MFC Maryland Prior Authorization Table

(Comprehensive Listing of Medications Requiring Prior Authorization and/or Step Therapy) (updated 12-20-2022)

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 Link (Hold CTRL and click link to open)
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.	***REQUIRES MFC PHYSICIAN REVIEW	ABECMA PI
Actimmune (interferon gamma-1b)	Indicated for: 1. Reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease (CGD). 2. Delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO).	***REQUIRES MFC PHYSICIAN REVIEW	ACTIMMUNE PI
Adcentris (brentuximab)	Indicated: 1. Adult patients with previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vinblastine, and dacarbazine. 2. Pediatric patients 2 years and older with previously untreated high risk classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide. 3. Adult patients with classical Hodgkin lymphoma (cHL) at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation. 4. Adult patients with classical Hodgkin lymphoma (cHL) after failure of auto-HSCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates. 5. Adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone. 6. Adult patients with systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen. 7. Adult patients with primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic	***REQUIRES MFC PHYSICIAN REVIEW	ADCENTRIS PI

	therapy.		
Adcirca (tadalafil)	Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class II – III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).	Rx by Pulmonologist, Cardiologist, or Rheumatologist.	ADCIRCA 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 adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.	Rx by Oncologist	ALUNBRIG 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.	***REQUIRES MFC PHYSICIAN REVIEW	AMONDYS 45 PI
Ampyra (dalfampridine)	Indicated to improve walking in adult patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.	1. Rx by Neurologist. 2. Documentation of MS with ambulatory dysfunction but must be able to walk 25 feet within 8-45 seconds at baseline. 3. Members must have a baseline gait assessment by PT within 90 days of 4. beginning Ampyra. 5. Members must have a repeat evaluation after 3 months on Ampyra. Improvement in walking speed must be documented in order to obtain further refills. 6. Members must not have a history of seizure disorder or renal impairment.	AMPYRA PI
Apretude (cabotegravir extended-release injectable suspension)	Indicated in at-risk adults and adolescents weighing at least 35 kg for PrEP to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.	1. Members with renal impairment (In individuals with severe renal impairment (creatinine clearance 15 to <30mL/min) or end stage renal disease (creatinine clearance <15mL/min), increased monitoring for adverse effects is recommended). See Apretude PI for details.	APRETUDE PI

		and/or 2. Members with inability to tolerate oral medications (ie, inability to swallow tablets)	
Austedo (deutetrabenazine)	Indicated for: 1. chorea associated with Huntington's disease. 2. tardive dyskinesia in adults.		AUSTEDO PI
Ayvakit (avapritinib)	Indicated for: Gastrointestinal Stromal Tumor (GIST) 1. treatment of adults with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Advanced Systemic Mastocytosis (AdvSM) 2. treatment of adult patients with AdvSM. AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), and mast cell leukemia (MCL).	Rx by Oncologist	AYVAKIT PI
Balversa (erdafitinib)	Indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has 1. susceptible FGFR3 or FGFR2 genetic alterations and 2. 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 1. patients aged 5 years and older with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy. 2. adult patients with active lupus nephritis who are receiving standard therapy		BENLYSTA PI
Bethkis (tobramycin inh sol)	Indicated for management of cystic fibrosis patients with Pseudomonas aeruginosa.	Rx by Pulmonologist	BETHKIS PI
Blenrep (belantamab mafodotin-blmf)	Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.	Rx by Oncologist	BLENREP PI
Blincyto (blinatumomab)	Indicated for the treatment of adults and children with: 1. B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%. This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. 2.Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).	*****REQUIRES MFC PHYSICIAN REVIEW**	BLINCYTO PI

Bosulif (bosutinib)	Indicated for the treatment of adult patients with: 1. Newly-diagnosed chronic phase Ph+ chronic myelogenous leukemia (CML). 2. Chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy.	Rx by Oncologist	BOSULIF PI
Botox (onabotulinumtoxinA)	Indicated for: 1. 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. 2. treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury, multiple sclerosis] in adults who have an inadequate response to or are intolerant of an anticholinergic medication. 3. treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication. 4. prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer. 5. treatment of spasticity in patients 2 years of age and older. 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 and older. 9. treatment of strabismus in patients 12 years of age and older.	1. Rx by Neurologist, Urologist, Ophthalmologist 2. Botox will NOT be approved for cosmetic purposes	BOTOX PI
Braftovi (encorafenib)	Indicated: 1. 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. 2. in combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.	Rx by Oncologist	BRAFTOVI PI
Breyanzi (lisocabtagene maraleucel)	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 (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.	*****REQUIRES MFC PHYSICIAN REVIEW**	BREYANZI PI

Cabenuva (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension)	Indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.	Documentation of clinical appropriateness is required and MUST include the following: 1. Most recent office note (<3 months old) showing member is under active care with an appropriate practitioner with a treatment plan that includes using Cabenuva. 2. Lab test showing HIV-1 RNA less than 50 copies per ml (lab must be < 3 months old).	CABENUVA PI
Cablivi (caplacizumab-yhdp)	Indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.	***REQUIRES MFC PHYSICIAN REVIEW	CABLIVI PI
Cabometyx (cabozantinib)	Indicated for the treatment of: 1. patients with advanced renal cell carcinoma (RCC) 2. patients with advanced renal cell carcinoma, as a first-line treatment in combination with nivolumab 3. patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib 4. adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible	Rx by Oncologist	CABOMETYX PI
Camzyos (mavacamten)	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.	1) Prescribed by a cardiologist experienced with the care and treatment of people with HCM and in accordance with ACC guidelines. 2) Cardiologist must be enrolled in the CAMZYOS REMS Program. 3) Must have echocardiogram assessments of left ventricular ejection fraction before use. 4) Documentation that echocardiogram assessments will be done during Camzyos use.	CAMZYOS PI

		5) According to the Black Box Warning the Ejection Fraction must be greater than 55% for initiation and continued use of Camzyos.	
Cerezyme (Imiglucerase)	Indicated for treatment of adults and pediatric patients 2 years of age and older with Type 1 Gaucher disease that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly.	***REQUIRES MFC PHYSICIAN REVIEW	CEREZYME PI
Cinryze (C1 Esterase Inhibitor [Human])	Indicated for routine prophylaxis against angioedema attacks in adults, adolescents, and pediatric patients (6 years of age and older) with Hereditary Angioedema.	***REQUIRES MFC PHYSICIAN 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
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
Crysvita (burosumab-twza)	Indicated for: 1. The treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older. 2. The treatment of FGF23-related hypophosphatemia in tumorinduced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.	***REQUIRES MFC PHYSICIAN REVIEW	CRYSVITA PI
Cutaquig (Immune Globulin Subcutaneous (Human) – hipp), 16.5% solution)	Indicated for treatment of primary humoral immunodeficiency (PI) in adults.		CUTAQUIG PI
Danyelza (*naxitamab-gqgk)*	Indicated, in combination with granulocyte-macrophage colony-stimulating factor (GMCSF), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy.	Rx by Oncologist	DANYELZA PI

Darzalex Faspro (daratumumab and hyaluronidase-fihj, SQ admin)	Indicated for the treatment of adult patients with: 1. multiple myeloma in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant. 2. multiple myeloma 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. multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant. 4. multiple myeloma in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy. 5. multiple myeloma in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor. 6. multiple myeloma in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. 7. multiple myeloma 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. 8. light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients.	Rx by Oncologist	DARZALEX FASPRO PI
Descovy (emtricitabine and tenofovir alafenamide)	Indicated: 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 14 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 emtricitabine tenofovir disoproxil (generic Truvada) for pre-exposure prophylaxis]. Descovy is covered only if there is a documented intolerance to or medical contraindication to emtricitabine tenofovir disoproxil (generic Truvada).	DESCOVY PI
DESMOPRESSIN NASAL SPRAY PRODUCTS:	DDAVP is indicated for: 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.		DDAVP FDA PI

DDAVP spray-0.01% **Stimate spray-1.5 mg/mL**	Stimate is indicated for: 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.	STIMATE: Hemophilia A with factor VIII coagulant activity greater than 5%: ➢ *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.	STIMATE PI
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: MFC Continuous Glucose Monitoring Devices Policy	DEXCOM G6 PI
Dificid (fidaxomicin)	Indicated in adult and pediatric patients 6 months of age and older for the treatment of C. difficile-associated diarrhea.	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: 1. thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure. 2. thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.	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
Egrifta SV (tesamorelin injection)	Indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy.		EGRIFTA SV PI
Elaprase (Idursulfase)	Indicated for patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II). Elaprase has been shown to improve walking capacity in patients 5 years and older. In patients 16 months to 5 years of age, no data are available to demonstrate improvement in disease-related symptoms or long-term clinical outcome; however, treatment with Eleprase has reduced spleen volume similarly to that of adults and children 5 years of age and older. The safety and efficacy of Eleprase have not been established in pediatric patients less than 16 months of age.	*****REQUIRES MFC PHYSICIAN REVIEW**	ELEPRASE PI

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
Empaveli (pegcetacoplan)	Indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria.	***REQUIRES MFC PHYSICIAN REVIEW	EMPAVELI PI
Enhertu (fam-trastuzumab deruxtecan-nxk)	Indicated for: 1. 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. 2. adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab based regimen.	Rx by Oncologist	ENHERTU PI
Enspryng (satralizumab-mwge) 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.	*** REQUIRES MFC PHYSICIAN REVIEW	ENSPRYNG PI
Entadfi (finasteride)	Indicated to initiate treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks.		ENTADFI PI
Envarsus XR (tacrolimus extended-release tablets)	Indicated for: 1. The prophylaxis of organ rejection in de novo kidney transplant patients in combination with other immunosuppressants. 2. The prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants.	MFC approves Envarsus XR for patients that meet the following criteria: 1. Age 18 years or older. 2. Recipient of a kidney transplant. 3. Prescribed by a Nephrologist and Transplant Specialist. 4. Evidence that the patient had at least three-month trial and failure of intolerance/ contraindication to immediate-release tacrolimus. 5. Documented evidence that the patient is unable to achieve or maintain an appropriate therapeutic drug level with immediate-release	ENVARSUS XR PI

		tacrolimus---Lab values must be submitted. 6. Must be used in combination with other immunosuppressants.	
Epclusa (sofosbuvir/ velpatasvir)	Indicated for: 1. 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). 2. 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.	For a full listing of all Prior Authorization requirements, please click the link below: Hepatitis C PRIOR AUTHORIZATION Submission Information	EPCLUSA PI
Erwinaze (asparaginase Erwinia chrysanthemi)	Indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with ALL who have developed hypersensitivity to E. coli-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). *****REQUIRES MFC PHYSICIAN REVIEW**	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	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.	All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTHORIZATION FORM	fentanyl PI
Firazyr (icatibant)	Indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults ≥18 years of age.	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
Gattex (teduglutide)	Indicated for the treatment of adults and pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.	***REQUIRES MFC PHYSICIAN REVIEW	GATTEX PI
Gavreto (pralsetinib)	Indicated for: 1. 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. 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	GAVRETO PI
Gralise (gabapentin)	Indicated for the management of Postherpetic Neuralgia (PHN).		GRALISE PI
Growth Hormone	See Norditropin; See Serostim		
Haegarda (C1 Esterase Inhibitor SubQ [Human])	Indicated for routine prophylaxis to prevent Hereditary Angioedema attacks in patients 6 years of age and older.	***REQUIRES MFC PHYSICIAN REVIEW	HAEGARDA PI
Hycamtin Capsules (topotecan)	Indicated for treatment of patients with relapsed small cell lung cancer.	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)	Indicated for: 1. chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors. 2. accelerated phase (AP) or blast phase (BP) CML or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other kinase inhibitors are indicated. 3. T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL	Rx by Oncologist	ICLUSIG PI
Imbruvica (ibrutinib)	Indicated for: 1. mantle cell lymphoma 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. 3. chronic lymphocytic leukemia/small lymphocytic lymphoma with 17p deletion. 4. Waldenström's macroglobulinemia. 5. marginal zone lymphoma 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
Jakafi (ruxolitinib)	Indicated for: 1. intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults. 2. polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea. 3. steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older. 4. chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.	Rx by Hematologist/Oncologist	JAKAFI PI

Jivi (empagliflozin)	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 LDL-C, total cholesterol, apolipoprotein B, and non-HDL-C in patients with homozygous familial hypercholesterolemia.	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.	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).	Patient must have documented evidence of failure/intolerance of both Jardiance and Invokana or a medical reason why these therapies are inappropriate in order to qualify for Kerendia.	KERENDIA PI

Kisqali (ribociclib)	Indicated for the treatment of adult patients with 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; or 2. fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.	Rx by Oncologist	KISQALI PI
Korlym (mifepristone)	Indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.	***REQUIRES MFC PHYSICIAN REVIEW	KORLYM PI
Krystexxa (pegloticase)	Indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.	***REQUIRES MFC PHYSICIAN REVIEW	KRYSTEXXA PI
Kymriah (tisagenlecluecel)	Indicated for: 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. 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: a. Recipient has relapsed or refractory B-cell ALL, defined as 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 e. Recipient is 25 years of age or younger; AND f. Documentation of CD19 tumor expression; AND g. Performance score on Karnofsky or Lansky Scale is greater than or equal to 50%;	Rx by Oncologist, see criteria to the left.	KYMRIAH PI

	AND h. Life expectancy > 12 weeks; AND i. Adequate cardiac, pulmonary, and other organ function (as determined by protocol from treatment facility); AND j. The treatment facility that dispenses and administers Kymriah is enrolled and complies with the Risk Evaluation and Mitigation Strategy; AND k. One-time, single administration with dosing in accordance with the FDA label. 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: 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.		
Libtayo (cemiplimab-rwlc)	Indicated : 1. for the treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation. 2. for the treatment of patients with locally advanced BCC (laBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate. 3. for the treatment of patients with metastatic BCC (mBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate. 4. for the first-line treatment of patients with NSCLC whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations, and is: a. locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or b. metastatic.	Rx by Oncologist	LIBTAYO PI

Livtencity (maribavir)	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.	If a patient has a paid claim in the MFC system for ganciclovir, valganciclovir, cidofovir, or foscarnet, Livtencity will process at the pharmacy without PA. If there is no evidence of a paid claim for ganciclovir, valganciclovir, cidofovir, or foscarnet, a PA is required, and documentation of previous use of one of these medications should be submitted.	LIVTENCITY 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]	LOLOESTRIN PI
Lorbrena (lorlatinib)	Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.	Rx by Oncologist	LORBRENA PI
Lovaza (omega-3-acid ethyl esters) (historical Omacor)	Indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.	Member must have tried and failed OTC fish oil.	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
Lupkynis (voclosporin)	Indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis.		LUPKYNIS PI
Lupron Depot (leuprolide acetate for depot suspension)	Indicated for: 1. Palliative treatment of advanced prostatic cancer. 2. Endometriosis 3. Uterine Fibroids	1) The treatment of endometriosis 2) The treatment of Uterine Fibroids 3) The palliative treatment for advanced prostatic cancer – Member must have documented evidence of failure/intolerance	LUPRON DEPOT PI

		of Camcevi and Eligard in the medical notes sent for MFC review.	
Lynparza (olaparib)	Indicated for: Ovarian cancer 1. for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated 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. in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: • a deleterious or suspected deleterious BRCA mutation, and/or • genomic instability. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza 3. 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. 4. for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. Breast Cancer 5. for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, 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 an FDA-approved companion diagnostic for Lynparza. Pancreatic Cancer 6. for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. Prostate Cancer 7. for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed	Rx by Oncologist	LYNPARZA PI

	following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.		
Macrilen (macimorelin)	Indicated for the diagnosis of adult growth hormone deficiency.	Rx by Endocrinologist	MACRILEN PI
Mavyret (glecaprevir and pibrentasvir)	Indicated for: 1. 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). 2. 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.	For a full listing of all Prior Authorization requirements, please click the link below: Hepatitis C PRIOR AUTHORIZATION Submission Information	MAVYRET PI
Mekinist (trametinib)	Indicated for: 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. the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test. 3. 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. 4. the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. 5. the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.	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)	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 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

Mounjaro (tirzepatide)	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	Must have tried and failed or have a contraindication to a formulary GLP-1 agonist.	MOUNJARO PI
MS Contin (morphine sulfate controlled release)	Indicated for the 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 PRIOR AUTHORIZATION FORM	MS CONTIN PI
Mulpleta (lusutrombopag)	Indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.		MULPLETA PI
Myalept (metreleptin)	Indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy. Limitations of Use: 1. The safety and effectiveness of MYALEPT for the treatment of complications of partial lipodystrophy have not been established. 2. The safety and effectiveness of MYALEPT for the treatment of liver disease, including nonalcoholic steatohepatitis (NASH), have not been established. 3. MYALEPT is not indicated for use in patients with HIV-related lipodystrophy. 4. MYALEPT is not indicated for use in patients with metabolic disease, without concurrent evidence of generalized lipodystrophy. (1)	*****REQUIRES MFC PHYSICIAN REVIEW**	MYALEPT PI
Myrbetriq (mirabegron)	Indicated for the treatment of: 1. Overactive bladder (OAB) in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency, either alone or in combination with the muscarinic antagonist solifenacin succinate. 2. Neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older and weighing 35 kg or more. MYRBETRIQ Granules is a beta-3 adrenergic agonist indicated for the treatment of NDO in pediatric patients aged 3 years and older. (1.2)	Must have tried and failed or have a contraindication to formulary anticholinergic agents and formulary urinary antispasmodic agents.	MYRBETRIQ PI
Natazia (estradiol valerate and estradiol valerate/dienogest)	Indicated for: 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	Indicated for: 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,	Rx by Endocrinologist	NORDITROPIN PI

	Idiopathic Short Stature (ISS), and growth failure due to Prader-Willi Syndrome. 2. Adult: Replacement of endogenous GH in adults with growth hormone deficiency.		
Nourianz (istradefylline)	Indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease experiencing "off" episodes.	Rx by Neurologist	NOURIANZ PI
NovoSeven RT (Coagulation Factor VIIa recombinant)	Indicated for: 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.	***REQUIRES MFC PHYSICIAN REVIEW	NOVOSEVEN RT PI
Noxafil (posaconazole)	Indicated for: 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)	Indicated for: 1. add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype. 2. add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP). 3. treatment of adult patients with eosinophilic granulomatosis with polyangiitis. 4. treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome for ≥6 months without an identifiable non-hematologic secondary cause.	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.	***REQUIRES MFC PHYSICIAN REVIEW	NULIBRY PI

Nurtec (rimegepant)	Indicated for: 1. Acute treatment of migraine with or without aura in adults 2. Preventive treatment of episodic migraine in adults	**Acute treatment of migraine:** Member must have tried and failed NSAIDs and Triptans or have a contraindication to taking either of these medications. **Preventive treatment of episodic migraine:** 1. Member must have documented evidence of failure/intolerance of beta blockers, Aimovig, and Emgality in the medical notes sent for MFC review. 2. Patient must have at least 4 headache days per month on average	NURTEC 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. 2. primary progressive MS, in adults.	Rx by Neurologist	OCREVUS PI
Ofev (nintedanib)	Indicated for: 1. treatment of idiopathic pulmonary fibrosis. 2. treatment of chronic fibrosing interstitial lung diseases with a progressive phenotype. 3. to slow the rate of decline in pulmonary function in patients with systemic sclerosis associated interstitial lung disease.	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 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
OPIOIDS **PRIOR AUTHORIZATION**	FOR IMPORTANT INFORMATION ABOUT PRESCRIBING OPIOIDS FOR MEDSTAR FAMILY CHOICE MEMBERS, PLEASE CLICK THE LINK BELOW:	The Opioid PA form can be accessed using the following link:	

TERMS	https://www.medstarfamilychoice.com/maryland-healthchoice/for-maryland-healthchoice-physicians/pharmacy/opioid/	OPIOID PRIOR AUTHORIZATION FORM	
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.	***REQUIRES MFC PHYSICIAN REVIEW	ORFADIN PI
Orkambi (lumacaftor/ivacaftor)	Indicated for the treatment of cystic fibrosis 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
Orladeyo (berotralstat)	Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older.	***REQUIRES MFC PHYSICIAN 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.	***REQUIRES MFC PHYSICIAN REVIEW	OXLUMO 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.	All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTHORIZATION FORM	OXYMORPHONE ER PI
Padcev (enfortumab vedotin-ejfv)	Indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who: 1. have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum containing chemotherapy, or 2. are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.	Rx by Oncologist or Urologist	PADCEV PI
Palforzia (peanut allergen powder - dnfp	Indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut.	Rx by Allergist or Immunologist	PALFORZIA 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 fusion or other rearrangement as detected by an FDA-approved test.	Rx by Oncologist	PEMAZYRE PI
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
Pomalyst (pomalidomide)	Indicated for: 1. in combination with dexamethasone, for patients with multiple myeloma (MM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy. 2. with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in patients with KS who are HIV-negative. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).	Rx by Oncologist	POMALYST PI
Poteligeo (mogamulizumab)	Indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy.	***REQUIRES MFC PHYSICIAN REVIEW	POTELIGEO PI
Pretomanid	Indicated, as part of a combination regimen with bedaquiline and linezolid for the treatment of adults with pulmonary extensively drug resistant, treatment-intolerant or nonresponsive multidrug-resistant tuberculosis.	Rx by Pulmonologist	PRETOMANID
Procysbi (cysteamine bitartrate)	Indicated for the treatment of nephropathic cystinosis in adults and pediatric patients 1 year of age and older.	***REQUIRES MFC PHYSICIAN REVIEW	PROCYSBI PI
Prolia (denosumab)	Indicated for: 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 patients to improve pulmonary function.	Rx by Pulmonologist	PULMOZYME PI
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
Qinlock **(**ripretinib)	Indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.	Rx by Oncologist	QINLOCK PI
Qulipta (atogepant)	Indicated for the preventive treatment of episodic migraine in adults.	1. Member must have documented evidence of failure/intolerance of beta blockers, Aimovig, and Emgality in the medical notes sent for MFC review. 2. Patient must have at least 4 headache days per month on average.	QULIPTA PI
Rasuvo (methotrexate inj)	Indicated for: 1. management of patients with severe, active rheumatoid arthritis and polyarticular juvenile idiopathic arthritis, 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. RAVICTI must be used with dietary protein restriction and, in some cases, dietary supplements.	***REQUIRES MFC PHYSICIAN REVIEW	RAVICTI PI
Retevmo (selpercatinib)	Indicated for: 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 (elapegademase-lvlr)	Indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients.	***REQUIRES MFC PHYSICIAN REVIEW	REVCOVI PI
Revlimid (lenalidomide)	Indicated for the treatment of adult patients with: 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 (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities. 4. Mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. 5. Previously treated follicular lymphoma (FL), in combination with a rituximab product. 6. Previously treated marginal zone lymphoma (MZL), in combination with a rituximab product.	Rx by Oncologist	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
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 cyclosporine, methotrexate, mycophenolate, sirolimus, and glucocorticoids or have a medical contraindication to these medications.	REZUROCK PI
Rituxan Hycela (rituximab and hyaluronidase human)	Indicated for: 1. Follicular Lymphoma (FL): • 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 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. 2. Diffuse Large B-cell Lymphoma (DLBCL) previously untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine,	Rx by Oncologist	RITUXAN HYCELA PI

	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)	Indicated for the treatment of: 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.	Rx by Oncologist	ROZLYTREK
Rubraca (rucaparib)	Indicated for: Ovarian Cancer 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 a 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. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA. Prostate Cancer 3. for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA. This indication is approved under accelerated approval based on objective response rate and duration of response.	Rx by Oncologist	RUBRACA PI
Rybrevant (amivantamab-vmjw)	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.	Rx by Oncologist	RYBREVANT PI
Santyl Ointment Collagenase	Indicated for debriding chronic dermal ulcers and severely burned areas.	Rx by Dermatologist or Wound Care Specialist	SANTYL PI
Saphnelo (anifrolumab-fnia)	Indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.	Member must have documented evidence of trial/intolerance of Benlysta first.	SAPHNELO 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.	1. Rx by Dermatologist. 2. Failure of at least one other oral tetracycline antibiotic.	SEYSARA PI
Sirturo (bedaquiline)	Indicated as part of combination therapy in adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB).	Rx by ID	SIRTURO 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
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. 3. The treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AchR) antibody positive. 4. The treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult. patients who are anti-aquaporin-4 (AQP4) antibody positive. Limitation of Use Soliris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).	***REQUIRES MFC PHYSICIAN REVIEW	SOLIRIS PI
Spinraza (nusinersen)	Indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.	***REQUIRES MFC PHYSICIAN REVIEW	SPINRAZA PI pi_sprycel.pdf
Sprycel (dasatinib) Kinase inhibitor	Indicated for: 1. newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. 2. adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib. 3. adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy. 4. pediatric patients 1 year of age and older with Ph+ CML in chronic phase. 5. pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy.	Rx by Oncologist	SPRYCEL PI
Stimate nasal spray (desmopressin)	See Desmopressin Products		

Stivarga (regorafenib)	Indicated for: 1. Patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an antiVEGF therapy, and, if RAS wild-type, an anti-EGFR therapy. 2. Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate. 3. Hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.	Rx by Oncologist	STIVARGA PI
Stromectol (ivermectin)	Indicated for the treatment of: 1. strongyloidiasis of the intestinal tract (i.e., nondisseminated) strongyloidiasis due to Strongyloides stercoralis. 2. onchocerciasis due to the nematode parasite Onchocerca volvulus.	At this time, outpatient use for COVID-19 treatment is prohibited.	STROMECTOL PI
Supprelin LA kit (histrelin) implant	Indicated for the treatment of children with central precocious puberty (CPP).		SUPPRELIN LA
Synagis (palivizumab)	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 oof 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
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.	Rx by Oncologist	TABRECTA PI
Tafinlar (dabrafenib)	Indicated in combination with trametinib, for: 1. the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test	Rx by Oncologist	TAFINLAR PI

	2. 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. the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. 4. the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.		
Tagrisso (osimertinib)	Indicated for: 1. as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test 2. the first-line treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. 3. the treatment of adult 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
Takhzyro (Lanadelumab-flyo)	Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years and older.	*****REQUIRES MFC PHYSICIAN REVIEW**	TAKHZYRO PI
Talzenna (talazoparib)	Indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer.	Rx by Oncologist	TALZENNA PI
Tarpeyo (budesonide)	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.	Rx by or in consultation with a nephrologist. Diagnosis is confirmed by biopsy. Must have tried and failed guideline recommended formulary therapy: 1) Lifestyle modification including: sodium and protein restriction, smoking cessation, weight control and exercise as appropriate. 2) BP control with maximally tolerated renin-angiotensin system blockade (ACE or ARB) for at least 90 days. 3) Failure of alternative systemic corticosteroids (e.g., prednisone, methylprednisolone)	TARPEYO PI

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. 1. 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: 1. adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection. 2. adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA- approved test and who have received at least 2 prior systemic therapies. 3. adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options.	Rx by Oncologist	TAZVERIK PI
Tepezza (teprotumumab-trbw)	Indicated for the treatment of Thyroid Eye Disease	***REQUIRES MFC PHYSICIAN REVIEW	TEPEZZA PI
Tezspire (tezepelumab-ekko)	Indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.	Rx by Allergist/Immunologist or Pulmonologist MFC will approve this medication for patients with severe asthma that meet criteria in #1 or #2 below: 1. Patient has refractory Type 2 airway inflammation (i.e., allergic asthma) AND has tried and failed at least one of the following: Nucala, Fasenra, Dupixent, or Xolair. 2. Patient has refractory non-Type 2 airway inflamation (i.e., non-allergic asthma).	TEZSPIRE PI

Tibsovo (ivosidenib tablets)	Indicated for the treatment of adult patients with a susceptible IDH1 mutation as detected by an FDA-approved test with: Acute Myeloid Leukemia (AML) 1. Newly diagnosed AML who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy. 2. Relapsed or refractory AML. Locally Advanced or Metastatic Cholangiocarcinoma 3. Locally advanced or metastatic cholangiocarcinoma who have been previously treated.	Rx by Oncologist	TIBSOVO PI
Tivdak (tisotumab vedotin-tftv)	Indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.	Rx by Oncologist	TIVDAK PI
Trikafta (elexacaftor, ivacaftor, and tezacaftor)	Indicated for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data. 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 or a mutation that is responsive based on in vitro data.	Rx by Pulmonologist	TRIKAFTA PI
Trodelvy (sacituzumab govitecan-hziy)	Indicated for the treatment of adult patients with: 1. metastatic triple-negative breast cancer who have received at least two prior therapies for metastatic disease. 2. Locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PDL1) inhibitor.	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 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.	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 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. Limitations of Use:	Rx by Oncologist	TYKERB PI

	1. Patients should have disease progression on trastuzumab prior to initiation of treatment with TYKERB in combination with capecitabine. 2. letrozole for the treatment of postmenopausal women with hormone receptor-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated		
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
Ultomiris (ravulizumab-cwvz)	Indicated for: • the treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH). • the treatment of adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA). Limitations of Use: ULTOMIRIS is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). • the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.	*****REQUIRES MFC PHYSICIAN REVIEW**	ULTOMIRIS PI
Ultram (Tramadol hydrochloride extended release)	Indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Limitations of Use Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve ULTRAM for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]: 1) Have not been tolerated or are not expected to be tolerated. 2) Have not provided adequate analgesia or are not expected to provide adequate analgesia.	All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTHORIZATION FORM	ULTRAM PI
Venclexta (venetoclax)	Indicated: 1. for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). 2. in combination with azacitidine, or decitabine, or low dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.	Rx by Oncologist	VENCLEXTA PI
Vazalore (aspirin capsules)	**OTC**	Patient must have significant side effects (GERD, PUD, persistent nausea and vomiting, abdominal pain, etc.) with standard enteric	VAZALORE PI

		coated aspirin. Side effects must be documented in the medical record that is submitted to MFC.	
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: MFC External Insulin Pumps Policy	V-GO WEBSITE
Viltepso (viltolarsen)	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.	***REQUIRES MFC PHYSICIAN REVIEW	VILTEPSO PI
Vimizim (elosulfase alfa)	Indicated for patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome).	***REQUIRES MFC PHYSICIAN REVIEW	VIMIZIM PI
Vitrakvi (larotrectinib)	Indicated for the treatment of adult and pediatric patients with solid tumors that: 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
Vizimpro (dacomitinib)	Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.	Rx by Oncologist	VIZIMPRO PI
Vocabria (cabotegravir)	Vocabria (cabotegravir) - Indicated in combination with EDURANT (rilpivirine) for short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine, for use as: 1. oral lead-in to assess the tolerability of cabotegravir prior to administration of CABENUVA (cabotegravir; rilpivirine) extended-release injectable suspensions. 2. oral therapy for patients who will miss planned injection dosing with CABENUVA. 3. Pre-exposure Prophylaxis in adults and adolescents 35kg to reduce the risk of sexually acquired HIV-1 infection. ***	Documentation of clinical appropriateness is required and MUST include the following: 1. most recent office note (<3 months old) with clear discussion of previous HIV regimen(s) and clinical response(s) to each. 2. lab test showing HIV-1 RNA less than 50 copies per mL (lab must be <3 months old). ***Although Vocabria is FDA approved for pre-exposure prophylaxis, MFC does not cover it for this indication. Vocabria is covered for HIV treatment only. [MFC covers emtricitabine tenofovir disoproxil (generic	VOCABRIA PI

		Truvada) for pre-exposure prophylaxis]. Vocabria is covered only if there is a documented intolerance to or medical contraindication to emtricitabine tenofovir disoproxil (generic Truvada).	
YERVOY (golodirsen)	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.	***** REQUIRES MFC PHYSICIAN REVIEW**	VYONDYS PI
Vytepi (eptinezumab-jjmr)	Indicated for the preventive treatment of migraine in adults.	1. Member must have documented evidence of failure/intolerance of beta blockers, Aimovig, and Emgality in the medical notes sent for MFC review. 2. Patient must have at least 4 headache days per month on average.	VYTEPI 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: 1. 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. 2. pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. Limitations of use: Limitations of Use: The safety and efficacy of XALKORI have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL.	Rx by Oncologist	XALKORI PI
Xgeva (denosumab)	Indicated for: 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 ophthalmic sol)	Indicated for the treatment of the signs and symptoms of dry eye disease.	1) Must have tried and failed artificial tears. 2) Must have tried and failed Restasis.	XIIDRA PI
Xolair (omalizumab)	Indicated for: 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)	Rx by Allergist or Pulmonologist Regarding ASTHMA indication only: 1. moderate to severe persistent ALLERGIC asthma (confirmed by a positive skin test or RAST for ≥ 1	XOLAIR PI

	who remain symptomatic despite H1 antihistamine treatment. 3. nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment (1.2)	perennial aeroallergen). 2. IgE level obtained prior to 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.	
Xospata (gilteritinib)	Indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia 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 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 PI
Xtandi (enzalutamide)	Indicated for the treatment of patients with: 1. castration-resistant prostate cancer. 2. metastatic castration-sensitive prostate cancer.	Rx by Oncologist or Urologist	XTANDI PI
Xyrem (sodium oxybate)	Indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy. ***Xyrem may only be dispensed to patients enrolled in the Xyrem Success Program	1. patient > 16 years old 2. alternative diagnoses must have been excluded 3. for cataplexy, must have failed tricyclic or SSRIs 4. for excessive daytime sleepiness, must have failed at least one formulary stimulant treatment (ex: methylphenidate or dextroamphetamine) 5. 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) 6. Rx by Neurologist	XYREM PI

Yervoy (ipilimumab)	Indicated for: **Melanoma** 1. Treatment of unresectable or metastatic melanoma in adults and pediatric patients 12 years and older. 2. Treatment of adult patients with unresectable or metastatic melanoma, in combination with nivolumab. 3. Adjuvant treatment of patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection, including total lymphadenectomy. **Renal Cell Carcinoma (RCC)** 1.Treatment of patients with intermediate or poor risk advanced renal cell carcinoma, as first-line treatment in combination with nivolumab. **Colorectal Cancer** 1. Treatment of adult and pediatric patients 12 years and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, in combination with nivolumab. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. **Hepatocellular Carcinoma** 1. Treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib, in combination with nivolumab. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. **Non-Small Cell Lung Cancer (NSCLC)** 1. Treatment of adult patients with metastatic non-small cell lung cancer expressing PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, as first-line treatment in combination with nivolumab. 2. Treatment of adult patients with metastatic or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations as first-line treatment, in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy. **Malignant Pleural Mesothelioma** 1. Treatment of adult patients with unresectable malignant pleural mesothelioma, as first-line treatment in combination with nivolumab. (1.7) Esophageal Cancer • Treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma, as first line treatment in combination with nivolumab.	*****REQUIRES MFC PHYSICIAN REVIEW**	YERVOY PI
Yescarta (axicabtagene ciloleucel)	Indicated for: 1. 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	Rx by Oncologist	YESCARTA PI

	(DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. 2. Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. 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: 1. Recipient is 18 years of age or older; AND 2. Histologically confirmed diagnosis of one of the following types of aggressive non-Hodgkin's lymphoma a. Diffuse large B-cell lymphoma (DLBCL), not otherwise specified; or b. High-grade B-cell lymphoma; or c. Primary mediastinal large B-cell lymphoma; or d. Transformed follicular lymphoma; AND 3. Relapsed or refractory disease, when a. Recipient has previously received two or more lines of systemic therapy; and 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 Human immunodeficiency virus (HIV); or Hepatitis B or C (if viral load is detectable).		
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.	Rx by Oncologist	ZEPZELCA PI
Zejula (niraparib)	Indicated for: 1. for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy. 2. 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. 3. for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 3 or 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 6 months • after response to the last platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA.	Rx by Oncologist	ZEJULA PI
Zelboraf (vemurafenib)	Indicated for: 1. the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. 2. the treatment of patients with Erdheim Chester Disease with BRAF V600 mutation.	Rx by Oncologist or Dermatologist	ZELBORAF PI
Zoladex (goserelin)	Indicated for: 1. Palliative treatment of advanced carcinoma of the prostate. (3.6 and 10.8mg) 2. Use in combination with flutamide for the management of locally confined carcinoma of the prostate. (3.6 and 10.8 mg) 3. The management of endometriosis. (3.6 mg) 4. Use as an endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. (3.6 mg) 5. Use in the palliative treatment of advanced breast cancer in pre-and perimenopausal women. (3.6 mg)	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.	***REQUIRES MFC PHYSICIAN REVIEW	ZOLGENSMA PI

Zontivity (vorapaxar)	Indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease.	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)	Indicated for: 1. 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. Limitations of use: Zydelig is not indicated and is not recommended for first-line treatment of any patient, including patients with CLL, small lymphocytic lymphoma (SLL), follicular lymphoma (FL), and other indolent non-Hodgkin lymphomas.	Rx by Oncologist	ZYDELIG PI
Zykadia (ceritinib)	Indicated for the treatment of adults with metastatic non-small cell lung cancer 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