vancocmycin oral therapy is not indicated and is not covered when used to treat systemic infections.

***Required Medical Information:***

Staphylococcal enterocolitis and antibiotic-associated pseudomembranous colitis produced by *C. difficile*. The parenteral product may also be given orally for these infections. For treating *C. difficile* – the patient must first be tried on Metronidazole for 10 to 14 days. If the patient fails on the Metronidazole therapy then the patient must try Vancocin 125mg qid for 14 days. To use Vancocin 250mg capsule – the prescriber must justify why other alternatives are not clinically appropriate. Alternatively, dosages of 125 mg 3 or 4 times daily for *C. difficile* colitis may be as effective as the 500 mg dose regimen.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 14 days

***Other Criteria:***

Vancomycin is also available in an injectable form (vial) which requires no PA. This may be given orally and is more cost effective than the Vancocin capsules.



***Drug Name:***

**VELCADE**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

***Required Medical Information:***

Velcade (Bortezomib) is indicated for the treatment of patients with mantle cell lymphoma who have received at least 1 prior therapy. The recommended starting dose of Velcade (Bortezomib) is 1.3mg/m<sup>2</sup>/dose administered as a 3 to 5 second bolus intravenous injection twice weekly for 2 weeks followed by a 10 day rest period.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** Initial approval: For 6 months Extended approval: Based on response

***Other Criteria:***



***Drug Name:***

**VENTAVIS**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

Ventavis is administered via a DME inhalation device and as such would be covered as a Part B benefit for non-institutionalized patients. Reasons for Non-Coverage: Safety and efficacy of Ventavis has not been established in: patients with a history of MI, stroke or life-threatening arrhythmia in the last 6 months, OR patients with a coronary artery disease causing unstable angina, OR patients with hypertension, OR patients with retinitis pigmentosa, OR patients with PAH secondary to sickle cell disease, OR patients that have PAH WHO group II, III, IV or V, OR patients that are functional NYHA class I or II

***Required Medical Information:***

Patient has been diagnosed with pulmonary arterial hypertension by a Pulmonologist or Cardiologist AND is in WHO Group I, AND patient is not a candidate for therapy with a calcium channel blocker, AND patient has functional NYHA class III or IV symptoms.

***Age Restrictions:*** pediatric patients (less than 18 years of age)

***Prescriber Restrictions:*** Pulmonologist or cardiologist

***Coverage Duration:*** Initial Approval: 4 months. Extended Approval: requires documentation of patient clinical response

***Other Criteria:***



***Drug Name:***

**VFEND**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Covered for patients with invasive aspergillosis or with a serious systemic fungal infection caused by *Scedosporium apiospermum* and *Fusarium* spp. Who can tolerate oral treatment (initial approval 12 weeks). Covered for the treatment of esophageal candidiasis that is resistant to treatment with fluconazole and itraconazole (maximum approval 3 weeks). Covered for the treatment of candidemia or other deep-seated candidal infections in non-neutropenic patients that are unresponsive to treatment with fluconazole (initial approval 12 weeks. Continue therapy for 14 days after the patient is afebrile and blood cultures are negative). If the patient meets the clinical criteria, failure on other lower tier medications is not required. Any treatment needing more than 12 weeks of therapy will require an additional authorization with documentation of the severity of the patient's underlying disease, recovery from immunosuppression, and clinical response.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 12 weeks

***Other Criteria:***



***Drug Name:***

**VIDAZA**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

VIDAZA is indicated for treatment of patients with the following myelodysplastic syndrome subtypes: refractory anemia or refractory anemia with ringed sideroblasts (if accompanied by neutropenia, or thrombocytopenia or requiring transfusions), or refractory anemia with excess blasts, or refractory anemia with excess blasts in transformation, or Chronic myelomonocytic leukemia, and are refractory to other chemotherapeutic agents. First Cycle: 75mg/m<sup>2</sup> SC or IV daily for seven days. Subsequent Cycles: Cycles repeat every 4 weeks. Dose may be increased to 100mg/m<sup>2</sup> if no benefit after 2 cycles is seen and no toxicities have developed. Recommended that patients receive a minimum of 4 cycles, treatment may continue for as long as patient continues benefit.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 4 month increments

***Other Criteria:***

Vidaza is approved for SC or IV administration. Doses and treatment cycles are the same regardless of route of administration.



***Drug Name:***

**VIRAZOLE**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

If this medication is administered incident to a physician's visit or in a hospital this would not be covered under Part D

***Required Medical Information:***

Treatment of hospitalized infants and young children with severe lower respiratory tract infections caused by respiratory syncytial virus (RSV). Therapy should not be initiated if respiratory involvement is not severe enough to warrant hospitalization for a full course of treatment, which ranges from 3 to 7 days.

***Age Restrictions:*** for use in infants and children

***Prescriber Restrictions:***

***Coverage Duration:*** 6 months

***Other Criteria:***



**Drug Name:**

**XOLAIR**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

**Required Medical Information:**

Documentation of the following: .Mod-severe persistent asthma (NHLBI definition) meeting all the following criteria: Evidence of reversible disease (12% or greater improvement in FEV1 with at least a 200ml increase or 20% or greater improvement in PEF as a result of a short-acting bronchodilator challenge).Evaluation and recommendation by an allergist, immunologist or pulmonologist. Evidence of specific allergic sensitivity to a perennial aeroallergen (+ skin test or in vitro test). Failure of an adequate trial of standard therapy. Wt less than 150 kg. IgE level greater than 30 and less than 700 IU/ml Dose calculated on basis of wt and IgE dose less than or equal to 750 mg/mo.Extended approval for 6 mo's if demonstrated benefit, meeting at least 2 of the following criteria:PEF improvement (12% or greater from baseline (prior to start of Xolair)), OR FEV1 improvement (12% or greater from baseline (prior to start of Xolair)), OR reduction in symptoms (wheezing, SOB, cough, chest tightness), OR reduction in systemic corticosteroids and rescue drug use, OR reduction of asthma-related hospitalizations and other medical contacts. Require continued non-smoking status (CO level required) (measured at time of request for continuation of therapy)

**Age Restrictions:** 12 years of age or older

**Prescriber Restrictions:** allergist, immunologist or pulmonologist

**Coverage Duration:** Initial: 6 months trial. Extended approval for 6 months if demonstrated benefit

**Other Criteria:**



***Drug Name:***

**ZAVESCA**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

The drug is contraindicated in women who are or may become pregnant.

***Required Medical Information:***

For adults with a diagnosis of mild to moderate type I Gaucher Disease after failure of enzyme therapy (including use of pre-medication).

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 1 year

***Other Criteria:***



***Drug Name:***

**ZOLINZA**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Covered for cutaneous manifestations of cutaneous T-cell Lymphoma when the following criteria have been met: failed minimum of two systemic treatments: The recommended dose is 400 mg orally once daily with food. Treatment may be continued as long as there is no evidence of progressive disease or unacceptable toxicity. If a patient is intolerant to therapy, the dose may be reduced to 300 mg orally once daily with food. The dose may be further reduced to 300 mg once daily with food for 5 consecutive days each week, as necessary.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** 6 months

***Other Criteria:***



**Drug Name:**

**ZOMETA**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Zometa is not FDA approved for postmenopausal osteoporosis

**Required Medical Information:**

Hypercalcemia of malignancy (HCM): For the treatment of hypercalcemia of malignancy. Safety and efficacy in the treatment of hypercalcemia associated with hyperparathyroidism or with other non-tumor related conditions has not been established. Dose: The maximum recommended dose of Zometa in HCM (albumin-corrected serum calcium greater than or equal to 12 mg/dL) is 4 mg/dL. The 4-mg dose must be given as a single-dose intravenous infusion over no less than 15 minutes. Retreatment with Zometa 4 mg, may be considered if serum calcium does not return to normal or remain normal after initial treatment. It is recommended that a minimum of 7 days elapse before retreatment, to allow for a full response to the initial dose. Multiple myeloma and documented bone metastases from solid tumors: For the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy. Dose: The recommended dose of Zometa in patients with multiple myeloma and metastatic bone lesions from solid tumors is 4 mg infused over 15 minutes every three to four weeks. Data is available to support use in the following tumors: prostate cancer, breast cancer (See Appendix I) and multiple myeloma, and other solid tumors (renal cell carcinoma, non small cell lung cancer, small cell lung cancer and thyroid cancer). Patients should also be administered an oral calcium supplement of 500 mg and a multiple vitamin containing 400 IU of vitamin D daily. Note: Consideration should be given to the severity of, as well as the symptoms of, tumor-induced hypercalcemia when considering use of Zometa. Vigorous saline hydration alone may be sufficient to treat mild, asymptomatic hypercalcemia.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** up to 3 months initially- dependent on diagnosis

**Other Criteria:**



**Drug Name:**

**ZORBTIVE**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Reasons for Non-Coverage: Repeat administration of Zorbtive therapeutic regimen. Patients with active neoplasia, either newly diagnosed or recurrent. If this medication is administered by a physician incident to a physician's visit this would be covered by Medicare Part B

**Required Medical Information:**

The diagnosis is documented as Short Bowel Syndrome, AND the patient has had a bowel resection and the length of remaining small intestine is less than 200 cm in length, AND The patient is receiving parental nutrition Zorbtive is indicated for the treatment of Short Bowel Syndrome in patients receiving specialized nutritional support. Zorbtive therapy should be used in conjunction with optimal management of Short Bowel Syndrome. Zorbtive is administered subcutaneously at a dose of 0.1 mg/kg/day, up to a maximum of 8 mg/day. The volume of administration can be up to 1 ml. Injection should be administered daily for four weeks. Zorbtive is available in 8.8 mg multi-use vials.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:** Approved for one 4-week treatment with therapeutic regimen. No repeat treatment will be covered

**Other Criteria:**



***Drug Name:***

**ZYVOX**

***Covered Uses:***

All FDA-approved indications not otherwise excluded from Part D

***Exclusion Criteria:***

***Required Medical Information:***

Indicated for the treatment of adult patients with the following infections caused by susceptible strains of the microorganism: Vancomycin-resistant enterococcus faecium infections including cases with concurrent bacteremia. Nosocomial pneumonia caused by methicillin-susceptible and methicillin-resistant Staphylococcus aureus or penicillin-susceptible Streptococcus pneumoniae. Complicated skin and skin structure infections caused by methicillin-susceptible and methicillin-resistant Staphylococcus aureus, Streptococcus pyogenes, and Streptococcus agalactiae. The IV formulation may be approved when the patient has met the criteria for oral therapy and there is a significant clinical reason the patient cannot use the oral form.

***Age Restrictions:***

***Prescriber Restrictions:***

***Coverage Duration:*** BID dosing: 2 wks for MRSA: up to 4 weeks for VRE.

***Other Criteria:***