

CY 2010 Prior Authorization Criteria

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Actemra	All FDA-approved indications not otherwise excluded from Part D.	N/A	1. Diagnosis of moderate to severe, active adult rheumatoid arthritis. 2. Inadequate response to at least ONE of the following medications (Sub-Q TNF inhibitors)OR does the patient have a contraindication to ALL of the following medications: Humira, Cimzia, Enbrel, Simponi.	N/A	N/A	Length of therapy	N/A
Afinitor	All FDA-approved indications not otherwise excluded from Part D.	N/A	N/A	N/A	N/A	Length of therapy	Failure of treatment with sunitinib or sorafenib.
Amitiza	All FDA-approved indications not otherwise excluded from Part D	N/A	Chronic idiopathic constipation or irritable bowel syndrome with constipation in women: Failure to polyethylene glycol or lactulose.	Chronic idiopathic constipation, IBS: 18 years and older.	N/A	Chronic idiopathic constipation, IBS: 12 months	N/A
Ampyra	All FDA-approved indications not otherwise excluded from Part D.	N/A	1. Diagnosis of MS 2. Moderate walking disability associated with MS, but maintains the ability to walk. 3. Trial and failure to physical therapy	N/A	N/A	Length of Therapy	N/A

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Anadrol-50	All FDA-approved indications not otherwise excluded from Part D	N/A	Acquired Aplastic Anemia: History of failure, or used in combination with, antilymphocyte globulin or both antilymphocyte globulin and corticosteroid treatment. Hypoplastic Anemia: Diagnosis of hypoplastic anemia due to myelotoxic drugs. Failure to an erythropoietic stimulating agent. Pure Red Cell Aplasia: Failure to immunosuppressive therapy. Chronic Renal Failure: Failure to an erythropoietic stimulating agent.	N/A	N/A	All uses: 12 months. Except Hypoplastic Anemia: Length of therapy.	N/A

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Avastin	All FDA-approved indications not otherwise excluded from Part D.	Non-Small Cell Lung Cancer: Squamous cell histology. History of hemoptysis. CNS metastases.	Colorectal Cancer: Diagnosis of metastatic colorectal cancer. Used in combination with 5-FU, or oxaliplatin plus capecitabine, or capecitabine. Non-Small Cell Lung Cancer: Diagnosis of unresectable locally advanced recurrent or metastatic NSCLC. Used in combination with paclitaxel and carboplatin. Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with interferon-alpha or refractory to either interferon alpha or interleukin-2. Breast Cancer: Diagnosis of metastatic breast cancer. Used in combination with paclitaxel. Age-related Macular Degeneration: Failure to FDA-approved therapies or likely to have greater benefit from the use of intravitreal bevacizumab.	N/A	Renal Cell Cancer, Breast Cancer: Prescribed by or in consultation with an oncologist. ARMD: Prescribed or recommended by retina specialist	Colorectal Cancer, NSCLC, Renal Cell Cancer, Breast Cancer, ARMD: Length of therapy.	Approve for continuation of prior therapy.
Cellcept (IV)	All FDA-approved indications not otherwise excluded from Part D.	N/A	Transplant: Patient received a renal (kidney), cardiac (heart), or hepatic (liver) transplant. Patient is unable to take oral formulations of mycophenolate. Lupus nephritis: Diagnosis of lupus nephritis. Failure to combination therapy with corticosteroids and cyclophosphamide. Patient is unable to take oral formulations of mycophenolate.	N/A	N/A	Transplant, Lupus nephritis: Length of therapy.	Subject to Part B vs. Part D review (not limited to new starts only). Approve for continuation of prior therapy if Part D.
Cellcept Suspension	All FDA-approved indications not otherwise excluded from Part D.	N/A	Transplant: Patient received a renal (kidney), cardiac (heart), or hepatic (liver) transplant. Patient received a bone marrow/stem cell transplant. Lupus nephritis: Diagnosis of lupus nephritis. Failure to combination therapy with corticosteroids and cyclophosphamide. Obliterative Bronchiolitis: Diagnosis of obliterative bronchiolitis following lung transplantation.	N/A	N/A	Transplant, Lupus nephritis, Obliterative Bronchiolitis: Length of therapy.	Subject to Part B vs. Part D review (not limited to new starts only). Approve for continuation of prior therapy if Part D.

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Cesamet	All FDA-approved indications not otherwise excluded from Part D.	N/A	Nausea and Vomiting Associated with Cancer Chemotherapy: Patient is receiving cancer chemotherapy. Failure to 5HT-3 receptor antagonist. Failure to one of the following agents: antihistamine, corticosteroid, prokinetic agent, antipsychotic.	N/A	N/A	CINV: 6 months	Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B and when patient is receiving cancer chemotherapy.
Cimzia	All FDA-approved indications not otherwise excluded from Part D	Patient must be evaluated for latent TB with a PPD test and be treated if positive. Patients are excluded if they have an active infection or on are on concurrent biologic response modifier. Patient must also be assessed for the risk of hepatitis B and if appropriate, be tested.	Diagnosis: Chron's Ds / Rheumatoid arthritis, moderately to sever. Patient must demonstrate inadequate response to at least 1 conventional therapy for Crohn's disease (i.e., prednisone, budesonide, sulfasalazine, azathioprine, mesalamine, infliximab or adalimumab)	Approve for those 18 years of age or older	N/A	12 months	N/A
Chorionic Gonadotropin	All FDA-approved indications not otherwise excluded from Part D.	N/A	N/A	N/A	N/A	6 months	N/A
Degarelix	All FDA-approved indications not otherwise excluded from Part D.	N/A	Failure to an LHRH agonist	N/A	N/A	12 months	N/A

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Dronabinol	All FDA-approved indications not otherwise excluded from Part D.	N/A	Nausea and Vomiting Associated with Cancer Chemotherapy (CINV): Patient is receiving cancer chemotherapy. Failure to 5HT-3 receptor antagonist. Failure to one of the following agents: antihistamine, corticosteroid, prokinetic agent, antipsychotic. AIDS anorexia: Diagnosis of anorexia with weight loss in patients with AIDS.	N/A	N/A	CINV: 6 months. AIDS anorexia: Length of therapy.	Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B when patient is receiving chemotherapy.
Effient	All FDA-approved indications not otherwise excluded from Part D.	N/A	Diagnosis: patients with acute coronary syndrome who are to be managed with percutaneous coronary intervention. Patient must meet at least ONE of the following: Unstable angina, NSTEMI, STEMI AND is being managed with primary or delayed PCU. Active pathological bleeding such as peptic ulcer or intracranial hemorrhage, prior transient ischemic attack or stroke, Patient is likely to go through CABG. Body weight and age for safety.	N/A	N/A	12 months	N/A
Emend	All FDA-approved indications not otherwise excluded from Part D.	N/A	Acute Chemotherapy-induced Nausea and Vomiting: Patient is currently receiving moderately or highly emetogenic chemotherapy. Patient is concurrently on both a corticosteroid and a 5-HT3 receptor antagonist. Delayed Chemotherapy-induced Nausea and Vomiting Prevention: Patient is currently receiving highly emetogenic chemotherapy and a steroid, or patient is on an anthracycline and cyclophosphamide. Postoperative Nausea and Vomiting: For the prevention of postoperative nausea and vomiting when administered prior to the induction of anesthesia.	N/A	N/A	Acute CINV, Delayed CINV, PONV: 6 months	Subject to Part B vs. Part D review.

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Enbrel	All FDA-approved indications not otherwise excluded from Part D.	Concurrent use of anakinra.	Rheumatoid Arthritis: Dx of mod-to-sev RA. Failed MTX or 2 DMARDs for 3 mo. Juvenile Idiopathic Arthritis: Dx of mod-to-sev polyarticular-course JIA Failed NSAID or steroid and methotrexate for three months. PsA: Dx of active PsA. Failed MTX or 2 DMARDs for 3 mo. Ankylosing Spondylitis: Dx of AS. Failed 2 NSAIDs for 3 mo. Plaque Psoriasis: Dx mod-to-sev chronic (greater than 6 months) plaque psoriasis. Failed phototherapy and systemic therapy with one of the following: MTX, cyclosporine, acitretin, hydroxyurea, sulfasalazine, 6-thioguanine, or mycophenolate. Reauthorization: demonstration of clinical response to therapy.	RA, PsA, AS, Plaque Psoriasis: 18 years and older. JIA: 2 years and older.	RA (Initial), JIA (Initial), PsA (Initial), AS (Initial): Prescribed or recommended by a rheumatologist. Plaque Psoriasis (Initial): Prescribed or recommended by a dermatologist.	Initial Auth: 12 months for all except Plaque Psoriasis: 3 mo. Reauth: All uses: 12 mo.	Plaque Psoriasis (Reauth) Enbrel dosage is 50 mg or less per week or less. All diagnoses: Verification that the pt has been evaluated for TB and treated accordingly.

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
<p>Epoetin alfa 1. Epogen 2. Procrit</p> <p>KCA Formulary ID: 10252 Version 17 Effective: 7/1/2010</p>	<p>All FDA-approved indications not otherwise excluded from Part D.</p>	<p>Anemia in cancer patients on chemotherapy: Patient is not receiving cancer chemotherapy or patient has malignancy for which therapy with epoetin is contraindicated. CRF: Patient is on dialysis (covered under Part B). For other off-label requests: Hgb greater than 10 g/dL or Hct greater than 30%</p>	<p>Anemia Due to Chronic Renal Failure: Hct less than 33% or Hgb less than 11 gm/dl. CRF (Reauth): Avg Hct was below 36% over 3-mo. 1 of the following: Hct reached target (30% to 36%), decr in blood transfusion, or Hgb is 1 g/dL or greater from pre-tx level. HIV: Anemia is d/t zidovudine tx or d/t HIV infection. Hgb less than 12 g/dL or Hct less than 36%. PtD-HIV (Reauth): Hct was below 36% over 3 mo. 1 of the following: Hct reached target (30% to 36%), decr in blood transfusion, or Hgb is 1 g/dL or greater from pre-tx level. Chemo: Verify other causes of anemia have been ruled out. Hct less than 30% or Hgb less than 10 gm/dl. Cancer is a non-myeloid malignancy. Concurrently on chemo, will be on concomitant chemo for 2 mo or anemia is caused by cancer chemo. Chemo (Reauth): Hct less than 36% or Hgb less than 12 gm/dl. Hct reached target (30% to 36%), decr in blood transfusion, or Hgb is 1 g/dL or greater from pre-tx level. Concurrently on chemo will be on concomitant chemo for 2 mo or anemia is caused by cancer chemo. Pre-op: Hgb greater than 10 to less than 13 g/dL scheduled to undergo elective, non-cardiac/vascular surgery to reduce blood transfusions or at high risk for perioperative transfusions with expected blood loss of 2 units or greater. MDS: Hct less than 33% or Hgb less than 11 g/dL. Serum erythropoietin of 500 mU/mL or less, or dx of transfusion-dependent MDS. MDS (Reauth): Avg Hct was below 36% over a 3 mo. 1 of the following: Hct reached target (30% to 36%), or decr in blood transfusion, or Hgb incr 1 g/dL or more from pre-tx level. HCV: Hgb less than 11 g/dL or Hct less than 33%. Is concurrently on ribavirin and interferon or peg-interferon alfa for the tx of HCV and the anemia is d/t tx. HCV (Reauth): Avg Hct was below 36% over a 3 mo. Hct reached target (30% to 36%), decr in blood transfusion, or Hgb is 1 g/dL or greater from pre-tx level. All uses: Verify Fe evaluation for adequate Fe stores.</p>	<p>N/A</p>	<p>N/A</p>	<p>Pre-op: 1 mo. Chemo, HCV, MDS: 3 mo. HCV (Reauth): 3 mo CRF, HIV: 6 mo. Other reauth: 12 mo.</p>	<p>Subject to Part B vs. Part D review. Chemotherapy-Induced Anemia: Hb/Hct levels collected within prior two weeks of request. All other indications: Hb/Hct levels collected within prior 30 days of request.</p>

Last Updated: 6.29.10

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Erbix	All FDA-approved indications not otherwise excluded from Part D.	N/A	Head and Neck Cancer: Confirmed diagnosis of locally or regionally advanced squamous cell carcinoma of the head and neck or recurrent or metastatic squamous cell head and neck cancer. Used in combination with radiation therapy, or after failure of platinum-based chemotherapy. Colorectal Cancer: Confirmed diagnosis of metastatic carcinoma of the colon or rectum. Used in combination with irinotecan-based chemotherapy or intolerance to irinotecan-based chemotherapy or failure of irinotecan or oxaliplatin-based chemotherapy regimens. Tumor expresses wild-type KRAS gene.	N/A	N/A	Head and Neck Cancer, Colorectal Cancer: Length of therapy.	Approve for continuation of prior therapy.
Fentanyl	All FDA-approved indications not otherwise excluded from Part D.	N/A	Cancer Pain: Confirmed diagnosis of malignant pain. Failure or contraindication to an immediate-release opioid. Demonstrated tolerance to opioids.	N/A	N/A	Cancer Pain: Length of therapy	N/A
Foradil	All FDA-approved indications not otherwise excluded from Part D.	N/A	Diagnosis of moderate or severe persistent asthma when used concurrently with an inhaled corticosteroid, or for the prevention of exercise-induced bronchospasm, or for COPD.	N/A	N/A	Long-term approval	N/A
Forteo	All FDA-approved indications not otherwise excluded from Part D.	Osteoporosis: History of Paget's disease, bone metastases of skeletal malignancies, radiation therapy, metabolic bone disease other than osteoporosis. Concurrent use of bisphosphonate.	Osteoporosis: BMD T score of -3.0 or less and a previous fracture resulting from minimal trauma, or both of the following: failure to a formulary bisphosphonate and patient has a history of fracture resulting from minimal trauma or BMD T score of -2.5 or less.	N/A	N/A	Osteoporosis: 2 years.	Subject to Part B vs. Part D review.

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Gleevec	All FDA-approved indications not otherwise excluded from Part D.	N/A	Chronic Myeloid Leukemia (Adults): Diagnosis of Philadelphia chromosome positive CML. CML (Children): Diagnosis of Philadelphia chromosome positive (Ph+) chronic phase CML. Not candidates for stem cell transplantation, disease has recurred after stem cell transplant, or for patients who are resistant to interferon-alfa therapy. Acute Lymphoblastic Leukemia: Adult patients with Philadelphia chromosome positive ALL. Myelodysplastic/myeloproliferative diseases: Adults diagnosed with MDS/MPD diseases associated with platelet-derived growth factor receptor gene rearrangements. Aggressive systemic mastocytosis: Adults diagnosed with aggressive systemic mastocytosis. Patient is without the D816V c-Kit mutation or c-Kit mutation status unknown. Hypereosinophilic syndrome and chronic eosinophilic leukemia: Adults diagnosed with HES or CEL. Dermatofibrosarcoma protuberans: Adults with unresectable, recurrent and/or metastatic DFSP. Gastrointestinal Stromal Tumors: Patients with a confirmed diagnosis of unresectable and/or metastatic GIST.	N/A	N/A	All diagnoses: Length of therapy.	Approve for continuation of prior therapy.

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<p>Growth Hormones</p> <ol style="list-style-type: none"> 1. Norditropin cartridge, 2. Norditropin 3. Nordiflex pen 4. Nutropin 5. Nutropin AQ 6. Omnitrope 7. Tev-Tropin <p>KCA Formulary ID: 10252 Version 17 Effective: 7/1/2010</p>	<p>All FDA-approved indications not otherwise excluded from Part D: Growth Hormone Deficiency (GHD) in Children, Prader-Willi Syndrome (PWS) or Small for Gestational Age (SGA), Turner Syndrome (TS) or Noonan Syndrome (NS), Growth Retardation associated with</p>	<p>COGHDA: Males with bone age greater than 17 yrs or females with bone age greater than 15 years, closed epiphyses on bone radiograph, growth velocity less than 2 cm/year during previous year of treatment unless COGHD criteria are met.</p>	<p>GHD (Child): Dx GH deficiency based on 2 GH stimulation tests or low IGF-1 levels. Demonstrate growth failure based on growth velocity or ht shorter than 2 SD below the mean ht for age. PWS, SGA: Dx of PWS confirmed by genetic testing or Dx of SGA confirmed by birth wt of less than 2500g at gestation of more than 37 wks or at birth wt or length below the 3rd percentile for gestational age who failed to catch up by 2 yrs of age. TS, NS: Tx of short stature in females w/bone age less than 15 yrs associated w/TS or NS or for tx of short stature in males w/bone age less than 17 yrs associated w/NS. GRCRF: Dx of chronic renal insufficiency. Ht shorter than or equal to 2 SD below the median age for children or where growth velocity falls to below 4.5 cm/yr. GHD (Child), PWS, SGA, TS, NS, GRCRF (Reauth): Incr in growth velocity of at least 2 cm/yr during previous yr of tx. Males w/bone age less than 17 yrs or females w/bone age less than 15 yrs. ISS: Ht less than or equal to 2.25 SD below the mean ht for age. Growth velocity less than the 25th percentile for bone age. Verify open epiphyses on last bone age radiograph. Absence of comorbid conditions that should be observed or treated by other means. ISS (Reauth): Incr in growth velocity of at least 4.5 cm/yr during previous yr of tx. Males w/bone age less than 17 yrs or females w/bone age less than 15 yrs. AOGHD: Pts who have GHD alone or multiple hormone deficiencies b/c of pituitary disease/insult, hypothalamic disease, surgery, or radiation tx. IGF-1 level less than 77 mcg/L or 2 SD below the mean value, matched by age and gender. COGHDA: Childhood onset in pts who were GH deficient during childhood who have GH deficiency confirmed as an adult before replacement tx w/GH is started. Persistent deficiency of GH documented by GH stimulation tests. IGHDA: Documented deficiency of GH documented by 2 GH stimulation tests.</p>	<p>N/A</p>	<p>GH Deficiency (Child), Turner Syndrome or Noonan Syndrome (Initial), GRCRF, ISS (Initial), AOGH, Childhood Onset GH Deficiency in Adults, Isolated GH Deficiency in Adults: Prescribed by an endocrinologist</p> <p>Last Updated: 6.29.10</p>	<p>All uses: 1 year. Except GH Deficiency in Adults: Length of therapy.</p>	<p>N/A</p>

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Hexalen	All FDA-approved indications not otherwise excluded from Part D.	N/A	Diagnosis of ovarian cancer, cancer has progressed or recurred following first-line tx with a cisplatin or alkylating agent-based combination	N/A	Prescribed by an oncologist	12 months	Approve for continuation of prior therapy.
Humira	All FDA-approved indications not otherwise excluded from Part D.	Concurrent use of anakinra	Moderate to severe active RA: Dx of mod-to-sev RA. Failed MTX or 2 DMARDs for 3 mo. Juvenile Idiopathic Arthritis: Dx of mod-to-sev polyarticular-course JIA. Failed NSAID or steroid and methotrexate for three months. Psoriatic Arthritis: Dx of active PsA. Failed MTX or 2 DMARDs for 3 mo. Ankylosing Spondylitis: Dx of AS. Failed 2 NSAIDs for 3 mo. Plaque Psoriasis: Dx mod-to-sev plaque psoriasis. Failed phototherapy and systemic therapy. Crohn's disease: Dx of mod-to-sev CD. Failed one conventional therapy. Reauthorization: demonstration of clinical response to therapy.	RA, PsA, CD, AS, Plaque Psoriasis: 18 years and older. JIA: 4 years and older.	RA, PsA, AS, JIA: Prescribed or recommended by a rheumatologist. Plaque Psoriasis: Prescribed or recommended by a dermatologist. CD: Prescribed or recommended by a gastroenterologist.	Initial Auth: 12 months for all except Plaque Psoriasis: 4 mo. Reauth for all 12 mo.	RA: Authorization is for 40 mg every other week unless documented treatment failure to Humira every other week dosing, then Humira may be approved for every week dosing if other criteria met. Plaque Psoriasis: Humira dosage is 40 mg every other week. All diagnoses: Verification that the patient has been evaluated for TB and treated accordingly.

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Miacalcin	All FDA-approved indications not otherwise excluded from Part D.		Postmenopausal Osteoporosis: Failure to a bisphosphonate or SERM. Failure to Miacalcin Nasal Spray. History of vertebral compression fractures, or fractures of the hip or distal radius resulting from minimal trauma, or T score of -2.5 or less. Paget's Disease (Initial): History of failure or intolerance to oral bisphosphonates. Paget's Disease (Reauthorization): Serum alkaline phosphatase concentration fails to normalize after the previous 6 months of therapy. Hypercalcemia: Corrected total serum calcium of 12 mg/dl or greater or corrected total serum calcium of 6 mEq/L or greater.			Postmenopausal osteoporosis: 12 months. Hypercalcemia: 1 month. Paget's: 6 months	Subject to Part B vs. Part D review.

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Immune Globulin 1. Gammagard 2. Polygam 3. Octagam	All FDA-approved indications not otherwise excluded from Part D.	N/A	ITP: For patients with ITP who require a rapid temporary increase in platelet count or to control excessive bleeding. KD: Confirmed diagnosis of KD. CLL: Documented hypogammaglobulinemia (IgG less than 600mg/dL) or history of bacterial infections associated with B-cell CLL. BMT: Confirmed allogeneic BMT within the last 100 days. Documented severe hypogammaglobulinemia (IgG less than 400 mg/dL). Dermatomyositis: Failure or intolerance to one of the following: corticosteroid therapy, MTX, AZA, or cyclophosphamide. HIV: Documented hypogammaglobulinemia (IgG less than 400 mg/dL). GBS: Confirmed diagnosis of severe GBS. Patients with severe disease requiring aid to walk. Onset of muscle weakness within the last 4 weeks. LEMS: Confirmed diagnosis of Lambert-Eaton myasthenic syndrome (LEMS). MG: Confirmed diagnosis of acute myasthenia gravis with myasthenic exacerbation, defined by either difficulty swallowing, acute respiratory failure, or major functional disability responsible for the discontinuation of physical activity. MS: Confirmed diagnosis of relapsing remitting form of MS. Failure to two of the following: Betaseron, Avonex, Rebif, Copaxone, Tysabri. Stiff Person Syndrome: Chart documentation confirming a diagnosis of stiff-person syndrome.	N/A	MG: Prescribed by a neurologist.	BMT: 100 days after transplant KD: 1 mo. MG, GBS: 1 tx course ITP, LEMS: 6 mo. Other uses: 1yr	Subject to Part B vs. Part D review. For Part D: For patients in which immune globulin is administered in the patient's home.

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Intron-A	All FDA-approved indications not otherwise excluded from Part D	N/A	<p>Hep B - HBeAg positive: HBsAg positive for at least 6 months. HBV DNA level greater than 100,000 copies/mL. Compensated liver disease. One of the following: persistent ALT 2 times ULN or moderate to severe hepatitis or fibrosis on biopsy. Hep B - HBeAg negative: HBsAg positive for at least 6 months. HBV DNA level of 2000 IU/mL or more or 11,200 copies/mL. Compensated liver disease. One of the following: persistent ALT 2 times ULN or moderate to severe hepatitis or fibrosis on biopsy. Hep C - Treatment Naive Patients (monotherapy): For patients with Chronic Hepatitis C with compensated liver disease with positive HCV antibody and HCV RNA. Hep C - Treatment Naive Patients (in combination with ribavirin): For patients with Chronic Hepatitis C with compensated liver disease with positive HCV antibody and HCV RNA. Hep C - Continuation of Therapy: For genotypes 2,3,5, or 6: loss of detectable HCV RNA from serum or 100 fold drop or more in HCV RNA level. Non-Hepatitis Diagnoses: Diagnosis of one of the following: Malignant Melanoma, Hairy cell leukemia, Stage III or IV follicular Non-Hodgkin's Lymphoma, condylomata acuminata, AIDS-related Kaposi's sarcoma, Multiple Myeloma. Acute Hep C: Patients with acute hepatitis C.</p>	<p>Hep B - HBeAg positive, Hep B - HBeAg negative: 1 year of age or older. Hep C - Treatment Naive Patients, Non-Hepatitis Diagnoses, Acute Hep C: 18 years old and older. Hep C - Treatment Naive Patients (in combination with ribavirin): 3 years of age and older.</p>	N/A	<p>HepB+: 6mo.(-):1yr.HepC:(2,3,5,6) 6mo(1,4,HIV/HCV):1 2mo.AcuteHepC,HC L,Kaposi:6mo.warts: 3wk.Other:1yr</p>	<p>Approve for continuation of prior therapy for neoplastic diseases.</p>

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Iressa	All FDA-approved indications not otherwise excluded from Part D.	N/A	N/A	N/A	Prescribed by an oncologist	6 months	Iressa will only be approved as continuation of therapy for patients currently receiving (or previously received) and benefiting from Iressa
Istodax	All FDA-approved indications not otherwise excluded from Part D.	N/A	Primary cutaneous T-cell lymphoma (CTCL): in patients who have received at least one prior systemic therapy.	N/A	N/A	12 months	N/A
Kineret	All FDA-approved indications not otherwise excluded from Part D.	Concurrent use of TNF-blockers or Orencia	RA (Initial): Diagnosis of moderate to severe active RA. Failure with a TNF-alpha-blocker. Failure on either methotrexate or at least 1 DMARD for at least 3 months. RA (Reauthorization): Submission of chart documentation demonstrating positive clinical response.	RA: 18 years or older	RA: Prescribed or recommended by a rheumatologist.	RA (Initial): 12 months. RA (Reauth): 1 year.	N/A
Letairis	All FDA-approved indications not otherwise excluded from Part D.	N/A	Pulmonary Arterial Hypertension: Patients with a confirmed diagnosis of pulmonary arterial hypertension (modified WHO Group I) which is symptomatic.	N/A	N/A	PAH: Length of therapy.	N/A

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Leukine	All FDA-approved indications not otherwise excluded from Part D	N/A	BMSCT: For patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT, or for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, or for peripheral stem cell transplant patients who have received myeloablative chemotherapy. AML: For patients with AML following induction or consolidation chemotherapy. NDDC: Patient is receiving NCI's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer or a dose-dense regimen for which the incidence of febrile neutropenia is unknown. CFN: Patient is receiving a chemotherapy regimen associated with more than 20% incidence of febrile neutropenia, or patient is receiving chemotherapy regimen associated with 10-20% incidence of febrile neutropenia and has risk factors associated with chemotherapy-induced infection, febrile neutropenia or neutropenia. FN: For patients receiving myelosuppressive anticancer drugs associated with neutropenia. Patient has febrile neutropenia at high risk for infection-associated complications or has a history of febrile neutropenia during a previous course of chemotherapy. HIVN: HIV-infected patients with an ANC less than or equal to 1,000 cells/mm ³ with or without one or more risk factors for developing chronic neutropenia.	AML: greater than or equal to 55 years old.	N/A	BMSCT, NDDC, CFN, FN, AML: 3 mo. HIVN: 6 mo	N/A

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Lotronex	All FDA-approved indications not otherwise excluded from Part D.	IBS (Initial): Male gender.	IBS (Initial): Confirmed diagnosis of (IBS) with diarrhea predominant symptoms for at least 6 months. Failure to an antispasmodic and an anti-diarrheal agent. IBS (Reauth): Recurrence of diarrhea-predominant IBS. Documentation of positive clinical response while on Lotronex.	IBS (Initial): 18 years and older.	IBS (Initial): Verification that physician has enrolled in the GlaxoSmithKline Prescribing Program.	IBS (Initial): 12 weeks IBS (Reauthorization): 6 months.	N/A
Lyrica	All FDA-approved indications not otherwise excluded from Part D.	N/A	Seizure Disorder: History of failure to a formulary anticonvulsant. As add-on therapy for the diagnosis of partial seizure. Diabetic Neuropathy: Diagnosis of Diabetes Mellitus. Diagnosis of peripheral neuropathy. Failure to gabapentin. Post-herpetic Neuropathic Pain: Failure to gabapentin.	N/A	N/A	All uses: Length of therapy.	Approve for continuation of prior therapy.
MS Agents: 1. Avonex 2. Betaseron 3. Copaxone 4. Rebif	All FDA-approved indications not otherwise excluded from Part D	N/A	diagnosis of relapsing-remitting MS	N/A	N/A	one year	Avonex will require a trail and failure of a preferred agent prior to approval
Mozobil	All medically accepted indications not otherwise excluded from Part D	Part B Coverage	Diagnosis: Harvesting of peripheral blood stem cells, In patients with non-Hodgkin's lymphoma and multiple myeloma. Patient's weight for dosage determination. Concurrent Treatments: used in combination with granulocyte-colony stimulating factor	Approve for those patients 18 years of age or older	N/A	12 months	N/A
mycophenolate mofetil	All FDA-approved indications not otherwise excluded from Part D.	N/A	Transplant: Patient received a renal (kidney), cardiac (heart), or hepatic (liver) transplant. Patient received a bone marrow/stem cell transplant. Lupus nephritis: Diagnosis of lupus nephritis. Failure to combination therapy with corticosteroids and cyclophosphamide. Obliterative Bronchiolitis: Diagnosis of obliterative bronchiolitis following lung transplantation.	N/A	N/A	Transplant, Lupus nephritis, Obliterative Bronchiolitis: Length of therapy.	Subject to Part B vs. Part D review (not limited to new starts only). Approve for continuation of prior therapy if Part D.

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Myozyme	All FDA-approved indications not otherwise excluded from Part D	N/A	Diagnosis of infantile-onset Pompe disease	N/A	N/A	one year	N/A

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Neupogen	All FDA-approved indications not otherwise excluded from Part D	N/A	<p>BMSCT: For pts with non-myeloid malignancies undergoing myeloablative chemo followed by autologous or allogeneic BMT, or for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, or for peripheral stem cell transplant pts who have received myeloablative chemotherapy. AML: For pts with AML following induction or consolidation chemotherapy. NDDC: Patient is receiving NCI's Breast Intergroup, INT C9741 dose dense chemo protocol for primary breast cancer or a dose-dense regimen for which the incidence of febrile neutropenia is unknown. CFN: Patient is receiving a chemotherapy regimen associated with more than 20% incidence of febrile neutropenia, or patient is receiving a chemotherapy regimen associated with 10-20% incidence of febrile neutropenia and has risk factors associated with chemotherapy-induced infection, febrile neutropenia or neutropenia. FN: For patients receiving myelosuppressive anticancer drugs associated with neutropenia. Pt either has febrile neutropenia at high risk for infection-associated complications or has a history of febrile neutropenia during a previous course of chemotherapy. SCN: For pts with severe chronic neutropenia. HCN: Neutropenia in Hepatitis C virus infected pts undergoing treatment with Peg-Intron or Pegasys after dose reduction, or for pts with HIV co-infection, or status post liver transplant, or established cirrhosis who experience interferon-induced neutropenia due to treatment with Peg-Intron or Pegasys. HIVN: HIV-infected pts with an ANC less than or equal to 1,000 cells/mm³ with or without one or more risk factors for developing chronic neutropenia.</p>	N/A	N/A	BMSCT, NDDC, CFN, FN, AML: 3 mo. SCN, HCN: 12 mo. HIVN: 6 mo.	N/A

KCA Formulary

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Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Nexavar	All FDA-approved indications not otherwise excluded from Part D.	N/A	Diagnosis of renal cell carcinoma with relapse following surgical excision, or diagnosis of renal cell carcinoma with medically or surgically unresectable tumor, or diagnosis of Stage IV renal cell carcinoma, or diagnosis of unresectable hepatocellular carcinoma.	N/A	Prescribed by an oncologist.	6 months	Approve for continuation of prior therapy.
Noxafil	All FDA-approved indications not otherwise excluded from Part D	N/A	N/A	13 years of age or older	N/A	For prophylaxis of invasive fungal infections 6 months. For oropharyngeal candidiasis 2 months	N/A

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Nuvigil	All FDA-approved indications not otherwise excluded from Part D	SWSD (Initial): Symptoms do not meet criteria for any other sleep disorder producing insomnia or excessive sleepiness.	Narcolepsy: Submission of sleep study confirming the diagnosis of narcolepsy. OSAHS (Initial): More than 5 obstructive apneas, each greater than 10 seconds in duration, per hour of sleep confirmed by a sleep study. Frequent arousals from sleep associated with apneas, or bradycardia, or arterial oxygen desaturation in association with apneas. Fully compliant and concurrently using continuous positive airway pressure (CPAP). Symptoms of excessive daytime sleepiness. OSAHS (Reauthorization): Patient continues to be fully compliant on concurrent CPAP and is experiencing relief of symptomatic hypersomnolence with Provigil use. SWSD (Initial): Symptoms of excessive sleepiness or insomnia, for at least 3 months, which is temporally associated with a work period that occurs during the habitual sleep phase, or sleep study demonstrating loss of a normal sleep-wake pattern. Sleep disturbance causes significant distress or significant impairment. No other disorder accounts for the symptoms. SWSD (Reauthorization): Patient is experiencing relief with use of Provigil for excessive sleepiness. Sleep disturbance continues to cause clinically significant distress or significant impairment in occupational functioning. Idiopathic Hypersomnia: Submission of sleep study confirming the diagnosis of Idiopathic Hypersomnia as defined by the International Classification of Sleep Disorders.	N/A	N/A	OSAHS, SWSD: 3 months. other uses: 12 months	N/A

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Octreotide acetate	All FDA-approved indications not otherwise excluded from Part D	N/A	Acromegaly: Inadequate response to surgery and/or radiotherapy, or who are not a surgical and/or radiotherapy candidate. Diagnosis of acromegaly by one of the following: serum GH level greater than 1 ng/mL after a 2-hour oral glucose tolerance test, or elevated serum IGF-1 levels as compared to normal reference values by age and gender. Carcinoid tumors: diagnosis of metastatic carcinoid tumor, for symptomatic treatment of severe diarrhea or flushing. Vasoactive Intestinal Peptide Tumors: Diagnosis of metastatic vasoactive intestinal peptide tumor, for symptomatic treatment of diarrhea associated with vasoactive intestinal peptide tumor. Cancer Chemotherapy Induced Diarrhea: Diagnosis of complicated diarrhea due to concurrent cancer chemotherapy, or both of the following: diagnosis of uncomplicated diarrhea due to concurrent cancer chemotherapy and history of failure to standard therapy. AIDS-related Diarrhea: Diagnosis of AIDS-related diarrhea. History of failure to standard therapy.	N/A	N/A	Acromegaly: long-term approval. Tumors: 6 mo. Chemo-induced diarrhea, AIDS-related Diarrhea: 3 mo.	N/A
Oral antifungals 1. Terbinafine 2. Itraconazole	Diagnosis of onychomycosis. All FDA-approved indications not otherwise excluded from Part D.	Lack of impaired mobility or significant pain.	Confirmation by positive fungal culture or positive KOH test AND at least one of the following must apply: diabetic patient, immunocompromised status - AIDS/immunosuppressive therapy/chemotherapy, onychomycosis of fingernails, significant impairment of mobility or significant pain	N/A	N/A	twelve weeks	N/A

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Orencia	All FDA-approved indications not otherwise excluded from Part D.	RA (Initial): Concurrent use with anakinra or a TNF antagonist.	Rheumatoid Arthritis: Dx of mod-to-sev RA. Failed MTX or 2 DMARDs for 3 mo. RA (reauth): submission of chart documentation demonstrating a positive clinical response. JIA: Failed NSAIDs or steroids and methotrexate for three months. JIA (reauth): submission of chart documentation demonstrating a positive clinical response.	RA: 18 years and older. JIA: 6 years and older.	RA/JJIA: Prescribed or recommended by a rheumatologist.	RA, JIA: 12 months.	RA, JIA: Verification that the patient has been evaluated for tuberculosis and treated accordingly.
Oxandrolone	All FDA-approved indications not otherwise excluded from Part D.	N/A	Bone Pain: Diagnosis of bone pain due to osteoporosis. AIDS Wasting (Initial): Diagnosis of AIDS wasting/cachexia and failure to hormone replacement therapy in patients with hypogonadism. AIDS wasting (Reauth): Verification that the patient's weight has increased a minimum of 2% while taking Oxandrin.	N/A	N/A	Initial therapy: 3 mo. Reauth: Length of therapy.	N/A

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Pegasys	All FDA-approved indications not otherwise excluded from Part D.	N/A	<p>Hep B - HBeAg positive: HBsAg positive for at least 6 months. HBV DNA level greater than 100,000 copies/mL. Compensated liver disease and one of the following: ALT 2 times ULN or moderate-to-severe hepatitis or fibrosis on biopsy. Hep B - HBeAg negative: HBsAg positive for at least 6 months. HBV DNA level of 2000 IU/mL or more or 11,200 copies/mL. Compensated liver disease and one of the following: ALT 2 times ULN or moderate-to-severe hepatitis or fibrosis on biopsy. Hep C - Treatment Naive Patients: Chronic Hepatitis C with compensated liver disease. Positive HCV antibody HCV RNA. HCV RNA level measurement. Genotype test result. For patients who have not previously been treated with interferon. Hep C - Continuation of Therapy: For genotypes 5 or 6: loss of detectable HCV RNA from serum or 100 fold drop or more in HCV RNA level. For genotype 1: undetectable HCV RNA after 24 weeks of therapy and one of the following: HCV RNA more than 50 IU/mL at 4 weeks into treatment or less than 100 fold drop or detectable HCV RNA 12 weeks into therapy. For genotype 3: baseline HCV RNA more than 600,000 IU/mL and steatosis or advanced fibrosis on liver biopsy. Hep C Retreatment: Retreatment in patients who have failed or relapsed following standard or pegylated interferon monotherapy, or for nonresponders or relapsers who have significant fibrosis or cirrhosis who have undergone previous regimens of treatment using non-pegylated interferon, or retreatment in patients with genotype 2 or 3 who have relapsed following 6 month treatment of pegylated interferon plus ribavirin combination therapy. Used in combination with ribavirin.</p>	Hep B - HBeAg positive, Hep B - HBeAg negative, Hep C - Treatment Naive Patients: 18 years and older	N/A	HepB:1yr. HepC(5,6):12 wk, (2,3): 24wk, (1,4,HIV/HCV):48wk. con't(1,3):24wk, (5,6):36wk.Retreat:1 yr	N/A

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
PEG-Intron	All FDA-approved indications not otherwise excluded from Part D.	N/A	Hepatitis C - Treatment Naive Patients: Chronic Hepatitis C with compensated liver disease. Positive HCV antibody HCV RNA. HCV RNA level measurement. Genotype test result. For patients who have not previously been treated with interferon. Hep C (Continuation): For genotypes 5 or 6: loss of detectable HCV RNA from serum or 100 fold drop or more in HCV RNA level. For genotype 1: undetectable HCV RNA after 24 weeks of therapy and one of the following: HCV RNA more than 50 IU/mL at 4 weeks into treatment or less than 100 fold drop or detectable HCV RNA 12 weeks into therapy. For genotype 3: baseline HCV RNA more than 600,000 IU/mL and steatosis or advanced fibrosis on liver biopsy. Hep C (Retreatment): Retreatment in patients who have failed or relapsed following standard or pegylated interferon monotherapy, or for nonresponders or relapsers who have significant fibrosis or cirrhosis who have undergone previous regimens of treatment using non-pegylated interferon, or retreatment in patients with genotype 2 or 3 who have relapsed following 6 month treatment of pegylated interferon plus ribavirin combination therapy. Used in combination with ribavirin.	Hepatitis C - Treatment Naive Patients: 3 years and older.	N/A	Type5,6: 12 wk, type2,3: 24wk, type1,4,HIV/HCV: 48wk.Con't: type1,3: 24wk type5,6: 36wk.Retreat: 1yr	N/A
Prograf (IV)	All FDA-approved indications not otherwise excluded from Part D.	N/A	Transplant: Patient received a renal (kidney), cardiac (heart), lung, kidney-pancreas, small bowel, or hepatic (liver) transplant, or bone marrow transplant. Patient is unable to take oral tacrolimus.	N/A	N/A	Transplant: Length of therapy.	Subject to Part B vs. Part D review (not limited to new starts only). Approve for continuation of prior therapy if Part D.

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Prograf (oral) tacrolimus (oral)	All FDA-approved indications not otherwise excluded from Part D.	N/A	Severe uveitis: Failure to one corticosteroid. Transplant: Patient received a renal (kidney), cardiac (heart), lung, pancreas, small bowel, hepatic (liver) transplant, or bone marrow/stem cell transplant.	N/A	N/A	Severe uveitis, Transplant: Length of therapy.	Subject to Part B vs. Part D review (not limited to new starts only). Approve for continuation of prior therapy if Part D.
Proleukin	All FDA-approved indications not otherwise excluded from Part D	N/A	Metastatic Renal Cell Carcinoma or Metastatic Melanoma: Measurable, histologically confirmed metastatic renal cell carcinoma or metastatic melanoma. Good neurologic or ambulatory performance status. Adequate organ function: normal cardiac stress test results, FEV1 greater than 2 L on pulmonary function tests, creatinine concentration 1.5 mg/dL or less or calculated creatinine clearance of greater than 60 ml/min, bilirubin concentration of 1.5 mg/dL or less, SGOT/AST less than 150 IU or 4x upper limit of normal. Platelet count greater than or equal to 100,000 / mcL. Hemoglobin greater than or equal to 10 g/dL. WBC greater than or equal to 3,500 / mcL. At least 7 weeks since prior therapy and complete recovery from therapy-related side effects.	Metastatic Renal Cell Carcinoma or Metastatic Melanoma: 18 years and older	N/A	Metastatic Renal Cell Carcinoma or Metastatic Melanoma: three months	All uses: For continuation of prior therapy. Metastatic Renal Cell Carcinoma or Metastatic Melanoma: Administered in a hospital setting. Additional courses of treatment should be given to patients only if there is some tumor shrinkage following the last course and if retreatment is not contraindicated.

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Provigil	All FDA-approved indications not otherwise excluded from Part D.	SWSD (Initial): Symptoms do not meet criteria for any other sleep disorder producing insomnia or excessive sleepiness.	Narcolepsy: Submission of sleep study confirming the diagnosis of narcolepsy. OSAHS (Initial): More than 5 obstructive apneas, each greater than 10 seconds in duration, per hour of sleep confirmed by a sleep study. Frequent arousals from sleep associated with apneas, or bradycardia, or arterial oxygen desaturation in association with apneas. Fully compliant and concurrently using continuous positive airway pressure (CPAP). Symptoms of excessive daytime sleepiness. OSAHS (Reauthorization): Patient continues to be fully compliant on concurrent CPAP and is experiencing relief of symptomatic hypersomnolence with Provigil use. SWSD (Initial): Symptoms of excessive sleepiness or insomnia, for at least 3 months, which is temporally associated with a work period that occurs during the habitual sleep phase, or sleep study demonstrating loss of a normal sleep-wake pattern. Sleep disturbance causes significant distress or significant impairment. No other disorder accounts for the symptoms. SWSD (Reauthorization): Patient is experiencing relief with use of Provigil for excessive sleepiness. Sleep disturbance continues to cause clinically significant distress or significant impairment in occupational functioning. Idiopathic Hypersomnia: Submission of sleep study confirming the diagnosis of Idiopathic Hypersomnia as defined by the International Classification of Sleep Disorders.	N/A	N/A	OSAHS, SWSD: 3 months. other uses: 12 months	N/A

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Ranexa	All FDA-approved indications not otherwise excluded from Part D	Patient concurrently using ketoconazole, itraconazole, erythromycin, clarithromycin, quinidine, procainamide, disopyramide, sotalol, dofetilide, amiodarone, diltiazem, a protease inhibitor.	Requires concurrent use with at least one medication of the following: amlodipine, beta blockers, or long-acting nitrates	N/A	N/A	one year	Approval will not be granted for patients concurrently taking a CYP3A inhibitor, a class 1a antiarrhythmic, a class III antiarrhythmic, or a protease inhibitor.
Regranex	All FDA-approved indications not otherwise excluded from Part D.	N/A	Diabetic Neuropathic Ulcers: Diabetic patient with ulcer wound. Debridement being performed as needed. At least two of the following are present: Stage III or IV wound, wound at least 1 cm x 1 cm, long-standing wound that does not heal with standard care, or patients at high risk for amputation (peripheral neuropathy, peripheral vascular disease, skin or nail abnormalities, previous foot ulcer amputation).	N/A	N/A	Diabetic Neuropathic Ulcers: Maximum 6 months.	N/A

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Remicade	All FDA-approved indications not otherwise excluded from Part D.	RA, PsA: Used in combination with anakinra.	Rheumatoid Arthritis: Dx of mod-to-sev active RA. Patient concurrently on MTX or failed MTX or 2 DMARDs (azathioprine, cyclosporine, gold, hydroxychloroquine, leflunomide, penicillamine, sulfasalazine) for 3 mo. Psoriatic Arthritis (PsA): Dx of active PsA. Failure or contraindication to methotrexate or 2 of the following for 3 months: cyclosporine, gold, leflunomide, or sulfasalazine. Ankylosing Spondylitis (AS): Dx of AS. Failed 2 NSAIDs for 3 mo. Plaque Psoriasis: Dx mod-to-sev chronic (greater than 6 months) plaque psoriasis. Failure, contraindication, intolerance or unavailability of phototherapy and one of the following: methotrexate, cyclosporine, acitretin, hydroxyurea, sulfasalazine, 6-thioguanine, mycophenolate. Crohn's Disease (CD): Mod to severe CD, failed one of the following: corticosteroids, 6-mercaptopurine, azathioprine, methotrexate, aminosalicylate. Fistulizing Crohn's Disease (FCD): Draining fistulas for 3 mo. On or failed one of the following: 6-mercaptopurine, azathioprine, antibiotics, oral corticosteroids, methotrexate. Ulcerative Colitis (UC): Mod to severe UC. Failed on one of the following: corticosteroids, 5-aminosalicylic acid, azathioprine, 6-mercaptopurine, cyclosporine. Sarcoidosis: Failed one steroid and one immunosuppressant. Reauthorization: demonstration of clinical response to therapy.	RA, PsA, AS, Plaque Psoriasis, FCD, UC: 18 years and older. Crohn's Disease: 6 years and older.	RA ,AS, PsA: Prescribed or recommended by a rheumatologist. Crohn's Disease, Fistulizing Crohn's Disease, UC: Prescribed by a gastroenterologist or by gastroenterologist consult. Plaque Psoriasis: Prescribed or recommended by a dermatologist. Sarcoidosis: Prescribed or recommended by a pulmonologist.	12 months	Verification that the patient has been evaluated for TB and treated accordingly.

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Remodulin	All FDA-approved indications not otherwise excluded from Part D.	N/A	PAH: Patients with a confirmed diagnosis of pulmonary arterial hypertension (modified WHO Group I) which is symptomatic.	N/A	N/A	PAH: Length of therapy.	Subject to Part B vs. Part D review.
Revatio	All FDA-approved indications not otherwise excluded from Part D.	PAH: Patients using organic nitrates.	PAH: Confirmed diagnosis of pulmonary arterial hypertension (modified WHO group I) which is symptomatic.	N/A	N/A	PAH: Length of therapy.	N/A
Revlimid	All FDA-approved indications not otherwise excluded from Part D	N/A	MDS: Diagnosis of myelodysplastic syndrome associated with a deletion 5q cytogenic abnormality and patient is transfusion dependent. OR Diagnosis of myelodysplastic syndrome without deletion 5q cytogenic abnormality and failure of initial treatment with epoetin alfa or darbopoetin alfa, hypomethylating agents (e.g., Vidaza, Dacogen), or immunosuppressive therapy (e.g., antithymocyte golbulin, cyclosporine). Multiple Myeloma: Used in combination with dexamethasone. Chronic Lymphocytic Leukemia: Relapsed or refractory to one prior therapy for CLL.	N/A	MDS, Multiple Myeloma, CLL: Prescribed by an oncologist or hematologist or by oncology or hemoatology consult.	MDS, Multiple Myeloma: 6 months.	Approve for continuation of prior therapy.
Ribasphere Ribavirin	All FDA-approved indications not otherwise excluded from Part D.	N/A	Hepatitis C: Adults with a diagnosis of Hepatitis C with compensated liver disease, and verification of concurrent use with an alfa interferon product.	N/A	N/A	Hepatitis C: Length of therapy.	N/A

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Rituxan	All FDA-approved indications not otherwise excluded from Part D. Chronic Lymphocytic Leukemia, Immune or idiopathic thrombocytopenic purpura, Waldenstrom's macroglobulinemia	N/A	Non-Hodgkin's Lymphoma: As first-line treatment of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma in combination with CHOP or other anthracycline-based chemotherapy regimens, or as first-line treatment of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with CVP chemotherapy, or for the treatment of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy, or confirmed diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma. RA (Initial): Diagnosis of moderate-to-severe active RA. Used in combination with methotrexate. Failure to a TNF antagonist. RA (Reauthorization): Documented positive clinical response. At least 24 weeks since last Rituxan tx.	RA: 18 years and older.	RA: Prescribed by a rheumatologist.	All uses except RA: 1 year. RA: One month	N/A
Serevent	All medically accepted indications not otherwise excluded from Part D	N/A	Diagnosis of moderate or severe persistent asthma when used concurrently with an inhaled corticosteroid, or for the prevention of exercise-induced bronchospasm, or for COPD.	N/A	N/A	Long-term approval	N/A
Stelara	All FDA-approved indications not otherwise excluded from Part D.	N/A	For the treatment of moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.	Approve for those patients 18 years of age or older	N/A	12 months	N/A

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Somatuline Depot	All FDA-approved indications not otherwise excluded from Part D.	N/A	Acromegaly: Patients who require long-term treatment due to inadequate response to surgery and/or radiotherapy, or who are not a surgical and/or radiotherapy candidate. Diagnosis of acromegaly by one of the following: serum GH level greater than 1 ng/mL after a 2-hour oral glucose tolerance test, or elevated serum IGF-1 levels as compared to normal reference values by age and gender.	N/A	N/A	Indefinite, long term therapy (open-ended)	N/A
Somavert	All FDA-approved indications not otherwise excluded from Part D.	N/A	Acromegaly (Initial): Inadequate response to surgery and/or radiation therapy or not a candidate for surgery or radiation. Inadequate response or intolerance to octreotide, or lanreotide, or IGF-1 value greater than 900 ng/mL. Acromegaly (Reauth): Serum IGF-1 level within the age-adjusted normal range.	N/A	N/A	Acromegaly (Initial): 12 weeks. Acromegaly (Reauth): indefinite	N/A
Sporanox (solution)	All FDA-approved indications not otherwise excluded from Part D	N/A	Fungal Infection: Diagnosis of blastomycosis, histoplasmosis, aspergillosis, or onychomycosis in patients unable to swallow tablets, or diagnosis of febrile neutropenia with suspected fungal infection, or oropharyngeal or esophageal candidiasis.	N/A	N/A	Fungal Infection: Length of therapy.	N/A
Sprycel	All FDA-approved indications not otherwise excluded from Part D.	N/A	CML: Diagnosis of Philadelphia chromosome positive or BCR-ABL positive chronic, accelerated, or myeloid or lymphoid blast phase chronic myeloid leukemia. Failure to Gleevec. ALL: Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia. Failure to Gleevec.	N/A	N/A	CML, ALL: Length of therapy.	Approve for continuation of prior therapy.

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Sutent	All FDA-approved indications not otherwise excluded from Part D.	N/A	GIST: Disease progression on or intolerance to Gleevec. Renal Cell Carcinoma: Diagnosis of renal cell carcinoma with relapse following surgical excision, or diagnosis of renal cell carcinoma with medically or surgically unresectable tumor, or diagnosis of Stage IV renal cell carcinoma.	N/A	Prescribed by an oncologist.	12 months	Approve for continuation of prior therapy.
Symlin	All FDA-approved indications not otherwise excluded from Part D	N/A	DM: Type 1 or type 2 diabetes. Concurrent use of insulin therapy.	DM: 18 years and older.	N/A	DM: Length of therapy.	N/A
Tarceva	All FDA-approved indications not otherwise excluded from Part D.	N/A	Patients diagnosed with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen. Pancreatic Cancer: Patient diagnosed with locally advanced, unresectable or metastatic pancreatic cancer. Used in combination with gemcitabine. Reauthorization: Patient has not experienced disease progression.	N/A	Prescribed by an oncologist.	6 months	Approve for continuation of prior therapy.
Targretin (oral)	All FDA-approved indications not otherwise excluded from Part D.	N/A	Definitive diagnosis of cutaneous T-cell lymphoma (CTCL)	N/A	N/A	12 months	Approve for continuation of prior therapy.
Tasigna	All FDA-approved indications not otherwise excluded from Part D.	N/A	Chronic Myelogenous Leukemia: Diagnosis of Philadelphia chromosome positive chronic or accelerated phase chronic myeloid leukemia and failure to Gleevec.	N/A	N/A	Chronic Myelogenous Leukemia: Length of therapy.	Approve for continuation of prior therapy.
Testosterone (injectable) 1. Testosterone cypionate 2. Testosterone enanthate	All FDA-approved indications not otherwise excluded from Part D.	N/A	Diagnosis of male hypogonadism with a pre-treatment total testosterone level below normal physiological value (less than 280 ng/dl), or pre-treatment free testosterone below normal reference value. Diagnosis of delayed puberty in males.	N/A	N/A	Hypogonadism: long-term. Delayed puberty: 6 months	N/A

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Testosterone (topical) 1. Androderm 2. Androgel 3. Testim	All FDA-approved indications not otherwise excluded from Part D.	N/A	Hypogonadism: Diagnosis of hypogonadism in men with a pre-treatment testosterone level below normal physiological value of 280 ng/dL or below normal reference level provided by the physician laboratory.	N/A	N/A	Hypogonadism: Length of therapy	N/A

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Topical Retinoids 1. Avita Cream 2. Avita Gel 3. Tretinoin Cream 4. Tretinoin Gel	All FDA-approved indications not otherwise excluded from Part D.	N/A	N/A	N/A	N/A	12 months	N/A
Tracleer	All FDA-approved indications not otherwise excluded from Part D.	N/A	PAH: Patients with a confirmed diagnosis of pulmonary arterial hypertension (modified WHO Group I) which is symptomatic.	N/A	N/A	PAH: Length of therapy.	N/A
Trimethobenzamide	All FDA-approved indications not otherwise excluded from Part D.	N/A	N/A	No PA required if less than 65 yo.	N/A	Length of therapy.	N/A
Tykerb	All FDA-approved indications not otherwise excluded from Part D.	N/A	Breast Cancer: Diagnosis of HER2-positive advanced or metastatic breast cancer. Confirmation of normal left ventricular ejection fraction.	N/A	N/A	Breast Cancer: Length of therapy.	Approve for continuation of prior therapy.
Vancocin	All FDA-approved indications not otherwise excluded from Part D.	N/A	Pseudomembranous Colitis: Diagnosis of pseudomembranous colitis due to Clostridium difficile. Failure to oral Flagyl.	N/A	N/A	Pseudomembranous Colitis: Length of therapy.	N/A
Vectibix	All FDA-approved indications not otherwise excluded from Part D.	N/A	Colorectal Cancer: Diagnosis of metastatic colorectal cancer. Relapsed, refractory, or disease progression on one standard chemotherapy regimen containing a fluoropyrimidine, oxaliplatin, or irinotecan. Tumor expresses wild-type KRAS gene.	N/A	N/A	Colorectal Cancer: 6 months	Approve for continuation of prior therapy.
Ventavis	All FDA-approved indications not otherwise excluded from Part D.	N/A	PAH: Patients with a confirmed diagnosis of pulmonary arterial hypertension (modified WHO Group I) which is symptomatic.	N/A	N/A	PAH: Length of therapy	Subject to Part B vs. Part D review.

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Victoza	All FDA-approved indications not otherwise excluded from Part D.	Concomitant use of insulin	1) Diagnosis 3) Trial and Failure of one of the following medications: metformin, sulfonylurea and/or thiazolidinedione	N/A	N/A	Length of Therapy	N/A
Vipriv	All FDA-approved indications not otherwise excluded from Part D.	N/A	Diagnosis of Type 1 Gaucher Disease	N/A	N/A	Length of therapy	N/A
Xolair	All FDA-approved indications not otherwise excluded from Part D.	N/A	Asthma (Initial): Diagnosis of moderate-to-severe persistent allergic asthma, defined by daily asthmatic symptoms, daily use of inhaled short-acting beta agonists, exacerbations affect/limit activity, exacerbations 2 or more times per week, nocturnal symptoms once a week or more, forced expiratory volume in one second or peak expiratory flow less than or equal to 80% of predicted, or PEF variability greater than 30%. Baseline IgE level greater than or equal to 30 IU/mL. Documented failure to combination therapy with an inhaled corticosteroid at the maximum dosage and a long-acting beta-agonist. Asthma (Reauthorization): Documented reduction in the frequency of asthma exacerbations while treated with Xolair. Documented reduction in the use of rescue medications or inhaled corticosteroids while treated with Xolair.	Asthma (Initial): 6 years and older.	Asthma (Initial): Prescribed by a pulmonologist or allergist/immunologist.	Asthma (Initial): 16 weeks. Asthma (Reauthorization): 1 year.	N/A
Xyrem	All FDA-approved indications not otherwise excluded from Part D	N/A	N/A	N/A	N/A	one year	Limited distribution only through the Xyrem Success program

Drug	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Physician Restrictions	Coverage Duration	Other Criteria
Zolinza	All FDA-approved indications not otherwise excluded from Part D.	N/A	Definitive diagnosis of cutaneous T-cell lymphoma (CTCL)	N/A	N/A	12 months	Approve for continuation of prior therapy.
Zyvox	All FDA-approved indications not otherwise excluded from Part D	N/A	Infections: One of the following: Infections caused by vancomycin-resistant enterococci (VRE) documented by culture and sensitivity report. Nosocomial pneumonia caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report. Complicated skin and skin structure infections (including diabetic foot infections) without osteomyelitis caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report. Empirical treatment of patients with community-acquired complicated skin and skin structure infections without osteomyelitis where MRSA infection is likely, in patients who have failed one of the following: trimethoprim-sulfamethoxazole, tetracycline, doxycycline, minocycline. As continuation of therapy when transitioning from intravenous daptomycin, intravenous vancomycin, or intravenous Zyvox therapy.	N/A	N/A	Infections: 28 days.	N/A

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

acetylcystine

albuterol inhalation solution

ANZEMET (TABLETS)

ATGAM

AZASAN

azathioprine (tablets)

BROVANA

budesonide inhalation solution

cromolyn inhalation solution

cyclophosphate (tablets)

cyclosporine

cyclosporine modified

gengraf

granisetron

Granisol

intralipid

ipratropium inhalation solution

Ipratropium bromide/albuterol sulfate

liposyn III

LIPOSYN II

MYFORTIC (TABLETS)

ondansetron

ondansetron odt

ORTHOCLONE

PULMICORT

RAPAMUNE (ORAL SOLUTION, TABLETS)

TRAVASOL

VIBATIV

XOPENEX

ZYPREXA RELPREVV