

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 Specifications	Manufacturer's Prescribing Info (Hold CTRL and click on link to open)
Aimovig (erenumab-aooe)	Indicated for the preventive treatment of migraine in adults.	<ol style="list-style-type: none"> 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. 	AIMBOVIG 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
Amitiza (lubiprostone)	<u>Indicated for:</u> <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, sennosides, polyethylene glycol 3350, lactulose, methylcellulose	AMITIZA PI
Ampyra (dalfampridine)	Indicated to help improve walking in adults with MS.	<ol style="list-style-type: none"> Rx by Neurologist. Documentation of MS with ambulatory dysfunction, but must be able to walk 25 feet within 8-45 seconds at baseline. 	AMPYRA PI

		<ol style="list-style-type: none"> 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. 	
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
Bethkis (tobramycin inh sol)	Indicated for management of cystic fibrosis patients with <i>Pseudomonas aeruginosa</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 <i>Burkholderia cepacia</i> .	Rx by Pulmonologist	BETHKIS PI
Bosulif (bosutinib)	Indicated for the treatment of adult patients with: <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)	<u>Indicated for:</u> <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. 	<ol style="list-style-type: none"> Rx by Neurologist, Urologist, Ophthalmologist Botox will NOT be approved for cosmetic purposes. 	BOTOX PI

	<ol style="list-style-type: none"> 2. 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. 3. prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer). 4. treatment of spasticity in adult patients. 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
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
chloroquine (brand: Aralen)	Indicated for the treatment of: <ol style="list-style-type: none"> 1. uncomplicated malaria due to susceptible strains of <i>P. falciparum</i>, <i>P. malariae</i>, <i>P. ovale</i>, and <i>P. vivax</i>. 2. prophylaxis of malaria in geographic areas where resistance to chloroquine is not present. 3. treatment of extraintestinal amebiasis. 	At this time, outpatient use for COVID-19 treatment is prohibited.	CHLOROQUINE PI
Cometriq (cabozantinib)	Indicated for treatment of progressive, metastatic medullary thyroid cancer.	Rx by Oncologist	COMETRIQ PI
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	COTELIC PI
Darzalex Faspro (daratumumab and hyaluronidase-fihj, SQ admin)	indicated for the treatment of adult patients with multiple myeloma: <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 		DARZALEX FASPRO PI

	<ol style="list-style-type: none"> 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 		
DDAVP (desmopressin)	See Desmopressin Nasal Spray Products		
DESMOPRESSIN NASAL SPRAY PRODUCTS: DDAVP spray- 0.01% Stimate spray- 1.5 mg/mL	<p>DDAVP is indicated for:</p> <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. <p>Stimate is indicated for:</p> <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 severe classic von 	DDAVP FDA PI STIMATE PI

		Willebrand's Disease (type I) or when there is evidence of an abnormal molecular form of Factor VIII antigen	
Descovy (emtricitabine and tenofovir alafenamide)	<u>Indicated:</u> 1. in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg. 2. in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 25 kg and less than 35 kg.	Although Descovy is FDA approved for pre-exposure prophylaxis, MFC does not cover it for this indication. Descovy is covered for HIV treatment only. [MFC covers Truvada for pre-exposure prophylaxis]	DESCOVY PI
Dexcom G6 Continuous Glucose Monitoring (CGM) System	Indicated for the management of diabetes in persons age 2 years and older.		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.	1. Rx by Hematologist 2. 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:</u> 1. treatment of adult patients aged 12 years 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 in patients with moderate-to-severe asthma aged 12 years and older 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	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	see Leuprolide		

(leuprolide SQ)			
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
Endari (L-glutamine)	Indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.	Rx by Hematologist	ENDARI PI
Enhertu (fam-trastuzumab deruxtecan-nxk)	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.	Rx by Oncologist	ENHERTU PI
Epclusa (sofosbuvir/ velpatasvir)	<p>EPCLUSA is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, and is 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 style="text-align: center;">Please note:</p> <p>The Maryland Department of Health (MDH) has <u>MANDATED</u> a test of viral load <u>after 2-4 weeks</u> on treatment. If this check is not completed, medication refills will NOT be authorized after week 8 of treatment. This is a MDH requirement and as such, MFC does not have the ability to waive this testing under any circumstances. Viral load testing is also mandatory at 8-12 weeks and 24 weeks (for extended regimens). Lastly, viral load testing MUST be completed 12 weeks after therapy has ended (to assess SVR).</p>	<p>Please submit: A COMPLETED PRIOR AUTHORIZATION FORM (see link below) via FAX to 410-933-2205</p> <p style="text-align: center;">PRIOR AUTHORIZATION AND PRESCRIPTION FORM</p> <p>To view the most up to date DHMH treatment criteria, follow the link below: MDH TREATMENT CRITERIA</p> <p>**Please note that MDH requires that members have a recent office visit with the prescriber (less than 3 months old) upon applying for Hepatitis C treatment.</p>	EPCLUSA PI
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

SEE SPECIAL NOTE REGARDING WEEK 4 VIRAL LOAD TESTING ***→**

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	<p>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. Patients considered opioid-tolerant are those taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid.</p> <p>Limitations of use: Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve DURAGESIC [fentanyl] for use in patients for whom alternative treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. DURAGESIC [fentanyl] is not indicated as an as-needed (prn) analgesic</p>	<p>The Department of Health and Mental Hygiene has mandated that all long-acting opioids require Prior Authorization (PA) as of July 1, 2017. The PA form can be accessed using the following link:</p> <p>OPIOID PRIOR AUTHORIZATION FORM</p>	fentanyl PI
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
FreeStyle Libre Continuous Glucose Monitoring (CGM) System	Indicated for replacing blood glucose testing and detecting trends and tracking patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments in persons (age 18 and older) with diabetes.		FREESTYLE LIBRE CGM SYSTEM 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
hydroxychloroquine (brand: Plaquenil)	Indicated for: <ol style="list-style-type: none"> 1. the treatment of uncomplicated malaria due to <i>P. falciparum</i>, <i>P. malariae</i>, <i>P. ovale</i>, and <i>P. vivax</i>. 2. prophylaxis of malaria in geographic areas where chloroquine resistance is not reported. 3. Lupus Erythematosus 4. Rheumatoid Arthritis 	At this time, outpatient use for COVID-19 treatment is prohibited.	HYDROXYCHLOROQUINE 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: <ol style="list-style-type: none"> 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)	Indicated for: <ol style="list-style-type: none"> 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)	Indicated for: <ol style="list-style-type: none"> 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). 	Rx by Oncologist	IMBRUVICA PI

	<p>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.</p> <p>6. Chronic graft versus host disease after failure of one or more lines of systemic therapy.</p>		
Insulin Pens	<p>Age 0-18: Insulin pens will be provided for members ages 0-18 years of age.</p> <p>Age 19 and older: Basaglar and Tresiba pens do NOT require prior authorization and are available to all members. All other insulin pens require prior authorization.</p> <p>The MFC Insulin Pen Policy (Policy 211) states that insulin pens will be approved for members who cannot properly use and draw up insulin from vials into syringes or whose caregiver(s) cannot properly use and draw up insulin from vials into syringes including members with:</p> <ol style="list-style-type: none"> 1) Poor visual acuity, 2) Poor manual dexterity, or 3) Limited ability to learn proper technique due to educational challenges <p>Medical records may be required to support the PA request.</p>		<p>BASAGLAR PI</p> <p>TRESIBA PI</p>
Jakafi (ruxolitinib)	<p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 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
Jardiance (empagliflozin)	<p><u>Indicated:</u></p> <ol style="list-style-type: none"> 1. as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. 2. to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease. 	Patients must have known cardiovascular disease to qualify for Jardiance.	JARDIANCE 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:	Rx by Hematologist	JIVI PI

	<ol style="list-style-type: none"> 1. On-demand treatment and control of bleeding episodes. 2. Perioperative management of bleeding. 3. Routine prophylaxis to reduce the frequency of bleeding episodes. 		
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-highdensity 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
Kisqali (ribociclib)	Indicated in combination with: <ol style="list-style-type: none"> 1. an aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy; or 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. 	Rx by Oncologist	KISQALI PI
Kymriah (tisagenlecleucel)	Indicated for: <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> KYMRIAHA is not indicated for treatment of patients with primary central nervous system lymphoma (1.2)</p> <p>In accordance with criteria developed by the Maryland Medicaid Program, 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 	Rx by Oncologist	KYMRIAHA PI

	<ul style="list-style-type: none"> a. Second or greater bone marrow relapse; OR b. Any bone marrow relapse after allogeneic stem cell transplantation; OR c. 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 d. 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 <ol style="list-style-type: none"> 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 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. 		
<p>LEUPROLIDE PRODUCTS:</p> <p>Eligard (leuprolide SQ)</p> <p>Lupron (leuprolide acetate)</p> <p>Lupron Depot</p>	<p><u>Indicated for:</u></p> <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)]. 		<p>ELIGARD PI</p> <p>LUPRON 3.75 mg PI</p> <p>LUPRON DEPOT 11.25 MG PI</p>

(leuprolide acetate for depot suspension) Lupron Depot-PED (leuprolide acetate for depot suspension)			LUPRON DEPOT-PED 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.		LIBTAYO PI
Linzess (linaclotide)	Indicated for: 1. irritable bowel syndrome with constipation. 2. chronic idiopathic constipation.	Failure of at least 2 of the following: docusate, sennosides, polyethylene glycol 3350, lactulose, methylcellulose	LINZESS PI
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
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: <ul style="list-style-type: none">• crizotinib and at least one other ALK inhibitor for metastatic disease; or• alectinib as the first ALK inhibitor therapy for metastatic disease; or• ceritinib as the first ALK inhibitor therapy for metastatic disease	Rx by Oncologist	LORBRENA PI
Lovaza (omega-3-acid ethyl esters) (historical Omacor)	Indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.		LOVAZA 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		
Lynparza (olaparib)	Indicated for:	Rx by Oncologist	LYNPARZA PI

	<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. 		
Macrilen (macimorelin)	Indicated for the diagnosis of adult growth hormone deficiency.	Rx by Endocrinologist	MACRILEN PI

<p>Mavyret (glecaprevir and pibrentasvir)</p> <p>SEE SPECIAL NOTE REGARDING WEEK 4 VIRAL LOAD TESTING *****→</p>	<p>MAVYRET is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is 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.</p> <p style="text-align: center;">Please note:</p> <p>The Maryland Department of Health (MDH) has <u>MANDATED</u> a test of viral load <u>after 2-4 weeks</u> on treatment. If this check is not completed, medication refills will NOT be authorized after week 8 of treatment. This is a MDH requirement and as such, MFC does not have the ability to waive this testing under any circumstances. Viral load testing is also mandatory at 8-12 weeks and 24 weeks (for extended regimens). Lastly, viral load testing MUST be completed 12 weeks after therapy has ended (to assess SVR).</p>	<p>Please submit: A COMPLETED PRIOR AUTHORIZATION FORM (see link below) via FAX to 410-933-2205</p> <p style="text-align: center;"><u>PRIOR AUTHORIZATION AND PRESCRIPTION FORM</u></p> <p>To view the most up to date DHMH treatment criteria, follow the link below: <u>MDH TREATMENT CRITERIA</u></p> <p>**Please note that MDH requires that members have a recent office visit with the prescriber (less than 3 months old) upon applying for Hepatitis C treatment.</p>	<p>MAVYRET PI</p>
<p>Mekinist (trametinib)</p>	<p>Indicated:</p> <ol style="list-style-type: none"> 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 V600E Mutation-Positive Metastatic NSCLC- in combination with dabrafenib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. 	<p>Rx by Oncologist</p>	<p>MEKINIST PI</p>

	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.		
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)	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. Limitations of Use Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with long-acting opioids, reserve methadone hydrochloride tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Methadone hydrochloride tablets are not indicated as an as needed (prn) analgesic.	The Department of Health and Mental Hygiene has mandated that all long-acting opioids require Prior Authorization (PA) as of July 1, 2017. The PA form can be accessed using the following link: OPIOID PRIOR AUTHORIZATION 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 controlled release)	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. Limitations of Use Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve MS CONTIN for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise	The Department of Health and Mental Hygiene has mandated that all long-acting opioids require Prior Authorization (PA) as of July 1, 2017. The PA form can be accessed using the following link: OPIOID PRIOR AUTHORIZATION FORM	MS CONTIN PI

	inadequate to provide sufficient management of pain. MS CONTIN is not indicated as an as-needed (prn) analgesic.		
Mulpleta (lusutrombopag)	Indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.		MULPLETA PI
Natazia (estradiol valerate and estradiol valerate/dienogest)	<u>Indicated for:</u> 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> 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
Noxafil (posaconazole)	<u>Indicated for:</u> 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
Nucala (mepolizumab)	<u>Indicated for:</u> 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
Ofev (nintedanib)	<u>Indicated for:</u> 1. The treatment of idiopathic pulmonary fibrosis.	Rx by Pulmonologist	OFEV PI

	2. To slow the rate of decline in pulmonary function in patients with systemic sclerosis associated interstitial lung disease (SSc-ILD).		
Onpattro (patisiran)	Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.	Rx by Rheumatology or Neurology	ONPATTRO PI
OPIOIDS PRIOR AUTHORIZATION TERMS	<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 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.</p> <p>PRIOR AUTHORIZATION Prior Authorization will be required for:</p> <ul style="list-style-type: none"> • 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. <p>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)</p> <p>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.</p>	OPIOID PRIOR AUTHORIZATION FORM	

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 800-905-1722, option 2, 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. Danielle Gerry at 410-933-2295.

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

The Maryland Department of Health (MDH) and the nine Medicaid Managed Care Organizations (MCOs) in Maryland’s HealthChoice Program require Prior Authorization 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 by the Maryland Department of Health in an effort to decrease the number of pills available for diversion. These medications are as follows:

Medication	Max per 30 days	Unit
Codeine compounds (all)	1,000	mL
	180	tab/ cap
Hydrocodone compounds (all)	2,750	mL
	180	tab/ cap
	675	mL

Hydromorphone (1 mg/mL solution, 2 mg tablet, 3 mg suppository)	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 (ex: CRISP- Chesapeake Regional Information System for our Patients). For more information about the PDMP, visit the [MDH web site](#).
If you are not already a registered CRISP user you can register for **free** on the [CRISP registration web site](#).
- 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.

	View the MDH FAQ on Opioid Prescribing Policies .		
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]	
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 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.		ORLISSA PI
Otezla (apremilast)	<u>Indicated for:</u> 1. treatment of adult patients with active psoriatic arthritis. 2. treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.	1. Rx by Dermatologist or Rheumatologist Failure of at least 1 of the following: methotrexate, plaquenil, Arava, Humira, Embrel	OTEZLA PI
oxymorphone ER	Indicated for the relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.	The Department of Health and Mental Hygiene has mandated that all long-acting opioids require Prior Authorization (PA) as of July 1, 2017. The PA form can be accessed using the following link: OPIOID PRIOR AUTHORIZATION FORM	OPANA ER PI
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.		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).	Rx by Pulmonologist	PRETOMANID

	<p>Pretomanid Tablets are not indicated for patients with:</p> <ol style="list-style-type: none"> 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 <p>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.</p>		
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)	<p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 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
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
Rasuvo (methotrexate inj)	<p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 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
Repatha (evolocumab)	<u>Indicated:</u>	See Prior Authorization protocol on MFC website by clicking link below:	REPATHA PI

	<ol style="list-style-type: none"> 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. 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. 	<p>PRIOR AUTHORIZATION FORM</p> <p>To view the most up to date MFC treatment criteria, follow the link below: MFC REPATHA PA CRITERIA</p> <p>After an initial authorization period of 3 months, an updated lipid panel will be required prior to refill authorization.</p>	
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). 		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
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
Rituxan Hycela (rituximab and hyaluronidase human)	<p><u>Indicated for:</u></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. • Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response 	Rx by Oncologist	RITUXAN HYCELA PI

	<p>to rituximab in combination with chemotherapy, as single agent maintenance therapy.</p> <ul style="list-style-type: none"> • 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"> 2. 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. 3. 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"> 1. Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive. 2. 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>Indicated for:</p> <ol style="list-style-type: none"> 1. 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. 2. 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
Santyl Ointment Collagenase	Indicated for debriding chronic dermal ulcers and severely burned areas.	Rx by Dermatologist or Wound Care Specialist	SANTYL 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
Seysera (seracycline)	Indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.	<ol style="list-style-type: none"> 1. Rx by Dermatologist. 2. Failure of at least one other oral tetracycline antibiotic. 	SEYSERA 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.		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
Stimate nasal spray (desmopressin)	See Desmopressin Products		
Stivarga (regorafenib)	<p><u>Indicated for:</u></p> <ol style="list-style-type: none"> treatment of metastatic colorectal cancer previously treated with ALL the following therapies: <ol style="list-style-type: none"> fluoropyrimidine-based chemotherapy oxaliplatin-based chemotherapy irinotecan-based chemotherapy an anti-vascular endothelial growth factor (VEGF) therapy if Kirsten RNA Associated Rat Sarcoma 2 Virus Gene (KRAS) wild type, an anti-epidermal growth factor receptor (EGFR) therapy 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)	<p>Indicated for the treatment of the following infections:</p> <ol style="list-style-type: none"> Strongyloidiasis of the intestinal tract (i.e., nondisseminated) strongyloidiasis due to the nematode parasite <i>Strongyloides stercoralis</i>. Onchocerciasis due to the nematode parasite <i>Onchocerca volvulus</i>. <p>Stromectol has no activity against adult <i>Onchocerca volvulus</i> parasites. The adult parasites reside in subcutaneous nodules which are infrequently palpable. Surgical excision of these nodules (nodulectomy) may be considered in the management of patients with onchocerciasis, since this procedure will eliminate the microfilariae-producing adult parasites.</p>	At this time, outpatient use for COVID-19 treatment is prohibited.	STROMECTOL PI

<p>Synagis (palivizumab)</p>	<p>Indicated for prevention of serious lower respiratory tract disease caused by RSV in pediatric Patients:</p> <ol style="list-style-type: none"> 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. <p>MedStar Family Choice uses the newest recommendations of the American Academy of Pediatrics (AAP).</p> <p>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.</p>	<p>Please submit: A COMPLETED PRIOR AUTHORIZATION FORM (see link below) via FAX to 410-933-2205</p> <p>PRIOR AUTHORIZATION AND PRESCRIPTION FORM</p> <p>To view the most up to date AAP Synagis Guidelines, follow the link below: AAP SYNAGIS GUIDELINES</p>	<p>SYNAGIS PI</p>
<p>Synjardy & Synjardy XR (empagliflozin/metformin)</p>	<p><u>Indicated:</u></p> <ol style="list-style-type: none"> 1. as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin hydrochloride is appropriate. 2. to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of SYNJARDY XR on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established 	<ol style="list-style-type: none"> 1. Rx by Cardiology or Endocrinologist 2. Patients must have known cardiovascular disease to qualify for Synjardy. 	<p>SYNJARDY PI</p>
<p>Synribo (omacetaxine)</p>	<p>Indicated to treat adults with chronic phase (CP) or accelerated phase (AP) CML with resistance and/or intolerance to two or more TKIs.</p>	<p>Rx by Oncologist</p>	<p>SYNRIBO PI</p>
<p>Syprine (trientine hydrochloride)</p>	<p>Indicated in the treatment of patients with Wilson’s disease who are intolerant of penicillamine.</p>		<p>SYPRINE PI</p>
<p>Tabrecta (capmatinib)</p>	<p>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.</p>		<p>TABRECTA PI</p>
<p>Tafinlar (dabrafenib)</p>	<p>Indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.</p>	<p>Rx by Oncologist</p>	<p>TAFINLAR PI</p>

	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		
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 exon 21 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
Tasigna (nilotinib)	<u>Indicated for:</u> <ol style="list-style-type: none"> 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. adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib. 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

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: <ol style="list-style-type: none"> 1. Adult patients with newly -diagnosed AML who are \geq 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
Trijardy XR (empagliflozin, linagliptin, and metformin hydrochloride extended-release tablets)	<u>Indicated:</u> <ol style="list-style-type: none"> 1. as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. 2. to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. 	Patients must have known cardiovascular disease to qualify for Trijardy XR.	TRIJARDY XR PI
Trikafta ((elxacaftor, 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.		TRODELVY 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.		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.		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
Venclexta (venetoclax)	<u>Indicated for:</u> 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
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
V-Go	Wearable insulin device indicated for use in adult patients requiring insulin.	Rx by Endocrinologist	V-GO WEBSITE
Vitrakvi (larotrectinib)	Indicated for the treatment of adult and pediatric patients with solid tumors that: • have a neurotrophic receptor tyrosine 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 no satisfactory alternative treatments or that have progressed following treatment.	Rx by Oncologist	VITRAKVI PI
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
Xadago (safinamide)	Indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.	Rx by Neurologist	XADAGO PI

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
Xgeva (denosumab)	<u>Indicated for:</u> <ol style="list-style-type: none"> 1. Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. 2. 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. 3. 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.	XIIDRA PI
Xolair (omalizumab)	<u>Indicated for:</u> <ol style="list-style-type: none"> 1. 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. 2. 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"> 1. moderate to severe persistent ALLERGIC asthma (confirmed by a positive skin test or RAST for ≥ 1 perennial aeroallergen) 2. IgE level obtained <u>prior to</u> initiation of therapy 3. currently using an inhaled corticosteroid at maximum dose; compliance must be confirmed in the patient's Caremark profile 4. 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	Rx by Oncologist	XPOVIO

	<p>two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.</p> <p>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</p>		
<p>Xyrem (sodium oxybate)</p>	<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>	<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) Rx by Neurologist 	<p>XYREM PI</p>
<p>Yescarta (axicabtagene ciloleucel)</p>	<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>In accordance with criteria developed by the Maryland Medicaid Program, 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 	<p>Rx by Oncologist</p>	<p>YESCARTA PI</p>

- b. Disease is refractory to the most recent therapy or relapsed within 1 year after autologous hematopoietic stem cell transplantation (HSCT); AND
 - 4. Must have received adequate prior therapy including, at a minimum, all of the following:
 - a. An anthracycline-containing chemotherapy regimen; and
 - b. For CD20+ disease, anti-CD20 monoclonal antibody; and
 - c. For subjects with transformed follicular lymphoma, prior chemotherapy for follicular lymphoma with chemotherapy refractory disease after transformation to DLBCL; AND
 - 5. Documentation of all of the following clinical findings:
 - a. Eastern Cooperative Oncology Group (ECOG) performance status of 0-1; and
 - b. Adequate cardiac, pulmonary, and other organ function (as determined by protocol from treatment facility); AND
 - 6. The treatment facility that dispenses and administers Yescarta is enrolled and complies with the Risk Evaluation and Mitigation Strategy; AND
 - 7. One-time, single administration with dosing in accordance with the FDA label
- 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:
- 1. 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
 - 2. 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
 - 3. History of allogeneic stem cell transplant, chimeric antigen receptor therapy or other genetically modified T-cell therapy; or
 - 4. Active, uncontrolled infection; or
 - 5. Human immunodeficiency virus (HIV); or Hepatitis B or C (if viral load is detectable).

Zejula (niraparib)

- Indicated:
- 1. 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.
 - 2. 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:
 - a deleterious or suspected deleterious *BRCA* mutation, or
 - genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy.

Rx by Oncologist

[ZEJULA PI](#)

	Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA		
Zelboraf (vemurafenib)	<p><u>Indicated for:</u></p> <ol style="list-style-type: none"> the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. the treatment of patients with Erdheim Chester Disease with BRAF V600 mutation. 	Rx by Oncologist or Dermatologist	ZELBORAF PI
Zoladex (goserelin)	<p><u>Indicated for:</u></p> <ol style="list-style-type: none"> palliative treatment of advanced carcinoma of the prostate. (3.6 and 10.8 mg) 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) management of endometriosis. (3.6 mg) palliative treatment of advanced breast cancer in pre- and peri-menopausal women. (3.6 mg) use as an agent to cause endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. (3.6 mg) 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
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)	<p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 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. treatment of patients with relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies. 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 (NSCLC) whose tumors are anaplastic lymphoma kinase-positive as detected by an FDA-approved test.	Rx by Oncologist	ZYKADIA PI

