PRESBYTERIAN

**Presbyterian Senior Care (HMO) / MediCare PPO Formulary**
**Prior Authorization Criteria**
**Effective June 1, 2013**

| Product Name | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restrictions | Prescriber Restrictions | Coverage Duration | Other Criteria |
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| Actiq (fentanyl transmucosal) | All FDA-approved indications not otherwise excluded from Part D. | Treatment of non-cancer pain, post-op pain, or chronic pain not related to cancer | Documented diagnosis of pain due to cancer. And patient is established on therapy with a long acting opiate and will continue on therapy with a long acting opiate. And patient has failed to achieve control of breakthrough pain using an immediate acting oral opiate. | | | 6 months | |
| Adcetris (brentuximab) | All FDA-approved indications not otherwise excluded from Part D. | | Patient must have Hodgkin's lymphoma that has failed autologous stem cell transplant (ASCT). Or if patient was not an ASCT candidate, then must have failed at least two prior multi-agent chemotherapy regimens OR the patient must have systematic anaplastic large cell lymphoma and has failed at least one prior multi-agent chemotherapy regimen. | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |
| Afinitor (everolimus) | All FDA-approved indications not otherwise excluded from Part D. | | For renal cell cancer: Medical records documenting trial and failure at therapeutic doses of sunitinib or sorafenib. For subependymal giant cell astrocytoma: documentation of the indicated diagnosis. | | | 1 year | Must be obtained through a specialty pharmacy. |

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| Alimta (pemetrexed disodium) | All FDA-approved indications not otherwise excluded from Part D. | | Malignant Pleural Mesothelioma: In combination with cisplatin and in patients who are not candidates for curative surgery or whose disease is unresectable. Nonsquamous Non-Small Cell Lung Cancer: Patients with locally advanced or metastatic disease and is used in combination with cisplatin or as a single-agent after prior history of a first-line chemotherapy agent. | | | 1 year | |
| Aloxi (palonosetron) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. Must be obtained through a specialty pharmacy. |

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| Androderm (testosterone topical) | All FDA-approved indications not otherwise excluded from Part D. | Testosterone replacement will not be covered for the treatment of sexual dysfunction | Confirmed diagnosis of testosterone deficiency OR absence of endogenous testosterone in males over the age of 18 with: Primary hypogonadism (congenital or acquired) AND two low total testosterone levels (drawn on separate days) with an elevated LH and FSH OR Hypogonadotropic hypogonadism (congenital or acquired) AND two low total testosterone levels (drawn on separate days) with a low to low-normal LH and FSH. | | | 1 year | |
| Androgel 1% (testosterone topical) | All FDA-approved indications not otherwise excluded from Part D. | Testosterone replacement will not be covered for the treatment of sexual dysfunction | Confirmed diagnosis of testosterone deficiency OR absence of endogenous testosterone in males over the age of 18 with: Primary hypogonadism (congenital or acquired) AND two low total testosterone levels (drawn on separate days) with an elevated LH and FSH OR Hypogonadotropic hypogonadism (congenital or acquired) AND two low total testosterone levels (drawn on separate days) with a low to low-normal LH and FSH. | | | 1 year | |

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| Androgel 1.62% (testosterone topical) | All FDA-approved indications not otherwise excluded from Part D. | Testosterone replacement will not be covered for the treatment of sexual dysfunction | Confirmed diagnosis of testosterone deficiency OR absence of endogenous testosterone in males over the age of 18 with: Primary hypogonadism (congenital or acquired) AND two low total testosterone levels (drawn on separate days) with an elevated LH and FSH OR Hypogonadotropic hypogonadism (congenital or acquired) AND two low total testosterone levels (drawn on separate days) with a low to low-normal LH and FSH. | | | 1 year | |
| Apokyn (apomorphine) | All FDA-approved indications not otherwise excluded from Part D. | | All of the following must be met: Documented diagnosis of Parkinson's disease AND Documented occurrence of hypomobility episodes, off episodes (end of dose wearing off and unpredictable on/off episodes) associated with advanced Parkinson's disease AND will be used as an adjunct to other medications for Parkinson's | | Prescriber must be a neurologist | 1 year | Must be obtained through a specialty pharmacy. |
| Aralast NP (proteinase inhibitor human) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |

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| Arcalyst (rilonacept) | All FDA-approved indications not otherwise excluded from Part D. | | Cryopyrin-Associated Periodic Syndromes (CAPS), drug will not be used in combination with Enbrel, Humira, Kineret, Orencia or Remicade, AND 2. Dose does not exceed FDA label maximum for the diagnosis. | Patient is 12 years of age or older. | | Annual | |
| Aredia (pamidronate) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 1 year | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |
| Arixtra (fondaparinux) | All FDA-approved indications not otherwise excluded from Part D. | | Medical records documenting failure of formulary low molecular weight heparin. | | | 1 time up to 32 days | |
| Arzerra (ofatumumab) | All FDA-approved indications not otherwise excluded from Part D. | | Documented trial and failure of Fludara and Campath. | | | 6 months | |

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| Avastin (bevacizumab) | All FDA-approved indications not otherwise excluded from Part D. | History of recent hemoptysis or serious hemorrhage. Bevacizumab should not be used within 28 days following major surgery or until the surgical incision is fully healed. | 1. Diagnosis and patient history, 2. Concurrent or previous medication trials. | | Prescribed by or in consultation with an oncologist | 1 year | |
| Benlysta (belimumab) | All FDA-approved indications not otherwise excluded from Part D. | Patients with severe active central nervous system lupus. Patients severe with active lupus nephritis. In combination with other biologics or intravenous cyclophosphamide. | Documentation that the patient is concurrently taking and is compliant with standard therapy for systemic lupus erythematosus (corticosteroids, antimalarials, or immunosuppressives (alone or in combination)). | | Rheumatologist | Initial:<br>6 months<br>Reauthorization:<br>1 year | Will not be approved as monotherapy. For reauthorization documentation must be submitted demonstrating a clinical benefit has been established and maintained compared to baseline. |
| Bosulif (bosutinib) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a Specialty pharmacy. |

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| Botox (onabotulinumtoxin A) | All FDA-approved indications not otherwise excluded from Part D. Dystonia, Cerebral Palsy, Facial Nerve Disorder/Hemi-facial Spasm, Migraines, Severe palmar hyperhydrosis | Cosmetic use | Severe primary axillary hyperhydrosis: Medical records documenting failure of drying agents such as topical aluminum chloride. Migraines: Medical records documenting headaches on 15 or more days per month AND headaches lasting at least 4 hours per day AND failure with two oral prophylactic therapies. Severe palmar hyperhydrosis: Medical records documenting failure of drying agents such as topical aluminum chloride. Urinary incontinence: documentation of detrusor overactivity associated with a neurologic condition in patients who have trial/failure of two anticholinergic medications. Treatment of cervical dystonia in adults. Treatment of blaphorspasms associated with dystonia in patients 12 years of age or older. Treatment of upper limb spasticity in adult patients. | | Migraines: must be prescribed by a neurologist. | 1 year | |
| Brilinta (ticagrelor) | All FDA-approved indications not otherwise excluded from Part D. | | A documented diagnosis of acute coronary syndrome (unstable angina, non-STEMI, or STEMI). Documentation of failure/contraindication/intolerance to clopidogrel (Plavix). | | | 6 months | |
| Bydureon (exenatide) | All FDA-approved indications not otherwise excluded from Part D. | | Patient must have a documented 30-day trial of Byetta (exenatide) or Victoza (liraglutide). The patient's hemoglobin A1c (within the past 90 days) must be less than 9 percent. | | | 6 months | |

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| Campath (alemtuzumab) | All FDA-approved indications not otherwise excluded from Part D. | | Diagnosis of B-Cell chronic lymphocytic leukemia (B-CLL). | | | 1 year | |
| Caprelsa (vandetanib) | All FDA-approved indications not otherwise excluded from Part D. | | Documentation that the patient has symptomatic or progressive medullary thyroid cancer and the cancer is unresectable locally advanced or metastatic disease. Documentation of failed therapies. | | | 6 months | Use of a Specialty Pharmacy is required |
| Carimune (human immune globulin IV) | All FDA-approved indications not otherwise excluded from Part D. | | Documented diagnosis | | | 1 year | |

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| Cellcept (mycophenolate mofetil ) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 1 year | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. Immunosuppressants used to prevent organ transplant rejection are a Part B benefit if the transplant was covered under Medicare. |
| Cinryze (C1 Inhibitor-Human) | All FDA-approved indications not otherwise excluded from Part D. | | Medical records documenting diagnosis of hereditary angioedema requiring prophylaxis. | | | 6 months | |
| Cometriq (cabozantinib) | All FDA-approved indications not otherwise excluded from Part D. | | Documentation that patient has progressive, metastatic medullary thyroid cancer (MTC). | | | 6 months | Must be obtained through a specialty pharmacy. |

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| (cyclosporine) Neoral, Sandimmune | All FDA-approved indications not otherwise excluded from Part D. | | | | | 1 year | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. Immunosuppressants used to prevent organ transplant rejection are a Part B benefit if the transplant was covered under Medicare. |
| Daliresp (roflumilast) | All FDA-approved indications not otherwise excluded from Part D. | | Patient must have a diagnosis of severe COPD with chronic bronchitis and documentation of continued exacerbation in the last 6 months. Patient must be currently receiving two standard treatments for severe COPD (i.e. long-acting beta-agonist, long-acting anticholinergic, short-acting anticholinergic). | | | 6 months | |
| Daunoxome (daunorubicin) | All FDA-approved indications not otherwise excluded from Part D. | | Documentation of diagnosis for which the medication is indicated. | | | 1 year | |

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| Dificid (fidaxomicin) | All FDA-approved indications not otherwise excluded from Part D. | | Diagnosis of Clostridium difficile associated diarrhea (CDAD) and a documented trial and failure of oral vancomycin. | | | 1 month | |
| Docefrez (docetaxel) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |
| Effient (prasugrel) | All FDA-approved indications not otherwise excluded from Part D. | | Medical records documenting all of the following: 1.The patient has had an acute coronary syndrome (unstable angina, NSTEMI, or STEMI) and was managed with percutaneous coronary intervention. 2. The patient weight will be submitted. 3. The patient does not have a history of stroke or transient ischemic attack. 4. The patient meets one of the following conditions: a. There is a documented allergy to Plavix (clopidogrel). b. There is a documented treatment failure with Plavix (clopidogrel). OR c. The patient is considered to be at high risk for stent thrombosis. | | Cardiologist | 1 year | |

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| Emcyt (estramustine) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Emend (aprepitant oral) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |
| Emend (fosaprepitant) injection | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |
| Enbrel (etanercept) | All FDA-approved indications not otherwise excluded from Part D | | Medical records documenting: A minimum of 3 months of current and continuous follow-up AND current PPD (tuberculosis) negative skin test within 6 months of starting therapy. Patients should be monitored for an infection or a history of chronic infections. | | | 1 year | Must be obtained through a specialty pharmacy. |

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| Erivedge (vismodegib) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Erwinaze (asparaginase erwinia chrysanthemi) | All FDA-approved indications not otherwise excluded from Part D. | | | | | | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |
| Extavia (interferon beta-1b) | All FDA-approved indications not otherwise excluded from Part D. | | Medical records documenting trial and failure of Copaxone and Avonex for the treatment of Multiple Sclerosis. | | Neurologist | 1 year | Must be obtained through a specialty pharmacy. |
| Ethyol (amifostine) | All FDA-approved indications not otherwise excluded from Part D. | | Documentation that amifostine being used for the following: prevention of xerostomia in patients undergoing postoperative radiation for head and neck cancer or prevention of renal toxicity associated with repeat courses of cisplatin. | | Prescriber must be a hematologist or oncologist | 6 months | |

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| Firazyr (icatibant) | All FDA-approved indications not otherwise excluded from Part D. | | 1. The diagnosis of hereditary angioedema (HAE) has been clinically established by, or in consultation with, an allergist or immunologist. 2. Diagnosis of HAE is documented based on evidence of a low C4 level AND one of the following: a low C1 inhibitor (C1-INH) antigenic level OR a normal C1-INH antigenic level and a low C1-INH functional level. 3. The member is not concurrently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy. 4. The member must be experiencing at least one symptom of a moderate or severe attack (ie. swelling of the face, throat, or abdomen). | | Allergist or Immunologist | 6 months | Must be obtained through a Specialty pharmacy. Medical records documenting frequency of acute HAE attacks and the patient's response to therapy must be provided. If the patient is experiencing more than one acute HAE attack per month medical records documenting use of a long-term prophylactic therapy (LTP) or the clinical rational for avoiding LTP must be provided. |
| Forteo (teriparatide) | All FDA-approved indications not otherwise excluded from Part D. | | Treatment of men and women with osteoporosis who have an increased risk for fractures, who have failed or are intolerant to an oral bisphosphonate, and the T score is less than or equal to -2.5. | | | New start: two years Renewal: one year | Must be obtained through a specialty pharmacy. |

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| Fortesta (testosterone topical) | All FDA-approved indications not otherwise excluded from Part D. | Testosterone replacement will not be covered for the treatment of sexual dysfunction | Confirmed diagnosis of testosterone deficiency OR absence of endogenous testosterone in males over the age of 18 with: Primary hypogonadism (congenital or acquired) AND two low total testosterone levels (drawn on separate days) with an elevated LH and FSH OR Hypogonadotropic hypogonadism (congenital or acquired) AND two low total testosterone levels (drawn on separate days) with a low to low-normal LH and FSH. | | | 1 year | |
| Gammagard liquid (human immune globulin IV) | All FDA-approved indications not otherwise excluded from Part D. | | Documented diagnosis | | | 1 year | |
| Gamunex (human immune globulin IV) | All FDA-approved indications not otherwise excluded from Part D. | | Documented diagnosis | | | 1 year | |
| Gamunex-C (human immune globulin IV or Sub-Q) | All FDA-approved indications not otherwise excluded from Part D. | | For Idiopathic Thrombocytopenic Purpura and Chronic Inflammatory Demyelinating Polyneuropathy: Medical records documenting diagnosis. For Primary Humoral Immunodeficiency: Medical records documenting diagnosis, and the patient must have infusion reaction. | | | 1 year | |

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| Gleevec (imatinib) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Hecoria (tacrolimus) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 1 year | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. Immunosuppressants used to prevent organ transplant rejection are a Part B benefit if the transplant was covered under Medicare |
| Hexalen (altretamine) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |

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| Humira (adalimumab) | All FDA-approved indications not otherwise excluded from Part D. | | Medical records documenting: A minimum of 3 months of current and continuous follow-up AND current PPD (tuberculosis) negative skin test within 6 months of starting therapy. Patients should be monitored for an infection or a history of chronic infections. | | | 1 year | Must be obtained through a specialty pharmacy. |
| Hycamtin (topotecan) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Iclusig (ponatinib) | All FDA-approved indications not otherwise excluded from Part D. | | Documentation that the patient has chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML)that is resistant or intolerant to two (2) prior tyrosine kinase inhibitor therapies. Documentation that the patient has Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) that is resistant or intolerant to two (2) prior tyrosine kinase inhibitor therapies. | 18 years of age or older | | 6 months | Must be obtained through a specialty pharmacy. |
| Ilaris (canakinumab) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |

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| Imuran (azathioprine) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 1 year | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. Immunosuppressants used to prevent organ transplant rejection are a Part B benefit if the transplant was covered under Medicare |
| Incivek (telaprevir) | All FDA-approved indications not otherwise excluded from Part D. | Will not be approved for patients with moderate or severe hepatic impairment (Child-Pugh B or C) or in patients with decompensated liver disease | Documented chronic hepatitis C genotype 1 AND to be used in combination with peginterferon alfa and ribavirin AND previously untreated with boceprevir or telaprevir. | 18 years of age or older | | 12 weeks | Submit HCV-RNA levels at treatment week 4.<br>Must be obtained through a specialty pharmacy. |

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| Increlex (mecasermin) | All FDA approved indications not otherwise excluded from Part D. | Secondary forms of IGF-1 deficiency. Combination treatment with growth hormone. | Must have documented severe primary IGF-1 deficiency or GH gene deletion with neutralizing antibodies to GH. Height standard deviation score less than or equal to negative 3 AND basal IGF-1 standard deviation score less than or equal to negative 3, AND normal or elevated growth hormone levels AND predicted adult height more than 1.5 standard deviations below the mid-parenteral height and growth rate less than 7 cm/year if less than or equal to 3 years old and less than 5 cm if greater than 3 years old AND open epiphyses on bone radiograph. | Ages 2 - 18 years of age | | 1 year | Must be obtained through a specialty pharmacy. |
| Inlyta (axitinib) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Jakafi (ruxolitinib) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Kadcyla (ado-trastuzumab) | All FDA-approved indications not otherwise excluded from Part D. | Kadcyla will not be allowed to be substituted for or with trastuzumab. | Patients with HER2 positive metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either received prior therapy for metastatic disease or developed disease recurrence during or within six months of completing adjuvant therapy. | | | 6 months | |

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| Kuvan (sapropterin) | All FDA-approved indications not otherwise excluded from Part D. | | Diagnosis of hyperphenylalaninemia caused by tetrahydrobiopterin-(BH4)- responsive phenylketonuria: Initial Authorizations: 1. Documentation showing low baseline phenylalanine (Phe) level (level immediately prior to Kuvan request) AND 2. Documentation of target blood phenylalanine level for the patient AND 3. Patient on phenylalanine restricted diet while taking Kuvan, 4. Dose does not exceed FDA label maximum for the diagnosis. Reauthorization: 1. Recent phenylalanine level is at target range AND 2. Patient is continuing a phenylalanine restricted diet. | Patient is 4 years of age or older | | Initial auth and titration to therapeutic response: 1 month. Reauth for stable therapy: 3 months | |
| Kytril (granisetron) tablet | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Coverage may fall under Medicare Part B or Part D. |
| Kytril (granisetron) IV soln | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Coverage may fall under Medicare Part B or Part D. |
| Leukine (sargramostim) | All FDA-approved indications not otherwise excluded from Part D. | Combination use with Neulasta or Neupogen | Documentation of neutropenia, post AML chemotherapy. Documented failure of Neupogen when used for PBPC mobilization, neutropenia post PBPC transplant, neutropenia post chemotherapy, and neutropenia post BMT. | | | 6 months | |

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| Lidoderm (lidocaine topical patch) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 3 months | |
| Linzess (linaclotide) | All FDA-approved indications not otherwise excluded from Part D. | | Documented failure of polyethylene glycol 3350. | | | 6 months | |
| Lumizyme (alglucosidase alfa) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |

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| Lyrica (pregabalin) | All FDA-approved indications not otherwise excluded from Part D. | | For Seizures, medical records documenting failure at therapeutic doses of at least two anticonvulsants indicated for the treatment of partial seizures, including carbamazepine, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, topiramate, or zonisamide. For Neuropathic Pain and post-herpetic neuralgia, medical records documenting failure at therapeutic doses of two of the following preferred alternatives: Tricyclic antidepressants, SNRI's, gabapentin, lamotrigine, Depakote, or carbamazepine. For Fibromyalgia, medical records documenting failure of a tricyclic antidepressant and gabapentin. | | | 1 year | |
| Marinol (dronabinol) | All FDA-approved indications not otherwise excluded from Part D. | | Nausea or vomiting associated with cancer chemotherapy (CINV). Patient is receiving cancer chemotherapy and has failed one 5-HT3 antagonist and one of the following: corticosteroid, anti-histamine, anti-psychotic, or prokinetic. For treatment of anorexia associated with weight loss in patients with HIV/AIDS documented trial and failure or contraindication or intolerance to Megestrol oral suspension. | | | 6 months | Coverage may fall under Medicare Part B or Part D |
| Matulane (procarbazine) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |

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| Myfortic (mycophenolic acid) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 1 year | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. Immunosuppressants used to prevent organ transplant rejection are a Part B benefit if the transplant was covered under Medicare. |
| Myleran (busulfan) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Neulasta (pegfilgrastim) | All FDA-approved indications not otherwise excluded from Part D. | | | | | Diagnosis Dependent | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit.. |

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| Neumega (oprelvekin) | All FDA-approved indications not otherwise excluded from Part D. | | Thrombocytopenia following myeloablative chemotherapy. 1. Verification that the cancer is a non-myloid malignancy AND 2. Platelet count is less than 30,000 cells/microliter 3. Dose does not exceed FDA label maximum for the diagnosis. | | | Initial authorization: up to 21 days per course. Reauthorization: up to 6 months | Must be obtained through a specialty pharmacy |
| Neupogen (filgrastim) | All FDA-approved indications not otherwise excluded from Part D. | | | | | Diagnosis Dependent | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |
| Nexavar (sorafenib) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Noxafil (posaconazole) | All FDA-approved indications not otherwise excluded from Part D. | | Documentation of diagnosis for which the medication is indicated. | | | 1 year | |

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| Nulojix (belatacept) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |
| Orencia (abatacept) | All FDA-approved indications not otherwise excluded from Part D. | | Documented trial and failure of both Enbrel (etanercept) and Humira (adalimumab). The patient must have a current PPD (tuberculosis) negative skin test. | | | 1 year | Patients should be monitored for an infection or a history of chronic infections. Orencia Sub-Q injection must be obtained through a specialty pharmacy. |
| Perjeta (pertuzumab) IV | All FDA-approved indications not otherwise excluded from Part D. | | Indicated in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. | | | | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |

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| Pomalyst (pomalidomide) | All FDA-approved indications not otherwise excluded from Part D. | | All FDA approved indications | | | 6 months | Use of a Specialty Pharmacy is required. |
| Potiga (ezogabine) | All FDA-approved indications not otherwise excluded from Part D. | | The patient must be diagnosed with partial-onset seizures and have history of 2 medications indicated for partial-onset seizures. | | | 6 months | |
| Pradaxa (dabigatran) | All FDA-approved indications not otherwise excluded from Part D. | Will not be approved if active pathological bleeding or a history of serious hypersensitivity reaction to Pradaxa | Documentation that the patient has a diagnosis of non-valvular atrial fibrillation (including any applicable labs and/or tests). Documentation of a trial/failure of warfarin or a contraindication to warfarin. Must provide a current serum creatinine or a calculated creatinine clearance, and the weight of the patient. | | | 6 months | |
| Pristiq (desvenlafaxine) | All FDA-approved indications not otherwise excluded from Part D. | | Documented trial and failure of Effexor XR (venlafaxine ER) at a therapeutic dose. | | | 1 year | |

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| Privigen (human immune globulin IV) | All FDA-approved indications not otherwise excluded from Part D. | | Documented diagnosis | | | 1 year | |
| Procrit (epoetin alfa) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 3 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |

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| Prograf (tacrolimus) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 1 year | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. Immunosuppressants used to prevent organ transplant rejection are a Part B benefit if the transplant was covered under Medicare. |
| Prolastin (proteinase inhibitor) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. Use of a Specialty Pharmacy is required. |

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| Prolia (denosumab) | All FDA-approved indications not otherwise excluded from Part D. | | 1. T-score of the hip, spine, or radius less than or equal to -2.5 as evidenced by a bone density scan OR 2. A 10-year hip fracture probability of greater than or equal to 3% OR 3. A 10-year major osteoporosis related fracture probability of greater than or equal to 20% based on the US-adapted WHO absolute fracture risk model, FRAX AND 4. Inadequate response to, or is unable to tolerate intravenous bisphosphonates or a creatinine clearance of less than 35 mL/min. | | | 1 year | Must be obtained through a specialty pharmacy. |
| Promacta (eltrombopag olamine) | All FDA-approved indications not otherwise excluded from Part D. | Coverage will not be provided when used in combination with Nplate | Initial authorization: 1. Platelet count is less than 30000/mcl, 2. Dose does not exceed the FDA label maximum for the diagnosis, 3. Treatment failure or contraindication to at least two of the following treatments: corticosteroids, immunoglobulin, or splenectomy. | | | 3 months | The patient and prescriber must be enrolled in the Promacta Cares Program. |
| Provenge (sipuleucel-t) | All FDA-approved indications not otherwise excluded from Part D. | Patients with visceral disease (metastases to liver, lung, or brain) | Documented diagnosis of metastatic castrate resistant prostate cancer with radiologic evidence of metastatic disease in lymph nodes and/ or bone with evidence of progression at either site. Patient has baseline testosterone levels of less than 50 ng/mL with documented hormone refractory prostate cancer. Chemotherapy and/or immunosuppressive therapies are not given concurrently. Patient does not have a life expectancy of less than 6 months. Patient has a ECOG performance status of 0-1 or a Karnofsky score of 80-100. | | | 6 months | |

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| Provigil (modafinil) | All FDA-approved indications not otherwise excluded from Part D.<br>MS Fatigue | | For Narcolepsy, medical records documenting failure on formulary agents' methylphenidate or dextroamphetamine. For Obstructive Sleep Apnea/Hypopnea Syndrome, medical records documenting use of CPAP for at least 2 months and is using it for 4 or more hours per night. Diagnosis of Shift Work Sleep Disorder. For MS Fatigue, a diagnosis of MS. | | Neurologist or Sleep Specialist | 1 year | |
| Pulmozyme (dornase alfa) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |

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| Rapamune (sirolimus) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 1 year | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. Immunosuppressants used to prevent organ transplant rejection are a Part B benefit if the transplant was covered under Medicare. |

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| Reclast (zoledronic acid) | | | Osteoporosis: Postmenopausal women and men with osteoporosis that have a hip, spine, or radius T-score of less than or equal to -2.5. Osteopenia: The prevention of osteoporosis in postmenopausal women with hip, spine, or radius T-Score between -1.0 and -2.5. Glucocorticoid-induced osteoporosis: Treatment and prevention of glucocorticoid-induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months. Patient does not meet criteria for osteoporosis, osteopenia or glucocorticoid-induced osteoporosis but does have a 10-year hip fracture probability greater than 3% or a 10-year major osteoporosis-related fracture probability of greater than 20% based on US-adapted WHO absolute fracture risk model, FRAX. AND for all of the above indications patient must have a documented trial and failure of one oral bisphosphonate. Paget's disease: The treatment of Paget's disease of bone in women and men. | | | 1 year | Must be obtained through a specialty pharmacy. |
| Relistor (methylnaltrexone) | All FDA-approved indications not otherwise excluded from Part D. | | Patients must have an advanced illness for which they are receiving palliative care. And documented diagnosis of opioid-induced constipation. And failure of polyethylene glycol or lactulose. | 18 years and older | | 6 months | |

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| Remicade (infliximab) | All FDA-approved indications not otherwise excluded from Part D. | | Medical records documenting: A minimum of 3 months of current and continuous follow-up AND current PPD (tuberculosis) negative skin test within 6 months of starting therapy. Patients should be monitored for an infection or a history of chronic infections. | | | 1 year | Must be obtained through a specialty pharmacy. |
| Revlimid (lenalidomide) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Rituxan (rituximab) | All FDA-approved indications not otherwise excluded from Part D. | Will not be approved for use in combination with tumor necrosis factor inhibiting drugs | | Equal to or greater than 18 years of age | | RA: 1 month, all other indications will be 1 year | |
| Somatuline Depot (lanreotide) | All FDA-approved indications not otherwise excluded from Part D. | | | | | Initial coverage: 3 months Reauthorization: 1 year | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |

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| Sprycel (dasatinib) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Stivarga (regorafenib) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a Specialty pharmacy. |
| Suboxone (buprenorphine/naloxone) | All FDA-approved indications not otherwise excluded from Part D. | Will not be approved for use in conjunction with medications that have agonist activity at the mu receptor | The prescriber must be approved to prescribe buprenorphine/naloxone. For use as maintenance therapy for the treatment of opioid dependence and used as part of a complete treatment plan to include counseling and psychosocial support. A recent urine drug screen must be submitted with each request. | | | Initial therapy: one month. Reauthorization: 3 months then 6 months thereafter | Justification must be provided for use in combination with benzodiazepines or other sedative/hypnotics. Provider must submit a Board of Pharmacy Controlled Substance report to the health plan. |

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| Subutex (buprenorphine) | All FDA-approved indications not otherwise excluded from Part D. | Will not be approved for use in conjunction with medications that have agonist activity at the mu receptor. | The prescriber must be approved to prescribe buprenorphine. For use as maintenance therapy for the treatment of opioid dependence and used as part of a complete treatment plan to include counseling and psychosocial support. A recent urine drug screen must be submitted with each request. Medical records documenting hypersensitivity or intolerance to buprenorphine/naloxone or the patient is pregnant or lactating. | | | Initial therapy: one month. Reauthorization: 3 months then 6 months thereafter | Justification must be provided for use in combination with benzodiazepines or other sedative/hypnotics. Provider must submit a Board of Pharmacy Controlled Substance report to the health plan. |
| Sutent (sunitinib) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Sylatron (peginterferon alfa-2b) | All FDA-approved indications not otherwise excluded from Part D. | | Documentation that the patient has melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy. | | | 1 year | Must be obtained through a specialty pharmacy. |

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| Symlin (pramlintide) | All FDA-approved indications not otherwise excluded from Part D. | | | | Initial request must be from an Endocrinologist. Subsequent requests may be from family practice or internal medicine. | 1 year | |
| Synarel (nafarelin acetate) | All FDA-approved indications not otherwise excluded from Part D. | | Documented diagnosis of endometriosis or central precocious puberty. Documented contraindication, intolerance, or treatment failure with leuprolide. | | | 6 months | |
| Synribo (omacetaxine) | All FDA-approved indications not otherwise excluded from Part D. | | Chronic myeloid leukemia, Chronic or accelerated phase with resistance to or intolerance of 2 or more tyrosine kinase inhibitors. | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |
| Tabloid (thioguanine) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |

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| Tarceva (erlotinib) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Targretin (bexarotene) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Tasigna (nilotinib) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Temodar (temozolomide) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |

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| Testopel (testosterone pellet) | All FDA-approved indications not otherwise excluded from Part D. | Testosterone replacement will not be covered for the treatment of sexual dysfunction | Confirmed diagnosis of testosterone deficiency OR absence of endogenous testosterone in males over the age of 18 with: Primary hypogonadism (congenital or acquired) AND two low total testosterone levels (drawn on separate days) with an elevated LH and FSH OR Hypogonadotropic hypogonadism (congenital or acquired) AND two low total testosterone levels (drawn on separate days) with a low to low-normal LH and FSH. | | | 1 year | |
| Testosterone Injection | All FDA-approved indications not otherwise excluded from Part D. | | | | | 1 year | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |
| Thalomid (thalidomide) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Tykerb (lapatinib) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |

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| Uloric (febuxostat) | All FDA-approved indications not otherwise excluded from Part D. | | Medical records documenting intolerance to allopurinol. Or Documented treatment failure of allopurinol due to renal insufficiency (CrCl less than or equal to 10 ml/min). Or Failure of allopurinol at maximal therapeutic doses (600mg/day). | | | 1 year | |
| Vfend (voriconazole) | All FDA-approved indications not otherwise excluded from Part D. | | Documented diagnosis of Invasive aspergillosis, Candida Krusei, or an organism known to be resistant to high dose fluconazole and is susceptible to voriconazole. Documentation must include a culture report or susceptibility report. | | | 1 year | |
| Victrelis (boceprevir) | All FDA-approved indications not otherwise excluded from Part D. | | Documented chronic hepatitis C genotype 1 AND to be used in combination with peginterferon alfa and ribavirin AND previously untreated with boceprevir or telaprevir. | 18 years of age or older | | 32 weeks | Will not be approved as monotherapy. Submit HCV-RNA levels at treatment weeks 8, 12, and 24. Must be obtained through a specialty pharmacy. |
| Vivitrol (naltrexone IM) | All FDA-approved indications not otherwise excluded from Part D. | | For treatment of opioid abuse: Documented trial and failure of oral naltrexone. For treatment of alcohol abuse: Documented trial and failure of oral naltrexone and one of the following: disulfiram or acamprosate. | | | 6 months | Patient is engaged in a comprehensive management program that includes a psychosocial component of the therapy. Must be obtained through a specialty pharmacy. |

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| Votrient (pazopanib) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |
| Xalkori (crizotinib) | All FDA-approved indications not otherwise excluded from Part D. | | Non Small Cell Lung Cancer - For the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved test. | | | 6 months | Must be obtained through a specialty pharmacy. |
| Xeloda (capecitabine) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |

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| Xenazine (tetrabenazine) | All FDA-approved indications not otherwise excluded from Part D. | Xenazine is not covered for members who are actively suicidal, or patients with untreated or inadequately treated depression, with impaired hepatic function, or patients currently taking monoamine oxidase inhibitors or patients taking reserpine. | Diagnosis of Huntington's Disease with chorea. Chart notes documenting that the patient's disease has improved based on prescriber's assessment while on therapy. Documentation that member is being monitored for depression and suicidal ideation. | | Neurologist | Initial: 3 months Reauthorization: 1 year | |
| Xgeva (denosumab) | All FDA-approved indications not otherwise excluded from Part D. | | Documented diagnosis for the prevention of skeletal related events with bone metastases from solid tumors. Documented failure or intolerance, or clinical rationale for the avoidance of Zometa. Documented serum calcium levels. | | | 6 months | Use of a specialty pharmacy is required |

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| Xifaxan (rifaximin) | All FDA-approved indications not otherwise excluded from Part D. | | Traveler's diarrhea: Diagnosis of traveler's diarrhea due to noninvasive strain of E.Coli, treatment failure with an oral antibiotic such as azithromycin, levofloxacin, or ofloxacin. Hepatic encephalopathy: Documented diagnosis of hepatic encephalopathy and documented treatment failure or documented intolerance/contraindication to lactulose. | | | Traveler's diarrhea: 3 days per request. Hepatic encephalopathy: one year | |
| Xolair (omalizumab) | All FDA-approved indications not otherwise excluded from Part D. | | Medical records documenting IgE level greater than or equal to 30 IU/ml AND specific evidence of allergic asthma, supported by clinical and lab findings such as positive skin tests, symptom patterns, etc. AND inadequate control with an inhaled corticosteroid and a long acting beta-2 agonist combination therapy at maximum doses AND evidence of persistent symptoms requiring frequent rescue therapy, practitioner visits despite inhaled corticosteroids, or ER visits. | 12 years of age or older | Allergist or Pulmonologist | 6 months | Must be obtained through a specialty pharmacy. |
| Xtandi (enzalutamide) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a Specialty pharmacy. |
| Yervoy (ipilimumab) | All FDA-approved indications not otherwise excluded from Part D. | | Documentation that the patient has unresectable or metastatic melanoma and has failed on previous systemic therapy. | | | 6 months | |

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| Zaltrap (aflibercept) | All FDA-approved indications not otherwise excluded by Part D. | | 1. Central retinal vein occlusion with macular edema 2. Exudative age-related macular degeneration 3. Metastatic colorectal cancer, in combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI), in patients whose disease is resistant to or has progressed following an oxaliplatin-based regimen | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. Must be obtained through a Specialty Pharmacy. |
| Zelboraf (vemurafenib) | All FDA-approved indications not otherwise excluded from Part D. | | For the treatment of unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA- approved test. Zelboraf is not recommended for use in patients with wild-type BRAF melanoma. | | | 6 months | Must be obtained through a specialty pharmacy. |
| Zolinza (vorinostat) | All FDA-approved indications not otherwise excluded from Part D. | | | | | 6 months | Must be obtained through a specialty pharmacy. |

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| Zometa (zoledronic acid) | All FDA-approved indications not otherwise excluded from Part D. | | Documentation of diagnosis. | | | 6 months | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |
| Zortress (everolimus) | All FDA-approved indications not otherwise excluded from Part D. | | Documented trial and failure of tacrolimus and sirolimus. | | | 1 year | Documented diagnosis is necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. Immunosuppressants used to prevent organ transplant rejection are a Part B benefit if the transplant was covered under Medicare |
| Zytiga (abiraterone) | All FDA-approved indications not otherwise excluded from Part D. | Women who are pregnant or may become pregnant. | Documented diagnosis of metastatic castration-resistant prostate cancer AND documented prior chemotherapy containing docetaxel AND to be used in combination with prednisone. | | Oncologist | 1 year | Must be obtained through a specialty pharmacy. |

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| Zyvox (linezolid) | All FDA-approved indications not otherwise excluded from Part D. | | Infectious Disease Specialist Consult, chart notes and culture and sensitivity report, and failure of other antimicrobials that the culture shows sensitivity to or contraindication to the other antimicrobials. | | | 1 time up to 28 days therapy | |