

**PRIOR AUTHORIZATION CRITERIA – GOLD Formulary**

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
Alimta	Malignant Pleural Mesothelioma (MPM)  Non-Small Cell Lung Cancer (NSCLC)		<p><b>Malignant Pleural Mesothelioma</b></p> <ol style="list-style-type: none"> <li>1. Disease is unresectable or patient is not a candidate for curative surgery; AND</li> <li>2. Used in combination with cisplatin.</li> </ol> <p><b>Non-Small Cell Lung Cancer:</b></p> <ol style="list-style-type: none"> <li>1. Confirmed diagnosis of locally advanced or metastatic (Stage III or IV) NSCLC; AND</li> <li>2. Prior history of first-line chemotherapy treatment for NSCLC.</li> </ol>			Length of the therapy	Alimta will be approved for continuation of prior therapy.
Amitiza	Chronic Idiopathic Constipation  Irritable Bowel Syndrome - Constipation  All FDA approved indications not otherwise excluded from Part D		<p><b>Chronic Idiopathic Constipation:</b> Failure to standard treatment.</p> <p><b>Irritable Bowel Syndrome with Constipation in women:</b> Failure to standard treatment.</p>	≥ 18 years and older.		12 months	

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Apokyn	Advanced Parkinson's Disease		<p><b>Advanced Parkinson's Disease:</b></p> <ol style="list-style-type: none"> <li>1. Confirmed diagnosis of advanced Parkinson's disease; AND</li> <li>2. Unable to control "off" symptoms with adequate combinations of conventional oral therapy; AND</li> <li>3. Used in combination with a non-5-HT3 antagonist antiemetic for initial therapy; AND</li> <li>4. Not used in combination with 5-HT3 antagonists.</li> </ol>			1 year	Apokyn will only be approved for intermittent subcutaneous injection.
Aranesp	<p>Anemia Due to Chronic Renal Failure (CRF)</p> <p>Anemia in cancer patients on chemotherapy</p> <p>Refractory anemia in Myelodysplastic Syndrome (MDS)</p>	<p><b>Chronic Renal Failure:</b></p> <ol style="list-style-type: none"> <li>1. Patient is on dialysis (covered under Part B).</li> <li>2. Chemotherapy patient does not receive cancer chemotherapy; OR patient has a malignancy for which Aranesp is contraindicated.</li> </ol>	<p><b>Initial Therapy for Chronic Renal Failure:</b></p> <ol style="list-style-type: none"> <li>1. Hct &lt; 33% OR Hgb &lt; 11 gm/dl; AND</li> <li>2. Verification of iron evaluation for adequate iron stores.</li> </ol> <p><b>Reauthorization for Chronic Renal Failure:</b></p> <ol style="list-style-type: none"> <li>1. Verification that average Hct was below 36% over a 3-month period; AND</li> <li>2. Verification of iron evaluation for adequate iron stores; AND</li> <li>3. One of the following: <ol style="list-style-type: none"> <li>a. Hct reached target range (30% to 36%); OR</li> <li>b. Decrease in blood transfusion; OR</li> <li>c. Hgb is ≥ 1 g/dL from pre-treatment level.</li> </ol> </li> </ol> <p><b>Initial Therapy for Chemotherapy:</b></p> <ol style="list-style-type: none"> <li>1. Verification that other causes of anemia have been ruled out; AND</li> <li>2. Verification of iron evaluation for adequate iron stores with one of the following: <ol style="list-style-type: none"> <li>a. Hct &lt; 36%; OR</li> <li>b. Hgb &lt; 12 gm/dl;</li> </ol> </li> <li>3. Verification that the cancer is a non-myeloid malignancy.</li> <li>4. AND one of the following: <ol style="list-style-type: none"> <li>a. Verification that the patient is concurrently on chemotherapy; OR</li> <li>b. Will be on concomitant chemotherapy for 2 months; OR</li> <li>c. The anemia is caused by cancer chemotherapy.</li> </ol> </li> </ol> <p><b>Reauthorization for Chemotherapy:</b></p> <ol style="list-style-type: none"> <li>1. Hct &lt; 36% OR Hgb &lt; 12 gm/dl; AND</li> <li>2. Hct reached target range (30% to 36%); AND</li> </ol>			<p><b>Initial Therapy:</b> Three months for chemotherapy and MDS. Six months for CRF.</p> <p><b>Reauthorization:</b> 12 months for CRF and MDS</p>	<p>Aranesp is subject to Part B vs. Part D review.</p> <p><b>Chemotherapy-Induced Anemia:</b> Hgb/Hct levels must be collected within prior two weeks of request.</p> <p><b>All other uses:</b> Hgb/Hct levels must be collected within prior 30 days of request.</p>

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			<p>3. One of the following:  a. Decrease in blood transfusion; OR  b. Hgb is 1 g/dL; OR  c. greater from pre-treatment level.</p> <p>4. One of the following:  a. Verification that the patient is concurrently on chemotherapy; OR  b. Will be on concomitant chemotherapy for 2 months; OR  c. The anemia is caused by cancer chemotherapy.</p> <p><b>Initial Therapy for Myelodysplastic Syndrome:</b>  1. Hct &lt; 33%; OR Hgb &lt; 11 g/dL; AND  2. One of the following:  a. Serum erythropoietin of ≤ 500 mU/mL; OR  b. Diagnosis of transfusion-dependent MDS.  3. Verification of adequate iron stores.</p> <p><b>Reauthorization of Myelodysplastic Syndrome:</b>  1. Verification that average Hct was below 36% over a 3 month period; AND  2. One of the following:  a. Verification that Hct reached target (30% to 36%); OR  b. Decrease in blood transfusion; OR  c. Hgb increase ≥ 1 g/dL from pre-treatment level.</p>				
Acalyst	Cryopyrin-Associated Periodic Syndromes, including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome		Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)	12 years and older		Indefinite, long-term therapy (open-ended)	

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Avastin	Colorectal Cancer  Non-Small Cell Lung Cancer (NSCLC)  Renal Cell Cancer  Breast Cancer  Age-related Macular Degeneration (ARMD)	<b>NSCLC:</b> 1. Squamous cell histology. 2. History of hemoptysis. 3. CNS metastases. 4. On-going therapeutic anticoagulation	<b>Colorectal Cancer:</b> 1. Diagnosis of metastatic colorectal cancer; AND 2. Used in combination with: a. 5-FU; OR b. oxaliplatin plus capecitabine; OR c. capecitabine.  <b>Non-Small Cell Lung Cancer:</b> 1. Diagnosis of unresectable locally advanced recurrent or metastatic NSCLC; AND 2. Used in combination with paclitaxel and carboplatin.  <b>Renal Cell Cancer:</b> 1. Diagnosis of metastatic renal cell cancer; AND 2. Used in combination with interferon-alpha or refractory to either interferon alpha or interleukin-2.  <b>Breast Cancer:</b> 1. Diagnosis of metastatic breast cancer; AND 2. Used in combination with paclitaxel.  <b>Age-Related Macular Degeneration:</b> 1. Failure to FDA-approved therapies; OR 2. Likely to have greater benefit from the use of intravitreal bevacizumab.		<b>Renal Cell Cancer, Breast Cancer:</b> Prescribed by or in consultation with an oncologist.  <b>ARMD:</b> Prescribed or recommended by retina specialist	Length of therapy	Avastin will be approved for continuation of prior therapy.  <b>Renal Cell Cancer:</b> Used in combination with interferon-alpha or refractory to either interferon alpha or interleukin-2.
Avonex	Relapsing forms of Multiple Sclerosis (MS)		<b>Relapsing Multiple Sclerosis:</b> 1. Recent history of a first clinical demyelinating event; AND 2. MRI-detected brain lesions consistent with MS. Trial on an alternative MS agent.			1 year	
Betaseron	Relapsing forms of Multiple Sclerosis		<b>Relapsing Multiple Sclerosis:</b> 1. Patients with relapsing form of MS; OR 2. Patients with secondary progressive MS who continue to experience relapses. Trial on an alternative MS agent.			1 year	

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Byetta	Type 2 Diabetes		<p><b>Type 2 Diabetes:</b></p> <ol style="list-style-type: none"> <li>1. Diagnosis of type 2 diabetes; AND</li> <li>2. For patients who have not achieved adequate glycemic control despite treatment with a maximally tolerated dose of two of the following (unless the patient has a contraindication to the specified agents):               <ol style="list-style-type: none"> <li>a. Metformin; OR</li> <li>b. A sulfonylurea; OR</li> <li>c. A thiazolidinedione.; AND</li> </ol> </li> <li>3. Used in combination with one of the following:               <ol style="list-style-type: none"> <li>a. Metformin; OR</li> <li>b. A sulfonylurea; OR</li> <li>c. A thiazolidinedione; OR</li> <li>d. Combination of metformin and a sulfonylurea; OR</li> <li>e. combination of metformin and a thiazolidinedione.</li> </ol> </li> </ol>	≥ 18 years		Length of therapy	
Cellcept Intravenous	Transplant  Lupus Nephritis		<p><b>Transplant</b></p> <ol style="list-style-type: none"> <li>1. Patient received a renal (kidney), cardiac (heart), or hepatic (liver) transplant; AND</li> <li>2. Patient is unable to take oral formulations of mycophenolate.</li> </ol> <p><b>Lupus Nephritis:</b></p> <ol style="list-style-type: none"> <li>1, Diagnosis of lupus nephritis; AND</li> <li>2. Failure to combination therapy with corticosteroids and cyclophosphamide.</li> </ol>			Length of therapy	<p>Cellcept is subject to Part B vs. Part D review.</p> <p>Cellcept will be approved for continuation of prior therapy.</p>

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Cellcept	<p>Transplant</p> <p>Lupus Nephritis</p> <p>Obliterative Bronchiolitis</p>		<p><b>Transplant:</b></p> <ol style="list-style-type: none"> <li>1. Patient received a renal (kidney), cardiac (heart), or hepatic (liver) transplant.</li> <li>2. Patient received a bone marrow/stem cell transplant.</li> </ol> <p><b>Lupus Nephritis:</b></p> <ol style="list-style-type: none"> <li>1. Diagnosis of lupus nephritis; AND</li> <li>2. Failure to combination therapy with corticosteroids and cyclophosphamide.</li> </ol> <p><b>Obliterative Bronchiolitis:</b></p> <p>Diagnosis of obliterative bronchiolitis following lung transplantation.</p>			Length of therapy	<p>Cellcept is subject to Part B vs. Part D review.</p> <p>Cellcept will be approved for continuation of prior therapy.</p>
Copaxone	Relapsing-remitting form of Multiple Sclerosis		<p><b>Relapsing Remitting Multiple Sclerosis:</b></p> <p>For patients with relapsing-remitting form of multiple sclerosis. Trial on an alternative MS agent.</p>			1 year	
Emend	<p>Acute Chemotherapy-induced Nausea and Vomiting (CINV)</p> <p>Delayed Chemotherapy-induced Nausea and Vomiting</p> <p>Prevention, Postoperative Nausea and Vomiting (PONV)</p>		<p><b>Acute Chemotherapy-Induced Nausea and Vomiting:</b></p> <ol style="list-style-type: none"> <li>1. Patient is currently receiving moderately or highly emetogenic chemotherapy; AND</li> <li>2. Patient is concurrently on both a corticosteroid and a 5-HT3 receptor antagonist.</li> </ol> <p><b>Delayed Chemotherapy-Induced Nausea and Vomiting:</b></p> <ol style="list-style-type: none"> <li>1. Patient is currently receiving highly emetogenic chemotherapy and a steroid; OR</li> <li>2. Patient is on an anthracycline and cyclophosphamide.</li> </ol> <p><b>Prevention of Postoperative Nausea and Vomiting:</b></p> <p>For the prevention of postoperative nausea and vomiting when administered prior to the induction of anesthesia.</p>			<p><b>Acute CINV, Delayed CINV, PONV:</b></p> <p>6 months</p>	Emend is subject to Part B vs. Part D review.

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Enbrel, Enbrel Sureclick	Rheumatoid Arthritis (RA)  Juvenile Rheumatoid Arthritis (JRA)  Psoriatic Arthritis (PsA)  Plaque Psoriasis (PPs)  Ankylosing Spondylitis (AS)	Concurrent use of anakinra.	<b>Rheumatoid Arthritis:</b> 1. Diagnosis of moderate-to-severe RA; AND 2. Failed methotrexate or 2 DMARDs for 3 months.  <b>Juvenile Rheumatoid Arthritis / Juvenile Idiopathic Arthritis:</b> Diagnosis of moderate-to-severe poly-articular course  <b>Juvenile Rheumatoid Arthritis:</b> Failed NSAID or steroid and DMARD for three months.  <b>Psoriatic Arthritis:</b> 1. Diagnosis of active PsA. 2. Failed methotrexate or 2 DMARDs for 3 months.  <b>Ankylosing Spondylitis:</b> 1. Diagnosis of AS. 2. Failed 2 NSAIDs for 3 months.  <b>Plaque Psoriasis:</b> 1. Diagnosis moderate-to-severe plaque psoriasis with min BSA 10%. 2. Failed phototherapy and systemic therapy.  <b>Reauthorization:</b> Demonstration of clinical response to therapy.	<b>RA, PsA, AS, PPs:</b> ≥ 18 years  <b>JRA:</b> ≥ 2 years	<b>Initial Therapy for RA, JRA, PsA, AS:</b> Prescribed or recommended by a rheumatologist.  <b>Initial Therapy for PPs:</b> Prescribed or recommended by a dermatologist.	<b>Initial Therapy:</b> 3 months for plaque psoriasis; 12 months for other uses  <b>Reauthorization:</b> 12 months for all uses	All diagnoses require verification that the patient has been evaluated for tuberculosis and has been treated accordingly  Reauthorization of Enbrel for PPs requires a dosage of 50 mg or less per week or less.
Procrit	Anemia Due to Chronic Renal Failure (CRF)  Anemia in HIV-infected patients (HIV)  Anemia in cancer patients on chemo-	<b>Chemotherapy:</b> Patient is not receiving cancer chemotherapy; OR Patient has malignancy for which therapy with epoetin is contra-indicated.	<b>Anemia due to Chronic Renal Failure:</b> 1. Hematocrit (Hct) less than 33%; OR 2. Hemoglobin (Hgb) less than 11 gm/dl.  <b>Reauthorization of CRF:</b> 1. Average Hct was below 36% over 3-months: AND 2. One of the following: a. Hct reached target (30% to 36%); OR b. Decrease in blood transfusion; OR c. Hgb is 1 g/dL or greater from pre-treatment level.  <b>Anemia in HIV-infected patients:</b> 1. Anemia is due to zidovudine treatment or due to			<b>Initial Therapy Pre-Op:</b> 1 month  <b>Chemo, HCV, and MDS:</b> 3 months.  <b>CRF, HIV:</b> 6 months  <b>Reauthorization CRF, HIV, MDS:</b> 12 months	Epoetin will be subject to Part B vs. Part D review.  For Chemotherapy Induced Anemia, Hgb/Hct levels must be collected within prior two weeks of request.

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	<p>therapy (Chemo)</p> <p>Pre-operative use in patients undergoing surgery for reduction of allogeneic blood transfusion (Pre-op)</p> <p>Refractory anemia in Myelodysplastic Syndrome (MDS)</p> <p>Treatment of anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon (HCV)</p>		<p>HIV infection; AND</p> <p>2. Hgb less than 12 g/dL or Hct less than 36%.</p> <p><b>Reauthorization in HIV:</b></p> <p>1, Hct was below 36% over 3 months; AND</p> <p>2. One of the following:</p> <p>a. Hct reached target (30% to 36%); OR</p> <p>b. Decrease in blood transfusion; OR</p> <p>c. Hgb is 1 g/dL or greater from pre-treatment level.</p> <p><b>Anemia in cancer patients on Chemotherapy:</b></p> <p>1. Verify other causes of anemia have been ruled out; AND</p> <p>2. Hct less than 36% or Hgb less than 12 gm/dl.</p> <p>3. Cancer is a non-myeloid malignancy; AND</p> <p>4. Concurrently on chemo, will be on concomitant chemo for 2 months OR anemia is caused by cancer chemotherapy.</p> <p><b>Reauthorization in Chemo:</b></p> <p>1. Hct less than 36% or Hgb less than 12 gm/dl; AND</p> <p>2. One of the following; AND:</p> <p>a. Hct reached target (30% to 36%)</p> <p>b. Decrease in blood transfusion</p> <p>c. Hgb is 1 g/dL or greater from pre-treatment level.</p> <p>3. Concurrently on chemotherapy for 2 months or anemia is caused by cancer chemo.</p> <p><b>Preoperative use in patients undergoing surgery for reduction of allogeneic blood transfusion (Pre-op):</b></p> <p>1. Hgb greater than 10 to less than 13 g/dL scheduled to undergo elective, non-cardiac/vascular surgery to reduce blood transfusions; OR</p> <p>2. Patient at high risk for peri-operative transfusions with expected blood loss of 2 units or greater.</p> <p><b>Refractory anemia in Myelodysplastic Syndrome:</b></p> <p>1. Hct less than 33% or Hgb less than 11 g/dL;</p>			<p><b>Chemo, HCV:</b></p> <p>3 months.</p>	<p>For all other indications, Hgb/Hct levels must be collected within prior 30 days of request.</p>

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			<p>AND</p> <p>2. One of the following:</p> <p>a. Serum erythropoietin of 500 mU/mL or less</p> <p>b. Diagnosis of transfusion-dependent MDS.</p> <p><b>Reauthorization for MDS:</b></p> <p>1. Avg Hct was below 36% over a 3 months; AND</p> <p>2. One of the following:</p> <p>a. Hct reached target (30% to 36%)</p> <p>b. Decrease in blood transfusion</p> <p>c. Hgb increase of 1 g/dL or more from pre-treatment level.</p> <p><b>Treatment of anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon:</b></p> <p>1. Hgb less than 12 g/dL or Hct less than 36%; AND</p> <p>2. Is concurrently on ribavirin and interferon or peg-interferon alfa for the treatment of HCV and the anemia is due to treatment.</p> <p><b>Reauthorization of HCV:</b></p> <p>1. Avg Hct was below 36% over a 3 months; And</p> <p>2. One of the following:</p> <p>a. Hct reached target (30% to 36%)</p> <p>b. Decrease in blood transfusion</p> <p>c. Hgb is 1 g/dL or greater from pre-treatment level.</p> <p><b>All uses:</b></p> <p>Verify iron evaluation for adequate Fe stores.</p>				
Eribitux	<p>Head and Neck Cancer</p> <p>Colorectal Cancer.</p>		<p><b>Head and Neck Cancer:</b></p> <p>1. One of the following:</p> <p>a. Confirmed diagnosis of locally or regionally advanced squamous cell carcinoma of the head and neck</p> <p>b. Recurrent or metastatic squamous cell head and neck cancer; AND</p> <p>2. One of the following:</p> <p>a. Used in combination with radiation therapy</p> <p>b. After failure of platinum-based chemotherapy.</p>			Length of therapy	Eribitux will be approved for continuation of prior therapy.

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			<b>Colorectal Cancer:</b> 1. Confirmed diagnosis of metastatic carcinoma of the colon or rectum; AND 2. One of the following: a. Used in combination with irinotecan-based chemotherapy b. Intolerance to irinotecan-based chemotherapy c. Failure of irinotecan or oxaliplatin-based chemotherapy regimens.				
fentanyl citrate oral transmucosal	Malignant pain		<b>Cancer Pain:</b> 1. Confirmed diagnosis of malignant pain; AND 2. Failure or contraindication to an immediate-release opioid; AND 3. Demonstrated tolerance to opioids.			Length of therapy	
Forteo	Osteoporosis	1. Paget's disease history 2. Bone metastases of skeletal malignancies 3. Radiation therapy 4. Metabolic bone disease other than osteoporosis 5. Concurrent use of bisphosphonate.	<b>Osteoporosis:</b> 1. Patient has a history of fracture resulting from minimal trauma (or BMD T score of -2.5 or less); OR 2. Both of the following: a. Failure to a formulary alternative b. BMD T score of - 3.0 or less and a previous fracture resulting from minimal trauma.			2 years	Forteo is subject to Part B vs. Part D review.

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Gamastan S/D	Hepatitis A Measles Varicella Rubella All FDA approved indications not otherwise excluded from Part D		<p><b>Hepatitis A:</b> For use before or soon after exposure.</p> <p><b>Measles:</b> For use in susceptible individuals exposed fewer than 6 days previously.</p> <p><b>Varicella:</b> For use in immunocompromised patients when Varicella Zoster Immune Globulin is not available.</p> <p><b>Rubella:</b> For pregnant women who will not consider a therapeutic abortion.</p>			Length of therapy	
Gleevec	Chronic Myeloid Leukemia (CML) Acute Lymphoblastic Leukemia (ALL) Myelo-dysplastic or myelo-proliferative diseases (MDS/MPD) Aggressive systemic mastocytosis (ASM) Hyper-eosinophilic syndrome (HES) and chronic		<p><b>Chronic Myeloid Leukemia (Adults):</b> Diagnosis of Philadelphia chromosome positive CML.</p> <p><b>Chronic Myeloid Leukemia (Children):</b>            1. Diagnosis of Philadelphia chromosome positive (Ph+) chronic phase CML; AND            2. One of the following:                a. Not candidates for stem cell transplantation                b. Disease has recurred after stem cell transplant                c. Patients who are resistant to interferon-alfa therapy.</p> <p><b>Acute Lymphoblastic Leukemia:</b> Adult patients with Philadelphia chromosome positive ALL.</p> <p><b>Myelodysplastic/Myeloproliferative disease:</b> Adults diagnosed with MDS/MPD diseases associated with platelet-derived growth factor receptor gene rearrangements.</p> <p><b>Aggressive systemic mastocytosis:</b>            1. Adults diagnosed with aggressive systemic mastocytosis; AND            2. One of the following:                a. Patient is without the D816V c-Kit mutation</p>			Length of therapy	Gleevec will be approved for continuation of prior therapy.

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	<p>eosinophilic leukemia (CEL)</p> <p>Dermatofibro-sarcoma protuberans (DFSP)</p> <p>Gastro-intestinal Stromal Tumors (GIST)</p>		<p>b. c-Kit mutation status unknown.</p> <p><b>Hypereosinophilic syndrome and chronic eosinophilic leukemia :</b> Adults diagnosed with HES or CEL.</p> <p><b>Dermatofibrosarcoma protuberans:</b> Adults with unresectable, recurrent and/or metastatic DFSP.</p> <p><b>Gastrointestinal Stromal Tumors:</b> Patients with a confirmed diagnosis of unresectable and/or metastatic GIST.</p>				
<p><b>Growth Hormones:</b> Genotropin, Genotropin Miniquick, Humatrope, Humatrope Combo Pack, Norditropin Cartridge, Norditropin Nordiflex Pen, Nutropin, Nutropin Aq, Nutropin Aq Pen, Saizen, Saizen Click.Easy, Tev-Tropin, Omnitrope</p>	<p>Growth Hormone Deficiency (GHD) in Children</p> <p>Prader-Willi Syndrome (PWS)</p> <p>Small for Gestational Age (SGA)</p> <p>Turner Syndrome (TS)</p> <p>Noonan Syndrome (NS)</p> <p>Growth Retardation associated with Chronic Renal Insufficiency (GRCRF)</p>	<p><b>Childhood Onset Growth Hormone Deficiency in Adults:</b></p> <ol style="list-style-type: none"> <li>1. Males with bone age greater than 17 yrs or females with bone age greater than 15 years</li> <li>2. Closed bone epiphyses on radiograph</li> <li>3. Growth velocity less than 2 cm/year during previous year of</li> </ol>	<p><b>GHD Children:</b></p> <ol style="list-style-type: none"> <li>1. Diagnosis of GH deficiency based on two GH stimulation tests or low Insulin-like growth factor 1 (IGF-1) levels; AND</li> <li>2. Demonstrate growth failure based on growth velocity or height shorter than 2 standard deviations (SD) below the mean height for age.</li> </ol> <p><b>Prader-Willi Syndrome or Small for Gestational Age:</b></p> <ol style="list-style-type: none"> <li>1. Diagnosis of PWS confirmed by genetic testing; OR</li> <li>2. Diagnosis of SGA confirmed by birth wt of less than 2500g at gestation of more than 37 wks or at birth weight or length below the 3rd percentile for gestational age who failed to catch up by 2 years of age.</li> </ol> <p><b>Turner Syndrome, Noonan Syndrome:</b></p> <ol style="list-style-type: none"> <li>1. Treatment of short stature in females w/bone age less than 15 years associated w/TS or NS; OR</li> <li>2. Treatment of short stature in males w/bone age less than 17 years associated w/NS.</li> </ol> <p><b>Growth Retardation associated with Chronic Renal Insufficiency:</b></p> <ol style="list-style-type: none"> <li>1. Diagnosis of chronic renal insufficiency; AND</li> <li>2. Height shorter than or equal to 2 SD below the</li> </ol>		<p><b>GHD (Child), AOGH, COGHDA, IGHDA, Initial Therapy for TS or NS, GRCRF, and ISS:</b> Prescribed by an endocrinologist.</p>	<p>Length of therapy for GHD in adults. One year for all other uses.</p>	

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	<p>Idiopathic Short Stature (ISS)</p> <p>Adult Onset Growth Hormone Deficiency (AOGHD),</p> <p>Childhood Onset GH Deficiency in Adults (COGHDA)</p> <p>Isolated GH Deficiency in Adults (IGHDA)</p>	<p>treatment unless COGHD criteria are met.</p>	<p>median age for children or where growth velocity falls to below 4.5 cm/year.</p> <p><b>Reauthorization for GHD in Children, PWS, SGA, TS, NS, GRCRF:</b></p> <ol style="list-style-type: none"> <li>1. Increase in growth velocity of at least 2 cm/year during previous year of treatment; AND</li> <li>2. Males with bone age less than 17 yrs or females with bone age less than 15 years.</li> </ol> <p><b>Idiopathic Short Stature:</b></p> <ol style="list-style-type: none"> <li>1. Height less than or equal to 2.25 SD below the mean height for age. Growth velocity less than the 25th percentile for bone age; AND</li> <li>2. Verify open epiphyses on last bone age radiograph; AND</li> <li>3. Absence of comorbid conditions that should be observed or treated by other means.</li> </ol> <p><b>Reauthorization of ISS:</b></p> <ol style="list-style-type: none"> <li>1. Increase in growth velocity of at least 4.5 cm/year during previous year of treatment; AND</li> <li>2. Males w/bone age less than 17 years or females w/bone age less than 15 years.</li> </ol> <p><b>Adult Onset Growth Hormone Deficiency:</b></p> <ol style="list-style-type: none"> <li>1. Pts who have GHD alone or multiple hormone deficiencies because of pituitary disease/insult, hypothalamic disease, surgery, or radiation treatment; AND</li> <li>2. IGF-1 level less than 77 mcg/L or 2 SD below the mean value, matched by age and gender.</li> </ol> <p><b>Childhood Onset GH Deficiency in Adults:</b></p> <ol style="list-style-type: none"> <li>1. Childhood onset in patients who were GH deficient during childhood who have GH deficiency confirmed as an adult before replacement treatment with GH is started; AND</li> <li>2. Persistent deficiency of GH documented by GH stimulation tests.</li> </ol> <p><b>Isolated GH Deficiency in Adults:</b></p> <p>Documented deficiency of GH documented by 2 GH stimulation tests.</p>				

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Humira, Humira Pen, Humira Pen-Crohns Disease	Moderate to severe active Rheumatoid Arthritis (RA)  Psoriatic Arthritis (PsA)  Ankylosing Spondylitis (AS)  Crohn's disease (CD)  Juvenile Idiopathic Arthritis (JIA)  Plaque Psoriasis (PP)	Concurrent use of anakinra	<b>Rheumatoid Arthritis:</b> 1. Diagnosis of moderate-to-severe RA; AND 2. Failed methotrexate or 2 DMARDs for 3 months.  <b>Juvenile Rheumatoid Arthritis / Juvenile Idiopathic Arthritis:</b> Diagnosis of moderate-to-severe poly-articular course  <b>Juvenile Rheumatoid Arthritis:</b> Failed NSAID or steroid and DMARD for three months.  <b>Psoriatic Arthritis:</b> 1. Diagnosis of active PsA. 2. Failed methotrexate or 2 DMARDs for 3 months.  <b>Ankylosing Spondylitis:</b> 1. Diagnosis of AS. 2. Failed 2 NSAIDs for 3 months.  <b>Plaque Psoriasis:</b> 1. Diagnosis moderate-to-severe plaque psoriasis with min BSA 10%. 2. Failed phototherapy and systemic therapy.  <b>Crohn's disease:</b> 1. Diagnosis of moderate to severe CD; AND 2. Failed conventional therapies.  <b>Reauthorization:</b> Demonstration of clinical response to therapy.	<b>RA, PsA, CD, AS, Plaque Psoriasis:</b> 18 years and older.  <b>JIA:</b> 4 years and older.	<b>RA, PsA, AS, JIA:</b> Prescribed or recommended by a rheumatologist.  <b>Plaque Psoriasis:</b> Prescribed or recommended by a dermatologist.  <b>CD:</b> Prescribed or recommended by gastroenterologist.	<b>Initial Authorization:</b> 4 months for Plaque Psoriasis; 6 months for other uses.  <b>Reauthorization</b> 12 months	<b>RA:</b> 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.  <b>All diagnoses:</b> Verification that the patient has been evaluated for TB and treated accordingly.
<b>Immune Globulin:</b> Carimune Nanofiltered, Flebogamma, Gammagard Liquid, Gamunex, Iveegam En, Octagam,	Idiopathic Thrombocytopenic Purpura (ITP)  Kawasaki Disease (KD)  B-cell		<b>Idiopathic Thrombocytopenic Purpura:</b> 1. For patients with ITP who require a rapid temporary increase in platelet count or to control excessive bleeding; AND 2. Platelet count less than $20 \times 10^9/L$ (or less than $30 \times 10^9/L$ with active bleeding or less than $50 \times 10^9/L$ with symptoms of severe bleeding).  <b>Kawasaki Disease:</b> Confirmed diagnosis of KD.	<b>BMT:</b> 20 years and older.  <b>HIV:</b> 13 years or younger.	<b>MG:</b> Prescribed by a neurologist.	<b>BMT:</b> 100 days after transplant  <b>KD:</b> 1 month  <b>MG, GBS:</b> 1 treatment course  <b>ITP, LEMS:</b>	Immune Globulin is subject to Part B vs. Part D review.

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
Panglobulin, Panglobulin Nf, Panglobulin., Polygam S/D	Chronic Lymphocytic Leukemia  Bone Marrow Transplantation (BMT)  Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)  Dermatomyositis  Multifocal Motor Neuropathy  Pediatric HIV  Guillane-Barre Syndrome (GBS)  Lambert-Eaton Myasthenic Syndrome (LEMS)  Acute Myasthenia Gravis Exacerbation (MG)  Relapsing-		<p><b>B-cell Chronic Lymphocytic Leukemia:</b></p> <ol style="list-style-type: none"> <li>1. Documented hypogammaglobulinemia (IgG less than 600mg/dL); OR</li> <li>2. History of bacterial infections associated with B-cell CLL.</li> </ol> <p><b>Bone Marrow Transplantation:</b></p> <ol style="list-style-type: none"> <li>1. Confirmed allogeneic BMT within the last 100 days; AND</li> <li>2. Documented severe hypogammaglobulinemia (IgG less than 400 mg/dL)</li> </ol> <p><b>Dermatomyositis:</b> Failure or intolerance to standard therapy.</p> <p><b>HIV:</b> Documented hypogammaglobulinemia (IgG less than 400 mg/dL).</p> <p><b>Guillane-Barre Syndrome:</b></p> <ol style="list-style-type: none"> <li>1. Confirmed diagnosis of severe GBS; AND</li> <li>2. Patients with severe disease requiring aid to walk; AND</li> <li>3. Onset of muscle weakness within the last 4 weeks.</li> </ol> <p><b>Acute Myasthenia Gravis Exacerbation :</b></p> <ol style="list-style-type: none"> <li>1. Confirmed diagnosis of myasthenia gravis with myasthenic exacerbation, defined by one of the following:               <ol style="list-style-type: none"> <li>a. Difficulty swallowing</li> <li>b. Acute respiratory failure</li> <li>c. Major functional disability responsible for the discontinuation of physical activity.</li> </ol> </li> </ol> <p><b>Relapsing-Remitting Multiple Sclerosis :</b> Failure to two standard MS agents.</p> <p><b>Stiff Person Syndrome :</b> Chart documentation confirming a diagnosis of stiff-person syndrome.</p>			6 months  <b>Other Uses:</b> 1year	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
	Remitting Multiple Sclerosis  Stiff Person Syndrome  All FDA approved indications not otherwise excluded from Part D						
Intron-A, Intron-A W/Diluent	Hepatitis B - HBeAg positive (HepB (+))  Hepatitis B - HBeAg negative (HepB (-))  Hepatitis C - Treatment Naive Patients (HepC Naive)  Hepatitis C - Continuation of Therapy (HepC-Con't)  Non-Hepatitis Diagnoses  Acute Hepatitis C		<p><b>Hepatitis B - HBeAg positive:</b></p> <ol style="list-style-type: none"> <li>1. HBsAg positive for at least 6 months; AND</li> <li>2. HBV DNA level greater than 100,000 copies/mL; AND.</li> <li>3. Compensated liver disease; AND</li> <li>4. One of the following: persistent ALT 2 times ULN or moderate to severe hepatitis or fibrosis on biopsy.</li> </ol> <p><b>Hepatitis B - HBeAg negative:</b></p> <ol style="list-style-type: none"> <li>1. HBsAg positive for at least 6 months; AND</li> <li>2. HBV DNA level of 2000 IU/mL or more or 11,200 copies/mL; AND</li> <li>3. Compensated liver disease; AND</li> <li>4. One of the following: persistent ALT 2 times ULN or moderate to severe hepatitis or fibrosis on biopsy.</li> </ol> <p><b>Hepatitis C - Treatment Naive Patients:</b> For patients with Chronic Hepatitis C with compensated liver disease with positive HCV antibody and HCV RNA.</p> <p><b>Hepatitis C - Continuation of Therapy:</b> For genotypes 2,3,5, or 6: loss of detectable HCV RNA from serum or 100 fold drop or more in HCV RNA level.</p> <p><b>Non-Hepatitis Diagnoses</b></p>	<p><b>Hep B - HBeAg positive, Hep B - HBeAg negative:</b> 1 year of age or older.</p> <p><b>Hep C - Treatment Naive Patients, Non-Hepatitis Diagnoses, Acute Hep C:</b> 18 years old and older.</p>		<p><b>HepB+:</b> 6 months to 1year.</p> <p><b>HepC: genotypes 2, 3, 5, 6:</b> 6 months</p> <p><b>HepC: genotypes 1, 4, HIV/HCV:</b> 12 months</p> <p><b>Acute HepC, HCL, Kaposi:</b> 6 months.</p> <p><b>Warts:</b> 3 weeks.</p> <p><b>Other uses:</b> 1year</p>	Intron A will be approved for continuation of prior therapy for neoplastic diseases.

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
	(Acute HepC)  All FDA approved indications not otherwise excluded from Part D		Diagnosis of one of the following: 1. Malignant Melanoma 2. Hairy cell leukemia 3. Stage III or IV follicular Non-Hodgkin's Lymphoma, 4. Condylomata acuminata 5. AIDS-related Kaposi's sarcoma 6. Multiple Myeloma.  <b>Acute Hepatitis C:</b> Patients with acute hepatitis C.				
Ketek	Community Acquired Pneumonia (CAP)		<b>Community-Acquired Pneumonia:</b> 1. Diagnosis of CAP in an adult outpatient; AND 2. Resistance or failure to either azithromycin or clarithromycin.			Ketek will be approved for the length of therapy.	
Kineret	Rheumatoid Arthritis	Concurrent use of TNF-blockers or Orencia	<b>Initial Therapy for Rheumatoid Arthritis:</b> 1. Moderate to severe active RA with at least 6 swollen joints and at least 6 tender/painful joints; AND 2. One of the following: a. More than 45 minutes of morning stiffness b. Elevated ESR c. Elevated CRP; AND 3. Failure with a TNF-alpha-blocker. Failure on either methotrexate or at least 2 DMARDs for at least 3 months.  <b>Reauthorization for RA:</b> 1. At least 20% improvement in the tender and swollen joint count; AND 2. At least 20% improvements in 3 of the following: a. MD or patient's global assessment b. Patient's assessment of pain c. Degree of disability d. Acute-phase reactant concentration; OR 3. Submission of chart documentation demonstrating the clinical equivalent of the above criteria.		<b>RA:</b> Prescribed or recommended by a rheumatologist.	<b>Initial Therapy for RA:</b> Kineret will be approved for 6 months.  <b>Reauthorization for RA:</b> Kineret will be approved for 1 year.	

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Letairis	Pulmonary Arterial Hypertension (PAH)		<p><b>Pulmonary Arterial Hypertension:</b> Patients with a confirmed diagnosis of pulmonary arterial hypertension (modified WHO Group I) in WHO functional class II or III.</p>			Length of therapy	
Leukine	<p>Bone Marrow/Stem Cell Transplant (BMSCT)</p> <p>Acute Myeloid Leukemia Induction or Consolidation Therapy (AML)</p> <p>Neutropenia associated with dose dense chemotherapy (NDDC)</p> <p>Chemotherapy with risk of febrile neutropenia (CFN)</p> <p>Febrile Neutropenia (FN)</p> <p>HIV-related neutropenia (HIVN)</p> <p>All FDA approved</p>		<p><b>Bone Marrow/Stem Cell Transplant:</b></p> <ol style="list-style-type: none"> <li>For patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT; OR</li> <li>For mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; OR</li> <li>For peripheral stem cell transplant patients who have received myeloablative chemotherapy.</li> </ol> <p><b>Acute Myeloid Leukemia Induction or Consolidation Therapy:</b> For patients with AML following induction or consolidation chemotherapy.</p> <p><b>Neutropenia associated with dose dense chemotherapy:</b></p> <ol style="list-style-type: none"> <li>Patient is receiving the National Comprehensive Cancer Network's (NCCN's) Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer; OR</li> <li>A dose-dense regimen for which the incidence of febrile neutropenia is unknown.</li> </ol> <p><b>Chemotherapy with risk of febrile neutropenia:</b></p> <ol style="list-style-type: none"> <li>Patient is receiving a chemotherapy regimen associated with more than 20% incidence of febrile neutropenia; OR</li> <li>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.</li> </ol> <p><b>Febrile Neutropenia:</b></p> <ol style="list-style-type: none"> <li>For patients receiving myelosuppressive anticancer drugs associated with neutropenia; AND</li> </ol>	<p><b>AML:</b> Greater than or equal to 55 years old.</p>		<p><b>BMSCT, AML:</b> 6 weeks</p> <p><b>NDDC, CFN:</b> One month or duration of treatment.</p> <p><b>FN:</b> 6 weeks or duration of chemotherapy</p> <p><b>HIVN:</b> One month, or three months with risk factors</p>	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
	indications not otherwise excluded from Part D		<p>2. Patient either has febrile neutropenia or has a history of febrile neutropenia during a previous course of chemotherapy.</p> <p><b>HIV-related neutropenia:</b> HIV-infected patients with an Absolute Neutrophil Count (ANC) less than or equal to 1,000 cells/mm<sup>3</sup> with or without one or more risk factors for developing chronic neutropenia.</p>				
Lotronex	Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS)	Initial therapy for IBS in the male gender.	<p><b>Initial Therapy for Irritable Bowel Syndrome:</b></p> <ol style="list-style-type: none"> <li>Confirmed diagnosis of (IBS) with diarrhea predominant symptoms for at least 6 months; AND</li> <li>Failure to an antispasmodic and an anti-diarrhea agent.</li> </ol> <p><b>Reauthorization for IBS:</b></p> <ol style="list-style-type: none"> <li>Recurrence of diarrhea-predominant IBS; AND</li> <li>Documentation of positive clinical response while on Lotronex.</li> </ol>	18 years and older.	Verification that physician has enrolled in the GlaxoSmithKline Prescribing Program.	<p><b>Initial Therapy:</b> 12 weeks</p> <p><b>Reauthorization:</b> 6 months</p>	
Lyrica	<p>Treatment of Seizure Disorder</p> <p>Diabetic Neuropathy</p> <p>Post-herpetic Neuropathic Pain</p> <p>Fibromyalgia</p>		<p><b>Seizure Disorder:</b></p> <ol style="list-style-type: none"> <li>History of failure to a formulary anticonvulsant; AND</li> <li>As add-on therapy for the diagnosis of partial seizure.</li> </ol> <p><b>Diabetic Neuropathy:</b></p> <ol style="list-style-type: none"> <li>Diagnosis of Diabetes Mellitus; AND</li> <li>Diagnosis of peripheral neuropathy; AND</li> <li>Failure to one formulary anticonvulsant.</li> </ol> <p><b>Post-herpetic Neuropathic Pain:</b> Failure to one formulary anticonvulsant.</p>			Length of therapy	Lyrica will be approved for continuation of prior therapy.

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
Marinol, dronabinol	<p>Nausea and Vomiting Associated with Cancer Chemotherapy (CINV)</p> <p>Anorexia in Patients with AIDS</p>		<p><b>Nausea and Vomiting Associated with Cancer Chemotherapy:</b></p> <ol style="list-style-type: none"> <li>1. Patient is receiving cancer chemotherapy; AND</li> <li>2. Failure to 5HT-3 receptor antagonist; AND</li> <li>3. Failure to one of the following agents:               <ol style="list-style-type: none"> <li>a. Antihistamine</li> <li>b. Corticosteroid</li> <li>c. Prokinetic agent</li> <li>d. Antipsychotic.</li> </ol> </li> </ol> <p><b>AIDS Anorexia:</b> Diagnosis of anorexia with weight loss in patients with AIDS.</p>			<p><b>CINV, AIDS anorexia:</b> length of therapy</p>	<p>Marinol is subject to Part B vs. Part D review.</p> <p><b>CINV:</b> Marinol will be approved for continuation of therapy for treatment covered under Part B when patient is receiving chemotherapy</p>
Miacalcin injection	<p>Post-menopausal Osteoporosis</p> <p>Paget's Disease</p> <p>Hypercalcemia</p>		<p><b>Postmenopausal Osteoporosis:</b></p> <ol style="list-style-type: none"> <li>1. Failure to a bisphosphonate or selective estrogen-receptor modulator (SERM); AND</li> <li>2. Failure to Miacalcin Nasal Spray; AND</li> <li>3. 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.</li> </ol> <p><b>Initial Therapy for Paget's Disease:</b> History of failure or intolerance to oral bisphosphonates.</p> <p><b>Reauthorization for Paget's Disease:</b> Serum alkaline phosphatase concentration fails to normalize after the previous 6 months of therapy.</p> <p><b>Hypercalcemia:</b></p> <ol style="list-style-type: none"> <li>1. Corrected total serum calcium of 12 mg/dl; OR</li> <li>2. Greater or corrected total serum calcium of 6 mEq/L or greater.</li> </ol>			<p><b>Post-menopausal Osteoporosis:</b> Miacalcin will be approved for the length of therapy.</p> <p><b>Paget's disease:</b> 6 months.</p> <p><b>Hypercalcemia:</b> One time only.</p>	<p>Miacalcin is subject to Part B vs. Part D review.</p>

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
Neulasta	<p>Chemotherapy with risk of febrile neutropenia (CFN)</p> <p>Neutropenia associated with dose dense chemotherapy (NDDC)</p> <p>Febrile Neutropenia (FN)</p>		<p><b>Chemotherapy with risk of febrile neutropenia :</b></p> <ol style="list-style-type: none"> <li>1. Patient is receiving a chemotherapy regimen associated with more than 20% incidence of febrile neutropenia; OR</li> <li>2. a. Patients is receiving chemotherapy regimen associated with 10-20% incidence of febrile neutropenia; AND</li> <li>b. Has risk factors associated with chemotherapy-induced infection, febrile neutropenia or neutropenia.</li> </ol> <p><b>Neutropenia associated with dose dense chemotherapy :</b></p> <ol style="list-style-type: none"> <li>1. Patients is receiving NCCN's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer; OR</li> <li>2. A dose-dense regimen for which the incidence of febrile neutropenia is unknown.</li> </ol> <p><b>Febrile Neutropenia:</b></p> <ol style="list-style-type: none"> <li>1. For patients receiving myelosuppressive anticancer drugs associated with neutropenia; AND</li> <li>2. Patient either has febrile neutropenia or has a history of febrile neutropenia during a previous course of chemotherapy.</li> </ol>			<p><b>CFN, NDDC:</b> One month or duration of treatment.</p> <p><b>FN:</b> One month or duration of chemotherapy.</p>	
Neumega	<p>Severe thrombocytopenia following myelosuppressive chemotherapy</p> <p>All FDA approved indications not otherwise excluded from Part D</p>	<p>Thrombocytopenia following chemotherapy: Following myeloablative chemotherapy.</p>	<p><b>Severe thrombocytopenia following myelosuppressive chemotherapy</b></p> <ol style="list-style-type: none"> <li>1. Verification that the cancer is a non-myeloid malignancy; AND</li> <li>2. Platelet count is less than 50,000 cells/microliter; AND</li> <li>3. Patients with one or more of the following risk factors: <ol style="list-style-type: none"> <li>a. Extensive prior cytotoxic chemotherapy</li> <li>b. Prior severe chemotherapy-induced thrombocytopenia</li> <li>c. Receiving chemotherapy regimens associated with high risk for thrombocytopenia.</li> </ol> </li> </ol>			<p>3 week intervals for up to 6 cycles post-chemotherapy.</p>	
Neupogen	Bone		<b>Bone Marrow/Stem Cell Transplant:</b>			<b>BMSCT, AML,</b>	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
	<p>Marrow or Stem Cell Transplant (BMSCT)</p> <p>Acute Myeloid Leukemia Induction or Consolidation Therapy (AML)</p> <p>Neutropenia associated with dose dense chemotherapy (NDDC)</p> <p>Chemotherapy with risk of febrile neutropenia (CFN)</p> <p>Febrile Neutropenia (FN)</p> <p>Severe Chronic Neutropenia (SCN)</p> <p>Hepatitis-C Treatment of Related Neutropenia (HCN)</p> <p>HIV-related neutropenia</p>		<p>1. For patients with non-myeloid malignancies undergoing myelo-ablative chemotherapy followed by autologous or allogeneic BMT; OR</p> <p>2. For mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; OR</p> <p>3. For peripheral stem cell transplant patients who have received myelo-ablative chemotherapy.</p> <p><b>Acute Myeloid Leukemia Induction or Consolidation Therapy:</b> For patients with AML following induction or consolidation chemotherapy.</p> <p><b>Neutropenia associated with dose dense chemotherapy:</b></p> <p>1. Patient is receiving NCCN's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer; OR</p> <p>2. A dose-dense regimen for which the incidence of febrile neutropenia is unknown.</p> <p><b>Chemotherapy with risk of febrile neutropenia:</b></p> <p>1. Patient is receiving a chemotherapy regimen associated with more than 20% incidence of febrile neutropenia; OR</p> <p>2. 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.</p> <p><b>Febrile Neutropenia:</b></p> <p>1. For patients receiving myelosuppressive anticancer drugs associated with neutropenia; AND</p> <p>2. Patient either has febrile neutropenia or has a history of febrile neutropenia during a previous course of chemotherapy.</p> <p><b>Severe Chronic Neutropenia:</b> For patients with severe chronic neutropenia.</p> <p><b>Hepatitis-C Treatment of Related Neutropenia:</b></p>			<p><b>NDDC, CFN, FN:</b> One month or treatment duration.</p> <p><b>SCN, HCN:</b> Treatment duration.</p> <p><b>HIVN:</b> One month; three months with risk factors.</p>	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
	(HIVN)  All FDA approved indications not otherwise excluded from Part D		<p>1. Neutropenia in Hepatitis C virus infected patients undergoing treatment with Peg-Intron or Pegasys after dose reduction; OR</p> <p>2. For patients 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.</p> <p><b>HIV-related neutropenia:</b> HIV-infected patients with an ANC less than or equal to 1,000 cells/mm<sup>3</sup> with or without one or more risk factors for developing chronic neutropenia.</p>				
oxandrolone	Weight Gain  Bone Pain  AIDS wasting/cachexia		<p><b>Weight gain:</b></p> <p>1. Patients with extensive surgery; OR</p> <p>2. Chronic infections causing unremitting weight loss; OR</p> <p>3. Severe trauma; OR</p> <p>4. Failure to gain or maintain normal weight without definite pathophysiologic reasons; OR</p> <p>5. To offset the protein catabolism associated with prolonged administration of corticosteroids.</p> <p><b>Bone Pain:</b> Diagnosis of bone pain due to osteoporosis.</p> <p><b>Initial Therapy for AIDS Wasting:</b> Diagnosis of AIDS wasting/cachexia and failure to hormone replacement therapy in patients with hypogonadism.</p> <p><b>Reauthorization for Weight Gain:</b> Verification that the patient's weight has increased a minimum of 2% while taking</p>			<p><b>Initial therapy:</b> 3 months</p> <p><b>Reauthorization:</b> Length of therapy</p>	
Pegasys	Hepatitis B - HBeAg positive  Hepatitis B - HBeAg negative		<p><b>Hepatitis B - HBeAg positive patients:</b></p> <p>1. HBsAg positive for at least 6 months; AND</p> <p>2. HBV DNA level greater than 100,000 copies/mL; AND.</p> <p>3. Compensated liver disease; AND</p> <p>4. One of the following:</p> <p>a. ALT (liver enzyme) 2 times upper limits of normal (ULN)</p>	<p><b>For all covered uses:</b> 18 years and older</p>		<p><b>Hepatitis B:</b> 1 year.</p> <p><b>Hepatitis C Genotypes 5, 6:</b> 12 weeks;</p> <p><b>Genotypes 2, 3:</b> 24 weeks;</p>	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
	<p>Hepatitis C - Treatment Naive Patients</p> <p>Hepatitis C - Continuation of Therapy</p> <p>Hepatitis C Retreatment.</p>		<p>b. Moderate-to-severe hepatitis or fibrosis on biopsy.</p> <p><b>Hepatitis - HBeAg negative patients:</b></p> <ol style="list-style-type: none"> <li>1. HBsAg positive for at least 6 months; AND</li> <li>2. HBV DNA level of 2000 IU/mL or more or 11,200 copies/mL; AND</li> <li>3. Compensated liver disease; AND</li> <li>4. One of the following:               <ol style="list-style-type: none"> <li>a. ALT 2 times ULN</li> <li>b. Moderate-to-severe hepatitis or fibrosis on biopsy.</li> </ol> </li> </ol> <p><b>Hepatitis C - Treatment Naive Patients:</b></p> <ol style="list-style-type: none"> <li>1. Chronic Hepatitis C with compensated liver disease; AND</li> <li>2. Positive HCV antibody HCV RNA; AND</li> <li>3. HCV RNA level measurement; AND</li> <li>4. Genotype test result; AND</li> <li>5. For patients who have not previously been treated with interferon.</li> </ol> <p><b>Continuation of Therapy:</b></p> <p><b>A. For genotypes 5 or 6:</b></p> <ol style="list-style-type: none"> <li>1. Loss of detectable HCV RNA from serum or 100 fold drop or more in HCV RNA level.</li> </ol> <p><b>B. For genotype 1:</b></p> <ol style="list-style-type: none"> <li>1. Undetectable HCV RNA after 24 weeks of therapy; AND</li> <li>2. One of the following:               <ol style="list-style-type: none"> <li>a. HCV RNA more than 50 IU/mL at 4 weeks into treatment</li> <li>b. Less than 100 fold drop or detectable HCV RNA 12 weeks into therapy.</li> </ol> </li> </ol> <p><b>C. For genotype 3:</b></p> <ol style="list-style-type: none"> <li>1. Baseline HCV RNA more than 600,000 IU/mL; AND</li> <li>2. Steatosis or advanced fibrosis on liver biopsy.</li> </ol> <p><b>Hepatitis C Retreatment:</b></p> <ol style="list-style-type: none"> <li>1. One of the following               <ol style="list-style-type: none"> <li>a. Retreatment in patients who have failed or</li> </ol> </li> </ol>			<p><b>Genotypes 1, 4:</b> (HIV/HCV co-infected patients): 48wk.</p> <p><b>Hepatitis C Continuation therapy:</b> <b>Genotypes 1,3:</b> 24 weeks, <b>Genotypes 5, 6:</b> 36wk.</p> <p><b>Hepatitis C Retreatment:</b> 1year</p>	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
			<p>relapsed following standard or pegylated interferon monotherapy; OR</p> <p>b. For non-responders or relapsers who have significant fibrosis or cirrhosis who have undergone previous regimens of treatment using non-pegylated interferon. AND</p> <p>2. Used in combination with ribavirin.</p>				
Peg-Intron, Peg-Intron Redipen	Hepatitis C		<p><b>Hepatitis C - Treatment Naive Patients:</b></p> <ol style="list-style-type: none"> <li>1. Chronic Hepatitis C with compensated liver disease; AND</li> <li>2. Positive HCV antibody HCV RNA; AND</li> <li>3. HCV RNA level measurement; AND</li> <li>4. Genotype test result; AND</li> <li>5. For patients who have not previously been treated with interferon.</li> </ol> <p><b>Hepatitis C (Continuation):</b></p> <p>A. <b>For genotypes 5 or 6:</b></p> <ol style="list-style-type: none"> <li>1. Loss of detectable HCV RNA from serum; OR</li> <li>2. 100 fold drop or more in HCV RNA level.</li> </ol> <p>B. <b>For genotype 1:</b></p> <ol style="list-style-type: none"> <li>1. Undetectable HCV RNA after 24 weeks of therapy; AND</li> <li>2. One of the following: <ol style="list-style-type: none"> <li>a. HCV RNA more than 50 IU/mL at 4 weeks into treatment</li> <li>b. Less than 100 fold drop or detectable HCV RNA 12 weeks into therapy.</li> </ol> </li> </ol> <p>C. <b>For genotype 3:</b></p> <ol style="list-style-type: none"> <li>1. Baseline HCV RNA more than 600,000 IU/mL; AND</li> <li>2. Steatosis or advanced fibrosis on liver biopsy.</li> </ol> <p><b>Hepatitis C (Retreatment):</b></p> <ol style="list-style-type: none"> <li>1. One of the following: <ol style="list-style-type: none"> <li>a. Retreatment in patients who have failed or relapsed following standard or pegylated interferon monotherapy; OR</li> <li>b. For non-responders or relapsers who have significant fibrosis or cirrhosis who have undergone previous regimens of treatment</li> </ol> </li> </ol>	Treatment Naive Patients: 18 years and older.		<p><b>Genotypes 5, 6:</b> 12 weeks</p> <p><b>Genotypes 2, 3:</b> 24 weeks</p> <p><b>Genotypes 1, 4, co-infection with HIV/HCV:</b> 48 weeks.</p> <p><b>Hepatitis C Continuation:</b> <b>Genotypes 1, 3:</b> 24 weeks <b>Genotypes: 5, 6:</b> 36 weeks.</p> <p><b>Hepatitis C Retreatment:</b> 1 year</p>	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
			<p>using non-pegylated interferon. AND</p> <p>2. Used in combination with ribavirin.</p>				
Prograf intravenous	Transplant		<p><b>Transplant:</b></p> <p>1. One of the following:</p> <p>a. Patient received a renal (kidney), cardiac (heart), lung, pancreas, small bowel, or hepatic (liver) transplant.</p> <p>b. Patient received a bone marrow/stem cell transplant. AND</p> <p>2. Patient is unable to take oral tacrolimus.</p>			Prograf will be approved for the length of therapy.	Prograf is subject to Part B vs. Part D review:
Prograf	<p>Severe Uveitis</p> <p>Transplant</p>		<p><b>Severe Uveitis:</b></p> <p>Failure to corticosteroids.</p> <p><b>Transplant:</b></p> <p>1. Patient received a renal (kidney), cardiac (heart), lung, pancreas, small bowel, hepatic (liver) transplant, bone marrow/stem cell transplant; AND</p> <p>2. Diagnosis of graft vs. host disease in patients receiving bone marrow transplants.</p>			Length of therapy	Prograf is subject to Part B vs. Part D review : Not limited to new starts only Approve Prograf for continuation of prior therapy if Part D.

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
Proleukin	<p>Metastatic Renal Cell Carcinoma</p> <p>Metastatic Melanoma</p> <p>All FDA approved indications not otherwise excluded from Part D</p>		<p><b>Metastatic Renal Cell Carcinoma or Metastatic Melanoma:</b></p> <ol style="list-style-type: none"> <li>1. Measurable, histologically confirmed metastatic renal cell carcinoma or metastatic melanoma; AND</li> <li>2. Good neurologic or ambulatory performance status; AND</li> <li>3. Adequate organ function determined by all of the following:               <ol style="list-style-type: none"> <li>a. Normal cardiac stress test results</li> <li>b. FEV1 greater than 2 L on pulmonary function tests</li> <li>c. Creatinine concentration 1.5 mg/dL or less or calculated creatinine clearance &gt; 60 ml/min</li> <li>d. Bilirubin concentration of 1.5 mg/dL or less</li> <li>f. SGOT/AST less than 150 IU or 4x upper limit of normal. AND</li> </ol> </li> <li>4. Platelet count greater than or equal to 100,000/ mL; AND</li> <li>5. Hemoglobin greater than or equal to 10 g/dL; AND</li> <li>6. WBC greater than or equal to 3,500 / mL; AND</li> <li>7. At least 7 weeks since prior therapy and complete recovery from therapy-related side effects.</li> </ol>	<p><b>All uses:</b> 18 years and older</p>		<p>1 course of therapy per request</p>	<p><b>All uses:</b> Proleukin will be approved for continuation of prior therapy.</p> <p><b>Metastatic Renal Cell Carcinoma or Melanoma:</b> Administered in a hospital setting.</p> <p><b>Additional treatment</b> authorized only if there is some tumor shrinkage following the last course and if re-treatment is not contra-indicated.</p>
Provigil	<p>Narcolepsy</p> <p>Obstructive Sleep Apnea /Hypopnea Syndrome (OSAHS)</p> <p>Shift Work Sleep Disorder (SWSD)</p> <p>Fatigue Associated</p>	<p><b>Initial Therapy for SWSD:</b> Symptoms do not meet criteria for any other sleep disorder producing insomnia or excessive sleepiness.</p>	<p><b>Narcolepsy:</b> Submission of sleep study confirming the diagnosis of narcolepsy, as defined by the International Classification of Sleep Disorders (1997).</p> <p><b>Initial Therapy for Obstructive Sleep Apnea/Hypopnea Syndrome:</b></p> <ol style="list-style-type: none"> <li>1. More than 5 obstructive apneas, each greater than 10 seconds in duration, per hour of sleep confirmed by a sleep study; AND</li> <li>2. One of the following:               <ol style="list-style-type: none"> <li>a. Frequent arousals from sleep associated with apneas</li> <li>b. Bradycardia</li> <li>c. Arterial oxygen de-saturation in association</li> </ol> </li> </ol>			<p><b>Narcolepsy, MS Fatigue, Idiopathic Hypersomnia:</b> Length of treatment</p> <p><b>OSAHS, SWSD:</b> 3 months</p> <p><b>Reauthorization for OSAHS:</b> 12 months</p>	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
	<p>with Multiple Sclerosis (MS)</p> <p>Idiopathic Hyper-somnia</p>		<p>with apneas. AND</p> <p>3. Fully compliant and concurrently using continuous positive airway pressure (CPAP); AND</p> <p>4. Symptoms of excessive daytime sleepiness.</p> <p><b>Reauthorization for Obstructive Sleep Apnea/Hypopnea Syndrome:</b>  Patient continues to be fully compliant on concurrent CPAP and is experiencing relief of symptomatic hyper-somnolence with Provigil use.</p> <p><b>Shift Work Sleep Disorder:</b></p> <p>1. One of the following:</p> <ul style="list-style-type: none"> <li>a. 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</li> <li>b. Sleep study demonstrating loss of a normal sleep-wake pattern. AND</li> </ul> <p>2. Sleep disturbance causes significant distress or significant impairment; AND</p> <p>3. No other disorder accounts for the symptoms.</p> <p><b>Reauthorization for Shift Work Sleep Disorder:</b></p> <p>1. Patient is experiencing relief with use of Provigil for excessive sleepiness; AND</p> <p>2. Sleep disturbance continues to cause clinically significant distress or significant impairment in occupational functioning.</p> <p><b>Idiopathic Hypersomnia:</b>  Submission of sleep study confirming the diagnosis of Idiopathic Hypersomnia as defined by the International Classification of Sleep Disorders.</p>				

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
Qualaquin	<p>Chloroquine-sensitive P. falciparum malaria</p> <p>Chloroquine-resistant P. falciparum malaria</p>	<ol style="list-style-type: none"> <li>1. Severe or complicated P. falciparum malaria.</li> <li>2. Prevention of Malaria</li> <li>3. For treatment or prevention of nocturnal leg cramps.</li> </ol>	<p><b>Chloroquine-sensitive malaria:</b></p> <ol style="list-style-type: none"> <li>1. Diagnosis of Malaria; AND</li> <li>2. History of failure, contraindication or intolerance to chloroquine.</li> </ol> <p><b>Chloroquine-resistant malaria:</b></p> <p>Diagnosis of malaria.</p>			7 days	
Ranexa	Chronic Angina	<ol style="list-style-type: none"> <li>1. Pre-existing QT prolongation</li> <li>2. On moderately potent CYP3A inhibitors</li> <li>3. Patients on QT prolonging drugs.</li> <li>4. Liver disease.</li> <li>5. Doses higher than 2,000 mg/day.</li> </ol>	<p><b>Chronic Angina:</b></p> <ol style="list-style-type: none"> <li>1. Diagnosis of chronic stable angina; AND</li> <li>2. Failure to two of the following standard therapies: a. beta-blocker, b. calcium channel blocker c. long-acting nitrate. AND</li> <li>3. Used in combination with one of the following:               <ol style="list-style-type: none"> <li>a. amlodipine</li> <li>b. beta-blocker</li> <li>c. nitrate</li> </ol> </li> </ol>		Prescribed by a cardiologist or cardiology consult.	Length of therapy	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
Raptiva	Plaque psoriasis		<p><b>Initial Therapy for Plaque psoriasis:</b></p> <ol style="list-style-type: none"> <li>1. Diagnosis of moderate to severe chronic (greater than or equal to 6 months) plaque psoriasis involving a minimum body surface of 10%; AND</li> <li>2. Failure or intolerance to phototherapy (ultraviolet light B, pulse dye laser, or psoralen with ultraviolet light A or photo-chemotherapy); AND</li> <li>3. Systemic therapy with at least one standard therapy; AND</li> <li>4. Platelet count greater than 130,000 cells per microliter at baseline.</li> </ol> <p><b>Reauthorization for Plaque psoriasis:</b></p> <ol style="list-style-type: none"> <li>1. Patient has achieved a scoring of "minimal" or almost "clear" by Physician Global Assessment; AND</li> <li>2. Platelet count greater than 130,000 cells per microliter.</li> </ol>		Prescribed by a dermatologist.	<p><b>Initial Therapy:</b> 12 weeks</p> <p><b>Reauthorization:</b> 1 year</p>	
Rebif, Rebif Titration Pack	Relapsing forms of Multiple Sclerosis		<p><b>Relapsing forms of Multiple Sclerosis:</b></p> <ol style="list-style-type: none"> <li>1. Patients with relapsing forms of MS: OR</li> <li>2. Patients with secondary progressive MS who continue to experience relapses; AND</li> <li>3. Trial on an alternative MS agent.</li> </ol>			1 year	
Regranex	Diabetic Neuropathic Ulcers		<p><b>Diabetic Neuropathic Ulcers</b></p> <ol style="list-style-type: none"> <li>1. Debridement at least once weekly; AND</li> <li>2. At least two of the following are present: <ol style="list-style-type: none"> <li>a. Stage III or IV wound</li> <li>b. Wound at least 1 cm x 1 cm</li> <li>c. Long-standing wound that does not heal with standard care</li> <li>d. Patients at high risk for amputation (peripheral neuropathy, peripheral vascular disease, skin or nail abnormalities, previous foot ulcer amputation).</li> </ol> </li> </ol>			6 months	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
Remicade	Rheumatoid Arthritis (RA)  Crohn's Disease (CD)  Fistulizing Crohn's Disease (FCD)  Ankylosing Spondylitis (AS)  Psoriatic Arthritis (PsA)  Ulcerative Colitis (UC)  Plaque Psoriasis  Sarcoidosis	<b>RA, PsA:</b> Used in combination with anakinra.	<b>Rheumatoid Arthritis:</b> 1. Diagnosis of moderate-to-severe RA 2. Failure to methotrexate or 2 DMARDs for 3 months.  <b>Psoriatic Arthritis:</b> 1. Diagnosis of active disease 2. Failure to methotrexate or 2 DMARDs for 3 months.  <b>Ankylosing Spondylitis:</b> 1. Diagnosis of AS 2. Failed 2 NSAIDs for 3 months  <b>Plaque Psoriasis:</b> 1. Moderate-to-severe plaque psoriasis (10% body surface); AND 2. Failed phototherapy and systemic therapy.  <b>Crohn's Disease:</b> 1. Moderate to severe CD; AND 2. Failed standard treatment.  <b>Fistulizing Crohn's Disease:</b> 1. Draining fistulas for 3 months; AND 2. On or failed standard treatment.  <b>Ulcerative Colitis:</b> 1. Moderate to severe UC; AND 2. Failed standard treatment.  <b>Sarcoidosis:</b> Failed steroids and an immunosuppressant.  <b>Reauthorization:</b> Demonstration of clinical response to therapy	<b>RA, PsA, AS, Plaque Psoriasis, UC:</b> 18 years and older.  <b>Crohn's Disease:</b> 6 years and older.	<b>RA, AS, PsA:</b> Prescribed or recommended by a rheumatologist.  <b>Crohn's Disease, Fistulizing Crohn's Disease, UC:</b> Prescribed by a gastroenterologist or by gastroenterologist consult.  <b>Plaque Psoriasis:</b> Prescribed or recommended by a dermatologist.  <b>Sarcoidosis:</b> Prescribed or recommended by a pulmonologist.	12 months	Verification that the patient has been evaluated for tuberculosis (TB) and treated accordingly.
Remodulin	Pulmonary Arterial Hypertension (PAH)		<b>Pulmonary Arterial Hypertension</b> 1. Patients with a confirmed diagnosis of pulmonary arterial hypertension (modified WHO Group I); AND 2. Patients in WHO functional class II, III, or IV.			Length of therapy	Remodulin is subject to Part B vs. Part D review.

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
Revatio	Pulmonary Arterial Hypertension (PAH)	<b>PAH:</b> Patients using organic nitrates.	<b>Pulmonary Arterial Hypertension:</b> 1. Confirmed diagnosis of pulmonary arterial hypertension (modified WHO group I); AND 2. Patients in WHO functional class II, III or IV.			Length of therapy	
Revlimid	Myelo-dysplastic Syndrome (MDS)  Multiple Myeloma  All FDA approved indications not otherwise excluded from Part D		<b>Myelo-dysplastic Syndrome:</b> 1. Diagnosis of myelo-dysplastic syndrome associated with a deletion 5q cytogenic abnormality; AND 2. Patient is transfusion dependent.  <b>Multiple Myeloma:</b> 1. Relapsed or refractory to one prior therapy for multiple myeloma; OR 2. All of the following: a. Diagnosis of advanced multiple myeloma (Durie-Salmon state II and stage III) b. Used in combination with dexamethasone.		<b>MDS, Multiple Myeloma:</b> Prescribed by an oncologist or hematologist or by oncology or hematology consult.	<b>MDS, Multiple Myeloma:</b> 6 months	Revlimid will be approved for continuation of prior therapy.
Rebetol, Ribasphere, Ribatab, ribavirin	Hepatitis C		<b>Hepatitis C:</b> Diagnosis of Hepatitis C with compensated liver disease, and verification of concurrent use with an alfa-interferon product.			Length of therapy	
Rituxan	Non-Hodgkin's Lymphoma  Chronic Lymphocytic Leukemia  Immune or idiopathic thrombocytopenic purpura  Waldenstrom's macroglobulin-		<b>Non-Hodgkin's Lymphoma:</b> One of the following: 1. As first-line treatment of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens 2. As first-line treatment of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with CVP (cyclophosphamide, vincristine, prednisolone/prednisone) chemotherapy 3. 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 4. Confirmed diagnosis of relapsed or refractory,	<b>RA:</b> 18 years and older.	<b>RA:</b> Prescribed by a rheumatologist.	Rituxan will be approved for one course of therapy (2 doses) for RA.  Rituxan will be approved for the length of therapy for other uses	Rituxan will be approved for continuation of prior therapy for neoplastic diseases.

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
	emia  Rheumatoid Arthritis (RA)		<p>low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma.</p> <p><b>Initial Therapy for Rheumatoid Arthritis:</b></p> <ol style="list-style-type: none"> <li>1. Diagnosis of moderate/severe RA defined by at least 6 swollen joints and 6 painful joints; &amp;</li> <li>2. One of the following:               <ol style="list-style-type: none"> <li>a. More than 45 minutes of morning stiffness</li> <li>b. Elevated ESR/CRP. AND</li> </ol> </li> <li>3. Used in combination with methotrexate; AND</li> <li>4. Failure to a TNF antagonist.</li> </ol> <p><b>Reauthorization for Rheumatoid Arthritis:</b></p> <ol style="list-style-type: none"> <li>1. At least 20% improvement in the tender and swollen joint count; AND</li> <li>2. At least 20% improvements in 3 of the following:               <ol style="list-style-type: none"> <li>a. Patient global assessment</li> <li>b. Physician global assessment</li> <li>c. Patient's assessment of pain</li> <li>d. Degree of disability</li> <li>e. Acute phase reactant OR</li> </ol> </li> <li>3. Documentation demonstrating the clinical equivalent of the above criteria; AND</li> <li>4. At least 24 weeks since last Rituxan treatment.</li> </ol>				
octreotide acetate	Acromegaly  Carcinoid Tumors  All FDA approved indications not otherwise excluded from Part D		<p><b>Acromegaly:</b></p> <ol style="list-style-type: none"> <li>1. Inadequate response to surgery and/or radiotherapy</li> <li>2. Patients who are not a surgical and/or radiotherapy candidate</li> <li>3. Diagnosis of acromegaly by one of the following:               <ol style="list-style-type: none"> <li>a. Serum growth hormone (GH) level greater than 1 ng/mL after a 2-hour oral glucose tolerance test</li> <li>b. Elevated serum IGF-1 levels as compared to normal reference values by age and gender.</li> </ol> </li> </ol> <p><b>Reauthorization for Acromegaly:</b></p> <ol style="list-style-type: none"> <li>1. Patient is on a dose that has stabilized GH levels to less than 5.0 ng/mL; OR</li> <li>2. Normalized (or near-normalized) IGF-1 levels (age and gender matched); OR</li> <li>3. Positive clinical response by one of the following:               <ol style="list-style-type: none"> <li>a. Reduction of tumor mass</li> </ol> </li> </ol>			<p><b>Initial Therapy for Acromegaly and tumors:</b> 6 months.</p> <p><b>Reauthorization for Acromegaly:</b> 12 months.</p>	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
			<ul style="list-style-type: none"> <li>b. Reduction of signs and symptoms of acromegaly</li> <li>c. Improvement of significant co-morbidities.</li> </ul> <p><b>Carcinoid Tumors:</b> Diagnosis of metastatic carcinoid tumor for symptomatic treatment of severe diarrhea or flushing.</p> <p><b>Vasoactive Intestinal Peptide Tumors:</b> Diagnosis of metastatic vasoactive peptide tumor, for symptomatic treatment of diarrhea associated with vasoactive peptide tumor.</p> <p><b>Cancer Chemotherapy Induced Diarrhea:</b> 1. Diagnosis of diarrhea due to concurrent cancer chemotherapy. 2. History of failure to standard therapy.</p> <p><b>AIDS-related Diarrhea:</b> 1. Diagnosis of AIDS-related diarrhea. 2. History of failure to standard therapy</p>				
Sandostatin LAR Depot	<p>Acromegaly</p> <p>Carcinoid Tumors</p> <p>Vasoactive Intestinal Peptide Tumors</p> <p>Cancer Chemotherapy Induced Diarrhea</p> <p>AIDS-related Diarrhea</p>		<p><b>Acromegaly:</b></p> <ul style="list-style-type: none"> <li>1. Inadequate response to surgery and/or radiotherapy;</li> <li>2. Patients who are not a surgical and/or radiotherapy candidate.</li> <li>3. Diagnosis of acromegaly by one of the following: <ul style="list-style-type: none"> <li>a. Serum growth hormone (GH) level greater than 1 ng/mL after a 2-hour oral glucose tolerance test</li> <li>b. Elevated serum IGF-1 levels as compared to normal reference values by age and gender</li> </ul> </li> </ul> <p><b>Reauthorization for Acromegaly:</b></p> <ul style="list-style-type: none"> <li>1. Patient is on a dose that has stabilized GH levels to less than 5.0 ng/mL; OR</li> <li>2. Normalized (or near-normalized) IGF-1 levels (age and gender matched); OR</li> <li>3. Positive clinical response defined by one of the following: <ul style="list-style-type: none"> <li>a. Reduction of tumor mass</li> <li>b. Reduction of signs and symptoms of</li> </ul> </li> </ul>			<p><b>Initial therapy for Acromegaly and tumors:</b> for 6 months</p> <p><b>Reauthorization for Acromegaly:</b> 12 months</p> <p><b>Chemo-induced diarrhea/AIDS-related diarrhea:</b> 3 months</p>	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
			<p>acromegaly c. Improvement of significant co-morbidities.</p> <p><b>Carcinoid Tumors:</b> 1. Diagnosis of metastatic carcinoid tumor, for symptomatic treatment of severe diarrhea or flushing; AND 2. Patient has been shown to respond to and tolerate octreotide.</p> <p><b>Vasoactive Intestinal Peptide Tumors:</b> 1. Diagnosis of metastatic vasoactive peptide tumor, for symptomatic treatment of diarrhea associated with vasoactive peptide tumor; AND 2. Patient has been shown to respond to and tolerate octreotide.</p>				
Somatuline Depot	Acromegaly		<p><b>Acromegaly:</b> 1. Patients who require long-term treatment due to: a. Inadequate response to surgery and/or radiotherapy; OR b. Who are not surgical and/or radiotherapy candidates. AND 2. Diagnosis of acromegaly by one of the following: a. Serum growth hormone level greater than 1 ng/mL after a 2-hour oral glucose tolerance test; OR b. Elevated serum IGF-1 levels as compared to normal reference values by age and gender.</p>			Indefinite, long-term therapy (open-ended)	
Somavert	Acromegaly		<p><b>Initial Therapy for Acromegaly:</b> 1. One of the following: a. Inadequate response to surgery and/or radiation therapy b. Not a candidate for surgery or radiation. AND 2. Inadequate response or intolerance to octreotide, or IGF-1 value greater than 900 ng/mL.</p> <p><b>Reauthorization for Acromegaly:</b> Serum IGF-1 level within the age-adjusted normal range.</p>			12 weeks	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
Sporanox	Fungal Infection  All FDA approved indications not otherwise excluded from Part D		<b>Fungal Infection:</b> 1. Diagnosis of one of the following: a. Blastomycosis b. Histoplasmosis c. Aspergillosis d. Onychomycosis 2. In patients unable to swallow tablets; OR 3. Diagnosis of febrile neutropenia with suspected fungal infection, or oropharyngeal or esophageal candidiasis.			Length of therapy	
Sprycel	Chronic Myeloid Leukemia (CML)  Acute Lymphoblastic Leukemia (ALL)		<b>Chronic Myeloid Leukemia:</b> 1. Diagnosis of Philadelphia chromosome positive or BCR-ABL positive chronic, accelerated, or myeloid or lymphoid blast phase chronic myeloid leukemia; AND 2. Failure to Gleevec.  <b>Acute Lymphoblastic Leukemia:</b> 1. Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia; AND 2. Failure to Gleevec.			Length of therapy	Sprycel will be approved for continuation of prior therapy.
Striant	Hypogonadism		<b>Hypogonadism:</b> Diagnosis of hypogonadism in men with a pre-treatment testosterone level of less than 280 ng/dL.			Length of therapy	
Symlin, Symlinpen	Diabetes Mellitus (DM)  All FDA approved indications not otherwise excluded from Part D	<b>DM:</b> Known diagnosis of gastroparesis	<b>Diabetes Mellitus:</b> 1. Type 1 or type 2 diabetes with hemoglobin A1c level of less than or equal to 9.0% 2. Type 1 diabetic patients with a previous history of insulin therapy and concurrently using insulin therapy 3. Type 2 diabetic patients with a previous history of insulin therapy and concurrently using insulin therapy with or without sulfonylurea and/or metformin.	18 years and older.		Length of therapy	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
Tasigna	Chronic Myelogenous Leukemia		<p><b>Chronic Myelogenous Leukemia:</b></p> <ol style="list-style-type: none"> <li>1. Diagnosis of Philadelphia chromosome positive chronic or accelerated phase chronic myeloid leukemia; AND</li> <li>2. Failure to Gleevec.</li> </ol>			Length of therapy	Tasigna will be approved for continuation of prior therapy.
<b>Topical testosterone:</b> Androderm, Androgel, Androgel Pump, Testim	Hypogonadism		<p><b>Hypogonadism:</b></p> <p>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.</p>			Length of therapy	
Thalomid	<p>Erythema Nodosum Leprosum (ENL)</p> <p>Multiple Myeloma (MM)</p> <p>Waldenstrom's Macroglobulinemia (WM)</p> <p>Aphthous stomatitis or ulcers (AS)</p> <p>Crohn's Disease,</p> <p>Graft-versus-Host Disease (GVHD)</p> <p>Primary Brain</p>		<p><b>Erythema Nodosum Leprosum:</b></p> <p>Confirmed diagnosis of moderate to severe ENL.</p> <p><b>Multiple Myeloma:</b></p> <ol style="list-style-type: none"> <li>1. For newly diagnosed multiple myeloma in combination with dexamethasone or conventional dose chemotherapy; OR</li> <li>2. In combination with high dose chemotherapy with stem cell rescue; OR</li> <li>3. Salvage therapy in refractory or relapsed multiple myeloma after primary therapy; OR</li> <li>4. In combination with dexamethasone, doxorubicin, cyclophosphamide, and etoposide as part of induction regimen prior to autologous transplant.</li> </ol> <p><b>Waldenstrom's Macro-globulinemia:</b></p> <p>Disease progression on an alkylating agent, nucleoside analog, or rituximab.</p> <p><b>Aphthous stomatitis or ulcers:</b></p> <ol style="list-style-type: none"> <li>1. One of the following: <ol style="list-style-type: none"> <li>a. Diagnosis of HIV-associated aphthous ulcers</li> <li>b. Recurrent aphthous stomatitis in immunocompromised patients. AND</li> </ol> </li> <li>2. Refractory to alternative therapies.</li> </ol> <p><b>Crohn's Disease:</b></p>			<p><b>AS:</b> 1 month</p> <p><b>ENL, MM:</b> Length of treatment</p> <p><b>WM, GVHD, and Primary Brain Tumors:</b> 6 months</p> <p><b>Other Uses:</b> 3 months</p>	Thalomid will be approved for continuation of prior therapy.

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
	<p>Tumors</p> <p>AIDS-related cachexia or wasting</p> <p>Renal Cell Carcinoma</p>		<p>Patient is refractory to all of the following standard treatment regimens:</p> <ol style="list-style-type: none"> <li>1. Corticosteroids</li> <li>2. 5-aminodalicylic acid</li> <li>3. Immunomodulators</li> <li>4. Remicade.</li> </ol> <p><b>Graft-versus-Host Disease:</b></p> <ol style="list-style-type: none"> <li>1. Diagnosis of chronic or refractory GVHD; AND</li> <li>2. In patient unresponsive to all of the following:               <ol style="list-style-type: none"> <li>a. Corticosteroids</li> <li>b. Azathioprine</li> <li>c. Tacrolimus</li> <li>d. Cyclosporine</li> <li>e. Antithymocyte globulin.</li> </ol> </li> </ol> <p><b>Primary Brain Tumors:</b></p> <ol style="list-style-type: none"> <li>1. As adjuvant therapy to current cytotoxic therapies; OR</li> <li>2. Previous failure to cytotoxic therapies and/or tumor resection.</li> </ol> <p><b>Initial Therapy for AIDS-related cachexia or wasting:</b></p> <ol style="list-style-type: none"> <li>1. Diagnosis of AIDS wasting or cachexia defined as chronic unremitting weight loss of more than 10% body weight in the previous 4 months; AND</li> <li>2. Nutritional evaluation since onset of wasting first occurred. Screened for hypogonadism; AND</li> <li>3. Failure to respond to hormone replacement therapy in patients with hypogonadism; AND</li> <li>4. Failure, contraindication or intolerance to standard treatments.</li> </ol> <p><b>Reauthorization for AIDS-related cachexia or wasting:</b></p> <p>Weight has stabilized or improved but not at goal weight.</p> <p><b>Advanced Renal Cell Carcinoma:</b></p> <ol style="list-style-type: none"> <li>1. Confirmed diagnosis of metastatic renal cell carcinoma; AND</li> <li>2. Patient is refractory to, or unsuitable of the following:</li> </ol>				

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
			<ul style="list-style-type: none"> <li>a. Interferon-alfa-2b</li> <li>b. Interleukin-2</li> <li>c. Sorafenib</li> <li>d. Sunitanib.</li> </ul>				
Topamax, Topamax Sprinkle	Seizure Disorder  Migraine Prophylaxis  Bipolar Disorder  Neuropathic Pain  Essential Tremor  All FDA approved indications not otherwise excluded from Part D		<b>Seizure Disorder:</b> History of failure or contraindication to two formulary alternatives.  <b>Migraine Prophylaxis:</b> 1. Patients experiencing 2 or more migraine headaches monthly that result in disability; AND 2. History of an adequate trial of 2 to 3 months to formulary alternatives for migraine prophylaxis.  <b>Bipolar Disorder:</b> 1. History of treatment failure, contraindication or intolerance to two formulary alternatives; OR 2. History of topamax therapy initiated during a hospitalization.  <b>Neuropathic Pain:</b> History of failure or contraindication to formulary alternatives.  <b>Essential Tremor:</b> History of failure or intolerance propranolol or primidone.		<b>Migraine Prophylaxis:</b> Prescribed by a neurologist.  <b>Bipolar Disorder:</b> Prescribed by a psychiatrist or by psychiatric consultation.	Length of therapy	Topamax will be approved for continuation of prior therapy.
Tracleer	Pulmonary Arterial Hypertension		<b>Pulmonary Arterial Hypertension:</b> Patients with a confirmed diagnosis of pulmonary arterial hypertension (modified WHO Group I) and in WHO functional class III or IV.			Length of therapy	
Treanda	Chronic lymphocytic leukemia					6 months	
Tykerb	Breast Cancer		<b>Breast Cancer:</b> 1, Diagnosis of HER2-positive advanced or metastatic breast cancer			Length of therapy	Tykerb will be approved for continuation

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
			2. History of prior therapy with an anthracycline, a taxane, and Herceptin. 3. Used in combination with Xeloda. 4. Confirmation of normal left ventricular ejection fraction.				of prior therapy.
Tysabri	Relapsing forms of Multiple Sclerosis (MS)  Crohn's Disease (CD)		<b>Relapsing forms of Multiple Sclerosis:</b> Failure to one of the following: Avonex, Betaseron, Copaxone, Rebif.  <b>Initial Therapy for Crohn's Disease:</b> 1. Moderate-to-severe Crohn's disease with evidence of inflammation; AND 2. History of conventional therapy. History of a TNF blocker. Patient is not receiving immunosuppressants.  <b>Reauthorization for Crohn's Disease:</b> Demonstrated remission or significant clinical response to Tysabri.	<b>Initial therapy for CD:</b> 18 years and older.	<b>Initial Therapy - Relapsing MS and CD:</b> Prescribing physician is enrolled in the CD TOUCH Prescribing Program.	<b>Initial Therapy:</b> Tysabri will be authorized for 1 year for MS and 3 months for CD  <b>Reauthorization:</b> Tysabri will be reauthorized for 6 months for patients on steroids. Otherwise, 3 months.	<b>For Relapsing MS:</b> Tysabri will not be authorized in combination with Avonex, Betaseron, Copaxone, or Rebif.
Vancocin	Pseudo-membranous Colitis		<b>Pseudo-membranous Colitis:</b> 1. Diagnosis of pseudo-membranous colitis due to Clostridium difficile; AND 2. Failure to oral Flagyl.			Length of therapy	
Vectibix	Colorectal Cancer		<b>Colorectal Cancer:</b> 1. Diagnosis of metastatic colorectal cancer; AND 2. Relapsed, refractory, or disease progression on one standard chemotherapy regimen containing a fluoropyrimidine, oxaliplatin, or irinotecan.			Length of therapy	Vectibix will be approved for continuation of prior therapy.
Ventavis	Pulmonary Arterial Hypertension		<b>Pulmonary Arterial Hypertension</b> Patients with a confirmed diagnosis of pulmonary arterial hypertension (modified WHO Group I) and in WHO functional class III or IV.			Length of therapy	Ventavis is subject to Part B vs. Part D review.
Xolair	Allergic Asthma		<b>Initial Therapy for Allergic Asthma:</b> 1. Diagnosis of moderate-to-severe persistent allergic asthma, defined by one of the following: a. Daily asthmatic symptoms	<b>Initial treatment</b> : 6 years	<b>Initial Therapy:</b> Prescribed by a pulmonologist	<b>Initial Therapy:</b> 16 weeks  <b>Reauthorization</b>	

Drugs	Covered Uses	Exclusion Criteria	Required Medical Information	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other Criteria
			<p>b. Daily use of inhaled short-acting beta agonists  c. Exacerbations affect/limit activity  d. Exacerbations 2 or more times per week  e. Nocturnal symptoms once a week or more  f.. Forced expiratory volume in one second or peak expiratory flow less than or equal to 80% of predicted  g. PEF variability greater than 30%. AND  2. Baseline IgE level greater than or equal to 30 IU/mL; AND  3. Documented failure to combination therapy with an inhaled corticosteroid at the maximum dosage and a long-acting beta-agonist.</p> <p><b>Reauthorization for Allergic Asthma:</b>  1. Documented reduction in the frequency of asthma exacerbations while treated with Xolair; AND  2. Documented reduction in the use of rescue medications or inhaled corticosteroids while treated with Xolair.</p>	and older.	ist or allergist/immunologist.	<b>for Asthma:</b> 1 year	
Zyvox	Infections  All FDA approved indications not otherwise excluded from Part D		<p><b>Infections:</b>  One of the following:  1. Infections caused by vancomycin-resistant enterococci (VRE) documented by culture and sensitivity report.  2. Nosocomial pneumonia caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report  3. Complicated skin and skin structure infections (including diabetic foot infections) without osteomyelitis caused by MRSA documented by culture and sensitivity report.  4. 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 previous antibiotics.  5. As continuation of therapy when transitioning from intravenous daptomycin, intravenous vancomycin, or intravenous Zyvox therapy.</p>			28 days.	

**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:**

- Acetylcysteine
- Acyclovir
- Adriamyc
- Adriamycin (20 mg INJ only)
- Albuterol sulfate
- Albuterol/ipratropium
- Aminess
- Aminosyn
- Amphotericin
- Anzemet
- Clinimix
- Clinimix E
- Clinisol SF
- Cromolyn Sodium
- Cyclophosphamide
- Cyclosporine
- Cyclosporine Modified
- Doxil
- Doxorubicin
- Engerix-B
- Foscarnet
- Freamine HBC
- Freamine III
- Gengraf
- Granisetron
- Granisol
- Hepatamine
- Hepatasol
- Intralipid (all, except 30% INJ)
- Ipratropium bromide
- Metaproterenol
- Myfortic
- Nephramine
- Novamine
- Ondansetron
- Ondansetron ODT
- Premasol
- Procalamine
- Prosol
- Pulmicort
- Rapamune
- Recombiva HB
- Renamin
- Travasol
- Trophamine (10% INJ only)
- Xopenex