Freedom Health 2009 Prior Authorization List

Prior Authorization Drug Description	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
adalimumab	Ankylosing spondylitis , Crohn's disease (moderate to severe) with inadequate response to conventional therapy, Juvenile idiopathic arthritis, psoriasis with arthropathy, rheumatoid arthritis (moderate to severe), chronic plaque psoriasis (moderate to severe)	Patients with mild rheumatoid arthritis, patients with mild Crohn's disease, patients with an active, serious infection, patients with a latent tuberculosis infection, concurrent use of anakinra	Dx: Rheumatoid, Psoriatic and Juvenile rheumatoid arthritis: 1. MD is a rheumatologist, AND2. Patient has had an inadequate response to one or more disease modifying antirheumatic drugs (DMARDS): Methotrexate, Sulfasalazine, Cyclosporine, hydroxychloroquine, injectable gold, azathioprine, or penicillamine. (Humira can be used in combination with methotrexate for patients who do not respond adequately to methotrexate alone.) 3. Patient is not currently using a Tumor Necrosis Factor (TNF) blocking agent or other biological agent such as Enbrel or Kineret. Dx: Moderate to Severe Active Crohn's disease: 1. MD is GI AND 2. Pt has had inadequate response to one or more of the following: DMARDs (Methotrexate, Sulfasalazine or azathioprine only), oral 5-ASA products (mesalamine, Asacol, Pentasa, Lialda, etc.), corticosteroids (Entocort EC, prednisone, etc.) or Remicade. Dx: Ankylosing Spondylitis: 1. MD is rheumatologist, AND 2. Pt has had inadequate response to UV light therapy AND a DMARD such as methotrexate or sulfasalazine for atleast 3 months prior. Dx: Plaque Psoriasis:1. MD is Dermatologist or			1 year	
agalsidase	Fabry's disease		Diagnosis			1 year	
alefacept	Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, psoriasis with arthropathy	Patients with mild psoriasis, patients also using other immunosuppressive agents, patients currently receiving phototherapy, patients also diagnosed with HIV/AIDs.	The prior authorization should be maintained for a lifetime limit of 180 days due to the lack of available studies of Amevive's safety and effectiveness beyond two treatment cycles. The first and second treatment cycles, each consisting of 12 weeks, must be separated by at least a 12-week interval. Retreatment with the second 12-week course may be initiated provided the CD4+ T-cell count is within the normal range. The physician should monitor CD4+ T-cell counts during treatment, dosing should be withheld if the CD4+ T-cell count is less than 250 /mm3 and treatment should be discontinued if the count remains less than 250 /mm3 for one month. Per manufacturer guidelines, Amevive should not be used concomitantly with other immunosuppressive agents or in patients currently receiving phototherapy. Amevive is contraindicated in patients with HIV/AIDs because it reduces CD4+ T-cell counts and, thus, may accelerate progression of HIV infection or increase complications of the disease.			1 year, lifetime limit of 180 days	
alglucerase	Symptomatic Gaucher's disease, Type 1	Patients less than 2 years old.	Diagnosis	Must be at least 2 years of age.		Lifetime	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.
alpha-1 proteinase inhibitor	Alpha-1 antitrypsin deficiency	Emphysema present that is caused by environment or cigarette smoking as causative factors, patients with selective IgA deficiencies (IgA less than 15 mg/dL) who have known antibodies against IgA (anti-IgA antibody), anaphylaxis to IgA products.	Diagnosis			Lifetime	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.
anakinra	rheumatoid arthritis, treatment refractory chronic infantile neurological, cutaneous and articular syndrome, graft versus host disease, Juvenile rheumatoid arthritis, sepsis syndrome	Patients who have not tried and failed at least one disease modifying antirheumatic drug (DMARD), patients with active infection	Dx: Adult Rheumatoid arthritis: 1. MD is a rheumatologist, AND 2. Patient has had an inadequate response to one or more disease modifying antirheumatic drugs (DMARDS): Methotrexate, Sulfasalazine, Cyclosporine, hydroxychloroquine, injectable gold, azathioprine, or penicillamine. 3. Patient is not currently using a Tumor Necrosis Factor (TNF) blocking agent or other biological agent such as Humira.			6 mo (refractory chronic infantile neurological, cutaneous and articular syndrome), 1 yr(all others)	

botulinum	All FDA-approved indications not otherwise excluded for Part D	Use for cosmetic purposes such as wrinkles	APPROVE AS REQUESTED if the Dx is any FDA-approved indication not overwise exclude for Part D, such as Achalasia, Bleharospasm, Cervical Dystonia, hyperhidrosis, Muscle Spasm for Patients w/Cerebral Palsy, Strabismus. For Dx of Migraine HA, approve if: 1) Prescriber is a Neurologist OR Pain Management specialist, 2) Dx is moderate to severe migraine (with or without aura), chronic daily headache, or chronic tension-type headache 3) and patient has a least 2 headaches a month 4)abortive medication is contraindicated or ineffective 5) patient has tried/failed at least 1preventative therapy within last 6 months (i.e. beta-blocker, antiepileptic, calcium channel blockers, etc.), 6) rebound headaches from medication overuse has been ruled out.			1 year	
chorionic gonadotropin human	All FDA-approved indications not otherwise excluded for Part D	Pregnancy or suspected pregnancy, Use for infertility or sexual dysfunction.	Category X –Human chorionic gonadotropin may cause fetal harm when administered to a pregnant woman. Diagnosis required	Must be at least 4 years of age		1 year	
darbepoetin	Anemia-chronic lymphoid leukemia, anemia in neoplastic disease due to chemotherapy (non-myeloid malignancy), anemia in neoplastic disease, anemia-multiple myeloma, anemia-myelodysplastic syndrome, anemia- Non-Hodgkin's lymphoma, anemia- chronic renal failure	Uncontrolled hypertension, known hypersensitivity to the active substance or any excipients, iron stores are inadequate, pre-treatment Hgb greater than 12 g/dl	Initiation of therapy: 1. Patients do not have uncontrolled hypertension 2. Patients do not have an allergy to any component of epoetin or allergy to mammalian cell derived products 3. Patients do not have an allergy to albumin 4. At least one of the below stated diagnosis and lab values For both epoetin and darbepoetin, patients must have one of the following diagnosis with specified lab values, Chronic renal failure requiring dialysis. Chronic renal failure not requiring dialysis with the following lab values: Hb less than10g/dL, HCT less than30%, TSAT greater than20%, Ferritin greater than100ng/dL, Non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy and the following lab values: Hb ?11g/dL, TSAT greater than20%, Ferritin greater than100ng/dL. For epoetin only, patients must have one of the following diagnosis with specified lab values: Zidovudine treated HIV patients with the following lab values: Zidovudine dose ?4,200mg/week, Endogenous erythropoietin levels ?500mU/mL, Ferritin greater than100ng/dL, TSAT gre			3 months	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage. The following information must be submitted in PA request: most recent hemoglobin (Hgb) labs, patient's weight, dosage, planned duration of therapy, is patient receiving iron supplementation? If not, request iron study lab values
desmopressin	Hemophilia A with factor VIII levels greater than 5%, neurohypophyseal diabetes insipidus, primary nocturnal enuresis, von Willebrand disease type 1 (mild to moderate) with factor VIII levels greater than 5%, diabetes insipidus caused by an adverse drug reaction, blood donation, carcinoma of bladder (adjunct), control of hemorrhage due to a surgical procedure, diagnosis of Cushing's syndrome, dengue, dense body defect, diagnosis of ectopic ureter, Ehlers-Danlos syndrome, facial rhytidoplasty, headache following lumbar puncture, hemoglobin SS disease with crisis, hemorrhage - thrombocytopenia, hemorrhage - uremia, impaired cognition, operation on thyroid gland, Osler hemorrhagic telangiectasia syndrome, renal colic, schizophrenia, urinary incontinence, urinary tract contrast procedure, urine concentration test	Patients with hypersensitivity to desmopressin acetate, patients with existing or history of hyponatremia, patients with moderate to severe renal impairment	Per manufacturer guidelines, desmopressin should not be used in patients with known hypersensitivity to desmopressin acetate, existing or history of hyponatremia or moderate to severe renal impairment.			1 year	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage. IV therapy is only approved in instances where oral therapy is neither appropriate or tolerable.
erlotinib	Treatment of locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen, treatment of pancreatic cancer in combination with gemcitabine, treatment of colorectal cancer, treatment of locally recurrent or metastatic squamous cell carcinoma of the head and neck, treatment of metastatic renal cell carcinoma, treatment of ovarian carcinoma	Concurrent use of platinum-based chemotherapy	Dosing or Quantity Limit Exception Approval Criteria: The prescribing physician must document that the patient has failed or is unresponsive to the lower dose or that the length of therapy dose limit is not meeting the clinical needs or the patient AND the dose/quantity requested is supported by one of the three CMS accepted compendia (DrugDex, USP or AHFS). The supporting documentation in such literature must be specific to that indication.			1 year	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage. ONLY APPLIES to NEW STARTS

erythropoietin	Reduction of allogenic blood transfusion in surgery patients, treatment of anemia due to: chronic renal failure, Zidovudine-treatment, trauma or surgical cause, congestive heart failure, chronic lymphoid leukemia, critical illness, radiation, during puerperium, epidermolysis bullosa, Hepatitis C in patients being treated with a combination of ribavirin and interferon alfa or ribavirin and peginterferon alfa, neoplastic disease due to chemotherapy (non-myeloid), neoplastic disease not due to chemotherapy, multiple myeloma, myelodysplastic syndrome, myelofibrosis, non-Hodgkin's lymphoma , prematurity, porphyria cutanea tarda, rheumatoid arthritis, beta Thalassemia, athletic performance enhancement, blood unit collection for autotransfusion, cancer, iron-overload from transfusion, sexual dysfunction, sickle cell anemia	Pre-treatment Hct greater than 36%, patients not receiving iron supplementation if iron stores are inadequate, unspecified diagnosis of "anemia", uncontrolled hypertension	FOR INITIAL AUTHORIZATION ALL FOUR MAJOR CRITERIA MUST BE MET. 1.) Anemia associated with one of the following: Chronic renal failure patients on dialysis, Chronic renal failure patients NOT on dialysis AND with hematocrit less than 30% or transfusion dependant and serum ferritin greater than100ng/ml transferrin sat.greater than20%. Endogenous Erythropoietin less than500mU/ml. Zidovudine-treated HIV-infected patients with endogenous erythropoietin level less than 500 mUnits/mL AND zidovudine dose is less than 4,200 mg/week. Serum ferritin greater than100ng/ml transferrin sat.greater than20%. Endogenous Erythropoietin less than500mU/ml. Concomitant chemotherapy treatment of non-myeloid malignancies (where anemia is not caused by other factors). Serum ferritin greater than100ng/ml transferrin sat.greater than20%. Endogenous Erythropoietin less than500mU/ml. Patients schedule to undergo elective, non-cardiac, non-vascular surgery with hemoglobin greater than10 g/dL but less than 13 g/dL 2.) Patients do not have uncontrolled hypertension 3.) Patients do not have allergy to any c			3 months	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage. Must send to PROF for review by a clinical pharmacist if diagnosis is chemo d/t Hep C, or anemia d/t Hep C, or Peg-Intron/Pegasys use. PROF SVS: medical justification will be required for doses that exceed 10,000 IU 3 times weekly (30,000 total per week)
etanercept	Moderately to severely active rheumatoid arthritis, moderately to severely active polyarticular juvenile rheumatoid arthritis (JRA) in patients with inadequate response to at least one disease-modifying antirheumatic drug, psoriatic arthritis, ankylosing spondylitis, moderate to severe chronic plaque psoriasis, autoimmune disorder of the inner ear, pain from bone metastases, Crohn's disease, graft versus host disease, heart failure, reactive hemophagocytic lymphohistiocytosis, severe, refractory hidradenitis suppurativa, Langerhans cell histiocytosis, myelosclerosis with myeloid metaplasia, myostitis, nephrotic syndrome, Pemphigoid, Sarcoidosis, Sjögren's syndrome, TNF receptor-associated periodic fever syndrome, uveitis, Wegener's granulomatosis, septic shock	Patients with sepsis or active infection	Diagnosis, Prior drug and/or non-drug therapy tried and failed, Confirmation if patient is currently using a Tumor Necrosis Factor (TNF) blocking agent such as Humira or Kineret. For psoriasis diagnosis, percent of body area affected.			1 year	
ethyol	Acute myeloid leukemia, Adverse effect of radiation therapy-radioiodine disturbance of salivary secretion, antineoplastic adverse reaction: myelosuppression, nephrotoxicity, neurotoxicity prophylaxis, cicplatin-induced ototoxicity prophylaxis, Bone marrow transplant adjunct, cisplatin neuropathy prophylaxis for non-small cell lung cancer and advanced ovarian cancer, drug-induced neutropenia prophylaxis, drug-induced xerostomia, hypercalcemia of malignancy, malignant melanoma adjunct, mucositis following radiation therapy, myelodysplastic syndrome, myelosuppression radiation-induced disorder, nephrotoxicity prophylaxis, non-small cell lung cancer adjunct, radiation-induced xerostomia post-operative in head and neck cancers prophylaxis, radiation proctitis, radiation respiratory disease		APPROVE for nephrotoxicity prophylaxis in patients receiving cisplatin for advanced ovarian cancer or non-small cell lung carcinoma: APPROVE for xerostomia prophylaxis in patients undergoing post-operative radiation treatment of head and neck cancer, where the radiation port includes a substantial portion of the parotid glands: APPROVE for bone marrow suppression prophylaxis, nephrotoxicity prophylaxis, or neurotoxicity prophylaxis in patients receiving antineoplastic agents and/or fractionated radiation therapy.			1 year	
filgrastim	Agranulocytosis, AIDS - Neutropenia, Aplastic anemia, Febrile neutropenia, Febrile neutropenia, In myeloid malignancies following bone marrow transplant - Prophylaxis, Febrile neutropenia, In non-myeloid malignancies following myelosuppressive chemotherapy - Prophylaxis, Febrile neutropenia, In non-myeloid malignancies following progenitor-cell transplantation - Prophylaxis, Febrile neutropenia, In patients with acute myeloid leukemia receiving chemotherapy - Prophylaxis, Glycogen storage disease, Harvesting of peripheral blood stem cells, Infectious disease - Prophylaxis, Leukemia, Meningitis, Mucositis following chemotherapy, Myelodysplastic syndrome, Neutropenia - Pre-eclampsia, Neutropenic disorder, chronic (Severe), Symptomatic, Neutropenic disorder - Renal transplant disorder, Pneumonia, Septicemia of newborn, Shwachman syndrome, Sinusitis, Tuberculosis	Diagnosis of any of the above indications without current weight, recent CBC with diff. or ANC, documented chemotherapy induced neutropenia, dose, duration, and target ANC/WBC for therapy, ANC of greater than10,000/mm3	Diagnosis of the any of the indications and the following information must be obtained before approval is authorized: patient's weight, most recent (within the past week) CBC with differential or absolute neutrophil count (ANC) (for chemotherapeutic regimens where patient has had history of significant neutropenia while on chemotherapy, provide CBC with diff. or ANC of last chemo cycle where patient experienced neutropenia), dose to administer, duration of therapy, target ANC or target WBC. Clinical trial data shows no clinical benefit seen once an ANC is greater than10,000/mm3.			7 days maximum (bone marrow ablation), 14 days maximum per cycle (all other diagnoses)	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.
fondiparinux	All FDA-approved indications not otherwise excluded for Part D		Diagnosis			7 days - 9 mo (diagnosis dependent)	

gefitinib	All FDA-approved indications not otherwise excluded for Part D	Treatment with gefitinib in patients that have not previously tried and failed platinum-based and docetaxel chemotherapies, pregnancy	Distribution of gefitinib is limited to the following patients under the Iressa Access Program: patients currently receiving and experiencing benefit from the drug, patients who previously have received and experienced benefit from the drug, and previously enrolled or new patients in non-Investigational New Drug (IND) clinical trials approved by an institutional review board prior to June 17, 2005. This is due to the fact that no survival benefit has been demonstrated for gefitinib therapy in patients with advanced non-small cell lung cancer. Gefitinib may cause fetal harm. Neonatal mortality soon after parturition, reduction in number of offspring born alive, and reduced fetal weight demonstrated in animals. Patient must have Non-small cell Lung Cancer for BOTH Metastatic or Advanced form. Must have failed on Platinum based therapy AND Docetaxel therapy. Does not have to be tested for EGRF or erbB-2 expression. Should be Monotherapy, if not: Radiation and HRT is approved but without concommitant chemotherapy.			1 year	
glatiramer	Treatment of relapsing-remitting or chronic progressive multiple sclerosis		A neurologist should be consulted to review the patient and determine the need as opposed to other options. It is associated with numerous adverse reactions (chest pain, CNS pain, pruritus, rash, nausea, diarrhea, injection site reaction, etc.) and additional guidance from a neurologist will be helpful in determining the most effective therapy for the patient.	Must be at least 18 year of age	Prescribing physician must be a neurologist	1 year	
imatinib	Acute lymphoid leukemia, Philadelphia chromosome-positive, newly diagnosed, as part of combination chemotherapy, Acute lymphoid leukemia, Relapsed/Refractory Philadelphia chromosome positive,Chronic eosinophilic leukemia, Chronic myeloid leukemia, Chronic myeloid leukemia, Philadelphia chromosome-positive, accelerated phase or blast crisis, Chronic phase chronic myeloid leukemia, Philadelphia chromosome-positive, after failure of interferon-alpha therapy, Chronic phase chronic myeloid leukemia, Philadelphia chromosome-positive, newly diagnosed, Chronic phase chronic myeloid leukemia, Philadelphia chromosome-positive, recurrence after stem cell transplant, Dermatofibrosarcoma protuberans, Unresectable, recurrent and/or metastatic, Gastrointestinal stromal tumor, malignant, Kit (CD117)-positive, unresectable and/or metastatic, Hypereosinophilic syndrome, Metastatic melanoma, Monotherapy, Myelodysplastic syndrome, with PDGFR (platelet-derived growth factor receptor) gene rearrangement, Myelofibrosis, Myeloproliferative disorder, chronic, with PDGFR (platelet-derived growth factor receptor) gene rearrange	Pregnancy	DX: acute lymphocytic leukemia (ALL), chronic myelogenous leukemia (CML), desmoid tumor, gastrointestinal stromal tumors (GIST). APPROVE AS REQUESTED for Hematology/Oncology or consult with Hem/Onc		Prescribing physician must be a hematology/oncology specialist or have consulted with one	1 year (maximum treatment duration 5 years)	ONLY APPLIES to NEW STARTS
imiglucerase	Chronic non-neuropathic Gaucher's disease		Diagnosis of non-neuropathic Gaucher's disease with one of the following: anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly, it has been designated an orphan product for use in the treatment of types I, II, and III Gaucher's disease, safety and effectiveness have not been established in children less than 2 years old.	Patient must be at least 2 years of age		1 year	
infliximab	Ankylosing spondylitis, Arthritis - Arthropathy in Crohn's disease, Behcet's syndrome, Congestive heart failure, Crohn's disease, Fistulizing, Crohn's disease (Moderate to Severe), In patients with an inadequate response to conventional therapy, Gastrointestinal tract transplantation - Transplanted organ rejection, Giant cell arteritis, Graft versus host disease, Hidradenitis suppurativa, Severe, refractory, Inflammatory bowel disease, Juvenile chronic arthritis, Juvenile idiopathic arthritis (Severe), Refractory to other therapies, Multiple sclerosis, Necrobiosis lipoidica diabeticorum, Plaque psoriasis, chronic (Severe), Psoriasis, Psoriasis with arthropathy, Pyoderma gangrenosum, Rheumatoid arthritis, Monotherapy, Rheumatoid arthritis (Moderate to Severe), In combination with methotrexate, SAPHO syndrome (Severe), Refractory, Sarcoidosis, Sprue, Refractory, Subcorneal pustular dermatosis, Systemic onset juvenile chronic arthritis, Ulcerative colitis, In patients with an inadequate response to conventional therapy, Uveitis, Refractory - Adjunct, Wegener's granu		Diagnosis, Prior drug and/or non-drug therapy tried and failed and length of therapy, For psoriasis diagnosis, percent of body area affected.			1 year	

interferon alfa-2b	AIDS-related Kaposi's sarcoma, Allergic granulomatosis angiitis, Angioblastoma, Breast cancer, Carcinoid tumor, Carcinoma of bladder, Superficial, Chronic myeloid leukemia, Cold autoimmune hemolytic anemia, Condyloma acuminatum, Involving external surfaces of the genital and perianal areas, Follicular lymphoma, In conjunction with non-anthracycline chemotherapy, Follicular lymphoma, Initial treatment in conjunction with anthracycline-containing combination chemotherapy, Hairy cell leukemia, Hepatitis C, acute, Hepatitis C, chronic, In patients with compensated liver disease, Hepatitis C - HIV infection, Hypereosinophilic syndrome, Laryngeal papillomatosis, Liver carcinoma, Malignant melanoma, Adjuvant to surgical therapy for high-risk patients, Malignant melanoma, Metastatic, Medullary thyroid carcinoma, Multiple myeloma, Mycosis fungoides, Neoplasm of conjunctiva - Neoplasm of cornea, Ovarian cancer, Peyronie's disease, Polycythemia vera, Pruritus of skin, Renal cell carcinoma, Skin cancer, Subacute sclerosing panencephalitis,	Not approvable for Hepatitis A - not indicated for this. Autoimmune hepatitis, decompensated liver disease, prior hypersensitivity to any interferon alfa preparations or components	Approved for the following diagnoses and duration of therapy:1) Hairy cell leukemia 2) Malignant melanoma 3) Condylomata acuminate AND tried and Aldara, Condylox, Podofilox or other genital/perianal wart therapies for 12-16 weeks. a. May approve for a second course if response is not satisfactory. b. May approve for additional courses of treatment if greater than 10 condylomata 4) AIDS-related Kaposi's sarcoma and must treat until patient is stable and no further evidence of tumor, 5) Chronic hepatitis B if the following criteria are met: 1. Hepatitis B duration less than 4 years, AND 2. HBeAg positive, AND 3. Hepatitis B DNA positive, AND 4. Elevated liver enzymes, AND 5. GI consult completed		Prescribing physician must be gastroenterologist, hepatologist, transplant specialist or infectious disease specialist	1 yr chronic Hep C, 6 mo-1yr Hep B	
interferon alfacon-1	All FDA-approved indications not otherwise excluded for Part D	Not approvable for Hepatitis A or B	Approved for the following diagnoses and duration of therapy:1) Hepatitis C infection ff MD is any of the following specialist: Gastroenterologist, Hepatologist, Transplant specialist, Infectious Disease specialist) AND the following labs are provided: HCV RNA levels, AST/ALT levels, Viral genotype, with or without results of liver biopsy.		Prescribing physician must be gastroenterologist, hepatologist or infectious disease specialist	1 yr chronic Hep C, 6 mo-1yr Hep B	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage. Coverage duration equal to 1 year with diagnosis of chronic Hep C, 6 months with Hepatitis B if: patient is less than 60 years old, MD is a gastroenterologist, infectious disease specialist or hepatologist, persistently elevated ALT (greater than 6 months) (normal 0 -45), positive HCV RNA, liver biopsy showing either portal or bridging fibrosis, and at least moderate degrees of inflammation and necrosis, 1 year with Hepatitis B if: all above criteria is met (for 6 month approval) and very high HCV RNA level (greater than 2million copies/ml), HCV genotype 1, or cirrhosis on biopsy (with otherwise high likelihood of response)
interferon alfa-n3	All FDA-approved indications not otherwise excluded for Part D		APPROVE for the treatment of refractory or recurring external condylomata acuminata (genital or venereal warts): Intralesional dosage: Adults: 0.05 ml (250,000 IU) per wart intralesionally twice weekly for up to 8 weeks. The maximum recommended dose per treatment session is 0.5 ml (2.5 million IU). The minimum effective dose of interferon alfa-n3 has not been established. Genital warts usually begin to disappear after several weeks of treatment. Treatment should be continued for a maximum of 8 weeks. In clinical trials, many patients who had a partial resolution of warts during treatment experienced further resolution of their warts after cessation of treatment. Of the patients who had complete resolution, half had complete resolution by the end of treatment and half had complete resolution of venereal warts during the 3 months after treatment cessation. Thus, it is recommended that no further treatment be given for 3 months after the initial 8-week course unless the lesions enlarge or new warts appear. Studies to determine the efficacy of a second treatment course have not been conducte			6mo-1yr (diagnosis dependent)	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage. Coverage Duration: Dx: Chronic Hep C Approve x 24 weeks if: 1) Patient is less than 60 years old, AND 2) MD is a gastroenterologist, infectious disease specialist or hepatologist, AND 3) Persistently elevated ALT (greater than 6 months) (normal 0 -45), AND 4) Positive HCV RNA, AND 5) Liver biopsy showing either portal or bridging fibrosis, and at least moderate degrees of inflammation and necrosis, AND Limit #2 kits per month x 24 weeks (6 months). If requesting for 48 weeks duration, approve if: 1) All above criteria is met (for 24 wk approval), AND 2) Very high HCV RNA level (greater than 2million copies/ml), OR 3) HCV genotype 1, OR 4) Cirrhosis on biopsy (with otherwise high likelihood of response) Limit #2 kits/mo x 48 weeks (12 months).
interferon beta-1a	All FDA-approved indications not otherwise excluded for Part D	Hypersensitivity to human albumin (Avonex(R) lyophilized powder vials and Rebif(R) prefilled syringes), hypersensitivity to natural or recombinant interferon	Approvable for treatment of MS when written by or consulted on by a neurologist.		Prescribing physician must be a neruologist	1 year, only extend for 1 month at a time beyond this duration	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.
interferon beta-1b	All FDA-approved indications not otherwise excluded for Part D	Hypersensitivity to E. coli-derived products, natural or recombinant interferon beta, albumin human or any other component of the formulation	Approvable for treatment of MS when written by or consulted on by a neurologist.		Prescribing physician must be a nuerologist	1 year	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.

interferon gamma-1b	All FDA-approved indications not otherwise excluded for Part D	Hypersensitivity to interferon gamma, E. coli derived proteins, or any component of the formulation	APPROVE as requested for diagnoses listed below. 1) Chronic granulomatous disease 2) Severe, malignant osteoporosis to delay the time to disease progression 3) Idiopathic pulmonary fibrosis 4) Adjuvant treatment of refractory mycobacterium infection due to Mycobacterium avium complex (MAC) in conjunction with traditional antimycobacterial agents 5) Ovarian cancer			1 year	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.ONLY APPLIES to NEW STARTS
itraconazole	All FDA-approved indications not otherwise excluded for Part D	Coadministration with cisapride, dofetilide, oral midazolam, pimozide, levacetylmethadol, quinidine, lovastatin, simvastatin, triazolam, ergot alkaloids metabolized by CYP3A4 (such as dihydroergotamine, ergometrine, ergotamine and methylergometrine), congestive heart failure or history of (capsules for treatment of onychomycosis), pregnant women or women contemplating pregnancy (capsules for treatment of onychomycosis), hypersensitivity to itraconazole	IF Dx equal to Onychomycosis member must have infection documentated by a positive KOH or other lab test PLUS one of the following, be a diabetic OR immunocomprised, OR have repeated ingrown nails requiring surgery, OR have pain severe enough that limits activities of daily living or interfers with work.			7 days - 1 yr (diagnosis dependent)	Although no PA is required for the preferred alternative, please provide dosing limits for educational purposes. Edits are not required. Approval duration: 7 days (superficial mycoses), 2 weeks (oropharyngeal candidiasis), 5 weeks (fingernail and esophageal candidiasis), 12 weeks (toenail with or without fingernail in adults or mild disseminated histoplasmosis in AIDS), 5 months (toenail with or without fingernail in adolescents and children), 12 months (chronic pulmonary or progressive disseminated histoplasmosis in AIDS), 18 months (cutaneous or systemic sporotrichosis), 1 year (prophylaxis of indicated fungal infections in HIV patients)
laronidase	Treatment of Hurler and Hurler-Scheie forms of mucopolysaccharidosis Type I (MPI) and the Scheie form of MPI (moderate to severe symptoms only)	Patients outside of the recommended age range.	Diagnosis	Patients must be greater than 5 years old		1 year	
lenalidomide	Multiple myeloma in combination with dexamethasone as first-line therapy, Multiple myeloma in combination with dexamethason in patients who have received at least 1 prior therapy, Myelodysplastic syndrome - transfusion dependent deletion 5g abnormality low or immediate-1 risk		APPROVE FOR 6 MONTHS if the following criteria is met: Being prescribed by Hematologist/Oncologist. Patient has tried thalidomide and has failed due to peripheral neuropathy. Diagnosis must be: MDS: myelodysplastic syndromes. Dosage is 10mg daily. Multiple Myeloma: 25 mg/day with water orally administered as a single 25 mg capsule on days 1 through 21 of repeated 28-day cycles. Patients should not break, chew, or open the capsules. The recommended dosage of dexamethasone is 40 mg/day on days 1 through 4, 9 through 12, and 17 through 20 of each 28-day cycle for the first 4 cycles of therapy and then 40 mg/day orally on days 1 through 4 every 28 days. Dosing is continued or modified based upon clinical and laboratory findings.			6 months	ONLY APPLIES to NEW STARTS
leuprolide	ACTH-dependent Cushing's syndrome, Amenorrhea, Induction, Anemia - Uterine leiomyoma, Preoperatively, with iron therapy, Breast cancer, Catamenial pneumothorax, Central precocious puberty, Chronic pelvic pain of female, Endometriosis, Growth hormone deficiency, Hypersexuality state, Irritable bowel syndrome, Malignant neoplasm of endometrium of corpus uteri, Ovarian cancer, Premenstrual syndrome, Prostate cancer, Prostate cancer, Advanced (palliative treatment), Prostate cancer, Neoadjuvant treatment, Uterine leiomyoma, Carcinoma of prostate, Metastatic breast cancer	Patients that fail to see the required specialty doctor and receive the required diagnosis, patients that are under 18 for all diagnoses, except for central precocious puberty, hypersensitivity to leuprolide, gonadotropin releasing hormone (GnRH), GnRH analogs or any of the excipients in the formulations, leuprolide implant dosage form in women or pediatrics patients, pregnancy, 4-month, 30-mg formulation is not for use in women, CHF or other conditions requiring severe sodium restriction, Excluded for infertility and in vitro fertilization use.	Must have a dx of at least one: Prostatic Carcinoma, Endometroisis, Uterine Leiomyomata (Fibroids), Central Precocious Puberty, Amenorrhea.	Patient must be at least 18 years of age for all diagnoses, except for central precocious puberty	Diagnosis of anemia in uterine leiomyoma in a patient that has not undergone surgery to correct, must be prescribed by an OB-GYN doctor. Diagnosis of endometriosis in an adult female, must be prescribed by an OB-GYN doctor. Diagnosis of advanced prostate cancer with the need for palliative treatment in an adult males greater than18 years of age as an alternative to orchiectomy, must be prescribed by an oncologist or urologist.	3 mo - 2 yrs (diagnosis dependent)	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage. PA must be reviewed by a clinical pharmacist if requesting for a second treatment course for endometriosis. Coverage duration: 2 yrs(advanced prostate cancer) 6 mo(endometriosis) 3 mo(uterine leiomyoma), 1 yr(central precocious puberty)

linezolid	Community acquired pneumonia, Endocarditis - Infection due to enterococcus, Febrile neutropenia, Infection of skin AND/OR subcutaneous tissue, Complicated, Infection of skin AND/OR subcutaneous tissue, Uncomplicated, Methicillin resistant Staphylococcus aureus infection, Mycobacteriosis, Nosocomial pneumonia, Vancomycin-resistant Enterococcus faecium infection	Patients that are currently myelosuppressed due to any cause	Diagnosis including micro-organism causing the infection		Presribing physician must be an infectious disease specialist	14 days. Addnl 14 days if confirmed vancomycin-resistant Enterococcus faecium infection	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage. IV therapy is only approved in instances where oral therapy is neither appropriate or tolerable.
octreotide	Acromegaly, Inadequate response to or ineligible for surgery, radiation, or bromocriptine mesylate, AIDS - Diarrhea, Bleeding esophageal varices, Bowel obstruction, Breast cancer, Carcinoid syndrome, Metastatic - symptomatic treatment, Cardiomyopathy, Chylothorax, Colorectal cancer, Cryptosporidiosis, Cushing's syndrome, Diabetes mellitus, Diabetic retinopathy - Prophylaxis, Diarrhea - Graft versus host disease, Disorder of colon - Hemorrhage of colon - Portal hypertension, Drug-induced hyperinsulinemia, Drug-induced hypoglycemia, Dumping syndrome, Gastrointestinal fistula, Glucagonoma, Hypercalcemia - Adjunct, Hypotension, Postprandial, Hypothalamic obesity, Insulinoma, Lymphorrhea, Macular retinal edema, Malignant tumor of thymus, Mesenteric vascular insufficiency, Necrotizing pancreatitis, acute - Adjunct, Neonatal hypoglycemia, Neoplasm of gastrointestinal tract - Neoplasm of pancreas, uroendocrine tumor - Adjunct, Neuroendocrine tumor - Nuclear medicine imaging procedure, Non-infective diarrhea, Pancreatic pleural effusion, Peptic ulcer disease - Adjunct, Pituitary adenoma, Pleural effusion a		APPROVE any of the following Dx: Acromegaly, Carcinoid, Diarrhea, Dumping Syndrome, Enterocutaneous fistula, Espophagel varices OR Variceal Bleeding, Hyperthyroidism, Ileostomy-associated diarrhea, Insulinoma, Orthostatic hypotension, Pancreatic fistula, Portal hypertension, Short bowel syndrome, Upper GI bleeding, VIPoma			1 year	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.
omalizumab	Allergic asthma, Allergic rhinitis - Prophylaxis, Allergy to peanuts, Latex allergy, Subcutaneous immunotherapy - Adjunct		All criteria from 1, 2, AND 3 MUST be met for approval: (1) MD must be allergic asthma specialist. Age must be greater than 12, Weight must be less than 150 kg. Dx must be BOTH Allergic Asthma (evidence of atopy) AND moderate/severe persistent asthma. Must show evidence of reversibility (greater than12% FEV1 OR greater than20% PEF improvement). AND IgE level greater than 30 (usual range 30-700) IU/ml. (2) Patient must be high-risk: Either uncontrolled on med-high dose ICS for 3 months, OR controlled on high dose inhaled or oral CS, OR Contraindication to high dose ICS AND long acting beta agonists.... AND documentation of hospital stays, missed days, night symptoms, etc. (3) Documentation of: Attempted meds in last year (w/date), presence/management of confounding morbidities, environmental control issues addressed, Pt compliance/method used.			6 months	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.
oprelvekin	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, Wiskott-Aldrich syndrome		Approve if: Dx: Chemo-induced thrombocytopenia AND Platelet count less than 100,000.			21 days per treatment cycle	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage. Platelet count must be less than100,000 and must be submitted with PA request. Once platelets reach 100,000 or greater, it will no longer be approved.
pegfilgrastim	Febrile neutropenia, In patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia, Prophylaxis	Patients with hypersensitivity to E coli-derived proteins, filgrastim, or pegfilgrastim, or any component of the product	Approve for the following Dx: 1. Chemotherapy-induced neutropenia prophylaxis in patients receiving myelosuppressive chemotherapy and to decrease the incidence of febrile neutropenia in patients with a previous episode of febrile neutropenia (secondary prophylaxis) 2. Primary prophylaxis in patients receiving chemotherapy regimens with an expected incidence of febrile neutropenia greater thanequal to 40% or in the presence of comorbid factors			1 year	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage. Forward to clinical pharmacist to review.
peginterferon alfa-2a	Active type B viral hepatitis, chronic, Hepatitis C, chronic, In patients with compensated liver disease, Hepatitis C, chronic, In patients with compensated liver disease - HIV infection, Hepatitis C - HIV infection, Renal cell carcinoma		Approved for the following diagnoses and duration of therapy: 1) Hepatitis C infection ff MD is any of the following specialist: Gastroenterologist, Hepatologist, Transplant specialist, Infectious Disease specialist) AND the following labs are provided: HCV RNA levels, AST/ALT levels, Viral genotype, with or without results of liver biopsy.			1 yr chronic Hep C, 6 mo-1yr Hep B	

peginterferon alfa-2b	Condyloma acuminatum, Treatment-resistant - HIV infection, Essential thrombocythemia, Hepatitis C, chronic, Hepatitis C - HIV infection, Multiple myeloma		Approved for the following diagnoses and duration of therapy: 1) Hepatitis C infection ff MD is any of the following specialist: Gastroenterologist, Hepatologist, Transplant specialist, Infectious Disease specialist) AND the following labs are provided: HCV RNA levels, AST/ALT levels, Viral genotype, with or without results of liver biopsy.			1 yr chronic Hep C, 6 mo-1yr Hep B	
pegvisomant	Acromegaly, Second-line therapy	Hypersensitivity to pegvisomant, polyethylene glycol, latex or any component of the formulation	Acromegaly who have had inadequate responses to or are not candidates for surgical resection, pituitary irradiation, and/or other medical therapies because considered second line therapy			1 year	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.
pulmonary arterial hypertension agents	All FDA-approved indications not otherwise excluded for Part D	Requests for uses other than each medications' specific indications, requests for titration schedules other than those proven to be safe and effective without documentation of failures at lower doses, quantities, or time schedules, initiation of therapy without documentation of other failed therapies, Letairis: known or suspected pregnancy, Tracleer: concomitant therapy with cyclosporine or glyburide, hypersensitivity to bosentan or any component of the film-coated tablet, pregnancy, Flolan: chronic use in congestive heart failure due to severe left ventricular systolic dysfunction, hypersensitivity to epoprostenol sodium or to any of its components, chronic use in patients who may develop pulmonary edema during initiation, Remodulin: hypersensitivity to treprostinil or any of its components	Diagnosis of PAH, as well as FDA approved indication for individual medications, documented that the patient has failed or is unresponsive to prior therapy at a lower dose or that the length of that therapy dose limit was not meeting the clinical needs of the patient AND the dose/quantity requested must be supported by one of the three CMS accepted compendia (DrugDex, USP or AHFS) or a published, peer reviewed article found on Medline with the supporting documentation in such literature being specific to that indication. These products are very difficult to maintain safe and effective dosages and should, therefore, only be used when absolutely necessary. Once initiated, this medication therapy becomes a lifelong commitment if it provides benefit to the patient without intolerable adverse effects.			Lifetime	
sargramostim	All FDA-approved indications not otherwise excluded for Part D	Chemotherapy or radiotherapy within 24 hours or concomitantly, excess leukemic myeloid blasts in the bone marrow or blood (10% or greater), hypersensitivity to granulocyte-macrophage colony-stimulating factor (GM-CSF) or yeast-derived products, allergic or anaphylactoid reactions to the medication in the past , severe preexisting cardiac disease	APPROVE for patients with low WBC counts for the following uses: 1) Acceleration of myeloid recovery in patients with Non-Hodgkin's lymphoma (NHL), Acute lymphoblastic leukemia (ALL) and Hodgkin's disease undergoing autologous bone marrow transplantation (BMT), 2) BMT failure or engraftment delay. 3) Induction chemotherapy in acute myelogenous leukemia (AML) (Chemotherapy for AML cancer treatment, patients receiving myelosuppressive chemotherapy agents), 4) Mobilization and following transplantation of autologous PBPC (Peripheral Blood Progenitor Cell (PBPC) Collection). After myeloablative chemotherapy, transplantation of an increased number of progenitor cells leads to a more rapid engraftmant, decreasing need for supportive care, 5) Myeloid reconstitution after Allogeneic Bone Marrow Transplantation. Unlabeled (but approvable) Uses: 1) To increase White Blood Cell Counts in patients with myelodysplastic syndromes and in AIDS patients receiving zidovudine, 2) For myelosuppressive chemotherapy treated patient and preleukemic patients, 3) Aplastic Anemia, 4) To decre	Patients requiring prophylaxis of febirle neutropenia in acute myelogenous leukemia following induction chemotherapy must be at least 55 years of age, other diagnoses do not specify an age restriction		1 year	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.
somatropin	growth hormone deficiency, renal function impairment with growth failure, dwarfism - Noonan's syndrome, decreased body growth - Prader-Willi Syndrome, dwarfism - short stature homeobox-containing gene (SHOX) deficiency, dwarfism - Turner's Syndrome, dwarfism, idiopathic, short bowel syndrome, cardiomyopathy, Crohn's disease, diabetic foot ulcer, hyperinsulinism, fat maldistribution associated with HIV, small for gestational age fetus, cachexia associated with AIDS	Growth promotion in pediatric patients with closed epiphyses, progression of any underlying intracranial lesion or actively growing intracranial tumor, acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure, evidence of active malignancy, active proliferative or severe nonproliferative diabetic retinopathy, use in patients with Prader-Willi syndrome without growth hormone deficiency (except Genotropin®) or in patients with Prader-Willi syndrome with growth hormone deficiency who are severely obese or have severe respiratory impairment, children with: constitutionally delayed growth and development (i.e., delayed skeletal maturation with normal growth velocities and rates of bone age advancement, members who are at the lowest 5% of the growth curve at age 3), steroid-induced growth failure, kidney transplant recipients, down syndrome, Fanconi's syndrome, Bloom syndrome, chromosomal and genetic disorders, adults with: chronic fatigue syndrome, fibromyalgia, obesity, athletic performance enhan	NEW THERAPY: Children: Criteria 1, 2 or 3 are required PLUS one below for approval x 1 year. 1. Child has hypopituitarism and hypoglycemia. 2. Child has failed two provocative growth hormone tests. 3. Child is to be treated for short stature associated with Turner Syndrome. PLUS ONE OF THESE A) A height of greater than 2.5 standard deviations below the median for age. B) A yearly growth rate of less than 4.5 cm/yr. C) A bone age of 2 standard deviations below chronological age. D) For Turner's Syndrome only - must supply height information- 1. Present height below 5th percentile 2. A height of greater than 2.0 standard deviations below the median for age. If none of the information above is provided send to Clinical Pharmacist. Adults (new therapy) MD must provide one of the following diagnosis: 1. Adult growth hormone deficiency 2. Cachexia or 3. HIV / AIDS wasting, or 4. Short bowel syndrome. If diagnosis is growth hormone deficiency, MD must document failure of two growth hormone tests. If diagnosis is cachexia or HIV / AIDS wasting, must answer YES to patient receiving concomitant an			4 weeks (adults with short bowel syndrome), 1 year (all other diagnoses)	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.

testosterone	Anemia, Antineoplastic adverse reaction - Leydig cell failure in adult, Anxiety, Breast cancer, Burn, Severe - Adjunct, Carcinoma of prostate, Cluster headache, Cognitive function finding, Congenital hypoplasia of penis, Contraception, Male, Coronary arteriosclerosis, Deficiency of testosterone biosynthesis, Female, Delayed puberty, Male, Depression, Female-to-male transsexual - Gender identity disorder, Hormone replacement therapy, Postmenopausal, Hypogonadism, Male infertility, Metastatic breast cancer, Female, Osteoporosis, Male, Portal cirrhosis, Postmenopausal osteoporosis - Prophylaxis, Sexual disorder, Weight gain	Male patients with normal or above normal testosterone levels (normal equal to 270-1070 ng/dl or 9.3-37 mmol), breast cancer in males, hypersensitivity to testosterone or any component of the product, pregnancy, known or suspected prostate cancer, use of the gel or patch in women	No form of this medication should be used recreationally, can also be approved for AIDS wasting			1 year (AIDS wasting), as requested for hypogonadism	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.
tretinoin (topical)	Acne scar, Acne vulgaris, Acne vulgaris, Combination therapy, Alopecia areata, Black hairy tongue, Chemical peeling of skin lesion, Chloasma, Disorder of skin pigmentation, Dysplasia of cervix, Ephelides, Fine wrinkles on face, With comprehensive skin care and sunlight avoidance programs - Adjunct, Geographic tongue, Hyperkeratosis, Hyperpigmentation of skin, Facial mottling, with comprehensive skin care and sunlight avoidance programs - Adjunct, Kaposi's sarcoma, Keloid scar, Leukoplakia, Malignant melanoma, Osteoma cutis, Miliary, Roughness of skin, Facial tactile roughness, with comprehensive skin care and sunlight avoidance programs - Adjunct, Senile lentigo, Systematized epidermal nevus, Systemic sclerosis, Ultraviolet-induced change in normal skin, Wound finding (Mild), Xerophthalmia	Diagnosis of acne vulgaris without trying and failing at least 1 preferred alternatives (such as generic acne products - erythromycin/benzoyl peroxide, clindamycin, etc), use for cosmetic purposes (hyperpigmentation/age spots, wrinkles, tactile roughness of the skin, sun damage, etc.)	Patients diagnosed with ACNE or other non-cosmetic diagnosis			1 month (warts/actinic keratosis), open-ended (acne vulgaris)	
triptorelin	Carcinoma of pancreas, Carcinoma of prostate, Carcinoma of prostate, Palliative treatment, advanced disease, Central precocious puberty, Dwarfism, Idiopathic, Endometrial hyperplasia, Endometriosis, Fibrocystic disease of breast, Growth hormone deficiency, hyperandrogenization syndrome, Metastatic breast cancer, Ovarian carcinoma, Uterine leiomyoma	Hypersensitivity to triptorelin or any other component of the product, hypersensitivity to any other luteinizing hormone-releasing hormone (LHRH) or LHRH agonist, existing or potential pregnancy	Dx: Breast cancer, Prostate cancer AND prescriber is Hematology/Oncology or consult with Hem/Onc specialist. Non-cancer Diagnosis: Endometriosis, Precocious puberty, Uterine leiomyomata.		Prescribing physician must be a hematology/oncology specialist or have consulted with one	1 year	Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage. Can be reviewed and approved by a clinical pharmacist if therapy exceeds maximum allowable cost. Diagnosis of infertility requires confirmation and must be forwarded to a clinical pharmacist.