PRESBYTERIAN

**Presbyterian Senior Care (HMO) / MediCare PPO Formulary**
**Prior Authorization Criteria**
**Effective November 1, 2012**

| 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 | |
| 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 | |
| Alimta (pemetrexed disodium) | All FDA-approved indications not otherwise | | Malignant Pleural Mesothelioma: In combination with cisplatin and in patients who are not candidates for curative surgery or whose disease is unresectable. Nonsquamous | | | 1 year | |

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| | excluded from Part D | | 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. | | | | |
| Aloxi (palonosetron) | All FDA-approved indications not otherwise excluded from Part D | | For the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses in patients treated with moderately emetogenic cancer chemotherapy. For the prevention of acute nausea and vomiting associated with initial and repeat courses in patients treated with highly emetogenic cancer chemotherapy. Documented trial and failure with ondansetron injection or granisetron injection. For the prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery, documentation that member has failed to achieve control of nausea and/or vomiting with IV ondansetron or IV granisetron. | | | 6 months | Use of a Specialty Pharmacy is required |
| 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 | Medical records documenting one of the following: At least two low total testosterone levels (drawn on separate days), OR at least two low free testosterone levels (drawn on separate days), OR one low total testosterone level with an elevated LH and FSH OR one low free testosterone level with an elevated LH and FSH. | | | 1 year | |
| Androgel 1% (testosterone topical) | All FDA-approved indications not | Testosterone replacement will not be | Medical records documenting one of the following: At least two low total testosterone levels (drawn on separate days), OR at least | | | 1 year | |

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| | otherwise excluded from Part D | covered for the treatment of sexual dysfunction | two low free testosterone levels (drawn on separate days), OR one low total testosterone level with an elevated LH and FSH OR one low free testosterone level with an elevated LH and FSH. | | | | |
| 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 | |
| Anzemet (dolasetron oral) | All FDA-approved indications not otherwise excluded from Part D | | Documented treatment failure with ondansetron OR granisetron. | | | 6 months | |
| 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 | |
| Aralast NP (proteinase inhibitor human) | All FDA-approved | | | | | 6 months | Documented diagnosis is |

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| | indications not otherwise excluded from Part D | | | | | | necessary to determine whether this medication is covered under the Medicare Part B (medical) or Part D (pharmacy) benefit. |
| 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 | |
| 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 by Part D | | Documented trial and failure of Fludara and Campath. | | | 6 months | |
| Avastin (bevacizumab) | All FDA approved indications not otherwise excluded from Part D | History of recent hemoptysis or serious hemorrhage. Bevacizumab should not be | 1. Diagnosis and patient history, 2. Concurrent or previous medication trials, 3. HER2 status for metastatic breast cancer. | | Prescribed by or in consultation with an oncologist | 1 year | |

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| | | used within 28 days following major surgery or until the surgical incision is fully healed. | | | | | |
| Banzel (rufinamide) | All FDA-approved indications not otherwise excluded from Part D | | Medical records documenting failure at therapeutic doses of at least two formulary anticonvulsants. | | | 1 year | |
| Benlysta (belimumab) | 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. |
| Berinert (C1 esterase inhibitor) | All FDA-approved indications not otherwise excluded from Part D | | Covered for the diagnosis of hereditary angioedema (HAE) that has been clinically established by an allergist or immunologist. | 18 years of age or older | | 6 months | Diagnosis of HAE must be documented by a low C4 level AND a low C1 inhibitor level (antigenic or functional). Cannot be concurrently taking an angiotensin converting enzyme |

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| | | | | | | | inhibitor or estrogen replacement therapy. Must be experiencing at least one symptom of the moderate or severe attack (ie. swelling of the face, throat, or abdomen). For continuation of therapy: 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 long-term prophylactic therapy (LTP) or the clinical rational for avoiding LTP must be provided. |
| Botox (onabotulinumtoxinA) | All FDA-approved indications not | Cosmetic use | Severe primary axillary hyperhydrosis: Medical records documenting failure of drying agents such as topical aluminum | | Migraines: must be prescribed by a neurologist | 1 year | |

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| | otherwise excluded from Part D Dystonia, Cerebral Palsy, Facial Nerve Disorder/Hemi-facial Spasm, Migraines, Severe palmar hyperhydrosis | | 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 hyperhidrosis: 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. | | | | |
| Brilinta (ticagrelor) | All FDA-approved indications not otherwise excluded by 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 by 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 | |
| Campath (alemtuzumab) | All FDA-approved indications not otherwise excluded from Part D | | Diagnosis of B-Cell chronic lymphocytic leukemia (B-CLL). | | | 1 year | |
| Campral (acamprosate) | All FDA-approved | | Diagnosis of Alcohol dependence and member is abstinent at treatment initiation. | | | 3 months | |

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| | indications not otherwise excluded from Part D | | Documentation from physician confirming alcohol abstinence and patient participation in an alcoholic recovery program during the entire course of therapy. Documentation of trial/failure with naltrexone or disulfiram. | | | | |
| 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 by Part D | | Documented diagnosis | | | 1 year | |
| Cellcept (mycophenolate mofetil ) | All FDA-approved indications not otherwise excluded by 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 |

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| | | | | | | | covered under Medicare. |
| Cervarix (HPV vaccine) | All FDA-approved indications not otherwise excluded from Part D | Males | | Between the ages of 9 and 25 | | 3 doses per 365 days | |
| 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 | |
| (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- | | Patient must have a diagnosis of severe | | | 6 months | |

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| | approved indications not otherwise excluded from Part D | | 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). | | | | |
| Daunoxome (daunorubicin) | All FDA-approved indications not otherwise excluded from Part D | | Documentation of diagnosis for which the medication is indicated. | | | 1 year | |
| Dexferrum (iron dextran) injection | All FDA-approved indications not otherwise excluded by Part D | | Treatment of documented chemotherapy-induced iron deficiency anemia. OR Treatment of documented iron deficiency anemia in a chronic kidney disease patient undergoing chronic hemodialysis. OR Treatment of documented iron deficiency anemia in a patient who has a documented disorder of the gastrointestinal tract of which symptoms may be aggravated by oral iron therapy, such as Inflammatory bowel disease. OR Treatment of documented iron deficiency anemia in a patient with documented severe intolerance to or treatment failure of an oral iron product after an adequate trial. Attempts must have been made to identify and treat the underlying cause of the deficiency. | | | 1 time | Coverage falls under Medicare Part B benefit. Documented iron deficiency anemia for the listed indications is defined as a hemoglobin <11 g/dl. |
| Differin (adapalene) | All FDA- | | | Exception | | 6 months | |

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| | approved indications not otherwise excluded from Part D | | | required for patient older than 40 years of age | | | |
| Dificid (fidaxomicin) | All FDA-approved indications not otherwise excluded by 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 by Part D | | | | | | 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 by 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 | Patient must be less than 75 years of age | Cardiologist | 1 year | |

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| | | | considered to be at high risk for stent thrombosis. | | | | |
| Emend (aprepitant oral) | All FDA-approved indications not otherwise excluded from Part D | | Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. Failure of 2 formulary agents: ondansetron, granisetron, or promethazine. For the prevention of postoperative nausea and vomiting (PONV) following surgery, documentation that member has failed to achieve control of nausea and/or vomiting with IV ondansetron or IV granisetron. | | | 6 months | Coverage may fall under Medicare Part B or Part D |
| Emend (fosaprepitant) injection | All FDA-approved indications not otherwise excluded from Part D | | Documentation that the patient is receiving combination therapy with a 5-HT3 antagonist AND dexamethasone for a cancer chemotherapy regimen which has high emetogenic potential.<br>OR<br>Documentation that the patient is receiving combination therapy with a 5-HT3 antagonist AND dexamethasone for a cancer chemotherapy regimen which includes anthracycline and cyclophosphamide in combination<br>OR<br>Documentation that the patient is receiving a cancer chemotherapy regimen which has moderate emetogenic potential and has failed antiemetic therapy with a 5-HT3 antagonist in | | | 6 months | Coverage may fall under Medicare Part B or Part D. |

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| | | | combination with dexamethasone. | | | | |
| 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 | |
| Erivedge (vismodegib) | All FDA-approved indications not otherwise excluded from Part D | | | | | 6 months | Use of Specialty Pharmacy is required |
| 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. |
| Ethyol (amifostine) | All FDA-approved indications not otherwise excluded from Medicare 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 | |
| Extavia (interferon beta-1b) | All FDA-approved indications not | | Medical records documenting trial and failure on the formulary alternatives, Copaxone and Rebif, or if the patient is a new member to the | | Neurologist | 1 year | |

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| | otherwise excluded from Part D | | plan and is currently taking Extavia. | | | | |
| Feraheme (ferumoxytol) injection | All FDA-approved indications not otherwise excluded from Part D | | Treatment of documented chemotherapy-induced iron deficiency anemia. OR Treatment of documented iron deficiency anemia in a chronic kidney disease patient undergoing chronic hemodialysis. OR Treatment of documented iron deficiency anemia in a patient who has a documented disorder of the gastrointestinal tract of which symptoms may be aggravated by oral iron therapy, such as Inflammatory bowel disease. OR Treatment of documented iron deficiency anemia in a patient with documented severe intolerance to or treatment failure of an oral iron product after an adequate trial. Attempts must have been made to identify and treat the underlying cause of the deficiency. | | | 1 time | Coverage falls under Medicare Part B benefit. Documented iron deficiency anemia for the listed indications is defined as a hemoglobin <11 g/dl. |
| Ferrlecit (Na ferric gluconate) injection | All FDA-approved indications not otherwise excluded from Part D | | Treatment of documented chemotherapy-induced iron deficiency anemia. OR Treatment of documented iron deficiency anemia in a chronic kidney disease patient undergoing chronic hemodialysis. OR Treatment of documented iron deficiency anemia in a patient who has a documented disorder of the gastrointestinal tract of which symptoms may be aggravated by oral iron therapy, such as Inflammatory bowel disease. OR Treatment of documented iron deficiency anemia in a patient with documented severe intolerance to or treatment failure of an oral | | | 1 time | Coverage falls under Medicare Part B benefit. Documented iron deficiency anemia for the listed indications is defined as a hemoglobin <11 g/dl. |

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| | | | iron product after an adequate trial. Attempts must have been made to identify and treat the underlying cause of the deficiency. | | | | |
| Firazyr (icatibant) | All FDA-approved indications not otherwise excluded from Part D | | Covered for the diagnosis of hereditary angioedema (HAE) that has been clinically established by an allergist or immunologist. | 18 years of age or older | | 6 months | Diagnosis of HAE must be documented by a low C4 level AND a low C1 inhibitor level (antigenic or functional). Cannot be concurrently taking an angiotensin converting enzyme inhibitor or estrogen replacement therapy. Must be experiencing at least one symptom of the moderate or severe attack (ie. swelling of the face, throat, or abdomen). For continuation of therapy: Medical records documenting frequency of acute HAE attacks and the patient's response to therapy must be provided. If the patient is |

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| | | | | | | | experiencing more than one acute HAE attack per month medical records documenting use of 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. | | | 1 year | |
| 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 | Medical records documenting one of the following: At least two low total testosterone levels (drawn on separate days), OR at least two low free testosterone levels (drawn on separate days), OR one low total testosterone level with an elevated LH and FSH OR one low free testosterone level with an elevated LH and FSH. | | | 1 year | |
| Gamastan S/D (human immune globulin IM) | All FDA-approved indications not otherwise excluded by Part D | | Medical records documenting diagnosis. For Immunoglobulin Deficiency: Patient must have infusion reactions with IVIG or inability to obtain IV access. | | | 1 year | |

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| Gammagard liquid (human immune globulin IV) | All FDA-approved indications not otherwise excluded by Part D | | Documented diagnosis | | | 1 year | |
| Gamunex (human immune globulin IV) | All FDA-approved indications not otherwise excluded by Part D | | Documented diagnosis | | | 1 year | |
| Gardasil (HPV vaccine) | All FDA-approved indications not otherwise excluded by Part D | | | Age 9 years to 26 years | | Series of 3 injections (1 year) | |
| Gralise (gabapentin) | All FDA-approved indications not otherwise excluded from Part D | | Claim history of gabapentin immediate release. | | | 6 months | |
| granisetron injection (Kytril) | All FDA-approved indications not otherwise excluded from Part D | | | | | 6 months | Coverage may fall under Medicare Part B or Part D |
| granisetron oral (Kytril) | All FDA-approved | | | | | 6 months | Coverage may fall under Medicare Part |

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| | indications not otherwise excluded from Part D | | | | | | B or Part D. |
| Hizentra (human immune globulin SQ) | All FDA-approved indications not otherwise excluded by Part D | | Medical records documenting diagnosis. Patient must have infusion reactions with IVIG or inability to obtain IV access. | | | 1 year | |
| 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 | |
| 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. |
| 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 |

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| | | | | | | | (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 | |
| 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 | Ages 2 - 18 years of age | | 1 year | |

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| | | | and less than 5 cm if greater than 3 years old AND open epiphyses on bone radiograph. | | | | |
| INFeD (iron dextran) injection | All FDA-approved indications not otherwise excluded from Part D | | Treatment of documented chemotherapy-induced iron deficiency anemia. OR Treatment of documented iron deficiency anemia in a chronic kidney disease patient undergoing chronic hemodialysis. OR Treatment of documented iron deficiency anemia in a patient who has a documented disorder of the gastrointestinal tract of which symptoms may be aggravated by oral iron therapy, such as Inflammatory bowel disease. OR Treatment of documented iron deficiency anemia in a patient with documented severe intolerance to or treatment failure of an oral iron product after an adequate trial. Attempts must have been made to identify and treat the underlying cause of the deficiency. | | | 1 time | Coverage falls under Medicare Part B benefit. Documented iron deficiency anemia for the listed indications is defined as a hemoglobin <11 g/dl. |
| Inlyta (axitinib) | All FDA-approved indications not otherwise excluded from Part D | | | | | 6 months | Use of a Specialty Pharmacy is required |
| Jakafi (ruxolitinib) | All FDA-approved indications not otherwise excluded from Part D | | | | | 6 months | Use of a Specialty Pharmacy is required |
| Kalbitor (ecallantide) | All FDA- | | Covered for the diagnosis of hereditary | 18 years of age | | 6 months | Diagnosis of HAE |

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| | approved indications not otherwise excluded from Part D | | angioedema (HAE) that has been clinically established by an allergist or immunologist. | or older | | | must be documented by a low C4 level AND a low C1 inhibitor level (antigenic or functional). Cannot be concurrently taking an angiotensin converting enzyme inhibitor or estrogen replacement therapy. Must be experiencing at least one symptom of the moderate or severe attack (ie. swelling of the face, throat, or abdomen). For continuation of therapy: 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 |

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| | | | | | | | documenting use of long-term prophylactic therapy (LTP) or the clinical rational for avoiding LTP must be provided. |
| 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 | |
| Kyprolis (carfilzomib) | All FDA-approved indications not otherwise excluded from Part D | | | | | 6 months | |
| Leukine (sargramostim) | All FDA-approved indications not otherwise excluded from | 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 | | | 6 months | |

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| | Part D | | neutropenia post BMT. | | | | |
| Lidoderm (lidocaine topical patch) | All FDA-approved indications not otherwise excluded by Part D | | | | | 3 months | |
| Lumizyme (alglucosidase alft) | 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. |
| Lunesta (eszopiclone) | All FDA-approved indications not otherwise excluded from Part D | | Documented trial and failure of zolpidem immediate release oral tablets or documented intolerance/contraindication to zolpidem immediate release. | | | 1 year | |
| 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 | | | 1 year | |

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| | | | antidepressants, SSRI's, SNRI's, gabapentin, lamotrigine, Depakote, or carbamazepine. For Fibromyalgia, medical records documenting failure of a tricyclic antidepressant and gabapentin. | | | | |
| 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 |
| Multaq (dronedarone) | All FDA-approved indications not otherwise excluded by Part D | | Paroxysmal or persistent atrial fibrillation or paroxysmal or persistent atrial flutter. The member does not have Class IV heart failure or Class II or III heart failure with a recent decompensation. | | | 1 year | |
| Myfortic (mycophenolic acid) | All FDA-approved indications not otherwise excluded by 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 |

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| | | | | | | | organ transplant rejection are a Part B benefit if the transplant was covered under Medicare. |
| Neulasta (pegfilgrastim) | All FDA-approved indications not otherwise excluded by 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.. |
| 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 | |
| Neupogen (filgrastim) | All FDA-approved indications not otherwise excluded by 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. |
| Norditropin (growth hormone) | All FDA-approved indications not | | GHD(child), ISS, TS, NS, PWS, GRCRF: Baseline height less than or equal to 2 SD below mean or at or below the 3rd percentile | | GHD (child), ISS, SGA, TS, NS, PWS, | 1 year | |

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| | otherwise excluded from Part D Growth Hormone Deficiency (GHD) in children, Idiopathic short stature (ISS), Small for gestational age or Intrauterine growth retardation (SGA), Prader-Willi Syndrome (PWS), Turner Syndrome (TS), Noonan Syndrome (NS), Growth retardation associated with Chronic Renal Insufficiency (GRCRF), Adult Onset Growth Hormone Deficiency (AOGHD), Childhood | | for age or gender. Growth rate less than 7cm/year if less than 3 years of age and less than 4cm/year if greater than 3 years of age. Bone x-ray is greater than 2 years behind chronological age. Epiphyses are not closed. Diagnosis of GHD(child): Subnormal response to 2 provocative stimulation tests (less than or equal to 10 ng/ml). For diagnosis of ISS: Predicted adult height not likely to reach 63in for males and 59in for females, and absence of comorbid conditions that should be treated by other means. SGA: Diagnosis confirmed by birth weight less than 2500g at gestation more than 37 weeks or birth weight or length below the 3rd percentile for gestational age who fail to catch up by age 2. Baseline height less than or equal to 2 SD below mean or at or below 3rd percentile for age or gender. Patient age 2 years and older. AOGHD: Multiple hormone deficiencies (hypopituitarism) resulting from pituitary or hypothalamic disease, surgery, radiation therapy or trauma. Low serum IGF-I. COGHD: Clinical diagnosis of GHD as child or adolescent. Subnormal response to 2 provocative tests (less than or equal to 10ng/ml) following a GH washout period (1-3 months). For diagnosis of PWS: only genetic testing. Reauthorization for AOGHD, COGHD: IGF-I is in normal range for age and gender. Reauthorization for GHD(child), ISS, SGA, TS, NS, PWS, GRCRF: Increase | | AOGHD, COGHD: must be prescribed by an endocrinologist. GRCRF: Must be prescribed by a nephrologist | | |

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| | Onset Growth Hormone Deficiency (COGHD), Full thickness skin loss associated with 3rd degree burns | | in growth velocity of at least 2 cm/year during previous year. Epiphyses are not closed. Not post renal transplant for patients with chronic renal insufficiency. Provocative stimulation tests could include arginine, clonidine, glucagon, insulin, and levodopa. Diagnosis of third degree burn with full thickness skin loss. | | | | |
| Noxafil (posaconazole) | All FDA-approved indications not otherwise excluded by Part D | | Documentation of diagnosis for which the medication is indicated. | | | 1 year | |
| 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 Remicade (infliximab) 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. Use of a Specialty Pharmacy is required. |
| Perjeta (pertuzumab) | All FDA-approved | | | | | 6 months | Use of a Specialty Pharmacy is |

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| | indications not otherwise excluded by Part D | | | | | | required |
| Potiga (ezogabine) | All FDA-approved indications not otherwise excluded by Part D | | The patient must be diagnosed with partial-onset seizures and have history of 2 medications indicated for partial-onset seizures. | | | 6 months | |
| Pristiq (desvenlafaxine) | All FDA-approved indications not otherwise excluded by Part D | | Documented trial and failure of Effexor XR (venlafaxine ER) at a therapeutic dose. | | | 1 year | |
| Privigen (human immune globulin IV) | All FDA-approved indications not otherwise excluded by Part D | | Documented diagnosis | | | 1 year | |
| Procrit (epoetin alfa) | All FDA-approved indications not otherwise excluded by 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. |
| Prograf (tacrolimus) | All FDA- | | | | | 1 year | Documented |

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| | approved indications not otherwise excluded by Part D | | | | | | 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. |
| Promacta (eltrombopag olamine) | All FDA-approved indications not | Coverage will not be provided when used in | Initial authorization: 1. Platelet count is less than 30000/mcl, 2. Dose does not exceed the FDA label maximum for the diagnosis, 3. | | | 3 months | The patient and prescriber must be enrolled in the |

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| | otherwise excluded from Part D | combination with Nplate | Treatment failure or contraindication to at least two of the following treatments: corticosteroids, immunoglobulin, or splenectomy. | | | | Promacta Cares Program. |
| Provenge (sipuleucel-t) | All FDA-approved indications not otherwise excluded by Part D<br>MS Fatigue | | Documented diagnosis of metastatic castrate resistant (hormone refractory) prostate cancer with radiologic evidence of metastatic disease in lymph nodes and/or bone with evidence of progression* at either site. Patient is asymptomatic or minimally asymptomatic, without cancer-related bone pain or use of opioid analgesics for cancer pain. Patient does not have visceral disease (metastases to liver, lung, or brain). Patient has baseline testosterone levels of <50ng/ml with documented "hormone refractory" prostate cancer defined as: Surgical (bilateral orchiectomy) castration; or three months of chemical castration (LHRH agonists or antagonists). Chemotherapy and/or immunosuppressive therapies are not given concurrently. Patient does not have a life expectancy of less than six months. Patient has an ECOG performance status of 0-1 Or Patient has a Karnofsky score of 80-100. | | | 3 doses | |
| Provigil (modafinil) | All FDA-approved indications not otherwise excluded by 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 | |

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| 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. |
| Rapamune (sirolimus) | All FDA-approved indications not otherwise excluded by 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. |
| Relistor (methylnaltrexone) | All FDA-approved indications not otherwise excluded by | | 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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| | Part D | | | | | | |
| 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 | Use of a Specialty Pharmacy is required. |
| 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 | |
| Rozerem (ramelteon) | All FDA-approved indications not otherwise excluded from Part D | | Documented trial and failure of zolpidem immediate release oral tablets or documented intolerance/contraindication to zolpidem immediate release. | | | 1 year | |
| Somatuline Depot (lanreotide) | All FDA-approved indications not otherwise excluded by 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. |
| Suboxone (buprenorphine/naloxone) | All FDA-approved indications not | Will not be approved for use in | The prescriber must be approved to prescribe buprenorphine/naloxone. For use as maintenance therapy for the treatment of | | | Initial therapy: 1 month. | Justification must be provided for use in combination with |

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| | otherwise excluded from Part D | conjunction with medications that have agonist activity at the mu receptor | opioid dependence. A recent urine drug screen must be submitted with each request. | | | Reauthorization: 3 months then 6 months thereafter | benzodiazepines or other sedative/hypnotics. |
| Subutex (buprenorphine sublingual) | 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. 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: 1 month. Reauthorization: 3 months then 6 months thereafter | Justification must be provided for use in combination with benzodiazepines or other sedative/hypnotics. |
| Sylatron (peginterferon alfa-2b) | All FDA-approved indications not otherwise excluded by 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 | |
| Symlin (pramlintide) | All FDA-approved indications not otherwise excluded by Part D | | | | Endocrinologist | 1 year | |
| Synarel (nafarelin acetate) | All FDA-approved indications not otherwise excluded from | | Documented diagnosis of endometriosis or central precocious puberty. Documented contraindication, intolerance, or treatment failure with leuprolide. | | | 6 months | |

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| | Part D | | | | | | |
| Tasigna (nilotinib) | All FDA-approved indications not otherwise excluded from Part D | | | | | 6 months | |
| Testim (testosterone topical) | All FDA-approved indications not otherwise excluded from Part D | Testosterone replacement will not be covered for the treatment of sexual dysfunction | Medical records documenting one of the following: At least two low total testosterone levels (drawn on separate days), OR at least two low free testosterone levels (drawn on separate days), OR one low total testosterone level with an elevated LH and FSH OR one low free testosterone level with an elevated LH and FSH. | | | 1 year | |
| 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 by Part D | | | | | 1 year | Documented diagnosis is necessary to determine whether this medication is covered under the |

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| | | | | | | | Medicare Part B (medical) or Part D (pharmacy) benefit. |
| Tev-Tropin (growth hormone) | All FDA-approved indications not otherwise excluded from Part D Growth Hormone Deficiency (GHD) in children, Idiopathic short stature (ISS), Small for gestational age or Intrauterine growth retardation (SGA), Prader-Willi Syndrome (PWS), Turner Syndrome (TS), Noonan Syndrome (NS), Growth retardation associated with Chronic Renal Insufficiency (GRCRF), | | GHD(child), ISS, TS, NS, PWS, GRCRF: Baseline height less than or equal to 2 SD below mean or at or below the 3rd percentile for age or gender. Growth rate less than 7cm/year if less than 3 years of age and less than 4cm/year if greater than 3 years of age. Bone x-ray is greater than 2 years behind chronological age. Epiphyses are not closed. Diagnosis of GHD(child): Subnormal response to 2 provocative stimulation tests (less than or equal to 10 ng/ml). For diagnosis of ISS: Predicted adult height not likely to reach 63in for males and 59in for females, and absence of comorbid conditions that should be treated by other means. SGA: Diagnosis confirmed by birth weight less than 2500g at gestation more than 37 weeks or birth weight or length below the 3rd percentile for gestational age who fail to catch up by age 2. Baseline height less than or equal to 2 SD below mean or at or below 3rd percentile for age or gender. Patient age 2 years and older. AOGHD: Multiple hormone deficiencies (hypopituitarism) resulting from pituitary or hypothalamic disease, surgery, radiation therapy or trauma. Low serum IGF-I. COGHD: Clinical diagnosis of GHD as child or adolescent. Subnormal response to 2 provocative tests (less than or equal to | | GHD (child), ISS, SGA, TS, NS, PWS, AOGHD, COGHD: must be prescribed by an endocrinologist. GRCRF: Must be prescribed by a nephrologist | 1 year | |

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| | Adult Onset Growth Hormone Deficiency (AOGHD), Childhood Onset Growth Hormone Deficiency (COGHD), Full thickness skin loss associated with 3rd degree burns | | 10ng/ml) following a GH washout period (1-3 months). For diagnosis of PWS: only genetic testing. Reauthorization for AOGHD, COGHD: IGF-I is in normal range for age and gender. Reauthorization for GHD(child), ISS, SGA, TS, NS, PWS, GRCRF: Increase in growth velocity of at least 2 cm/year during previous year. Epiphyses are not closed. Not post renal transplant for patients with chronic renal insufficiency. Provocative stimulation tests could include arginine, clonidine, glucagon, insulin, and levodopa. Diagnosis of third degree burn with full thickness skin loss. | | | | |
| Tysabri (natalizumab | All FDA-approved indications not otherwise excluded from Part D | | Diagnosis of relapsing form of multiple sclerosis, to be used as monotherapy. Patient must have a documented trial and failure or inability to tolerate Copaxone (glatiramer) AND an interferon beta 1A or 1B product such as Avonex, Rebif, Extavia. | | Neurologist | 1 year | Use of a Specialty Pharmacy is required |
| 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 | |
| Valcyte (valganciclovir) | All FDA-approved indications not otherwise excluded from Part D | | Treatment of cytomegalovirus (CMV) retinitis in adult AIDS patients. Prevention of CMV disease in kidney, heart, and kidney-pancreas transplant adults patients at high risk. Prevention of CMV disease in kidney and heart pediatric transplant patients at high | | | 1 year | |

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| | | | risk. | | | | |
| Vancocin (vancomycin) | All FDA-approved indications not otherwise excluded by Part D | | Failure of oral metronidazole or documentation of severe C.Diff infection (WBC greater than 15000 or Serum Creatinine greater than 1.5 times premorbid level). | | | C. Diff: 10 days per request, other diagnosis 1 month | |
| Vandetanib (vandetanib) | All FDA-approved indications not otherwise excluded by 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 |
| Venofer (iron sucrose) injection | All FDA-approved indications not otherwise excluded by Part D | | Treatment of documented chemotherapy-induced iron deficiency anemia. OR Treatment of documented iron deficiency anemia in a chronic kidney disease patient undergoing chronic hemodialysis. OR Treatment of documented iron deficiency anemia in a patient who has a documented disorder of the gastrointestinal tract of which symptoms may be aggravated by oral iron therapy, such as Inflammatory bowel disease. OR Treatment of documented iron deficiency anemia in a patient with documented severe intolerance to or treatment failure of an oral iron product after an adequate trial. Attempts must have been made to identify and treat the underlying cause of the deficiency. | | | 1 time | Coverage falls under Medicare Part B benefit. Documented iron deficiency anemia for the listed indications is defined as a hemoglobin <11 g/dl. |
| Vfend (voriconazole) | All FDA-approved indications not | | Documented diagnosis of Invasive aspergillosis, Candida Krusei, or an organism known to be resistant to high dose fluconazole | | | 1 year | |

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| | otherwise excluded by Part D | | and is susceptible to voriconazole. Documentation must include a culture report or susceptibility report. | | | | |
| Victrelis (boceprevir) | All FDA-approved indications not otherwise excluded from Part D | Pregnant women and men whose female partners are pregnant. | 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 | | 1 year | Will not be approved as monotherapy |
| Viibryd (vilazodone) | All FDA-approved indications not otherwise excluded from Part D | Concomitant use with MAOI or within 14 days of stopping or starting an MAOI. | Documented diagnosis of major depressive disorder AND a documented trial and failure of an SSRI and an SNRI. | | | 1 year | |
| Vimpat (lacosamide) | All FDA-approved indications not otherwise excluded by Part D | | Medical records documenting trial and failure at therapeutic dose of at least two formulary anticonvulsants. | | | 1 year | |
| Vivitrol (naltrexone IM) | All FDA-approved indications not otherwise excluded by 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. |
| Xalkori (crizotinib) | All FDA-approved | | Non Small Cell Lung Cancer - For the treatment of patients with locally advanced or | | | 6 months | Use of a Specialty Pharmacy is |

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| | indications not otherwise excluded by Part D | | metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved test. | | | | required |
| 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 by 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 |
| Xifaxan (rifaximin) | All FDA-approved | | Travelers' diarrhea: Diagnosis of travelers' diarrhea due to noninvasive strain of E.Coli, | | | travelers' diarrhea: 3 | |

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| | indications not otherwise excluded by Part D | | treatment failure with an oral antibiotic such as azithromycin or ciprofloxacin. Hepatic encephalopathy: Documented diagnosis of hepatic encephalopathy and documented treatment failure or documented intolerance/contraindication to lactulose. | | | days per request. Hepatic encephalopathy: 1 year | |
| Xolair (omalizumab) | All FDA-approved indications not otherwise excluded by 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. | Greater than 12 years of age | Allergist or Pulmonologist | 6 months | |
| Yervoy (ipilimumab) | All FDA-approved indications not otherwise excluded by Part D | | Documentation that the patient has unresectable or metastatic melanoma and has failed on previous systemic therapy. | | | 6 months | |
| Zaltrap (ZIV-aflibercept) | All FDA-approved indications not otherwise excluded from Part D | | | | | 6 months | |
| Zelboraf (vemurafenib) | All FDA-approved indications not | | For the treatment of unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA- approved | | | 6 months | Use of a Specialty Pharmacy is required |

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| | otherwise excluded from Part D | | test. Zelboraf is not recommended for use in patients with wild-type BRAF melanoma. | | | | |
| Zometa (zoledronic acid) | All FDA-approved indications not otherwise excluded from Part D | | Documentation of diagnosis. | | | 6 months | |
| 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 |
| Zostavax (live zoster vaccine) | All FDA-approved indications not otherwise excluded by Part D | | Documentation that patient does not have a contraindication to use Zostavax, such as immunosuppression or active Zoster infection. | Greater than or equal to 50 years of age. | | 1 time | |

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| 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 | Use of a Specialty Pharmacy is required |
| Zyvox (linezolid) | All FDA-approved indications not otherwise excluded by 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 | |