

| Medication | FDA Indications Note: Although every effort is made to keep this FDA indication list up to date, please consult the web link in the far right column for the most accurate information. | MFC-DC Specifications | Manufacturer's Prescribing Info (Hold CTRL and click on link to open) |
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| Abecma (idecabtagene vicleucel) | Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. | ***MFC-DC Pharmacist Review*** | ABECMA PI |
| Actimmune (interferon gamma-1b) | Indicated for: 1. reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease. 2. delaying time to disease progression in patients with severe, malignant osteoporosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. | ***MFC-DC Pharmacist Review*** | ACTIMMUNE PI |
| Adcirca (tadalafil) | Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability. | Rx by Pulmonologist, Cardiologist, or Rheumatologist | ADCIRCA PI |
| Aimovig (erenumab-aooe) | Indicated for the preventive treatment of migraine in adults. | Rx by Neurologist Member must have tried and failed at least 2 previous migraine prophylaxis medications. Examples of migraine prophylaxis medications include, but are not limited to, divalproex, metoprolol, propranolol, timolol, topiramate, amitriptyline, venlafaxine, atenolol. | AIMOVIG PI |
| Alecensa (alectinib) | Indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. | Rx by Oncologist | ALECENSA PI |
| Alunbrig (brigatinib) | Indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. | Rx by Oncologist | ALUNBRIG PI |

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| hcvAmitiza (lubiprostone) | Indicated for: <ol style="list-style-type: none"> chronic idiopathic constipation (CIC) in adults. opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Limitations of Use: Effectiveness of Amitiza in the treatment of OIC in patients taking diphenylheptane opioids (e.g., methadone) has not been established. irritable bowel syndrome with constipation (IBS-C) in women \geq 18 years old. | Failure of at least 2 of the following: docusate, mineral oil, sennosides, psyllium, psyllium /aspartame, calcium polycarbophil, polyethylene glycol 3350, lactulose, methylcellulose | AMITIZA PI |
| Amondys 45 (casimersen) | Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping. | ***MFC-DC Pharmacist Review*** | AMONDYS 45 PI |
| Ampyra (dalfampridine) | Indicated to help improve walking in adults with MS. | Rx by Neurologist. <ol style="list-style-type: none"> Documentation of MS with ambulatory dysfunction but must be able to walk 25 feet within 8-45 seconds at baseline. Members must have a baseline gait assessment by PT within 90 days of beginning Ampyra. Members must have a repeat evaluation after 3 months on Ampyra. Improvement in walking speed must be documented in order to obtain further refills. Members must not have a history of seizure disorder or renal impairment. | AMPYRA PI |
| Apretude (cabotegravir extended-release) | Indicated to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35 kg for PrEP (Pre-exposure prophylaxis). <p>PA SUBMISSION REQUIREMENTS:</p> <ol style="list-style-type: none"> Attestation that patient is considered high-risk for HIV infection Risk-reduction and medication adherence counseling documentation Negative HIV-1 test prior to initiating therapy and before each injection | | APRETUDE PI |

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| | <p>4. Patient will not receive concomitant therapy with any of the following medications due to contraindication and decreased levels of cabotegravir seen with co-administration:</p> <ol style="list-style-type: none"> Anticonvulsants: Carbamazepine, oxcarbazepine, phenobarbital, phenytoin Antimycobacterials: Rifampin, rifapentine | | |
| Austedo (deutetrabenazine) | <p>Indicated for the treatment of:</p> <ol style="list-style-type: none"> Chorea associated with Huntington’s disease. Tardive dyskinesia in adults. | | AUSTEDO PI |
| Ayvakit (avapritinib) | Indicated for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. | Rx by Oncologist | AYVAKIT PI |
| Balversa (erdafitinib) | Indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 or FGFR2 genetic alterations and progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. | Rx by Oncologist | BALVERSA PI |
| Benlysta (belimumab) | Indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy. | | BENLYSTA PI |
| Bethkis (tobramycin inh sol) | Indicated for management of cystic fibrosis patients with <i>Pseudomonas aeruginosa</i> . *** <i>Safety and efficacy have not been demonstrated in patients under the age of six years, patients with a forced expiratory volume in one second (FEV1) less than 40% or greater than 80% predicted, or patients colonized with Burkholderia cepacia.</i> | Rx by Pulmonologist | BETHKIS PI |
| Bosulif (bosutinib) | <p>Indicated for the treatment of adult patients with:</p> <ol style="list-style-type: none"> Newly diagnosed chronic phase Ph+ chronic myelogenous leukemia (CML). This indication is approved under accelerated approval based on molecular and cytogenetic response rates. Continued approval for this indication may be contingent upon verification and confirmation of clinical benefit in an ongoing long-term follow up trial. Chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy. | Rx by Oncologist | BOSULIF PI |
| Botox (onabotulinumtoxin A) | <p><u>Indicated for:</u></p> <ol style="list-style-type: none"> treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication. treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication. prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer). treatment of spasticity in adult patients. | <ol style="list-style-type: none"> Rx by Neurologist, Urologist, Ophthalmologist Botox will NOT be approved for cosmetic purposes. | BOTOX PI |

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| | <ol style="list-style-type: none"> 5. treatment of spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy. 6. treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain. 7. treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients. 8. treatment of blepharospasm associated with dystonia in patients ≥ 12 years of age. 9. treatment of strabismus in patients ≥ 12 years of age. | | |
| Braftovi (encorafenib) | Indicated, in combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test. | Rx by Oncologist | BRAFTOVI PI |
| Breyanzi (lisocabtagene maraleucel) | <p>Indicated for:</p> <ol style="list-style-type: none"> 1. treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including: <ol style="list-style-type: none"> a. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma) b. High-grade B-cell lymphoma c. Primary mediastinal large B-cell lymphoma d. Follicular lymphoma grade 3B. <p>Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.</p> | ***MFC-DC Pharmacist Review*** | BREYANZI PI |
| Cabometyx (cabozantinib) | <ol style="list-style-type: none"> 1. Indicated for the treatment of patients with advanced renal cell carcinoma. 2. Indicated for treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. | Rx by Oncologist | CABOMETYX PI |
| Camzyo (mavacamten) | CAMZYOS is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms | | CAMZYOS.PI |
| Cialis (tadalafil) | <p>Indicated for the treatment of:</p> <ol style="list-style-type: none"> 1. erectile dysfunction (ED) – <i>(drug coverage not provided for this indication)</i> 2. the signs and symptoms of benign prostatic hyperplasia (BPH) 3. ED and the signs and symptoms of BPH (ED/BPH) | Rx by Pulmonologist or Cardiologist | CIALIS PI |
| Cinryze (C1 Esterase Inhibitor [Human]) | <p>Indicated for routine prophylaxis against angioedema attacks in adults, adolescents, and pediatric patients (6 years of age and older) with Hereditary Angioedema.</p> <p>Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.</p> | ***MFC-DC Pharmacist Review*** | CINRYZE PI |
| Cometriq (cabozantinib) | Indicated for treatment of progressive, metastatic medullary thyroid cancer. | Rx by Oncologist | COMETRIQ PI |
| Cosela (trilaciclib) | Indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer. | Rx by Oncologist | COSELA PI |

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| Cotellic (cobimetinib) | Indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. | Rx by Oncologist | COTELLIC PI |
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| Cutaquig (Immune Globulin Subcutaneous (Human) - hipp) | Indicated for treatment of primary humoral immunodeficiency (PI) in adults. | Rx by Immunologist | CUTAQUIG PI |
| Darzalex Faspro (daratumumab and hyaluronidase-fihj, SQ admin) | <u>Indicated for the treatment of adult patients with multiple myeloma:</u> <ol style="list-style-type: none"> 1. in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant. 2. in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy. 3. in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy. 4. as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. | Rx by Oncologist | DARZALEX FASPRO PI |
| DESMOPRESSIN NASAL SPRAY PRODUCTS: <u>DDAVP spray-</u> 0.01% <u>Stimate spray-</u> 1.5 mg/mL | <u>DDAVP is indicated for:</u> <ol style="list-style-type: none"> 1. antidiuretic replacement therapy in the management of central cranial diabetes insipidus. 2. treatment of transient polyuria and polydipsia post head trauma or surgery in the pituitary region. <u>Stimate is indicated for:</u> <ol style="list-style-type: none"> 1. hemophilia A with Factor VIII coagulant activity levels greater than 5% - will stop bleeding in patients with hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas or mucosal bleeding. 2. mild to moderate classic von Willebrand's disease (Type I) with Factor VIII levels greater than 5% - will stop bleeding in patients with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas, mucosal bleeding or menorrhagia. | <ol style="list-style-type: none"> 1. STIMATE: Hemophilia A with factor VIII coagulant activity greater than 5%: <ul style="list-style-type: none"> ➤ *peri-operatively to prevent bleeding ➤ to treat spontaneous or trauma induced bleeding ***Note- Patients with factor VIII levels equal to or less than 5% or patients who have factor VIII antibodies are not candidates for the drug. It is contraindicated in patients under 3 months old. It is NOT indicated for Hemophilia B. 2. STIMATE: Patients with von Willebrand's Disease (type I) with factor VIII coagulant activity greater than 5%: <ul style="list-style-type: none"> ➤ used peri-operatively to prevent bleeding. ➤ to treat spontaneous or trauma induced bleeding. ***Note- The drug is NOT indicated for treatment of | DDAVP FDA PI STIMATE PI |

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| | | severe classic von Willebrand's Disease (type I) or when there is evidence of an abnormal molecular form of Factor VIII antigen | |
| Dexcom G6 Continuous Glucose Monitoring (CGM) System | Indicated for the management of diabetes in persons age 2 years and older. | Rx by Endocrinologist. Please click link below for CGM Policy: Continuous Glucose Monitoring Devices | DEXCOM G6 PI |
| Dificid (fidaxomicin) | Indicated for the treatment of <i>Clostridium difficile</i> -associated diarrhea in adults (≥18 years of age). | Pt must have documented failures with both metronidazole and vancomycin, or contraindication(s) to the use of these agents. | DIFICID PI |
| Doptelet (avatrombopag) | Indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure. Indicated for Chronic Immune Thrombocytopenia in adult patients who have had an insufficient response to a previous treatment. | Rx by Hematologist A recent (less than 1 month old) platelet count must be supplied with the clinical request, as well as information regarding the planned procedure. | DOPTELET PI |
| Dupixent (dupilumab) | <u>Indicated for:</u> <ol style="list-style-type: none"> 1. treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids. 2. add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent asthma. 3. add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis. 4. treatment of adult and pediatric patients aged 12 years and older, weighing at least 40kg, with eosinophilic esophagitis | Rx by Allergist or Dermatologist | DUPIXENT PI |
| Egrifta SV (tesamorelin injection) | Indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy. | | EGRIFTA SV PI |
| Eligard (leuprolide SQ) | see Leuprolide | | |
| Elzonris (tagraxofusp-erzs) | Indicated for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older. | Rx by Oncologist | ELZONRIS PI |
| Emgality (galcanezumab-gnlm) | A calcitonin-gene related peptide antagonist indicated for the preventative treatment of migraine and treatment of episodic cluster headache. | Rx by Neurologist 1. Member must have tried and failed at least | EMGALITY PI |

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| | | <p>2 previous migraine prophylaxis medications. Examples of migraine prophylaxis medications include, but are not limited to, divalproex, metoprolol, propranolol, timolol, topiramate, amitriptyline, venlafaxine, atenolol.</p> <p>2. Medication not to be used with another CGRP antagonist or inhibitor used for preventative treatment of migraines (Ajovy, Nurtec ODT, Vyepti (eptinezumab-jjmr))</p> | |
| <p>Empaveli (pegcetacoplan)</p> | <p>Indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria.</p> <p>Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.</p> | <p>***MFC-DC Pharmacist Review***</p> | <p>EMPAVELI PI</p> |
| <p>Enhertu (fam-trastuzumab deruxtecan-nxk)</p> | <p>Indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.</p> | <p>Rx by Oncologist</p> | <p>ENHERTU PI</p> |
| <p>Enspryng (satralizumab-mwge)</p> | <p>An interleukin-6 (IL-6) receptor antagonist indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.</p> <p>PA SUBMISSION REQUIREMENTS:</p> <ol style="list-style-type: none"> 1. Documentation of positive test for AQP4-IgG antibodies 2. Documentation of at least one relapse in the last 12 months OR 2 or more relapses that require rescue therapy in the last 24 months 3. Documentation of inadequate response, contraindication or intolerance to rituximab or Truxima (rituximab-abbs) | <p>Rx by Neurologist</p> | <p>ENSPRYNG PI</p> |
| <p>Epclusa (sofosbuvir/ velpatasvir)</p> <p>SEE SPECIAL NOTE REGARDING PA REQUIREMENTS AND FORM *****→</p> | <p>Indicated for the treatment of patients with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A) and with decompensated cirrhosis for use in combination with ribavirin (Child-Pugh B and C). EPCLUSA is also indicated for the treatment of adult and pediatric patients 6 years and older or weighing at least 17 kg with HCV genotypes 1, 2, 3, 4, 5, or 6 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS5B protease inhibitor, but not both.</p> <p>PA SUBMISSION REQUIREMENTS:</p> | <p>To get the latest copy of the hepatitis C Prior Authorization form, please click the link below:</p> <p>HEPATITIS C PA FORM</p> | <p>EPCLUSA PI</p> |

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| | <ol style="list-style-type: none"> 1. A completed Hepatitis C Prior Authorization Form (see link on right). 2. Medical records including: <ol style="list-style-type: none"> a. Most recent office visit note(s) which includes: <ol style="list-style-type: none"> i. detail on all previous hepatitis C treatments; if none, the note must say "treatment naïve." ii. Child-Pugh score (if cirrhotic). iii. social history with detail provided on use of ETOH and/orillicit substances. 3. Laboratory studies including: <ol style="list-style-type: none"> a. a recent (less than 6 months old) baseline viral load. b. genotype. c. (if applicable) HIV viral load and/or hepatitis B viral load. d. NO fibrosis score required. <p><u>Note:</u> Generic formulation (sofosbuvir/velpatasvir) is covered with a prior authorization, not BRAND Epclusa.</p> | | |
| Erwinaze (asparaginase <i>Erwinia chrysanthemi</i>) | Indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with ALL who have developed hypersensitivity to <i>E. coli</i> -derived asparaginase. | Rx by Oncologist | ERWINAZE PI |
| Esbriet (pirfenidone) | Indicated for the treatment of idiopathic pulmonary fibrosis IPF. | Rx by Pulmonologist or Cardiologist | ESBRIET PI |
| Eucrisa (crisaborole) On Step Therapy | Indicated for topical treatment of mild-to-moderate atopic dermatitis in adult and pediatric patients 3 months of age and older. | Step Therapy: First must have tried and failed: At least one topical steroid AND topical tacrolimus. | EUCRISA PI |
| Evkeeza (evinacumab-dgnb) | Indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH). | Must submit genetic testing confirming homozygous familial hypercholesterolemia (HoFH). | EVKEEZA PI |
| Exkivity (mobocertinib) | Indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. | | EXKIVITY PI |
| Fasenra (benralizumab) | Indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. | Rx by Pulmonologist or Allergist | FASENRA PI |
| Fentanyl SEE SPECIAL NOTE REGARDING PA REQUIREMENTS AND FORM *****→ | Indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate | All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: Opioid PA Form | FENTANYL PI |

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| Firazyr (icatibant) | Indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults ≥18 years of age (self-administered by the patient upon recognition of symptoms of an HAE attack after training under the guidance of a healthcare professional). | Rx by Allergist or ENT | FIRAZYR PI |
| Fotivda (tivozanib) | Indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. | Rx by Hematology Oncology | FOTIVDA PI |

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| Gavreto (pralsetinib) | Indicated for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion- positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test Rx by Oncologist | Rx by Oncologist | GAVRETO PI |
| Gralise (gabapentin) | Indicated for the management of Postherpetic Neuralgia (PHN). (GRALISE is not interchangeable with other gabapentin products because of differing 6 pharmacokinetic profiles that affect the frequency of administration) | | GRALISE PI |
| Growth Hormone | See Norditropin ; See Serostim | | |
| Haegarda (C1 Esterase Inhibitor SubQ (Human)) | Indicated for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients. | Rx by Allergist/Immunologist | HAEGARDA PI |
| Hycamtin caps (topotecan) | Indicated for treatment of patients with relapsed small cell lung cancer (SCLC) in patients with a prior complete or partial response and who are at least 45 days from the end of first-line chemotherapy. | Rx by Oncologist | HYCAMTIN PI |
| Ibrance (palbociclib) | Indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with: 1. an aromatase inhibitor as initial endocrine based therapy in postmenopausal women or in men; 2. fulvestrant in patients with disease progression following endocrine therapy. | Rx by Oncologist | IBRANCE PI |
| Iclusig (ponatinib) | <u>Indicated for:</u> 1. treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) or Ph+ ALL for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated. 2. treatment of adult patients with T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). | Rx by Oncologist | ICLUSIG PI |
| Imbruvica (ibrutinib) | <u>Indicated for:</u> 1. Mantle cell lymphoma (MCL) who have received at least one prior therapy. Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials. 2. Chronic lymphocytic leukemia/small lymphocytic lymphoma (SLL). 3. Chronic lymphocytic leukemia/small lymphocytic lymphoma with 17p deletion. 4. Waldenström's macroglobulinemia (WM). 5. Marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy. Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. 6. Chronic graft versus host disease after failure of one or more lines of systemic therapy. | Rx by Oncologist | IMBRUVICA PI |

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| Jakafi (ruxolitinib) | <u>Indicated for:</u> 1. treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis in adults. 2. treatment of adults with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea. 3. treatment of steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older. | Rx by Hematologist/Oncologist | JAKAFI PI |
| Jivi (empagliflozin) | Recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for: 1. On-demand treatment and control of bleeding episodes. 2. Perioperative management of bleeding. 3. Routine prophylaxis to reduce the frequency of bleeding episodes. | Rx by Hematologist | JIVI PI |
| Juxtapid (lomitapide) | Indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). | Rx by Cardiology or Endocrinologist | JUXTAPID PI |
| Jynarque (tolvaptan) | Indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD). | Rx by Nephrologist | JYNARQUE PI |
| Kalbitor (ecallantide) | Indicated for treatment of acute attacks of hereditary angioedema (HAE) in patients 12 years of age and older. | Rx by Immunologist or Allergist | KALBITOR PI |
| Kalydeco (ivacaftor) | Indicated for the treatment of cystic fibrosis (CF) in patients age 6 months and older who have one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. | Rx by Pulmonologist | KALYDECO PI |
| Kerendia (finerenone) | Indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). PA SUBMISSION REQUIREMENTS: 1. Type II Diabetes Mellitus diagnosis 2. Laboratory results and clinical note 3. Serum creatinine \leq 5.0 mEq/L 4. eGFR \geq 25 mL/min/1.73 m ² 5. Urine albumin-to-creatinine ratio \geq 30mg/g 6. Concomitant use with maximum tolerated doses of ACE-Inhibitor or ARB 7. Intolerance or contraindication to ACE-inhibitor or ARB if not taking 8. Intolerance, failed trial or contraindication to both Jardiance and Invokana | | KERENDIA PI |
| Kisqali (ribociclib) | <u>Indicated in combination with:</u> 1. an aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 | Rx by Oncologist | KISQALI PI |

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| | <p>(HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy; or</p> <p>2. fulvestrant for the treatment of postmenopausal women with HER2-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine based therapy or following disease progression on endocrine therapy.</p> | | |
| <p>Kymriah (tisagenlecleucel)</p> | <p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 1. Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. 2. Adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. <p><u>Limitation of Use:</u> KYMRIAH is not indicated for treatment of patients with primary central nervous system lymphoma.</p> <p>MedStar Family Choice considers Kymriah medically necessary when all of the following conditions are met:</p> <ol style="list-style-type: none"> 1. Recipient has relapsed or refractory B-cell ALL, defined as <ul style="list-style-type: none"> • Second or greater bone marrow relapse; OR • Any bone marrow relapse after allogeneic stem cell transplantation; OR • Primary refractory as defined by not achieving a complete remission after 2 cycles of a standard chemotherapy regimen or chemorefractory as defined by not achieving a complete remission after 1 cycle of standard chemotherapy for relapsed leukemia; OR • Patients with Philadelphia chromosome positive (Ph+) ALL are eligible if they are intolerant to or have failed 2 lines of tyrosine kinase inhibitor therapy (TKI), or if TKI therapy is contraindicated; AND 2. Recipient is 25 years of age or younger; AND 3. Documentation of CD19 tumor expression; AND 4. Performance score on Karnofsky or Lansky Scale is greater than or equal to 50%; AND 5. Life expectancy > 12 weeks; AND 6. Adequate cardiac, pulmonary, and other organ function (as determined by protocol from treatment facility); AND 7. The treatment facility that dispenses and administers Kymriah is enrolled and complies with the Risk Evaluation and Mitigation Strategy; AND 8. One-time, single administration with dosing in accordance with the FDA label. <p>Kymriah is considered investigational and not medically necessary when the above medically necessary criteria are not met, and for all other indications, including but not limited to:</p> <ol style="list-style-type: none"> 1. Isolated extra-medullary disease relapse; or 2. Patients with Burkitt's lymphoma/leukemia (i.e. patients with mature B-cell ALL, leukemia with B-cell [sIg positive and kappa or lambda restricted positivity] ALL, with FAB L3 morphology and /or a MYC translocation); or 3. Prior malignancy, except carcinoma in situ of the skin or cervix treated with curative intent and with no evidence of active disease; or | <p>Rx by Oncologist</p> | <p>KYMRIAH PI</p> |

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| | <ol style="list-style-type: none"> 4. Treatment with any other chimeric antigen receptor therapy or genetically modified T cell therapy; or 5. Any active uncontrolled infection; or 6. Hepatitis B or C (if viral load is detectable); or 7. Human Immunodeficiency Virus (HIV); or 8. Presence of grade 2 to 4 acute or extensive chronic graft-versus-host disease(GVHD); or 9. Active CNS involvement by malignancy, defined by CNS-3 per NCCN guidelines. | | |
| Latuda (lurasidone hydrochloride) | <u>Indicated for:</u> <ol style="list-style-type: none"> 1. Schizophrenia in adults and adolescents (13 to 17 years). 2. Depressive episode associated with Bipolar I Disorder (bipolar depression) in adults and pediatric patients (10 to 17 years) as monotherapy. 3. Depressive episode associated with Bipolar I Disorder (bipolar depression) in adults as adjunctive therapy with lithium or valproate. | | LATUDA PI |
| LEUPROLIDE PRODUCTS: <u>Eligard</u> (leuprolide SQ) <u>Lupron</u> (leuprolide acetate) <u>Lupron Depot</u> (leuprolide acetate for depot suspension) <u>Lupron Depot-PED</u> (leuprolide acetate for depot suspension) | <u>Indicated for:</u> <ol style="list-style-type: none"> 1. palliative treatment for advanced prostate cancer (Eligard). 2. treatment of pediatric patients with central precocious puberty (Lupron Depot- PED). 3. treatment of endometriosis (Lupron and Lupron Depot). 4. Management of endometriosis, including pain relief, recurrence symptoms and reduction of endometriotic lesions, (Lupron and Lupron Depot). 5. uterine leiomyomata (fibroids) along with concurrent iron therapy in preparation for surgery [duration of treatment should be for 6 months or less (Lupron and Lupron Depot)]. | | ELIGARD PI LUPRON 3.75 mg PI LUPRON DEPOT 11.25 MG PI LUPRON DEPOT-PED PI |
| Librium (chlordiazepoxide) | Indicated for the management of anxiety disorders or for the short-term relief of symptoms of anxiety, withdrawal symptoms of acute alcoholism, and preoperative apprehension and anxiety. | | LIBRIUM PI |
| Libtayo (cemiplimab-rwlc) | Indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. | Rx by Oncologist | LIBTAYO PI |
| Livtency (maribavir) | A cytomegalovirus (CMV) pUL97 kinase inhibitor indicated for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet. | | LIVTENCITY PI |

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| LO Loestrin Fe (norethindrone, ethinyl estradiol and ferrous fumarate) | See Oral Contraceptive | ANY OCP on prior authorization requires documentation demonstrating a compelling reason why formulary OCPs cannot be used [ex: intolerance, prior side effects, failures, etc. documented after a 3-month trial of formulary OCPs] | LO LOESTRIN PI |
| Loprox (Ciclopirox cream) On Step Therapy | Indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum, and Microsporum canis; candidiasis (moniliasis) due to Candida albicans; and tinea (pityriasis) versicolor due to Malassezia furfur. | Step Therapy: First must have tried and failed; Clotrimazole, clotrimazole/betamethasone, ketoconazole, nystatin or nystatin/triamcinolone | LOPROX PI |
| Lorbrena (lorlatinib) | Indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on: 1. crizotinib and at least one other ALK inhibitor for metastatic disease; or 2. alectinib as the first ALK inhibitor therapy for metastatic disease; or 3. ceritinib as the first ALK inhibitor therapy for metastatic disease. | Rx by Oncologist | LORBRENA PI |
| Lovaza (omega-3-acid ethyl esters) | Indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. | | LOVAZA PI |
| Lumakras (sotorasib) | Indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy. | Rx by Oncologist | LUMAKRAS PI |
| Lumoxiti (moxetumomab pasudotox-tdfk) | Indicated for the treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least 2 prior systemic therapies, including treatment with a purine nucleoside analog. | Rx by Oncologist | LUMOXITI PI |
| Lupron and Lupron Depot | See Leuprolide | | |
| Lupkynis (voclosporin) | Indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis. | | LUPKYNIS PI |

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| <p>Lybalvi (olanzapine and samidorphan)</p> | <p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 1. Schizophrenia in adults 2. Bipolar I disorder in adults <ol style="list-style-type: none"> a. Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate b. Maintenance monotherapy treatment <p>PA SUBMISSION REQUIREMENTS:</p> <ol style="list-style-type: none"> 1. Laboratory findings and clinical notes 2. Cholesterol levels, fasting blood glucose, A1c, current weight and BMI, complete blood count 3. Urine drug screen 4. No known substance use disorder 5. Do not initiate within 14 days of opioid medication use 6. 4-week trial and failure of at least two formulary atypical antipsychotic agents | | <p>LYBALVI PI</p> |
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| | 7. If clinically stable on olanzapine provide documentation of metabolic syndrome, weight gain, or glucose intolerance | | |
| Lynparza (olaparib) | Indicated for: <ol style="list-style-type: none"> 1. First-Line Maintenance Treatment of BRCA-mutated Advanced Ovarian Cancer - For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic <i>BRCA</i>-mutated (<i>gBRCAm</i> or <i>sBRCAm</i>) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. 2. Maintenance Treatment of Recurrent Ovarian Cancer- For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy. 3. Advanced <i>gBRCA</i>-mutated Ovarian Cancer After 3 or More Lines of Chemotherapy- For the treatment of adult patients with deleterious or suspected deleterious germline <i>BRCA</i>-mutated (<i>gBRCAm</i>) advanced ovarian cancer who have been treated with 3 or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA. 4. Germline <i>BRCA</i>-mutated HER2-negative Metastatic Breast Cancer – In patients with deleterious or suspected deleterious <i>gBRCAm</i>, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on FDA-approved companion diagnostic for Lynparza. | Rx by Oncologist | LYNPARZA PI |
| Macrilen (macimorelin) | Indicated for the diagnosis of adult growth hormone deficiency. | Rx by Endocrinologist | MACRILEN PI |
| Mavyret (glecaprevir and pibrentasvir) SEE SPECIAL NOTE REGARDING PA REQUIREMENTS AND FORM *****→ | Indicated for the treatment of patients with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A). MAVYRET is also indicated for the treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. PA SUBMISSION: NONE REQUIRED effective 9/1/2022: (Also No PA required for Vosevi effective 9/1/2022) | To get the latest copy of the hepatitis C Prior Authorization form, please click the link below: HEPATITIS C PA FORM | MAVYRET PI |

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| Mekinist (trametinib) | Indicated: 1. BRAF V600E or V600K Mutation-Positive Unresectable or Metastatic Melanoma - as a single agent in BRAF-inhibitor treatment-naïve patients or in combination with dabrafenib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test. 2. Adjuvant Treatment of BRAF V600E or V600K Mutation-Positive Melanoma-indicated in combination with dabrafenib, for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection. 3. BRAF V600EMutation-Positive Metastatic NSCLC- in combination with dabrafenib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAFV600E mutation as detected by an FDA-approved test. 4. BRAF V600EMutation-Positive Locally Advanced or Metastatic Anaplastic Thyroid Cancer - in combination with dabrafenib, for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer. | Rx by Oncologist | MEKINIST PI |
| Mektovi (binimetinib) | Indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test. | Rx by Oncologist | MEKTOVI PI |
| methadone (for pain) SEE SPECIAL NOTE REGARDING PA REQUIREMENTS AND FORM *****→ | Indicated for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. | All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: Opioid PA Form | METHADONE PI |
| Minastrin 24 Fe (norethindrone, ethinyl estradiol and ferrous fumarate) | See Oral Contraceptive ***CHEWABLE*** | ANY OCP on prior authorization requires documentation demonstrating a compelling reason why formulary OCPs cannot be used [ex: intolerance, prior side effects, failures, etc. documented after a 3-month trial of formulary OCPs] | MINASTRIN 24 Fe PI |
| Movantik (naloxegol) | Indicated for the treatment of opioid-induced constipation in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. | Failure of at least 2 of the following: docusate, sennosides, polyethylene glycol 3350, lactulose, methylcellulose | MOVANTIK PI |
| MS Contin (morphine sulfate extended release) SEE SPECIAL NOTE REGARDING PA | Indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. | All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: Opioid PA Form | MS CONTIN PI |

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| REQUIREMENTS AND FORM *****→ | | | |
| Mulpleta (lusutrombopag) | Indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure. | | MULPLETA PI |
| Namenda XR (memantine hydrochloride) | Indicated for the treatment of moderate to severe dementia of the Alzheimer's type. | | NAMENDA XR PI |
| Natazia (estradiol valerate and estradiol valerate/dienogest) | <u>Indicated for:</u> <ol style="list-style-type: none"> 1. use by women to prevent pregnancy. 2. treatment of heavy menstrual bleeding in women without organic pathology who choose to use an oral contraceptive as their method of contraception. | ANY OCP on prior authorization requires documentation demonstrating a compelling reason why formulary OCPs cannot be used [ex: intolerance, prior side effects, failures, etc. documented after a 3-month trial of formulary OCP(s)] | NATAZIA PI |
| Norditropin (somatropin (fDNA origin) injection) | <u>Indicated for:</u> <ol style="list-style-type: none"> 1. Pediatric: Treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone (GH), short stature associated with Noonan syndrome, short stature associated with Turner syndrome, short stature born small for gestational age (SGA) with no catch-up growth by age 2 to 4 years, Idiopathic Short Stature (ISS), and growth failure due to Prader-Willi Syndrome. 2. Adult: Replacement of endogenous GH in adults with growth hormone deficiency. | Rx by Endocrinologist | NORDITROPIN PI |
| Nourianz (istradefylline) | Indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes. | Rx by Neurologist | NOURIANZ PI |
| NovoSeven RT (Coagulation Factor VIIa recombinant) | <u>Indicated for:</u> <ol style="list-style-type: none"> 1. treatment of bleeding episodes and perioperative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets. 2. treatment of bleeding episodes and perioperative management in adults with acquired hemophilia. <p>Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.</p> | ***MFC-DC Pharmacist Review*** | NOVOSEVEN RT PI |
| Noxafil (posaconazole) | <u>Indicated for:</u> <ol style="list-style-type: none"> 1. prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy. 2. treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole. | Rx by ID | NOXAFIL PI |
| Nubeqa (darolutamide) | Indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer. | Rx by Oncologist or Urologist | NUBEQA PI |

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| Nucala (mepolizumab) | Indicated for: 1. The add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype. 2. The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). | Rx by Allergist or Pulmonologist | NUCALA PI |
| Nulibry (fosdenopterin) | Indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A. | ***MFC-DC Pharmacist Review*** | NULIBRY PI |
| Nuvigil (armodafinil) | Indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea, narcolepsy, or shift work disorder. | | NUVIGIL PI |
| Nuedexta (dextromethorphan hydrobromide and quinidine sulfate) | Indicated for the treatment of pseudobulbar affect. | Rx by Neurologist | NUEDEXTA PI |
| Ocrevus (ocrelizumab) | Indicated for the treatment of: 1. relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults ≤ 55 y.o. 2. primary progressive MS, in adults ≤ 55 y.o. | Rx by Neurologist | OCREVUS PI |
| Ofev (nintedanib) | Indicated for: 1. The treatment of idiopathic pulmonary fibrosis. 2. To slow the rate of decline in pulmonary function in patients with systemic sclerosis associated interstitial lung disease (SSc-ILD). | Rx by Pulmonologist | OFEV PI |
| OmniPod-Insulin Management (EIM) Systems | Indicated for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro) from the finger. | RX Endocrinology Must meet criteria found in Policy 1413.DC Please click link below for EIM Policy: MFC External Insulin Pumps Policy | OMNIPOD PI |
| Onpattro (patisiran) | Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. | Rx by Rheumatology or Neurology | ONPATTRO PI |
| Onureg (azacitidine) | Indicated for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and are not able to complete intensive curative therapy. | Rx by Oncologist | ONUREG PI |

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| <p>OPIOIDS</p> <p>PRIOR AUTHORIZATION TERMS</p> | <p>IMPORTANT INFORMATION ABOUT PRESCRIBING OPIOIDS FOR MEDSTAR FAMILY CHOICE MEMBERS</p> <p>EARLY REFILL REQUESTS</p> <p>“Early” Opioid Refills Will No Longer be Covered by MedStar Family Choice - Effective 1/1/2019 Beginning 1/1/2019, MedStar Family Choice will not authorize early refills of controlled medications. Specifically, MedStar Family Choice will not approve early refills, override Managed Drug Limitations (MDL), replace lost/stolen medications, or provide early</p> | <p>The PA form can be accessed using the following link:</p> <p>Opioid PA Form</p> | |
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SEE SPECIAL NOTE REGARDING PA REQUIREMENTS AND FORM

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refills for travel for controlled medications. Exceptions may be granted if a member is receiving controlled medication(s) for cancer treatment, sickle cell disease, or is in hospice/receiving palliative care.

PRIOR AUTHORIZATION

Prior Authorization will be required for:

- Prescriptions > 50 MME/day or more than 7 day for an opioid naïve patient (no opioids taken in the previous 90 days **or one ≤ 50 MME per day, ≤ 7 day prescription taken in the previous 90 days**) as described in **Section I** below.
- opioid experienced patients as described in **Section II** below.

SECTION I. OPIOID NAÏVE PATIENTS (defined as no opioids in the previous 90 days or one fill of ≤ 50 MME per day for ≤ 7 days prescription taken in the previous 90 days)

A “new” prescription means that a patient has not had an opioid medication filled under MedStar Family Choice in the preceding 90 days or had one short-acting opioid at ≤ 50 morphine equivalents per day for 7 or fewer days in previous 90 days. New prescriptions for more than 7-days’ supply or greater than 50 MME per day will require Prior Authorization. It is our hope that limiting opioid quantities to a 7-day supply will discourage abuse, both by our patients and by the community at large. This change is also consistent with Medicare policy (effective 2019) which limits opioid naïve patients to a 7-day supply.

According to the CDC 2016 Guidelines for Prescribing Opioids, “When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.”

Examples of a typical 3-day supply and a 7-day supply of frequently prescribed opioids are below:

| Medication | 3-day supply quantity* | 7-day supply quantity* (maximum allowable) |
|----------------------------|-------------------------------|---|
| HYDROMORPHONE TAB 2MG | 18 tablets | 42 tablets |
| MORPHINE SULFATE TAB 15MG | 18 tablets | 42 tablets |
| OXYCODONE SOLUTION 5MG/5ML | 180 mL | 420 mL |
| OXYCODONE TAB 5MG | 18 tablets | 42 tablets |
| TRAMADOL HCL TAB 50MG | 18 tablets | 42 tablets |

**Quantities are based on starting dose recommendations in the respective FDA Package Inserts for each medication.*

Please contact MedStar Family Choice at 888-798-4244 for Prior Authorization of new opioid prescriptions that exceed the limits. Should you have any questions or concerns about this new policy, please call Dr. Kazmi at 202-469-6727.

MedStar Family Choice strongly encourages you to prescribe the least amount of opioid at the lowest dose possible to achieve pain relief goals.

SECTION II. OPIOID EXPERIENCED PATIENTS

Prior Authorization is required for the following medications:

- Long-acting opioids
- Fentanyl products
- Methadone for pain
- Any opioid prescription (or combination of opioid prescriptions) that results in a patient exceeding 90 morphine milliequivalents (MME) per day. Instructions on calculating MME are available at the [CDC website](#).

For the sake of illustration of what constitutes 90 MME, the following is a list of daily doses of commonly prescribed opioids that **equal 90 MME/day**:

Fentanyl 112.5 mcg/day

Hydrocodone 90 mg/day

Hydromorphone 22.5 mg/day

Morphine 90 mg/day

Oxycodone 60 mg/day

Oxymorphone 30 mg/day

The following are examples of common prescriptions that **equal 90 MME/day**:

oxycodone 20 mg tid

methadone 20 mg qd

hydrocodone 10/325, 3 tabs tid

Additionally, some smaller doses of immediate release medications will require prior authorization at **less than 90 MME**. The decision to limit these medications was made in an effort to decrease the number of pills available for diversion. These medications are as follows:

| Medication | Max per 30 days | Unit |
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| Codeine compounds (all) | 1,000 | mL |
| | 180 | tab/ cap |

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| Hydrocodone compounds (all) | 2,750 | mL |
| | 180 | tab/ cap |
| Hydromorphone (1 mg/mL solution, 2 mg tablet, 3 mg suppository) | 675 | mL |
| | 180 | tab/ supp |
| Morphine (5 mg suppository, 10 mg/5mL solution, 10 mg suppository) | 1,350 | mL |
| | 180 | supp |
| Oxycodone compounds (2.5 mg, 5 mg, 7.5 mg of all formulations) | 1,800 | mL |
| | 180 | tab/ cap |
| Tramadol (100 mg, 200 mg) | 180 | tab/ cap |

In order to receive prior authorization, prescribers **must** attest to the following:

- Prescriber has reviewed controlled substance prescriptions in a Prescription Drug Monitoring Program.
- Prescriber will utilize random Urine Drug Screens.
- Prescriber has provided or offered a prescription for naloxone to the patient or patient's household if the patient has:
 - a history of substance use disorder
 - requires more than 50 MME (for example, more than Fentanyl 62.5 mcg/72 hours, hydrocodone 50 mg/day, hydromorphone 12.5 mg/day, morphine 50 mg/day, oxycodone 33 mg/ day, and oxymorphone 16 mg/day)
 - is prescribed both opioids and benzodiazepines
 - is prescribed other sedative hypnotics
 - or for any other reason deemed clinically appropriate
- Prescriber and patient have signed a Pain Management/Opioid Treatment Agreement/Contract and it is stored in the patient's medical record.

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| Oral Contraceptives | While some oral contraceptives have additional indications (ex: Beyaz for acne, PMDD, folate replacement; Estrostep Fe for acne; Safyral for folate replacement; Natazia for heavy periods), most are simply indicated for the prevention of pregnancy. | ANY OCP on prior authorization requires documentation demonstrating a compelling reason why formulary OCPs cannot be used [ex: intolerance, prior side effects, failures, etc. documented after a 3-month trial of formulary OCPs] | |
| Orfadin (nitisinone) | Indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 in combination with dietary restriction of tyrosine and phenylalanine. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. | ***MFC-DC Pharmacist Review*** | ORFADIN PI |
| Orkambi (lumacaftor/ivacaftor) | Indicated for the treatment of cystic fibrosis (CF) in patients age 2 years and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. | Rx by Pulmonologist | ORKAMBI PI |
| Oriahnn (elagolix, estradiol, and norethindrone acetate capsules) | Indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. | Must have tried and failed at least two of the following: NSAIDs, hormonal options (OCP, progesterone, hormonal IUD), or have a contraindication to using these therapies. | ORIAHNN PI |
| Orilissa (elagolix) | Indicated for the management of moderate to severe pain associated with endometriosis. | Must have tried and failed at least two of the following: NSAIDs, hormonal options (OCP, progesterone, hormonal IUD), or have a contraindication to using these therapies. | ORLISSA PI |
| Orladeyo (berotralstat) | Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. | ***MFC-DC Pharmacist Review*** | ORLADEYO PI |
| Oxlumo (lumasiran) | Indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. | ***MFC-DC Pharmacist Review*** | OXLUMO PI |
| Oxymorphone ER SEE SPECIAL NOTE REGARDING PA REQUIREMENTS AND FORM *****→ | Indicated for the relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time. | All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: Opioid PA Form | OPANA ER PI |

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| Pemazyre (pemigatinib) | Indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. | Rx by Oncologist | PEMAZYRE PI |
| Pretomanid | Indicated, as part of a combination regimen with bedaquiline and linezolid for the treatment of adults with pulmonary extensively drug resistant (XDR), treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB). Pretomanid Tablets are not indicated for patients with: 1. Drug-sensitive (DS) tuberculosis. 2. Latent infection due to Mycobacterium tuberculosis Extra-pulmonary infection due to Mycobacterium tuberculosis. 3. MDR-TB that is not treatment-intolerant or nonresponsive to standard therapy Safety and effectiveness of Pretomanid Tablets have not been established for its use in combination with drugs other than bedaquiline and linezolid as part of the recommended dosing regimen. | Rx by Pulmonologist | PRETOMANID |
| Piqray (alpelisib) | Indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen. | Rx by Oncologist | PIQRAY PI |
| Polivy (polatuzumab vedotin) | Indicated in combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, after at least two prior therapies. | Rx by Oncologist | POLIVY PI |
| Prolia (denosumab) | <u>Indicated for:</u> 1. treatment of postmenopausal women with osteoporosis at high risk for fracture. 2. treatment to increase bone mass in men with osteoporosis at high risk for fracture. 3. treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture. 4. treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. 5. treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. | | PROLIA PI |
| Provigil (modafinil) | Indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, or shift work disorder. | | PROVIGIL PI |
| Pulmozyme (dornase alfa) Inhalation solution | Indicated in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function. | Rx by Pulmonologist | PULMOZYME PI |
| Pyrukynd (mitapivat) | Indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency. PA SUBMISSION REQUIREMENTS 1. Laboratory evidence of reduced PK enzymatic activity in red blood cell 2. Confirmatory genetic testing of PKLR gene showing 2 mutant alleles with at least one-missense mutation 3. Concomitant use with folic acid | Rx by or in consultation with a Hematologist | PYRUKYND |

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| Qbrexza (glycopyrronium) | Indicated for topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older | 1. Must have tried and failed OTC Clinical Strength antiperspirants and at least one prescription strength antiperspirant (ex: Drysol). 2. Documentation that symptoms are persistent despite previous treatment attempts and that the degree of symptomatology impacts quality of life must be clearly indicated in a recent (<6 month old) clinical encounter note. | QBREXZA PI |
| Qelbree (viloxazine extended-release capsules) | Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age. | | QELBREE PI |
| Qulipta (atogepant) | Indicated for the preventive treatment of episodic migraine in adults | 1. Trial and failure or intolerance to at least three of the following agents: beta blockers, topiramate, Aimovig, and Ubrelvy, in medical documentation submitted. 2. Patient must have at least 4 headache days per month on average. | QULIPTA PI |
| Rasuvo (methotrexate inj) | <u>Indicated for:</u> 1. Management of patients with severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA), who are intolerant of or had an inadequate response to first-line therapy. 2. Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy. | Rx by Rheumatology or Dermatology | RASUVO PI |
| Ravicti (glycerol phenylbutyrate) | Indicated for chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. | ***MFC-DC Pharmacist Review*** | RAVICTI PI |
| Repatha (evolocumab) | <u>Indicated:</u> 1. to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease. 2. as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol. | Rx by Cardiologist or by Lipid Specialist. | REPATHA PI |

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| | 3. as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C. | | |
| Retevmo (selpercatinib) | <p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 1. Adult patients with metastatic RET (rearranged during transfection) fusion-positive non-small cell lung cancer (NSCLC). 2. Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy. 3. Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). | Rx by Oncologist | RETEVMO PI |
| Revatio (sildenafil) | Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) in adults to improve exercise ability and delay clinical worsening. Studies establishing effectiveness were short-term (12 to 16 weeks) and included predominately patients with NYHA Functional Class II–III symptoms. Etiologies were idiopathic (71%) or associated with connective tissue disease (25%). | Rx by Pulmonologist or Cardiologist | REVATIO PI |
| Revcovi (elapegedemase-lvlr) | <p>Indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients.</p> <p>Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial</p> | ***MFC-DC Pharmacist Review*** | REVCOVI PI |
| Revlimid (lenalidomide) | <p>Indicated for the treatment of adult patients with:</p> <ol style="list-style-type: none"> 1. Multiple myeloma (MM), in combination with dexamethasone. 2. MM, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT). 3. Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes. 4. (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities. 5. Mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. 6. Previously treated follicular lymphoma (FL), in combination with a rituximab product. 7. Previously treated marginal zone lymphoma (MZL), in combination with a rituximab product | | REVLIMID PI |
| Reyvow (lasmiditan) | Indicated for the acute treatment of migraine with or without aura in adults. | Member must have tried and failed NSAIDs and Triptans or have a contraindication to taking either of these medications. | REYVOW PI |

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| Rezurock (belumosudil) | Indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy. | Member must have tried and failed, have intolerance or medical contraindication to at least three of these medications: cyclosporine, methotrexate, mycophenolate, sirolimus, and glucocorticoids. | REZUROCK PI |
| Rituxan (rituximab) | <p>Indicated for:</p> <ol style="list-style-type: none"> 1. Pediatric patients aged 6 months and older with mature B-cell NHL and mature B-cell acute leukemia (B-AL) <ol style="list-style-type: none"> a. Previously untreated, advanced stage, CD20-positive, diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy. 2. Moderate to severe Pemphigus Vulgaris (PV) in adult patients <p>Demonstrated failure or intolerance to Truxima for the following indications:</p> <ol style="list-style-type: none"> 1. Adult patients with Non-Hodgkin’s Lymphoma (NHL) <ol style="list-style-type: none"> a. Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent. b. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy. c. Non-progressing (including stable disease), low-grade, CD20-positive, Bcell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. d. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens. 2. Adult patients with Chronic Lymphocytic Leukemia (CLL) <ol style="list-style-type: none"> a. Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC). 3. Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies 4. Granulomatosis with Polyangiitis (GPA) (Wegener’s Granulomatosis) and Microscopic Polyangiitis (MPA) in adult patients in combination with glucocorticoids <p><u>Note:</u> Prior authorization requirements apply for patients new to starting therapy. Documentation showing history of prior use of Rituxan within the past 90 days will be considered and PA Criteria will not apply.</p> | | RITUXAN PI |
| Rituxan Hycela (rituximab and hyaluronidase human) | <p>Indicated for:</p> <ol style="list-style-type: none"> 1. Follicular Lymphoma (FL) <ul style="list-style-type: none"> • Relapsed or refractory, follicular lymphoma as a single agent. | Rx by Oncologist | RITUXAN HYCELA PI |

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| | <ul style="list-style-type: none"> Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single agent maintenance therapy. Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. <ol style="list-style-type: none"> Diffuse Large B-cell Lymphoma (DLBCL) previously untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens. Chronic Lymphocytic Leukemia (CLL) previously untreated and previously treated CLL in combination with fludarabine and cyclophosphamide (FC). | | |
| Rozlytrek (entrectinib) | <p>Indicated for the treatment of:</p> <ol style="list-style-type: none"> Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive. Adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity and have either progressed following treatment or have no satisfactory alternative therapy. <p>This indication is approved under accelerated approval based on tumor response rate and durability of response.</p> | Rx by Oncologist | ROZLYTREK |
| Rubraca (rucaparib) | <p><u>Indicated for:</u></p> <ol style="list-style-type: none"> maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. treatment of adult patients with deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. | Rx by Oncologist | RUBRACA PI |
| Rybrevant (amivantamab-vmjw) | <p>Indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.</p> | Rx by Oncologist | RYBREVANT PI |
| Sabril (vigabatrin) | <p><u>Indicated for:</u></p> <ol style="list-style-type: none"> the treatment of Refractory Complex Partial Seizures as adjunctive therapy in patients 2 years of age and older who have responded inadequately to several alternative treatments; SABRIL is not indicated as a first line agent. Infantile Spasms - monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss. | Rx by Neurologist | SABRIL PI |
| Santyl Ointment Collagenase | <p>Indicated for debriding chronic dermal ulcers and severely burned areas.</p> | Rx by Dermatologist or Wound Care Specialist | SANTYL PI |
| Saphnelo (anifrolumab-fnia) | <p>Indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.</p> <p>PA SUBMISSION REQUIREMENTS:</p> <ol style="list-style-type: none"> Confirmed diagnosis of SLE | | SAPHNELO PI |

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| | <ol style="list-style-type: none"> 2. Lab report showing autoantibodies (e.g., ANA, anti-ds, anti-Sm) 3. Current therapy for SLE alone or in combination with: <ol style="list-style-type: none"> a. Glucocorticoid (e.g. prednisone, methylprednisone, dexamethasone) b. Antimalarials (e.g. hydroxychloroquine) c. Immunosuppressants (e.g. azathioprine, methotrexate, mycophenolate, cyclosporine, cyclophosphamide) 4. Excluded use with Benlysta 5. Excluded to use with active lupus nephritis or central nervous system lupus 6. Trial and failure or intolerance to Benlysta | | |
| Scemblix (asciminib) | <p>A kinase inhibitor indicated for the treatment of adult patients with:</p> <ol style="list-style-type: none"> 1. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs). This indication is approved under accelerated approval based on major molecular response (MMR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). 2. Ph+ CML in CP with the T315I mutation. | Rx by Oncologist or Hematologist | SCSEMBLIX PI |
| Serostim (somatropin (rDNA origin)) | Indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance. | Rx by ID or HIV Specialist | SEROSTIM PI |
| Seysara (seracycline) | Indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older. | Rx by Dermatologist. Failure of at least one other oral tetracycline antibiotic. | SEYSARA PI |
| Signifor LAR (pasireotide) | Indicated for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option. | Rx by Endocrinologist | SIGNIFOR LAR PI |
| Sirturo (bedaquiline) | Indicated as part of combination therapy in adult and pediatric patients (12 to less than 18 years of age and weighing at least 30 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB). [Reserved for use when an effective treatment regimen cannot otherwise be provided; not indicated for the treatment of latent, extra pulmonary or drug-sensitive tuberculosis; should be administered by directly observed therapy. Safety and efficacy of SIRTURO in HIV-infected patients with MDR-TB have not been established, as clinical data are limited. | Rx by ID | SITURO PI |
| Sklice (ivermectin) On Step Therapy | Indicated for the topical treatment of head lice infestations in patients 6 months of age and older | Step Therapy: First must have tried and failed: Age < 6 – OTC permethrin 1% Age > 6 – malathion | SKLICE PI |

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| Soliris (eculizumab) | Indicated for: 1. treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. 2. treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy. The effectiveness of Soliris in aHUS is based on the effects on thrombotic microangiopathy (TMA) and renal function. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial | ***MFC-DC Pharmacist Review*** | SOLIRIS PI |
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| Spinraza (nusinersen) | Indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. | ***MFC-DC Pharmacist Review*** | SPINRAZA PI |
| Stimate nasal spray (desmopressin) | See Desmopressin Products | | |
| Stivarga (regorafenib) | Indicated for: 1. treatment of metastatic colorectal cancer previously treated with ALL the following therapies: a. fluoropyrimidine-based chemotherapy b. oxaliplatin-based chemotherapy c. irinotecan-based chemotherapy d. an anti-vascular endothelial growth factor (VEGF) therapy e. if Kirsten RNA Associated Rat Sarcoma 2 Virus Gene (KRAS) wild type, an anti-epidermal growth factor receptor (EGFR) therapy 2. treatment of locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST), previously treated with imatinib mesylate and sunitinib malate. hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. | Rx by Oncologist | STIVARGA PI |
| Stromectol (ivermectin) | Indicated for the treatment of the following infections: 1. Strongyloidiasis of the intestinal tract (i.e., nondisseminated) strongyloidiasis due to the nematode parasite <i>Strongyloides stercoralis</i> . 2. Onchocerciasis due to the nematode parasite <i>Onchocerca volvulus</i> . | At this time, outpatient use for COVID-19 treatment is prohibited. | STROMECTOL PI |
| Synagis (palivizumab) SEE SPECIAL NOTE REGARDING PA REQUIREMENTS AND FORM *****→ | Indicated for prevention of serious lower respiratory tract disease caused by RSV in pediatric Patients: 1. with a history of premature birth (≤ 35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season 2. with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season 3. with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season. MedStar Family Choice uses the newest recommendations of the American Academy of Pediatrics (AAP). Recommendations were last updated in the journal Pediatrics (7/28/2014 issue): Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. | Please submit: A COMPLETED PRIOR AUTHORIZATION FORM (see link below) SYNAGIS PRIOR AUTHORIZATION AND PRESCRIPTION FORM To view the most up to date AAP Synagis Guidelines, follow the link below: AAP SYNAGIS GUIDELINES | SYNAGIS PI |
| Synribo (omacetaxine) | Indicated to treat adults with chronic phase (CP) or accelerated phase (AP) CML with resistance and/or intolerance to two or more TKIs. | Rx by Oncologist | SYNRIBO PI |

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| Syprine (trientine hydrochloride) | Indicated in the treatment of patients with Wilson’s disease who are intolerant of penicillamine. | | SYPRINE PI |
| Tabrecta (capmatinib) | Indicated for treatment of adults with metastatic NSCLC whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an approved test. | | TABRECTA PI |
| Tafinlar (dabrafenib) | Indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. TAFINLAR in combination with trametinib is indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test. The use in combination is based on the demonstration of durable response rate. Improvement in disease-related symptoms or overall survival has not been demonstrated for TAFINLAR in combination with trametinib | Rx by Oncologist | TAFINLAR PI |
| Tagrisso (osimertinib) | <u>Indicated:</u> <ol style="list-style-type: none"> for the treatment of first-line treatment of patients with metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) Exon 19 deletions or exon21 L858R mutations, as detected by an FDA approved test. For the treatment of patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA approved test, whose disease has progressed on or after EGFR TKI therapy. | Rx by Oncologist | TAGRISSO PI |
| Talzenna (talazoparib) | Indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (<i>gBRCAm</i>) HER2-negative locally advanced or metastatic breast cancer. | Rx by Oncologist | TALZENNA PI |
| Tarceva (erlotinib) | <u>Indicated for:</u> <ol style="list-style-type: none"> treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine. | Rx by Oncologist | TARCEVA PI |
| Tarpeyo (budesonide delayed-release capsules) | Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g. PA SUBMISSION REQUIREMENTS <ol style="list-style-type: none"> Confirmed diagnosis of primary immunoglobulin A nephropathy History of failure, contraindication or intolerance to a glucocorticoid Patient does not have severe hepatic impairment (Child-Pugh Class C) Estimated glomerular filtration rate (eGFR) ≥ 35 mL/min/1.73 m² Proteinuria ≥ 1g/day Patient is on a stable and maximally tolerated dose of a renin-angiotensin system (RAS) inhibitor (angiotensin converting enzyme [ACE] inhibitor or angiotensin receptor blocker [ARB]), for at least 3 months, unless contraindicated | Rx by Nephrologist or Immunologist | TARPEYO PI |

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| Tasigna (nilotinib) | Indicated for: 1. adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. 2. adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib. 3. pediatric patients greater than or equal to 1 year of age with Ph+ CML-CP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy. | Rx by Oncologist | TASIGNA PI |
| Tavalisse (fostamatinib disodium hexahydrate) | Indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. | Rx by Hematologist | TAVALISSE PI |
| Tavneos (avacopan) | Indicated for: 1. adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. TAVNEOS does not eliminate glucocorticoid use. PA SUBMISSION REQUIREMENTS 1. Patient must be ≥ 18 years of age. 2. Patient must have a diagnosis of active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis. 3. Laboratory tests before initiating Tavneos (avacopan) therapy: a. Liver test panel b. Screening the patient for hepatitis B infection by measuring HBsAg and anti-HBc 4. Documentation of baseline Birmingham vasculitis activity score (BVAS), with either one of the following: a. At least one major item b. At least 3 minor items c. At least 2 renal items, proteinuria and hematuria are present 5. Documentation that patient will continue standard therapy including glucocorticoids. | Rx by Rheumatologist | TAVNEOS PI |
| Taytulla (norethindrone/ethinyl estradiol capsules and ferrous fumarate) | See Oral Contraceptive | ANY OCP on prior authorization requires documentation demonstrating a compelling reason why formulary OCPs cannot be used [ex: intolerance, prior side effects, failures, etc. documented after a 3-month trial of formulary OCPs] | TAYTULLA PI |
| Tazverik (tazemetostat) | Indicated for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection. | Rx by Oncologist | TAZVERIK PI |
| Tibsovo (ivosidenib) | Indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test in: 1. Adult patients with newly -diagnosed AML who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy. 2. Adult patients with relapsed or refractory AML. | Rx by Oncologist | TIBSOVO PI |

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| Trikafta (elexacaftor, ivacaftor, and tezacaftor) | Indicated for the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation. | Rx by Pulmonologist | TRIKAFTA PI |
| Trodelvy (sacituzumab govitecan-hziy) | Indicated for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease. | Rx by Oncologist | TRODELVY PI |
| Truseltiq (infigratinib) | Indicated for the treatment of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma (CCA) with a fibroblast growth factor receptor II (FGFR2) fusion in adult patients. | Rx by Oncologist | TRUSELTIQ PI |
| Tukysa (tucatinib) | Indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. | Rx by Oncologist | TUKYSA PI |
| Turalio (pexidartinib) | Indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery. | Rx by Oncologist | TURALIO PI |
| Tykerb (lapatinib) | Indicated in combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress human epidermal growth factor receptor 2 (HER2) and who have received prior therapy including an anthracycline, a taxane, and trastuzumab. Patients should have disease progression on trastuzumab prior to initiation of treatment with TYKERB in combination with capecitabine | Rx by Oncologist | TYKERB PI |
| Ubrelvy (ubrogepant) | Indicated for the acute treatment of migraine with or without aura in adults. | Member must have tried and failed NSAIDs and Triptans or have a contraindication to taking either of these medications. | UBRELVY PI |
| Uplizna (inebilizumab-cdon) | Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive | | UPLIZNA PI |
| Vabysmo (faricimab-svoa) | A vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor for intravitreal indicated for the treatment of patients with: <ol style="list-style-type: none"> 1. Neovascular (Wet) Age-Related Macular Degeneration (nAMD) 2. Diabetic Macular Edema (DME) <p>PA SUBMISSION REQUIREMENTS</p> <ol style="list-style-type: none"> 1. Diagnosis of nAMD or DME 2. History of prior use, intolerance or contraindication to bevacizumab 3. Patient does not have ocular or peri-ocular infections 4. No active intraocular inflammation 5. No concomitant use with other ophthalmic VEGF inhibitors | Rx by an Ophthalmologist | VABYSMO PI |

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| | 6. Best corrected visual activity measured at baseline and periodically during treatment | | |
| Vazalore (aspirin) | <p><u>OTC Product Indicated for:</u></p> <ol style="list-style-type: none"> 1. Pain relief 2. Reduce fever 3. Anti-inflammatory 4. Cardiovascular event prevention | Documentation of significant side effects (gastrointestinal distress, GERD, PUD, persistent nausea and vomiting, abdominal pain, etc.) with standard enteric coated aspirin tablet formulation. | VAZALORE PI |
| Venclexta (venetoclax) | <p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 1. for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy. 2. In combination with azacitidine or decitabine or low dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. his indication is approved under accelerated approval based on response rates. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. | Rx by Oncologist | VENCLEXTA PI |
| V-Go | Wearable insulin device indicated for use in adult patients requiring insulin. | Rx by Endocrinologist Please click link below for External Insulin Pump Policy: External Insulin Pump Policy | V-GO WEBSITE |
| Vijoice (alpelisib) | VIJOICE is a kinase inhibitor indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA Related Overgrowth Spectrum (PROS) who require systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). | | VIJOICE.PI |
| Viltepsa (viltolarsen) | <p>Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.</p> <p>Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.</p> | | VILTEPSO PI |
| Vitrakvi (larotrectinib) | <p>Indicated for the treatment of adult and pediatric patients with solid tumors that:</p> <ol style="list-style-type: none"> 1. have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, 2. are metastatic or where surgical resection is likely to result in severe morbidity, and 3. have no satisfactory alternative treatments or that have progressed following treatment. | Rx by Oncologist | VITRAKVI PI |

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| Vizimpro (dacomitinib) | Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test. | Rx by Oncologist | VIZIMPRO PI |
| Vimizim (elosulfase alfa) | Indicated for patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome). | | VIMIZIM PI |
| Vyvanse (lisdexamfetamine) On Step Therapy | A central nervous system (CNS) stimulant indicated for the treatment of (1): Attention Deficit Hyperactivity Disorder (ADHD) Moderate to Severe Binge Eating Disorder (BED) in adults. | Step Therapy: At least a 4-week trial of an amphetamine salt combination AND a 4-week trial of methylphenidate. | VYVANSE PI |
| Xiidra (lifitegrast ophthal) On Step Therapy | Indicated for the treatment of the signs and symptoms of dry eye disease (DED). | Step Therapy: Must have tried and failed artificial tears and Restasis | XIIDRA PI |

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| | Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. | | |
| Vocabria (cabotegravir) | <p>Indicated to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35 kg for short-term PrEP (Pre-exposure prophylaxis). Used as oral lead in for Apretude (cabotegravir extended-release injectable suspension) to assess tolerability and oral therapy for patients who miss a planned injection of Apretude.</p> <p><u>Note:</u> HIV-treatment is covered under Fee-for-service (FFS) for DC Healthy Families enrollees and AIDS Drug Assistance Program (ADAP) for DC Alliance enrollees.</p> <p>PA SUBMISSION REQUIREMENTS:</p> <ol style="list-style-type: none"> 1. Attestation that patient is considered high-risk for HIV infection 2. Risk-reduction and medication adherence counseling documentation 3. Negative HIV-1 test prior to initiating therapy and before subsequent use 4. Patient will not receive concomitant therapy with any of the following medications due to contraindication and decreased levels of cabotegravir seen with co-administration: <ol style="list-style-type: none"> a. Anticonvulsants: Carbamazepine, oxcarbazepine, phenobarbital, phenytoin b. Antimycobacterials: Rifampin, rifapentine | | VOCABRIA PI |
| Vonjo (pacritinib) | <p>A kinase inhibitor indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50×10^9 /L.</p> <p>PA SUBMISSION REQUIREMENTS:</p> <ol style="list-style-type: none"> 1. Laboratory studies including: serum potassium level, CBC w/differential, CMP, LFTs, INR, PT, coagulation studies 2. Platelet count below 50×10^9/L 3. Electrocardiogram (ECG) showing baseline QTc below 480 msec 4. Avoid concomitant use with CYP3A4 inhibitors or inducers 5. Patient does not have hepatic impairment (Child-Pugh B and Child-Pugh C) 6. No active bleeding 7. eGFR > 30 mL/min/1.72m² | Rx by Oncologist or Hematologist | VONJO PI |
| Voxzogo (vosoritide) | <p>Indicated to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses. This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).</p> <p>PA SUBMISSION REQUIREMENTS:</p> <ol style="list-style-type: none"> 1. Patient's age 5 – 18 years' old 2. Diagnosis of achondroplasia 3. Genetic testing confirming a mutation in the fibroblast growth factor receptor3 (FGFR3) gene 4. Documentation of radiographic evidence indicating open epiphyses (growth plates) | Rx by or in consultation with a Pediatric Endocrinologist | VOXZOGO PI |

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| | <ol style="list-style-type: none"> 5. Documentation of baseline annualized growth velocity, calculated based on standing height measured over the course of 6 months prior to request 6. Documentation of member's current weight (in kg) for appropriate dosing 7. Voxzogo is not prescribed concurrently with any human growth hormone products (e.g., Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Saizen®, Zomacton®) | | |
| Vyepti (eptinezumab-jjmr) | Indicated for the preventive treatment of migraine in adults | <ol style="list-style-type: none"> 1. Trial and failure or intolerance to at least three of the following agents: beta blockers, topiramate, Aimovig, Emgality, and Ubrelvy, in medical documentation submitted. 2. Patient must have at least 4 headache days per month on average. | VYEPTI PI |
| Vyvgart (efgartigimod alfa-fcab) | <p>Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive</p> <p>PA SUBMISSION REQUIREMENTS:</p> <ol style="list-style-type: none"> 1. Diagnosis of gMG 2. Patient age at least 18 years 3. Myasthenia Gravis-Activities of Daily Living (MG-ADL) score \geq 5 at baseline 4. Greater than 50% of the baseline MG-ADL score is due to non-ocular symptoms 5. Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV 6. Documentation of positive serologic test for anti-AChR antibodies 7. Trial and failure of or documented intolerance or contraindication to a cholinesterase inhibitor 8. Trial and failure of or documented intolerance or contraindication to a corticosteroid 9. Trial and failure of or documented intolerance to at least two of the following immunosuppressive therapies or contraindication to all of the therapies below: <ol style="list-style-type: none"> a. Rituximab or biosimilar Truxima b. Cyclophosphamide c. Azathioprine d. Mycophenolate mofetil 10. Vyvgart is not prescribed concurrently with Soliris® 11. Documentation of member's current weight (in kg) for appropriate dosing 12. Dose does not exceed 10 mg/kg (1,200 mg per infusion for members weighing 120 kg or more) once weekly for the first 4 weeks of every 8-week cycle. | Rx by or in consultation with a Neurologist | VYVGART PI |
| Xadago (safinamide) | Indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes. | Rx by Neurologist | XADAGO PI |

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| Xalkori (crizotinib) | Indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test. | Rx by Oncologist | XALKORI PI |
| Xenazine (tetrabenazine) | Indicated for the treatment of chorea associated with Huntington’s disease. | Rx by Neurologist | XENAZINE PI |
| Xgeva (denosumab) | <u>Indicated for:</u> <ol style="list-style-type: none"> Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. | Rx by Oncologist | XGEVA PI |
| Xiidra (lifitegrast ophthal) | Indicated for the treatment of the signs and symptoms of dry eye disease. | Must have tried and failed artificial tears and Restasis | XIIDRA PI |
| Xolair (omalizumab) | <u>Indicated for:</u> <ol style="list-style-type: none"> moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids. chronic idiopathic urticaria in adults and adolescents (12 years of age and above) who remain symptomatic despite H1 antihistamine treatment. | Rx by Allergist or Pulmonologist Regarding ASTHMA indication only: <ol style="list-style-type: none"> moderate to severe persistent ALLERGIC asthma (confirmed by a positive skin test or RAST for ≥ 1 perennial aeroallergen) IgE level obtained <u>prior to</u> initiation of therapy currently using an inhaled corticosteroid at maximum dose; compliance must be confirmed in the patient’s Caremark profile currently using a long-acting inhaled beta₂-agonist OR a leukotriene modifier; compliance must be confirmed in the patient’s Caremark profile NOT approved for monotherapy | XOLAIR PI |
| Xospata (gilteritinib) | Indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test. | Rx by Oncologist | XOSPATA PI |
| Xpovio (selinexor) | Indicated for in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody. | Rx by Oncologist | XPOVIO |

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| | This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial | | |
| Xyrem (sodium oxybate) | <p><u>Indicated for:</u></p> <ol style="list-style-type: none"> for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy. <p><i>***Xyrem may only be dispensed to patients enrolled in the Xyrem Success Program</i></p> | <p>Rx by Neurologist</p> <ol style="list-style-type: none"> patient > 16 years old alternative diagnoses must have been excluded for cataplexy, must have failed tricyclic or SSRIs for excessive daytime sleepiness, must have failed at least one formulary stimulant treatment (ex: methylphenidate or dextroamphetamine) initial approval for maximum of 1-month supply with subsequent renewals for maximum approval period of 3 months at a time (Patients are to be re-evaluated by physician no less frequently than every 3 months) | XYREM PI |
| Yescarta (axicabtagene ciloleucel) | <p>Indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.</p> <p>MedStar Family Choice considers Yescarta (Axicabtagene Ciloleucel) medically necessary when ALL of the following criteria are met:</p> <ol style="list-style-type: none"> Recipient is 18 years of age or older; AND Histologically confirmed diagnosis of one of the following types of aggressive non-Hodgkin's lymphoma <ol style="list-style-type: none"> Diffuse large B-cell lymphoma (DLBCL), not otherwise specified; or High-grade B-cell lymphoma; or Primary mediastinal large B-cell lymphoma; or Transformed follicular lymphoma; AND Relapsed or refractory disease, when <ol style="list-style-type: none"> Recipient has previously received two or more lines of systemic therapy; and Disease is refractory to the most recent therapy or relapsed within 1 year after autologous hematopoietic stem cell transplantation (HSCT); AND | Rx by Oncologist | YESCARTA PI |

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| | <p>4. Must have received adequate prior therapy including, at a minimum, all of the following:</p> <ol style="list-style-type: none"> An anthracycline-containing chemotherapy regimen; and For CD20+ disease, anti-CD20 monoclonal antibody; and For subjects with transformed follicular lymphoma, prior chemotherapy for follicular lymphoma with chemotherapy refractory disease after transformation to DLBCL; AND <p>5. Documentation of all of the following clinical findings:</p> <ol style="list-style-type: none"> Eastern Cooperative Oncology Group (ECOG) performance status of 0-1; and Adequate cardiac, pulmonary, and other organ function (as determined by protocol from treatment facility); AND <p>6. The treatment facility that dispenses and administers Yescarta is enrolled and complies with the Risk Evaluation and Mitigation Strategy; AND</p> <p>7. One-time, single administration with dosing in accordance with the FDA label</p> <p>Yescarta (Axicabtagene ciloleucel) is considered investigational and not medically necessary when the above medically necessary criteria are not met, and for all other indications, including but not limited to:</p> <ol style="list-style-type: none"> History of malignancy other than nonmelanoma skin cancer or carcinoma in situ (e.g. cervix, bladder, breast) or follicular lymphoma unless disease free for at least 3 years; or Any central nervous system (CNS) disease, for example, detectable CSF malignant cells, brain metastases, CNS lymphoma, or a history or presence of CNS disorders such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or autoimmune disease with CNS involvement; or History of allogeneic stem cell transplant, chimeric antigen receptor therapy or other genetically modified T-cell therapy; or Active, uncontrolled infection; or Human immunodeficiency virus (HIV); or Hepatitis B or C (if viral load is detectable). | | |
| Zejula (niraparib) | <p><u>Indicated for:</u></p> <ol style="list-style-type: none"> for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either: <ul style="list-style-type: none"> a deleterious or suspected deleterious <i>BRCA</i> mutation, or genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy. | Rx by Oncologist | ZELJULA PI |
| Zelboraf (vemurafenib) | <p><u>Indicated for:</u></p> <ol style="list-style-type: none"> the treatment of patients with unresectable or metastatic melanoma with BRAFV600E mutation as detected by an FDA-approved test. | Rx by Oncologist or Dermatologist | ZELBORAF PI |

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| | 2. the treatment of patients with Erdheim Chester Disease with BRAF V600 mutation. | | |
| Zepzelca (lurbinectedin) | Indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum -based chemotherapy. | | ZEPZULCA PI |
| Zoladex (goserelin) | <u>Indicated for:</u> <ol style="list-style-type: none"> 1. palliative treatment of advanced carcinoma of the prostate. (3.6 and 10.8 mg) 2. use in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. (3.6 and 10.8 mg) 3. management of endometriosis. (3.6 mg) 4. palliative treatment of advanced breast cancer in pre- and peri-menopausal women. (3.6 mg) 5. use as an agent to cause endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. (3.6 mg) 6. for the management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. Experience with ZOLADEX for the management of endometriosis has been limited to women 18 years of age and older treated for 6 months. | Rx by Oncologist | ZOLADEX 3.6 mg PI ZOLADEX 10.8 mg PI |
| Zolgensma (onasemnogene abeparvovec-xioi) | Indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 gene. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. | ***MFC-DC Pharmacist Review*** | ZOLGENSMA PI |
| Zontivity (vorapaxar) | Indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). | Rx by Cardiology, Neurology or Vascular Surgery | ZONTIVITY PI |
| Zurampic (lesinurad) | Indicated in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone. | Rx by Rheumatologist | ZURAMPIC PI |
| Zydelig (idelalisib) | <u>Indicated for:</u> <ol style="list-style-type: none"> 1. treatment of patients with relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities. 2. treatment of patients with relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies. 3. treatment of patients with relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies. | Rx by Oncologist | ZYDELIG PI |
| Zykadia (ceritinib) | Indicated for the treatment of adults with metastatic non-small cell lung cancer (NSLC) whose tumors are anaplastic lymphoma kinase-positive as detected by an FDA-approved test. | Rx by Oncologist | ZYKADIA PI |
| Zynlonta (loncastuximab tesirine-lpyl) | Indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma. | Rx by Oncologist | ZYNLONTA PI |