MedStar Family Choice Prior Authorization and Step Therapy Table

Disclaimer: Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	**Approval Criteria & Submission Requirements**	**Additional Considerations**
alectinib (**Alecensa)** capsule 150mg	1. Ordered for an approved indication for use: • Treatment of patients with anaplastic lymphoma kinase (ALK)- positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. 2. Medication ordered by an Oncologist.	
amivantamab-vmjw (**Rybrevant**) solution 350mg/7ml	1. Ordered for an approved indication for use: • 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. 2. Medication ordered by an oncologist	• This indication is approved under accelerated approval; continued approval for this indication may be contingent upon verification and description of a clinical benefit in a confirmatory trial.
anifrolumab-fnia (**Saphnelo**) solution 300mg/2ml	1. Ordered for an approved indication for use: • treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy. 2. Member must have documented evidence of trial/intolerance of Benlysta first. 3. Lab report showing autoantibodies (e.g., ANA, anti-ds, anti-Sm) 4. Current therapy for SLE alone or in combination with: • Glucocorticoid (e.g. prednisone, methylprednisone, dexamethasone) • Antimalarials (e.g. hydroxychloroquine) • Immunosuppressants (e.g. azathioprine, methotrexate, mycophenolate, cyclosporine, cyclophosphamide)	**<u>Limitations of Use:</u>** • Efficacy of Saphnelo has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use is not recommended in these situations. • Excluded use with Benlysta

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armodafinil (Nuvigil) tablets 50mg, 150mg 200mg, 250mg	1. Ordered for an approved indication for use: • To improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea, narcolepsy, or shift work disorder. 2. Medication ordered by a Neurologist or certified sleep specialist.	**Limitations of Use:** • In OSA, Nuvigil is indicated to treat excessive sleepiness and not as a treatment for the underlying obstruction.
asciminib (**Scemblix**) tablets 20mg, 40mg	1. Ordered for an approved indication for use: • Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs). • Ph+ CML in CP with the T315I mutation. 2. Medication ordered by Oncologist or Hematologist	
aspirin (**Vazalore**) capsules 81mg, 325mg	1. Ordered for an approved indication for use: • Pain relief • Reduce fever • Anti-inflammatory • Cardiovascular event prevention 2. Patient must have significant side effects (GERD, PUD, persistent nausea and vomiting, abdominal pain, etc.) with standard enteric coated aspirin. Side effects must be documented in the medical record that is submitted to MFC.	
atogepant (**Qulipta**) tablets 10mg, 30mg, 60mg	1. Ordered for an approved indication for use: • preventive treatment of migraine in adults 2. Trial and failure or intolerance to at least three of the following agents: beta blockers, topiramate, Aimovig, and Ubrelvy, in medical documentation submitted. 3. Patient must have at least 4 headache days per month on average.	
avacopan (**Tavneos**) capsule 10mg	1. Ordered for an approved indication for use: • adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis	

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	[GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. 2. Documentation of baseline Birmingham vasculitis activity score (BVAS), with either one of the following: • At least one major item • At least 3 minor items • At least 2 renal items, proteinuria and hematuria are present 3. Documentation that patient will continue standard therapy including glucocorticoids 4. Medication ordered by a Rheumatologist.	
avapritinib (**Ayvakit**) tablets 100mg, 200mg, 300mg	1. Ordered for an approved indication for use: • <u>Gastrointestinal Stromal Tumor (GIST)</u> ○ Treatment of adults with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. • <u>Advanced Systemic Mastocytosis (AdvSM)</u> ○ 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). • <u>Indolent Systemic Mastocytosis (ISM)</u> ○ Treatment of adult patients with ISM.	**<u>Limitations of Use</u>**: • AYVAKIT is not recommended for the treatment of patients with AdvSM with platelet counts of less than 50 X 10^9 /L
avatrombopag (**Doptelet**) tablets 20mg	1. Ordered for an approved indication for use: • thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure. • thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. 2. A recent (less than 1 month old) platelet count must be	

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	supplied with 3. Medication ordered by a Hematologist	
axicabtagene ciloleucel (**Yescarta**) Injection	1. Ordered for an approved indication for use: • treatment of adult patients with large B- cell lymphoma that is refractory to first-line chemotherapy. 2. The treatment facility that dispenses and administers Yescarta is enrolled and complies with the Risk Evaluation and Mitigation Strategy; AND 3. Medication ordered by an Oncologist.	**Limitations of Use:** • Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.
azacitadine (**Onureg**) tablets 200mg, 300mg	1. Ordered for an approved indication for use: • 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. 2. Medication ordered by an Oncologist.	• Do not substitute ONureg (azacitidine) for intraveneous or subcutaneous azacitidine.
bedaquiline (**Sirturo**) tablets 20mg, 100mg	1. Ordered for an approved indication for use: • as part of combination therapy in adult and pediatric patients ≥ 5 years of age and weighing at least 15 kg with pulmonary multi-drug resistant tuberculosis (MDR-TB). [Reserved for use when an effective treatment regimen cannot otherwise be provided. 2. Medication ordered by infectious disease	**Limitations of Use:** • Do not use for the treatment of latent, extra pulmonary, or drug-sensitive tuberculosis.
belimumab (**Benlysta**) Inj 200mg/ml	1. Ordered for an approved indication for use: • patients ≥ 5 years of age with active systemic lupus erythematosus (SLE) who are receiving standard therapy. • Patients ≥ 5 years of age with active lupus nephritis who are receiving standard therapy.	**Limitations of Use:** • The efficacy of BENLYSTA has not been evaluated in patients with severe active central nervous system lupus. Use of BENLYSTA is not recommended in this situation.
belumosudil (**Rezurock**) tablets 200mg	1. Ordered for an approved indication for use:	

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	• 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. 2. Member must have tried and failed, have intolerance or medical contraindication to at least three of these medications: cyclosporine, methotrexate, mycophenolate, sirolimus, and glucocorticoids.	
benralizumab (**Fasenra**) Pen 30mg/ml	1. Ordered for an approved indication for use: • add-on maintenance treatment of patients ≥ 12 years of age with severe asthma and with an eosinophilic phenotype. 2. Medication ordered by a Pulmonologist or Allergist	**Limitations of Use:** • Not for treatment of other eosinophilic conditions. • Not for relief of acute bronchospasm or status asthmaticus.
binimetinib (**Mektovi**) tablets 15mg	1. Ordered for an approved indication for use: • 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. 2. Medication ordered by an Oncologist	
bosutinib (**Bosulif**) tablets 100mg, 500mg	1. Ordered for an approved indication for use: • Newly diagnosed chronic phase Ph+ chronic myelogenous leukemia (CML). • Chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy. 2. Medication ordered by an Oncologist.	
brigatinib (**Alunbrig**) tablets 30mg, 90mg,180mg	1. Ordered for an approved indication for use: • 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. 2. Medication ordered by an Oncologist.	

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budesonide delayed-release (**Tarpeyo**) capsules 4mg	1. Ordered for an approved indication for use: • 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. 2. History of failure, contraindication or intolerance to a glucocorticoid. 3. Patient is on a stable and maximally tolerated dose of a renin-angiotensin system (RAS) inhibitor (ACEI or ARB), for at least 3 months, unless contraindicated. 4. Medication ordered by a nephrologist.	**Limitations of Use:** • This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether TARPEYO slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.
cabotegravir (**Apretude**) extended-release intramuscular injection 600mg/3mL (**Vocabria**) tablets 30 mg	1. Ordered for an approved indication for use: • To reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) 2. Attestation the patient is considered high-risk for HIV infection. 3. Documentation of completed risk-reduction and medication adherence counseling. 4. Negative HIV-1 test prior to initiating therapy and before each injection. 5. Patient is not ordered to receive concurrent therapy with a contraindicated medication: • Anticonvulsants: carbamazepine, oxcarbazepine, phenobarbital, phenytoin • Antimycobacterials: rifampin, rifapentine	**Limitations of Use:** • Vocabria is used as oral lead in for Apretude to assess tolerability and oral therapy for patients who miss a planned injection of Apretude. • **Medication is only covered for DC Alliance Enrollees for a PrEP indication.** HIV treatment is carved out as described in MFC-DC policy #223.DC Prior Authorization Policy PrEP.
cabozantinib (**Cabometyx)** tablets 20mg, 40mg, 60mg (**Cometriq**) kit	1. Ordered for an approved indication for use: • Patients with advanced renal cell carcinoma (RCC) • Patients with advanced renal cell carcinoma, as a first-line treatment in combination with nivolumab • Patients with hepatocellular carcinoma (HCC) who have	

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60mg, 100mg, 140mg	been previously treated with sorafenib • Adult and pediatric patients ≥ 12 years of age 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 2. Medication ordered by an Oncologist.	
capmatinib (**Tabrecta**) tablets 150mg, 200mg	1. Ordered for an approved indication for use: • 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. 2. Medication ordered by an oncologist.	
casimersen (**Amondys 45**) injection 50mg/ml	1. Ordered for an approved indication for use: • Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping. 2. Confirmed diagnosis of DMD with genetic confirmation of the DMD gene that is amenable to exon 45 skipping. 3. Provider attestation of baseline and subsequent evaluation and monitoring as appropriate such as hypersensitivity reactions and renal function. 4. Be on a stable dose of corticosteroid for ≥ 24 weeks. 5. Not ventilator dependent 6. Not receiving other RNA antisense therapy or gene therapy for DMD. 7. Maximum dose 30 mg/kg/dose once weekly 8. Prescribed by or in consultation with a pediatric neurologist with expertise in DMD.	Requires MFC Physician or Pharmacist review prior to approval. • This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with AMONDYS 45. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials. • Duration of approval is limited to 6 months. **Renewal Criteria:** • Not receiving other antisense therapy or gene therapy. • Not ventilator dependent.

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		• Provider attestation of continued benefit without ADE • Max dose 30 mg/kg/dose/week • Duration: 6 months
cemiplimab-rwlc (**Libtayo**) injection 350mg/7ml	1. Ordered for an approved indication for use: • 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. • 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. • treatment of patients with metastatic BCC (mBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate. • 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: ○ locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or metastatic. 2. Medication ordered by an Oncologist	
ceritinib (**Zykadia**) 150mg	1. Ordered for an approved indication for use: • treatment of adults with metastatic non-small cell lung cancer whose tumors are anaplastic lymphoma kinase-positive as detected by an FDA-approved test. 2. Medication ordered by an Oncologist	
chlordiazepoxide (Librium) capsules 5mg, 10mg, 25mg,	1. Ordered for an approved indication for use: • management of anxiety disorders or for the short-term relief of symptoms of anxiety, withdrawal symptoms of acute alcoholism, and preoperative apprehension and	

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	anxiety.	
cobimetinib (**Cotellic**) tablets 20mg	1. Ordered for an approved indication for use: • Treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. • As a single agent for the treatment of adult patients with histiocytic neoplasms. 2. Medication ordered by an Oncologist.	
collagenase (**Santyl**) ointment 250units/gm	1. Ordered for an approved indication for use: • Debriding chronic dermal ulcers and severely burned areas. 2. Medication ordered by a dermatologist or wound care specialist	
crisaborole (**Eucrisa**) ointment 2% **STEP THERAPY**	1. Ordered for an approved indication for use: • Topical treatment of mild-to-moderate atopic dermatitis in adult and pediatric patients ≥ 3 months of age. 2. Step Therapy: First must have tried and failed: At least one topical steroid AND topical tacrolimus OR pimecrolimus.	
crizotinib (**Xalkori**) capsule 200mg, 250mg	1. Ordered for an approved indication for use: • 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. 3. Medication ordered by an Oncologist	**Limitations of Use:** • The safety and efficacy of XALKORI have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL.
dabrafenib (**Tafinlar**) capsules 50mg, 75mg	1. Ordered for an approved indication for use: • treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test	**Limitations of use:** • Tafinlar is not indicated for treatments of patients with colorectal cancer because of

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	• 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. • treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. • treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options. • Treatment of adult and pediatric patients ≥ 6 years of age with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. • Treatment of pediatric patients ≥ 1 year of age with low-grade glioma (LGG) with BRAF V600E mutation who require systemic therapy. 2. Medication ordered by an Oncologist	known intrinsic resistance to BRAF inhibition. • Tafinal is not indicated for treatment of patients with wild-type BRAF solid tumors • The indication for treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trials.
dacomitinib (**Vizimpro**) tablets 15mg, 30mg, 45mg	1. Ordered for an approved indication for use: • first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test. 2. Medication ordered by an Oncologist	
dalfampridine (Ampyra) ER tablets 10mg	1. Ordered for an approved indication for use: • To Improve walking in adult patients with multiple sclerosis (MS). 2. Must be able to walk 25 feet within 8 to 45 seconds at baseline. 3. Must have a gait assessment by PT within 90 days of	**<u>Contraindications:</u>** • History of seizure • Renal impairment CrCl ≤ 50 mL/min

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	beginning Ampyra. 4. **Initial approval for 3 months only** Renewal criteria: Must show documented improvement in walking speed from baseline; Approval period 12 months. 5. Medication ordered by a Neurologist.	
daratumumab and hyaluronidase (**Darzalex Faspro**) solution	1. Ordered for an approved indication for use: • multiple myeloma in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant. • 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. • multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant. • 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. • 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. • light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients. • multiple myeloma in combination with bortezomib and dexamethasone in patients who have received at least one	**Limitations of Use:** • DARZALEX FASPRO is not indicated and is not recommended for the treatment of patients with light chain (AL) amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of controlled clinical trials.

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	prior therapy. • 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. 2. Medication ordered by an Oncologist	
darolutamide (**Nubeqa**) tablets 300mg	1. Ordered for an approved indication for use: • treatment of non-metastatic castration-resistant prostate cancer (mmCRPC). • Metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel. 2. Medication ordered by an Oncologist or Urologist	
dasatinib (**Sprycel**) tablets 20mg, 50mg, 70mg, 80mg 100mg,140mg	1. Ordered for an approved indication for use: • Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. • Adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib. • Adults with Ph+ ALL with resistance or intolerance to prior therapy. • Pediatric patients ≥ 1 year of age with Ph+ CML in chronic phase. • Pediatric patients ≥ 1 year of age with newly diagnosed Ph+ ALL in combination with chemotherapy. 2. Medication ordered by an Oncologist.	
dulaglutide (**Trulicity**)	1. Ordered for an approved indication for use: • As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. • Titration dose (0.75 mg) limited to 8 pens in 365 days without medical director review.	**Cannot be approved for indication of weight management.** **Limitations of Use:** • Contraindicated in patients with personal or family history of

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	• Requires A1c within past 3 months or CGM reports that include time in range (TIR) • Maximum 30-day supply per dispense. • May not be concurrently taking a DPP4i (e.g. alogliptin, januvia, or tradjenta)	medullary thyroid carcinoma (MTC) and in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2). • Not for the treatment of type 1 diabetes or diabetic ketoacidosis. • Not for patients with pre-existing severe gastrointestinal disease • Not studied in patients with history of pancreatitis, consider alternate therapy.
denosumab (**Prolia**; **Xgeva**) injection 60mg/ml (prolia)	1. Ordered for an approved indication for use: • treatment of postmenopausal women with osteoporosis at high risk for fracture. • treatment to increase bone mass in men with osteoporosis at high risk for fracture. • treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture. • treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. • treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. 2. Tried and failed, had adverse reaction to, or contraindication to formulary preferred products (e.g. alendronate, calcitonin nasal spray)	
desmopressin nasal spray products (DDAVP)	**DDAVP 0.1 mg/ml** **1.** Ordered for an approved indication for use: • antidiuretic replacement therapy in the management of central cranial diabetes insipidus.	**Limitations of Use:** • Not indicated for treatment of: ○ nephrogenic diabetes insipidus ○ primary nocturnal enuresis

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	• Management of temporary polyuria and polydipsia following head trauma or surgery in the pituitary region. **<u>Desmopressin acetate 1.5 mg/ml</u>** 1. Ordered for an approved indication for use: • Hemophilia A with Factor VIII coagulant activity levels greater than 5%. • Mild to moderate classic von Willebrand's disease (Type I) with Factor VIII levels greater than 5%.	○ in patients with conditions that compromise the intranasal route of administration ○ patients with impaired consciousness ○ patients requiring doses less than 10 mcg or greater than 10 mcg but not a multiple of 10 mcg. **<u>Contraindications:</u>** • in moderate to severe renal impairment, CrCl < 50 ml/min. • in patients with or with a history of hyponatremia.
deutetrabenzine (**Austedo**) tablets 6mg, 9mg 12mg	1. Ordered for an approved indication for use: • Chorea associated with Huntington's disease. • Tardive dyskinesia in adults.	**<u>Contraindications:</u>** • Suicidal, or untreated/inadequately treated depression in patients with Huntington's disease. • Hepatic impairment. • Taking reserpine, MAOI's, tetrabenazine or valbenazine.
Continuous Glucose Monitoring (CGM) systems (Dexcom G6, G7)	1. Ordered for an approved indication for use: • The management of diabetes in persons aged 2 years and older. 2. Must report A1c with past 3 months or CGM report with 70% utilization or greater 3. Explanation of clinical need to use the requested CGM system instead of a formulary-preferred option.	Please click link below for CGM Policy: Continuous Glucose Monitoring Devices-DC
dextromethorphan and quinidine (**Nuedexta**)capsules 20mg-10mg,	1. Ordered for an approved indication for use: • Treatment of pseudobulbar affect (PBA). 2. Medication ordered by a Neurologist	• Contraindicated with concomitant use with quinidine, quinine, or mefloquine.

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dornase alfa (**Pulmozyme**) solution 1mg/ml	1. Ordered for an approved indication for use: • in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function. 2. Medication ordered by a Pulmonologist	
ecallantide (**Kalbitor**) injection 10mg/ml	1. Ordered for an approved indication for use: • Treatment of acute attacks of hereditary angioedema (HAE) in patients ≥ 12 years of age. 2. Medication ordered by immunologist or allergist.	
efgartigimod alfa-fcab (**Vyvgart**) injection 400mg/20ml	1. Ordered for an approved indication for use: • Treatment of adult patients with anti-acetylcholine receptor antibody positive (AChR+) generalized myasthenia gravis (gMG) as monotherapy or in combination with glucocorticoids in patients with glucocorticoid-resistant or glucocorticoid-dependent disease. 2. Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II, III, or IV at initiation of therapy. 3. MG activities of daily living (MG-ADL) total score of ≥ 5. 4. Documentation of positive serologic test for anti-AChR antibodies. 5. Greater than 50% of baseline MG-ADL score is due to non-ocular symptoms. 6. Patient is currently receiving a stable dose of at least one gMG treatment (including cholinesterase inhibitors, corticosteroids, or non-steroidal immunosuppressants). 7. Documentation of patient's current weight for appropriate dosing. 8. Trial and failure, contraindication or documentation of intolerance to at least two of the following: • Rituximab or biosimilar (e.g. truxima) • Cyclophosphamide • Azathioprine	Requires MFC Physician or Pharmacist review prior to approval. **Limitations of Use:** • Not concurrently prescribed with Eculizumab (Soliris) • Dosed according to FDA labeled dosing up to a maximum of 1,200 mg/dose • Immunization with live-attenuated or live vaccines not recommended during treatment due to transient reduction in IgG levels during therapy.

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	• Mycophenolate mofetil 9. Medication ordered by or in consultation with a neurologist.	
elagolix (**Orilissa**) tablets 150mg	1. Ordered for an approved indication for use: • the management of moderate to severe pain associated with endometriosis. 2. Must have tried and failed at least two of the following: NSAIDs, hormonal options (OCP, progesterone, hormonal IUD), or have a contraindication to using these therapies.	**Contraindications:** • Pregnancy • Osteoporosis • Severe hepatic impairment (Child-Pugh class C) • Concomitant use of Organic Anion Transporting Polypeptide (OATP) 1B1 e.g. pazopanib, vandetanib, nilotinib, canertinib, or erlotinib. **Limitations of use:** • Limit the duration of use based on the dose and coexisting condition per prescribing guidelines. Max duration 6 to 24 months depending on patient specific variables.
elagolix, estradiol, and norethindrone acetate (**Oriahnn**) capsule	1. Ordered for an approved indication for use: • the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. 2. Must have tried and failed at least two of the following: NSAIDs, hormonal options (OCP, progesterone, hormonal IUD), or have a contraindication to using these therapies.	• Contraindicated in women with current or history of thrombotic/thrombolic disorders and women at increased risk of these events, including women > 35 years who smoke and women with uncontrolled hypertension. **Limitations of use:** • Due to risk of bone density loss that may not be reversible following discontinuation, limit duration of treatment to 24 months.
elexacaftor, ivacaftor, and tezacaftor (**Trikafta**) tablets 150mg	1. Ordered for an approved indication for use:	

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	• treatment of cystic fibrosis (CF) in patients ≥ 2 years with at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data. 2. 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. 3. Medication ordered by a Pulmonologist	
encorafenib (**Braftovi**) capsules 75mg	1. Ordered for an approved indication for use: • 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. • 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. 2. Medication ordered by an Oncologist.	**Limitations of Use** • Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma or wild-type BRAF CRC
entrectinib (**Rozlytrek**) Capsules 100mg, 200mg	1. Ordered for an approved indication for use: • adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive. • adult and pediatric patients ≥ 12 years of age 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. 2. Medication ordered by an Oncologist.	
eptinezumab-jjmr (**Vyepti**) injection 100mg/ml	1. Ordered for an approved indication for use: • preventive treatment of migraine in adults. • Trial and failure or intolerance to at least three of the	

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	following agents: beta blockers, topiramate, Aimovig, Emgality, and Ubrelvy, in medical documentation submitted. • Patient must have average least 4 headache days per month. 2. Medication ordered by a Neurologist	
erdafitinib (**Balversa**) tablets 3mg, 4mg, 5mg	1. Ordered for an approved indication for use: • Urothelial carcinoma in adults with locally advanced or metastatic with susceptible fibroblast growth factor receptor FGFR3 or FGFR2 genetic alterations ***AND*** • Progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. 2. Medication ordered by an Oncologist.	
erenumab-aooe (**Aimovig**) injection 70mg/ml, 140mg/ml	1. Ordered for an approved indication for use: • Prevention of migraines in adults. 2. Documented adequate trials of ≥ 2 previous migraine prophylaxis medications (at least 6 months at therapeutic dose), or contraindication or other intolerance to using other migraine prophylaxis medications. 3. Medication ordered by a Neurologist.	• Select formulary migraine prophylaxis medications: ○ Beta blockers: metoprolol, propranolol, timolol ○ Antidepressants: amitriptyline, venlafaxine ○ Anticonvulsants: divalproex, topiramate, valproate, valproic acid • CGRP antagonists (PA required): Emgality, Nurtec, Qulipta, Vyepti
esketamine (**Spravato**) solution 56mg DOS, 84mg DOS	1. Ordered for an approved indication for use: • Treatment-resistant depression in adults, in conjunction with an oral antidepressant. • Treatment of adults with major depressive disorder with suicidal ideation or behavior. • Intolerance to or prior trial/treatment failure of at least 2 preferred oral antidepressant treatments of adequate	Requires MFC Physician or Pharmacist review prior to approval. • Initial PA approval is for 4 weeks. Reauthorization for continued treatment is contingent on evidence of therapeutic benefit. • Patient must be observed in office for

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	treatment dose and duration of at least 42 days each for medication within the past 12 months • Major depressive disorder with acute suicidal ideation or behavior (MDD with SI) • Continue therapy for a total of 4 weeks (inpatient doses will be included) 2. Age: ≥ 18 years 3. MUST be given concurrently with oral antidepressant medication. 4. No history of aneurysmal vascular disease, history of intracerebral hemorrhage, or hypersensitivity to any components of drug 5. Quantity Limit: • Induction: 8 dose kits per 28 days • Maintenance: 4 dose kits per 28 days 6. Approval Duration: 6 months (TRD); 4 weeks (MDD with SI) • If ordered for treatment-resistant depression, the patient must also be prescribed an oral antidepressant medicine. 7. Ordered by REMS registered psychiatrist.	at least 2 hours following each administration. • Renewal Criteria ○ TRD: Prescriber attests need of continued use based on clinical benefit. • Quantity Limit: 4 dose kits per 28 days (maintenance) • Approval Duration: 6 months ○ MDD with SI – no PA renewal – one-time approval ○ Any subsequent request would need a new PA and review to support repeat use, including any recent hospitalization data.
estradiol and dienogest (**Natazia**) tablets	1. Ordered for an approved indication for use: • Treatment of non-acute heavy menstrual bleeding in women without organic pathology. • Contraception 2. Documentation with clinical reason that other formulary OCP cannot be used (ex: intolerance, prior side effects, failure after at least 3-month trial of formulary OCP).	
evinacumab-dgnb (**Evkeeza**) injection 345mg/2.3ml, 1200mg/8ml	1. Ordered for an approved indication for use: • An adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, ≥ 12 years of age, with homozygous familial hypercholesterolemia (HoFH).	Requires MFC Physician or Pharmacist review prior to approval. **Limitations of Use:** • The safety and effectiveness of

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	2. Documented genetic test confirming homozygous familial hypercholesterolemia (HoFH). 3. Baseline laboratory information required (full lipid panel, genetic testing, negative pregnancy test and documentation of use/counseling regarding contraception to prevent pregnancy 4. Prior trial/failure and/or documented intolerance to one high potency statin (atorvastatin, rosuvastatin) and concurrent ezetimibe. • Must provide laboratory data to support failure/intolerance (full lipid panel, creatinine kinase). • If failure, but no intolerance, lipid lowering therapy should be continued with aa statin and/or ezetimibe. 5. Dosing 15 mg/kg IV every 4 weeks. 6. Initial Approval Duration: 6 months.	EVKEEZA have not been established in patients with other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH). • The effects of EVKEEZA on cardiovascular morbidity and mortality have not been determined. **Renewal Criteria:** • Meets all initial criteria • Must provide documentation of laboratory information to support continued use (full lipid panel) and continued use of concurrent therapies to lower cholesterol • Renewal Approval Duration: 12 months
evolocumab (**Repatha**) injection 140mg/ml Pushtronex 420mg/3.5ml SureClick 140mg/ml	1. Ordered for an approved indication for use: • to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease. • as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults or children ≥ 13 years of age with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol. 2. Current LDL-level for initial and continuation requests obtained within previous 6 months.	

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	3. Medication ordered by Cardiologist or Lipid Specialist	
factor VIIa, recombinant human (**NovoSeven RT**) injection 1mg, 2mg, 5mg, 8mg	1. Ordered for an approved indication for use: • 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 3. Medication ordered by a Hematologist	Requires MFC Physician or Pharmacist review prior to approval. • Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
factor VIII, recombinant human pegylated (**Jivi**) injection 500 unit, 1000unit, 2000unit, 3000unit	1. Ordered for an approved indication for use: • On-demand treatment and control of bleeding episodes in adults and adolescents ≥ 12 years of age with hemophilia A. 2. Perioperative management of bleeding. 3. Routine prophylaxis to reduce the frequency of bleeding episodes. 4. Medication ordered by a Hematologist	Requires MFC Physician or Pharmacist review prior to approval. **<u>Limitations of use:</u>** • Jivi is not indicated for use in previously untreated patients (PUPs). • Jivi is not indicated for the treatment of von Willebrand disease.
fam-trastuzumab deuxtecan-nxk (**Enhertu**) injection 100mg	1. Ordered for an approved indication for use: • Adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in a. The metastatic setting OR b. In the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy • Adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer, who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant	

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	chemotherapy. • Adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) mutations and who have received a prior systemic therapy • Adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab based regimen. 2. Medication ordered by an Oncologist.	
faricimab-svoa (**Vabysmo**) injection 6mg/0.05 ml	1. Ordered for an approved indication for use: • Neovascular (Wet) Age-Related Macular Degeneration (nAMD) 2. Diabetic Macular Edema (DME) 3. History of prior use, intolerance, or contraindication to bevacizumab 4. Baseline best corrected visual acuity measured 5. Medication ordered by an Ophthalmologist	• No concomitant use with other ophthalmic VEGF inhibitors, e.g., Avastin (bevacizumab), Beovu (brolucizumab-dbll); Lucentis (ranibizumab); Cimerli (ranibizumab-eqrn), biosimilar to Lucentis; Eylea (aflibercept); Byooviz (ranibizumab-nuna)
fentanyl (Duragesic) transdermal patch 12mcg/hr, 25mcg/hr, 37.5mcg/hr, 50mcg/hr, 62.5mcg/hr, 75mcg/hr, 87.5mcg/hr, 100mcg/hr	1. Ordered for an approved indication for use: • 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 request form can be access using the following links: OPIOID PRIOR AUTH FORM-DC
finerenone (**Kerendia**) tablets 10mg, 20mg	1. Ordered for approved indication: • to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial	**Contraindications:** • patients with adrenal insufficiency • concomitant treatment with

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	infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). 2. PA SUBMISSION REQUIREMENTS: • Serum potassium ≤ 5.0 mEq/L • eGFR ≥ 25 mL/min/1.73 m2 • Urine albumin-to-creatinine ratio ≥ 30 mg/g • Concomitant use with maximum tolerated doses of ACE-Inhibitor or ARB unless intolerant to or contraindicated. • Failed trial or contraindication to two formulary SGLT2i.	strong CYP3A4 inhibitors (e.g adagrasib, atazanavir, ceritinib, clarithromycin, cobicistat and cobicistat-containing formulations, darunavir, idelalisib, indinavir, itraconazole, ketoconazole, levoketoconazole, lonafarnib, lopinavir, mifepristone, nefazodone, nelfinavir, Posaconazole, ritonavir and ritonavir-containing coformulations, saquinavir, telithromycin, tucatinib, voriconazole.
fosdenopterin (**Nulibry**) injection 9.5mg	1. Ordered for an approved indication for use: • To reduce mortality risk in patients with molybdenum cofactor deficiency (MoCD) Type A. • Diagnosis confirmed by genetic testing.	Requires MFC Physician or Pharmacist review prior to approval. **Limitations of use:** • Clinical studies of Nulibry did not include patients 65 years of age and older. • Significant potential for drug-drug interactions.
fostamatinib disodium hexahydrate (**Tavalisse**) tablets 100mg, 150mg	1. Ordered for an approved indication for use: • the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) when a prior treatment for ITP has not worked well enough. 2. Medication ordered by a Hematologist.	**Limitations of use:** • Should not be used in patients on hemodialysis. • Additional benefit of doses > 1800 mg/day has not been established. • Unknown if safe or effective in children
gabapentin extended-release (**Gralise**) tablets 300mg, 600mg	1. Ordered for an approved indication for use: • the management of Postherpetic Neuralgia (PHN).	**Limitations of use:** • Additional benefit of doses > 1800 mg/day has not been established. • Should not be used in patients

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	2. Not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect dosing frequency.	on hemodialysis.
galcanezumab-gnlm (**Emgality**) injection 100mg/ml, 120mg/ml	1. Ordered for an approved indication for use: • preventative treatment of migraine in adults • prevention of cluster headache in adults. 2. Member must have documented failure or intolerance to at least 2 previous migraine prophylaxis medications. (Including, but are not limited to, divalproex, metoprolol, propranolol, timolol, topiramate, amitriptyline, venlafaxine, atenolol) 3. Medication ordered by a Neurologist	• Should not be used with another CGRP antagonists or inhibitors used for preventative treatment of migraines (e.g., fremanezumab (Ajovy®), Rimegepant (Nurtec ODT®), eptinezumab-jjmr (Vyepti®))
gilteritinib (**Xospata**) tablets 40mg	1. Ordered for an approved indication for use: • the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test. 2. Medication ordered by an Oncologist	
glycopyrronium (**Qbrexza**) pad 2.4%	1. Ordered for an approved indication for use: • topical treatment of primary axillary hyperhidrosis in adults and pediatric patients ≥ 9 years of age. 2. Must have tried and failed OTC Clinical Strength antiperspirants and at least one prescription strength antiperspirant (ex: Drysol). 3. 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 (within past 6 months) clinical encounter note.	• Contraindicated in medical conditions that can be exacerbated by the anticholinergic effect of glycopyrronium (e.g., glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, Sjogren's syndrome.)
ibrutinib (**Imbruvica**) capsules 140mg	1. Ordered for an approved indication for use: • Chronic lymphocytic leukemia (CLL) in adult patients who have received at least one prior therapy. • CLL in Adult patients with 17p deletion. • Waldenström's macroglobulinemia in adult patients	**Limitations for use:** • Indications for Mantle Cell Lymphoma and Marginal Zone Lymphoma were voluntarily withdrawn, April 2023 **New dose modification guidelines**

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	• Adult and pediatric patients ≥ 1 year of age with chronic graft versus host disease after failure of one or more lines of systemic therapy. 1. Medication ordered by an Oncologist.	**adopted in December 2022:** • Therapy should be withheld for any new onset or worsening Grade 2 cardiac failure or Grade 3 cardiac arrhythmia. Once symptoms have resolved to Grade 1 cardiac failure or Grade 2 or lower cardiac arrhythmia, Imbruvica can be restarted at recommended adjusted doses.
icatibant acetate (Firazyr) injection 30mg/3ml	1. Ordered for an approved indication for use: • treatment of acute attacks of hereditary angioedema (HAE) in adults ≥ 18 years of age. 2. Medication ordered by an Allergist or ENT	• Self-administered by the patient upon recognition of symptoms of an HAE attack after training under the guidance of a healthcare professional.
idecabtagene vicleucel (**Abecma**) injection	1. Ordered for an approved indication for use: • To treat relapsed or refractory multiple myeloma in adults after ≥4 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. 2. Lymphodepleting chemotherapy (with fludarabine and cyclophosphamide) is ordered for administration for 3 days followed by Abecma dose infusion 2 days after completion of lymphodepleting therapy. 3. Diagnosis of relapsed or refractory multiple myeloma (MM) 4. Age ≥ 18 years 5. Must have received at least 4 prior MM therapies (induction with or without hematopoietic stem cell transplant with or without maintenance therapy is considered a single regimen) 6. Must have received an immunomodulatory drug (iMiD), proteasome inhibitor (PI), and an anti-CD38 antibody 7. ECOG performance status of 0 or 1 8. HBV, HCV, and HIV screening within previous 30 days. 9. Provider attestation: Drug specific baseline evaluation and monitoring completed according to package insert (CBC/CMP,	Requires MFC Physician or Pharmacist review prior to approval. **Limitations of use:** • Will be approved for ONE treatment dose. • Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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	screening for HBV, hepatitis C, HIV), patient is not pregnant and is using effective contraception, counseling/assessment of recent live vaccine use. 10. Monitor immunoglobulin levels, blood counts, and for cytokine release syndrome during and after therapy. 11. Medication ordered by Hematologist or Oncologist enrolled in ABECMA REMS and compliance with REMS program criteria.	
idelalisib (**Zydelig**) tablets 100mg, 150mg	1. Ordered for an approved indication for use: • treatment of patients with relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities. 2. treatment of patients with relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies. 3. treatment of patients with relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies. 4. Medication ordered by an Oncologist	**<u>Limitations of use:</u>** • Zydelig is not indicated nor 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. • Zydelig is not indicated and is not recommended in combination with bendamustine and rituximab, or in combination with rituximab for treatment of FL, SLL, and other indolent non-Hodgkin lymphomas. • Only available through specialty pharmacies.
immune globulin subcutaneous (human) (**Cutaquig**) solution 1gm, 1.65gm, 2gm, 3.3gm, 4gm, 8gm	1. Ordered for an approved indication for use: • Replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients ≥ 2 years of age. • Prevention of bacterial infection in patients with hypogammaglobulinemia and/or recurrent bacterial	

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	infections with malignancy (e.g., B-cell chronic lymphocytic leukemia) or primary humoral immunodeficiency disorders. 2. Medication ordered by an Immunologist.	
inebilizumab-cdon (**Uplizna**) solution 100mg	1. Ordered for an approved indication for use: • treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. 2. Medication ordered by neurologist or ophthalmologist.	**Limitations for use:** • It is not known if Uplizna is safe or effective in children. • Contraindicated in patients with an active hepatitis B infection. • Contraindicated in patients with an active or untreated inactive (latent) tuberculosis.
infigratinib (**Truseltiq**) capsules 50mg, 75mg, 100mg, 125mg	1. Ordered for an approved indication for use: • treatment of adults with 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. 2. Confirmed presence of FGFR2 fusion or rearrangement prior to initiation of treatment. 3. Medication ordered by an Oncologist	• Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. • Avoid concomitant use of Truseltiq with strong or moderate CYP3A inducers.
interferon gamma-1b (**Actimmune)** injection 2 million IU/0.5ml	1. Ordered for an approved indication for use: • To reduce frequency and severity of serious infections associated with chronic granulomatous disease (CGD). • To delay time to disease progression in patients with severe, malignant osteopetrosis (SMO).	Requires MFC Physician or Pharmacist review prior to approval. • Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
istradefylline (**Nourianz**) tablet 20mg, 40mg	1. Ordered for an approved indication for use: • Adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes. 2. Medication ordered by a Neurologist.	• Use not recommended in severe hepatic impairment (Child-Pugh class C)

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ivermectin (Sklice) lotion 0.5% **STEP THERAPY**; OTC product	1. Ordered for an approved indication for use: • the topical treatment of head lice infestations in patients ≥ 6 months of age.	Step Therapy: First must have tried and failed: • Age < 6 years – OTC permethrin 1% • Age > 6 years– malathion
ivermectin (Stromectol) tablets 3mg	1. Ordered for an approved indication for use: • Strongyloidiasis of the intestinal tract (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis. • Onchocerciasis due to the nematode parasite Onchocerca volvulus.	**Limitations for use:** • At this time, **outpatient use for COVID-19 treatment is** prohibited. • Ivermectin has no activity against adult *Onchocerca volvulus* parasites. • Ivermectin is not active against *L. loa* (adult worms).
ivosidenib (**Tibsovo**) tablets 250mg	1. Ordered for an approved indication for use: • treatment of adult patients with a susceptible IDH1 mutation as detected by an FDA-approved test with: 2. Acute Myeloid Leukemia (AML), newly diagnosed who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy. 3. Relapsed or refractory AML 4. Locally Advanced or Metastatic Cholangiocarcinoma who have been previously treated. 5. Medication ordered by an Oncologist	
lapatinib (Tykerb) tablets 250mg	1. Ordered for an approved indication for use: • 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:** • Lapatinib in combination with an aromatase inhibitor has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer.

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	2. In combination with 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. 3. Medication ordered by an Oncologist.	
lasmiditan (**Reyvow**)	1. Ordered for an approved indication for use: • the acute treatment of migraine with or without aura in adults. 2. Member must have tried and failed NSAIDs and Triptans or have a contraindication to taking either of these medications.	
larotrectinib (**Vitrakvi**) capsules 25mg, 100mg	1. Ordered for an approved indication for use: • Treatment of adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and no satisfactory alternative treatments or that have progressed following treatment. 2. Medication ordered by an Oncologist	
lecanemab-irmb (**Leqembi)** intraveneous solution 200 mg/2 ml	1. Ordered for an approved indication: • Treatment of Alzheimer disease; to be initiated in patients with mild cognitive impairment or mild dementia stage of disease, with confirmed presence of amyloid beta pathology prior to initiation of treatment. 2. Patient has signed informed consent on file. 3. Patient meets criteria for mild cognitive impairment (MCI) or mild AD dementia. 4. Patient has had an MRI scan within last 12 months. 5. Amyloid PET imaging and/or CSF analysis consistent with AD. 6. Functional Assessment Staging Test Stage score of 2 to 4. 7. Mini-Mental State Examination score greater than 21, or St. Louis University Mental Status (SLUMS) score or Montreal Cognitive Assessment (MoCA) score of greater than 16.	**<u>Renewal Criteria:</u>** • Patient continues to meet criteria for initial approval • Absence of unacceptable toxicity from drug AND • Patient has responded to therapy compared to pretreatment as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment in one or more of the following (not all-inclusive): ADAS-Cog 13; ADCS-ADL-MCI; MMSE: CDR-SB etc, AND

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	8. Patient does not have any of the following risk factors for intracerebral hemorrhage: • prior cerebral hemorrhage greater than 1 cm in greatest diameter, more than 4 microhemorrhages, superficial siderosis, • evidence of vasogenic edema, • evidence of cerebral contusion, • aneurysm, • vascular malformation, • infective lesions, • multiple lacunar infarcts or stroke involving a major vascular territory, • and severe small vessel or white matter disease. 9. Ordered by a Board-certified neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia.	• Patient has not progressed to moderate or severe AD; AND • Patient has received a pre-5th, 7th, AND 14th infusion MRI for monitoring of Amyloid Related Imaging Abnormalities-edema (ARIA-E) and Amyloid Related Imaging Abnormalities hemosiderin (ARIA-H) microhemorrhages.
lenalidomide (**Revlimid**) capsules 2.5mg, 5mg, 10mg, 15mg, 20mg, 25mg	1. Ordered for an approved indication for use: • Treatment of adult patients with multiple myeloma (MM) in combination with dexamethasone. • Maintenance therapy in adult patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT). • 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. • Adults with Mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. • Previously treated adults with follicular lymphoma (FL), in combination with a rituximab product. • Previously treated marginal zone lymphoma (MZL) in	**<u>Limitations for use:</u>** • Not indicated nor recommended for treatment of patients with chronic lymphocytic leukemia (CLL) outside of controlled trials

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	combination with a rituximab product in adults. 2. Medication ordered by an oncologist registered in the Lenalidomide REMS program.	
leuprolide injection 14mg/2.8mL (5mg/mL) kit (**Eligard**) injection 45 mg (**Lupron Depot**) injection 3.75mg, 7.5mg, 11.25mg, 22.5mg, 30mg (**Lupron Depot-PED**) injection 7.5mg, 11.25mg 15mg, 30mg (**Fensolvi**) injection 45 mg	1. Ordered for an approved indication for use: • **Eligard or Lupron** (leuprolide acetate SQ): ○ Palliative treatment of advanced prostate cancer. • **Lupron Depot**: ○ Treatment of advanced prostate cancer. ○ Management of Endometriosis, including pain relief and reduction of endometriotic lesions (3.75 or 11.25 mg strengths). ○ In combination with norethindrone acetate for initial management of painful symptoms of endometriosis and recurrence of symptoms (3.75 or 11.25 mg strengths). ○ Uterine leiomyomata (fibroids) concomitantly with iron therapy for preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary. • **Endometriosis** • **Lupron Depot-PED:** • Treatment of pediatric patients with central precocious puberty (CPP).	**Limitations of use:** • Lupron Depot is not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids. • Total duration of therapy with Lupron Depot plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density. • When indicated for endometriosis, Lupron-Depo for adults ≥ 18 years of age 3.75 mg monthly for 6 months. • When indicated for endometriosis in patients < 18 years of age, should be reserved for pain refractory to conservative surgical therapy in combinations with add-back therapy.
lifitegrast ophthalmic (**Xiidra**) Drop 5%	1. Ordered for an approved indication for use: • the treatment of the signs and symptoms of dry eye disease (DED). 2. Must have tried and failed artificial tears AND cyclosporine (ophth) emulsion 0.05% (generic of Restasis)	
liraglutide (**Victoza**)	1. Ordered for an approved indication for use:	**Cannot be approved for indication of weight management.**

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	• As an adjunct to diet and exercise to improve glycemic control in patients ≥ 10 years of age with type 2 diabetes mellitus. 2. To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease. 3. A1c within previous 3-months. 4. Recent CGM report if applicable. 5. Limited to 30-day supply per dispense. 6. May not be concurrently taking a DPP4i (e.g. alogliptin, januvia, or tradjenta)	**Limitations of Use:** • Should not be coadministered with other liraglutide-containing products (e.g. Xultophy) • Contraindicated in patients with personal or family history of medullary thyroid carcinoma (MTC) and in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2). • Not for the treatment of type 1 diabetes or diabetic ketoacidosis. • Not for patients with pre-existing severe gastrointestinal disease • Not studied in patients with history of pancreatitis, consider alternate therapy.
lisdexamfetamine (**Vyvanse**) capsules 10mg, 20mg, 30mg, 40mg, 50mg, 60mg, 70mg chewables 10mg, 20mg, 30mg, 40mg, 50mg, 60mg	1. Ordered for an approved indication for use: • Attention Deficit Hyperactivity Disorder (ADHD) in children ≥ 6 years of age. 2. Moderate to Severe Binge Eating Disorder (BED) in adults. 3. Step therapy: at least 4-week trial of an amphetamine salt combination AND a 4-week trial of methylphenidate.	**Limitations to use:** • Not for use in pediatric patients younger than 6 years of age. • Not indicated nor recommended for weight loss.
lisocabtagene maraleucel (**Breyanzi**) injection	1. Ordered for an approved indication for use: • Treatment of adult patients with large B-cell lymphoma (LBCL) 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	Requires MFC Physician or Pharmacist review prior to approval. **Limitations of Use:** • BREYANZI is not indicated for the treatment of patients with

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	follicular lymphoma grade 3B, who have: a. refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or b. refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or c. relapsed or refractory disease after two or more lines of systemic therapy. 2. Age ≥ 18 years of age. 3. Prescriber attestation that all baseline evaluations have been done, and no contraindications to use are present. 4. Prescriber attests that subsequent appropriate evaluation and monitoring will be done based on the package insert. 5. Dose: 50-110 x 10^6 CAR positive viable T cells, one time dose. 6. Medication ordered by an Oncologist or Hematologist.	primary central nervous system lymphoma.
lomitapide (**Juxtapid**) capsules 5mg, 10mg, 20mg, 30mg	1. Ordered for an approved indication for use: • 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. 2. Medication ordered by a REMS registered cardiologist or endocrinologist.	**Limitations of Use:** • The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH). • The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined.
loncastuximab tesirine-lpyl (**Zynlonta**) solution 10mg	1. Ordered for an approved indication for use: • the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic	Requires MFC Physician or Pharmacist review prior to approval.

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	therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma. 2. Medication ordered by an Oncologist	• Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
lorlatinib (**Lorbrena**) tablets 25mg, 100mg	1. Ordered for an approved indication for use: • 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. 2. Medication ordered by Oncologist	• Contraindicated with concomitant use of strong CYP3A inducers.
lubiprostone (Amitiza) capsules 8mcg, 24 mcg	1. Ordered for an approved indication for use: • chronic idiopathic constipation (CIC) in adults. • opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Limitations of Use: • irritable bowel syndrome with constipation (IBS-C) in females ≥ 18 years old. 2. Failure of at least 2 of the following: docusate, mineral oil, sennosides, psyllium, psyllium/aspartame, calcium polycarbophil, polyethylene glycol 3350, lactulose, methylcellulose	**Limitations of use:** • Effectiveness of Lupiprostone in the treatment of OIC in patients taking diphenylheptane opioids (e.g., methadone) has not been established.
lumacaftor/ivacaftor (**Orkambi**) tablets 100mg-125mg, 200mg-125mg	1. Ordered for an approved indication for use: • the treatment of cystic fibrosis (CF) in patients aged 1 year and older who are homozygous for the F508del mutation in the CFTR gene. 2. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of the F508del mutation on both alleles of the CFTR gene. 3. Medication ordered by Pulmonologist	**Limitations of use**: 3. The efficacy and safety of Orkambi have not been established in patients with CF other than those homozygous for the F508del mutation. 4. Not recommended in CF patients who have undergone organ transplantation; has not been studied in this population.

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lumasiran (**Oxlumo**) injection 94.5mg/0.5ml	1. Ordered for an approved indication for use: • treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients.	Requires MFC Physician or Pharmacist review prior to approval. • Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
lumateperone (**Caplyta**) capsules 10.5mg, 21mg, 42mg	1. Ordered for an approved indication for use: • Treatment of depressive episodes associated with bipolar disorder I or II in adults as monotherapy or as an adjunct to lithium or valproate. 2. Treatment of schizophrenia in adults. 3. Documented trial and failure of at least two other antipsychotic medications indicated to treat the medical diagnosis. 4. Risk versus benefit evaluation if being ordered for adults older than 65 years. 5. Medication ordered by a psychiatrist or other behavioral health specialist.	**Limitations of use:** • Caplyta is not approved for the treatment of patients with dementia-related psychosis and will not be approved for this indication. • Use with caution in patients at risk of seizures or with conditions that lower the seizure threshold.
lurasidone (Latuda) tablets 20mg, 40mg, 60mg, 80mg	1. Ordered for an approved indication for use: • Schizophrenia in adults and adolescents (13 to 17 years). • Depressive episode associated with Bipolar I Disorder (bipolar depression) in adults and pediatric patients (10 to 17 years) as monotherapy. • Depressive episode associated with Bipolar I Disorder (bipolar depression) in adults as adjunctive therapy with lithium or valproate. 2. Medication ordered by psychiatrist or other behavioral health specialist.	**Limitations of use:** • Lurasidone is not approved for the treatment of patients with dementia-related psychosis and will not be approved for this indication.
lurbinectedin (**Zepzelca**) solution	1. Ordered for an approved indication for use:	• Continued approval for this indication may be contingent

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	• treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy. 2. Medication ordered by an Oncologist	upon verification and description of clinical benefit in confirmatory trials.
lusutrombopag (**Mulpleta**) tablets 3mg	1. Ordered for an approved indication for use: • Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.	**Limitations for use:** • Mulpleta has been investigated only as a single 7-day once daily dosing regimen in clinical trials in patients with chronic liver disease. Mulpleta should not be administered to patients with chronic liver disease in an attempt to normalize platelet counts.
macimorelin (**Macrilen**) packets 60mg	1. Ordered for an approved indication for use: • The diagnosis of adult growth hormone deficiency. 2. Medication ordered by an endocrinologist	**Limitations of Use:** • The safety and diagnostic performance have not been established for subjects with BMI > 40kg/m^2 • Potential for False Positive Test Results with use of strong CYP3A4 inducers; discontinue and washout out before testing. • Potential for False Negative Test Results in recent onset hypothalamic disease: consider repeat testing if indicated.
maribavir (**Livtencity**) tablets 200mg	1. Ordered for an approved indication for use: • 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

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		claim for ganciclovir, valganciclovir, cidofovir, or foscarnet, a PA is required, and documentation of previous use of one of these medications should be submitted.
mavacamten (**Camzyos**) capsules 2.5mg, 5mg, 10mg 15mg	1. Ordered for an approved indication for use: • The treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms. 2. Must have echocardiogram assessment of left ventricular ejection fraction before use. 3. Must include documentation that echocardiogram assessments will be conducted during Campzyos use. 4. Prescribed by cardiologist experienced with care and treatment of people with HCM in accordance with ACC guidelines and enrolled in the CAMZYOS REMS program.	**<u>Limitations of Use:</u>** • Initiation of mavacamten in patients with LVEF <55% is not recommended. • Interrupt mavacamten if LVEF <50% at any visit or if patient experiences heart failure symptoms or worsening clinical status. • Contraindicated with moderate to strong CYP2C19 inhibitors, strong CYP3A4 inhibitors, moderate-to-strong CYP2C19 inducers or moderate-to-strong CYP3A4 inducers.
mepolizumab (**Nucala**) injection 100mg,	1. Ordered for an approved indication for use: • Add-on maintenance treatment for severe asthma with eosinophilic phenotype in patients aged 6 years and older. 2. Add-on treatment of adult patients with chronic rhinosinusitis with nasal polyps. 3. Treatment of eosinophilic granulomatosis with polyangiitis (EGPA) in adults. 4. Treatment of adult and pediatric patients aged ≥ 12 years of age with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause. 5. Medication ordered by an Allergist or Pulmonologist.	

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methadone (for Pain) concentrate 10mg/ml solution 5mg/5ml, 10mg/5ml tablets 5mg, 10mg	1. Ordered for an approved indication for use: • The management of chronic 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 AUTH FORM-DC **Limitations of Use:** • Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with long-acting opioids, reserve Methadone for use in patients for whom alternative treatment options are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
methotrexate SubQ (**Rasuvo**) injection 7.5mg, 10mg, 12.5mg, 15mg, 17.5mg, 20mg, 22.5mg, 25mg, 30mg	1. Ordered for an approved indication for use: • management of patients with severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA), who are intolerant of or had an inadequate response to first-line therapy. • Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy. 2. Dosed appropriately based on indication for use. Max dose not to exceed 25 mg/week. 3. Concomitant order for folic acid to reduce the risk of adverse effects (for chronic methotrexate use only). 4. Medication ordered by a Rheumatologist or Dermatologist	**Limitations of Use:** • Rasuvo is not indicated for the treatment of neoplastic diseases. • Contraindicated for pregnant or nursing mothers, in patients with alcoholism or liver disease, in immunodeficiency syndromes, or with preexisting blood dyscrasias.

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mirabegron (**Myrbetriq**) tablets 25mg, 50mg	1. Ordered for an approved indication for use: • 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. Pediatric neurogenic detrusor overactivity (NDO) in patients weighing ≥ 35 kg. 3. OAB: adequate trial (30 days), or intolerance to at least 2 preferred bladder agents. 4. NDO: Adequate trial (30 days), or intolerance to oxybutynin IR or ER OR the patient is ≥ 5 years of age 5. No concurrent diagnosis of severe hepatic impairment (Child-Pugh Class C)	• MYRBETRIQ Granules is a beta-3 adrenergic agonist indicated for the treatment of NDO in pediatric patients aged 3 years and older. Indication: Neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older and weighing 35 kg or more. **Limitations for use:** • Extended-release tablets and granules are not bioequivalent and cannot be substituted on a mg:mg basis. Do not combine dosage forms to achieve a specific dose.
mitapivat (**Pyrukynd**) tablets 5mg, 20mg, 50mg	1. Ordered for an approved indication for use: • The treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency 2. Confirmatory genetic testing of PKLR gene showing ≥ 2 variant alleles with at least one- missense mutation in the liver and red blood cell (PKLR) gene. 3. Prescribed by or in consultation with a Hematologist	**Limitations of Use:** • Avoid use of Pyrukynd in patients with moderate and severe hepatic impairment. • Numerous and significant drug-drug interactions requiring dose adjustment or avoidance of concomitant use. • Discontinue Pyrukynd if no benefit observed by 24 weeks, based on hemoglobin and hemolysis laboratory results and transfusion requirements. • Should not be stopped abruptly.
mobocertinib (**Exkivity**) capsules 40mg	1. Ordered for an approved indication for use: • Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with	• Black box warning for Qtc-prolongation. Avoid concomitant use of drugs that prolong QTc and

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	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. 2. Medication ordered by an oncologist.	use of strong/moderate CYP3A inhibitors. • 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.
modafinil (Provigil) tablets 100mg, 200mg	**1.** Ordered for an approved indication for use: • to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, or shift work disorder.	
morphine sulfate extended-release (MS Contin) tablets 15mg, 30mg, 60mg 100mg, 200mg	**1.** Ordered for an approved indication for use: • 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 AUTH FORM-DC** **Limitations of Use:** • Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and greater risk of overdose and death with extended-release opioid formulations, reserve MS CONTIN for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or

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		would be otherwise inadequate to provide sufficient management of pain.
naloxegol (**Movantik**) tablets 12.5mg, 25mg	1. Ordered for an approved indication for use: • treatment of opioid-induced constipation in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. 2. Failure of at least 2 of the following: docusate, sennosides, polyethylene glycol 3350, lactulose, methylcellulose.	**Limitations of use:** • Contraindicated with known or suspected GI obstruction • Contraindicated with concomitant use with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, etc.)
nilotinib (**Tasigna**) capsules 200mg	1. Ordered for an approved indication for use: • adult and pediatric patients ≥ 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. • adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib. • pediatric patients ≥ 1 year of age with Ph+ CML-CP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy. 2. Medication ordered by an Oncologist.	
nintedanib (**Ofev**) capsule 100mg, 150mg	1. Ordered for an approved indication for use: • Treatment of adults for idiopathic pulmonary fibrosis. • Treatment of adults for chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype. • To slow the rate of decline in pulmonary function in patients with systemic sclerosis associated interstitial lung disease (SSc-ILD). 2. Medication ordered by a pulmonologist	**Limitations to Use:** • Smoking may decrease exposure to nintedanib; patients should stop smoking prior to treatment and avoid smoking during therapy.
niraparib (**Zejula**) capsules 100mg	1. Ordered for an approved indication for use: • maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal	• Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA.

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	cancer who are in a complete or partial response to first-line platinum-based chemotherapy. 2. Maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy. 3. Medication ordered by an Oncologist.	
nitisinone (Orfadin) capsules Nitisinone is preferred for 2mg, 5mg 10mg	1. Ordered for an approved indication for use: • treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine. 2. Diagnosis of type 1 tyrosinemia. 3. Patient adherent to dietary restrictions of tyrosine and phenylalanine. 4. Patient is under the care of a nutritionist. 5. Dose not to exceed 2 mg/kg/day.	Requires MFC Physician or Pharmacist review prior to approval.
norethindrone ace-ethinyl estradiol-fe cap 1 mg-20 mcg (Minastrin 24 FE) **Charlotte 24 Chew FE 1/20** **Meldotta Chew 24 FE** **Milbelas 24 chew FE** **norethindrone ace-ethinyl estradiol-fe cap 1 mg-20 mcg** (Taytulla) **Gemmily cap 1/20**	1. 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]	• 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.
nusinersen (**Spinraza**)	1. Ordered for an approved indication for use: • Diagnosis of SMA Type I, II, or III.	Requires MFC Physician or Pharmacist review prior to approval.

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	2. Genetic testing confirming both: • 5q SMA homozygous gene deletion, homozyous gene mutation, or compound heterozygous mutation: AND • At least 2 copies of SMN2 3. AND • Patient is not dependent on invasive ventilation or tracheostomy • Patient is not dependent on non-invasive ventilation beyond use for naps and nighttime sleep; • Patients with Type II and III SMA must have some functional upper extremity use: 4. **A) Initial therapy** • Medical records must be submitted documenting all of the above criteria: • Medical records must be submitted documenting a baseline motor examination utilizing at least one of the following exams (based on patient age and motor ability) to establish baseline motor ability; • Hammersmith infant neurological exam (HINE); • Hammersmith Functional Motor Scale Expanded (HFMSE); • Upper Limb Module Test (non-ambulatory; or • Childrens Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) **Spinraza will initially preauthorized for 4 loading doses when criteria are met 4. **B) Continuation Criteria:** • Each Spinraza maintenance dose must be preauthorized; • All the criteria for initial therapy must be met: ○ Medical records must be submitted that document repeat motor testing since the most recent Spinraza® dose using the same motor test done to establish baseline motor ability, unless it is	**Limitations of use:** • Cannot be used in combination with Zolgensma (onasemnogene abeparvovec).

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	determined that the original test is no longer appropriate; ○ Repeat motor testing must document a response to treatment as defined by the following: **HINE:** • Improvement or maintenance of previous improvement of at least 2 points (or max score of 4) in ability to kick (improvement in at least 2 milestones); **OR** • Improvement or maintenance of previous improvement of at least 1 point increase in motor milestones of head control, rolling, sitting, crawling, standing or walking (consistent with improvement by at least 1 milestone); **AND** • Improvement or maintenance of previous improvement in more HINE motor milestones than worsening; **HFMSE:** • Improvement or maintenance of improvement of at least a 3 point increase in score; **ULM:** • Improvement or maintenance of previous improvement of at least 2 point increase in score; **CHOP-INTEND:** • Improvement or maintenance of previous improvement of at least 4 point increase in score. 5. Prescribed by a neurologist	
ocrelizumab (**Ocrevus**) injection 300mg/10ml	1. Ordered for an approved indication for use: • Primary progressive MS • Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease 2. Medication ordered by a neurologist	**Limitations to Use:** • Effectiveness not studied in adults ≥ 55 years of age. • Contraindicated in patient with active hepatitis B infection.

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olanzapine and smidorphan (**Lybalvi**) tablets 5mg/10mg, 10mg/10mg, 15mg/10mg, 20mg/10mg	1. Ordered for an approved indication for use: • Schizophrenia in adults • Bipolar I disorder in adults as acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate • Bipolar I disorder in adults as maintenance monotherapy treatment 2. Urine drug screen 3. 4-week trial and failure of at least two formulary atypical antipsychotic agents.	**Limitations to Use:** • Contraindicated in patients using opioids; do not initiate within 14 days of opioid medication use. • Contraindicated in patients undergoing acute opioid withdrawal.
olaparib (**Lynparza**) tablets 100mg, 150mg	1. Ordered for an approved indication for use: • **Ovarian cancer** 2. Recurrent, maintenance therapy 3. Advanced, germline or somatic BRCA-mutated, first-line maintenance therapy (monotherapy). 4. Advanced, homologous recombination deficient-positive, first-line maintenance therapy (in combination with bevacizumab). • **Breast Cancer** 5. Early, high-risk, HER2-negative, germline BRCA-mutated, adjuvant therapy 6. Metastatic, HER2-negative, germline BRCA-mutated, monotherapy. • **Pancreatic Cancer**; metastatic, germline BRCA-mutated, first-line maintenance therapy. • **Prostate Cancer**; metastatic, castration-resistant, homologous recombination repair gene-mutated in combination with a gonadotropin-releasing hormone analog OR bilateral orchiectomy. 7. Medication ordered by an Oncologist.	• When treating with Olaparib as maintenance therapy for recurrent ovarian cancer, biomarker testing is not required.
omacetaxine (**Synribo**) Injection 3.5mg	1. Ordered for an approved indication for use:	

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	• treat adults with chronic phase (CP) or accelerated phase (AP) CML with resistance and/or intolerance to two or more TKIs 2. Medication ordered by an oncologist	
omalizumab (**Xolair**) Injection 75mg/0.5ml, 150mg/ml Solution for injection 150mg	1. Ordered for an approved indication for use: • moderate to severe persistent asthma in patients ≥ 6 years of age with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids. • chronic spontaneous urticaria (CSU) in adults and adolescents ≥ 12 years of age who remain symptomatic despite H1 antihistamine treatment. • Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients ≥ 18 years of age with inadequate response to nasal corticosteroids, as add-on maintenance treatment. 2. Medication ordered by allergist or Pulmonologist	• Regarding ASTHMA indication only: • moderate to severe persistent ALLERGIC asthma (confirmed by a positive skin test or RAST for ≥ 1 perennial aeroallergen). • IgE level obtained prior to initiation of therapy. • currently using an inhaled corticosteroid at maximum dose; compliance must be confirmed in the patient's Caremark profile. • currently using a long-acting inhaled beta2-agonist OR a leukotriene modifier; compliance must be confirmed in the patient's Caremark profile. NOT approved for monotherapy.
omega-3-acid ethyl esters (Lovaza) capsules 1 Gram	1. Ordered for an approved indication for use: • as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia 2. Member must have tried and failed OTC fish oil.	
Omnipod insulin pump management system	1. Ordered for an approved indication for use: • Subcutaneous delivery of insulin at set and variable rates to manage diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro) from the finger. 2. Medication ordered by an Endocrinologist.	Please click link below for EIM Policy: MFC External Insulin Pumps Policy-DC Must meet criteria found in Policy 1413.DC

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	3. Patient must also be ordered for a pump-compatible insulin.	
onabotulinumtoxinA (**Botox**) injection 100 Unit, 200 Unit	1. Ordered for an approved indication for use: • 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. • 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. • Neurogenic detrusor overactivity (NDO) in pediatric patients ≥ 5 years of age who have an inadequate response to or are intolerant of anticholinergic medication. • Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting ≥ 4 hours a day. • Spasticity in adult patients. • Cervical dystonia in adult patients to reduce the severity of abnormal head position and neck pain. • Severe axillary hyperhidrosis of adults inadequately managed by topical agents. • Treatment of blepharospasm associated with dystonia in patients 12 years of age and older. • Treatment of strabismus in patients 12 years of age and older. 2. Medication ordered by a Neurologist, Urologist, Ophthalmologist, or applicable specialist.	**Limitations for Use:** • **Botox will NOT be approved for cosmetic purposes** • Safety and effectiveness have not been established for: • Prophylaxis of episodic migraine (≤ 14 headache days/month). • treatment of upper or lower limb spasticity in pediatric patients. • treatment of hyperhidrosis in body areas other than axillary.
Oral Contraceptives	1. 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)	• While some oral contraceptives have additional indications (ex: Beyaz for acne,

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		PMDD, folate replacement; Estrostep Fe for acne; Safyral for folate replacement; Natazia for heavy periods), most are simply indicated for the prevention of pregnancy.
Opioids	FOR IMPORTANT INFORMATION ABOUT PRESCRIBING OPIOIDS FOR MEDSTAR FAMILY CHOICE MEMBERS, PLEASE VISIT THE OPIOID PRIOR AUTHORIZATION REQUIREMENTS PAGE OF THE MFC-DC WEBSITE.	The Opioid PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-DC
osimertinib (**Tagrisso**) tablets 40mg, 80mg	1. Ordered for an approved indication for use: • 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. • first-line treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations. • treatment of adult patients with metastatic EGFR T790M mutation-positive NSCLC, whose disease has progressed on or after EGFR TKI therapy. 2. Medication ordered by an Oncologist	
oxcarbazepine extended release 24-hour (**Oxtellar XR**) tablets 150mg, 300mg, 600mg	1. Ordered for an approved indication for use: • Treatment of partial-onset seizures in adults and in children ≥ 6 years of age. 2. Treatment failure, adverse effects, or contraindication to formulary preferred agents. 3. Medication ordered by a Neurologist.	• Immediate-release and extended-release preparations are not bioequivalent and not interchangeable on a mg per mg basis.

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oxymorphone extended release 12-hour (Opana) tablets 5mg, 7.5mg, 10mg, 15mg, 20mg, 30mg, 40mg, **SEE SPECIAL NOTE REGARDING PA REQUIREMENTS & FORM** **********	1. Ordered for an approved indication for use: • 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 AUTH FORM-DC
pacritinib (**Vonjo**) capsules 100mg	1. Ordered for an approved indication for use: • treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 109 /L. 2. Prescribed by Oncologist or Hematologist.	**Limitations of Use:** • Contraindicated with strong CYP3A4 inhibitors or inducers. • Avoid use in patients with baseline QTc interval > 480. • Avoid use in patients with eGFR < 30 ml/min. • Avoid use in moderate to severe hepatic impairment (Child-Pugh B or C)
palbociclib (**Ibrance**) capsules 75mg, 100mg, 125mg	1. Ordered for an approved indication for use: • Treatment of adult patients with hormone receptor positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer in combination with: a. An aromatase inhibitor as initial endocrine based therapy. b. Fulvestrant in patients with disease progression following endocrine therapy. 2. Medication ordered by an Oncologist	
palivizumab (**Synagis**) injection 50mg, 50mg/0.5ml, 100mg/ml	1. Ordered for an approved indication for use:	Please submit: A COMPLETED PRIOR AUTHORIZATION FORM (see link below)

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	• with a history of premature birth (≤35 weeks gestational age) and who are ≤ 6 months of age at the beginning of RSV season • with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and ≤ 24 months of age or younger at the beginning of RSV season 2. with hemodynamically significant congenital heart disease (CHD) and ≤ 24 months of age at the beginning of RSV season.	SYNAGIS PRIOR AUTHORIZATION AND PRESCRIPTION FORM-DC To view the most up to date AAP Synagis Guidelines, follow the link below: AAP SYNAGIS GUIDELINES **Limitations of Use:** • Safety and efficacy of Synagis have not been established for treatment of RSV.
pasireotide (**Signifor LAR**) Injection 10mg, 20mg, 30mg, 40mg, 60mg	1. Ordered for an approved indication for use: • treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option. • Patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. 2. Medication ordered by an Endocrinologist	
patisiran (**Onpattro**) Solution 10mg/5ml	1. Ordered for an approved indication for use: • Treatment of polyneuropathy in adults with hereditary transthyretin-mediated amyloidosis. 2. Medication ordered by a Rheumatologist or Neurologist.	Requires MFC Physician or Pharmacist review prior to approval.
pegcetacoplan (**Empaveli**) injection 1080mg	1. Ordered for an approved indication for use: • Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). 2. Prescribed by provider registered with Empaveli REMS program.	Requires MFC Physician or Pharmacist review prior to approval. **Limitations for Use:** • Follow Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria.

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		• Recommended vaccinations at least 2 weeks prior to administration of first dose of Empaveli.
pemigatinib (**Pemazyre**) tablets 4.5mg, 9mg, 13.5mg	1. Ordered for an approved indication for use: • treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 fusion (FGFR2) or other rearrangement as detected by an FDA-approved test. • Treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement. 2. Medication ordered by an Oncologist.	• 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.
pexidartinib (**Turalio**) capsules 125mg, 200mg	1. Ordered for an approved indication for use: • treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery. 2. Medication ordered by an Oncologist registered with the Turalio REMS program.	**Limitations of Use:** • Avoid concomitant use with proton pump inhibitors. • Significant potential for drug-drug interactions.
pirfenidone (Esbriet) capsules 267mg	1. Ordered for an approved indication for use: • The treatment of idiopathic pulmonary fibrosis (IPF). 2. Medication ordered by a Pulmonologist or Cardiologist.	• Significant potential for drug-drug interactions.
pirtobrutinib (**Jaypirca**) 50 mg	1. Ordered for an approved indication for use: • Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor. 2. Medication ordered by an oncologist.	• This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
polatuzumab vedotin (**Polivy**) injection	1. Ordered for an approved indication for use:	

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140mg	• In combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index score ≥ 2. • in combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory DLBCL, NOS, after at least 2 prior therapies. 2. Medication ordered by an Oncologist	
ponatinib (**Iclusig**) tablets 15mg, 45mg	1. Ordered for an approved indication for use: • Chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least 2 prior kinase inhibitors. • 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. 2. T315I-positive CML (chronic-, accelerated-, or blast phase) or T315I-positive Ph+ ALL. Medication ordered by an Oncologist	**Limitations of Use:** • Iclusig is not indicated and is not recommended for the treatment of patients with newly diagnosed CP-CML. • Risk for significant drug-drug interactions.
posaconazole (Noxafil**)** **40mg/ml suspension** **100mg tablets**	1. Ordered for an approved indication for use: • Treatment of invasive aspergillosis in adults and pediatric patients ≥ 13 years of age. (Injection and tablets). • Prophylaxis of invasive Aspergillus and Candida infections in patients at high risk of infection development (ages vary by dose formulation). • Treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adults or pediatric patients ≥ 13 years of age.	• Patient at high infection risk: severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy. • Oral suspension is not substitutable with tablets or PowderMix oral suspension due

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	2. Medication ordered by Infectious Disease specialist.	to differences in dosing of each formulation. • Coadministration is Contraindicated with sirolimus, ergot alkaloids, HMG-CoA reductase inhibitors. • Significant risk for drug-drug interactions.
pralsetinib (**Gavreto**) capsule 100mg	1. Ordered for an approved indication for use: • treatment of adult patients with metastatic rearranged during transfection (RET) fusion- positive non-small cell lung cancer (NSCLC). • Adult and pediatric patients ≥ 12 years of age with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy. • Adult and pediatric patients ≥ 12 years of age with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). 2. Medication ordered by an Oncologist	
regorafenib (**Stivarga**) tablet 40mg	1. Ordered for an approved indication for use: • treatment of metastatic colorectal cancer previously treated with: fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) therapy, and, if RAS wild-type, an anti-EGFR therapy. • Treatment of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST), previously treated with imatinib mesylate and sunitinib malate. • hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. 2. Medication ordered by Oncologist.	**Limitations of Use:** • According to guidelines from the American Society of Clinical Oncology for systemic therapy for advanced HCC, regorafenib is a potential second-line therapy option in patients who received atezolizumab and bevacizumab as first-line therapy, although sorafenib or lenvatinib are preferred in this setting. Regorafenib is also a second-line

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		therapy option in patients who received first-line therapy with sorafenib or lenvatinib. • Interrupt therapy in patients who develop new or acute onset ischemia or infarction; resume only if the benefit of therapy outweighs the cardiovascular risk.
ribociclib (**Kisqali**) tablets 200 mg dose, 400 mg dose, 600 mg dose	1. Ordered for an approved indication for use: • 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: a. An aromatase inhibitor as initial endocrine-based therapy; or b. Fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men. 2. Medication ordered by Oncologist	
rimegepant (**Nurtec**) tablet 75mg ODT	1. Ordered for an approved indication for use: • Acute treatment of moderate to severe migraines. o Member must have tried and failed NSAIDs and Triptans or have a contraindication to taking either of these medications. • Migraine prevention. o Member must have documented evidence of failure/intolerance of beta blockers, Aimovig, and Emgality in the medical notes sent for MFC review. o Patient must average ≥ 4 headache days per month. 2. Limit use to patients with significant disability from frequent migraines who are unable to tolerate or do not respond to adequate trials of other preventive therapies	• Triptan contraindications may include: cardiovascular risk factors), ineffective, or poorly tolerated. • Avoid use in patients with recent cardiovascular or cerebrovascular ischemic events. • An adequate trial for assessment of effect is considered at least 8 weeks at a therapeutic dose

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rituximab (**Rituxan**) injection 100mg, 500mg	1. Ordered for an approved indication for use: • Pediatric patients aged 6 months and older with mature B-cell NHL and mature B-cell acute leukemia (B-AL) 2. Previously untreated, advanced stage, CD20-positive, diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy. • Moderate to severe Pemphigus Vulgaris (PV) in adult patients • Demonstrated failure or intolerance to Truxima for the following indications: • Adult patients with Non-Hodgkin's Lymphoma (NHL) 3. Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent. 4. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy. 5. Non-progressing (including stable disease), low-grade, CD20-positive, Bcell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. 6. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens. • Adult patients with Chronic Lymphocytic Leukemia (CLL) 7. Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC). • Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to	• Note: Prior authorization requirements apply for patients new to starting therapy. Documentation showing history of prior use of Rituxan within the past 90 days will be considered and PA Criteria will not apply.

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	severely-active RA who have inadequate response to one or more TNF antagonist therapies • Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients ≥ 2 years of age in combination with glucocorticoids 8. Prescribed by oncologist or rheumatologist.	
rucaparib (**Rubraca**) tablets 200mg, 250mg, 300mg	1. Ordered for an approved indication for use: • <u>Ovarian Cancer</u> o 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. o 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 are in a complete or partial response to platinum-based chemotherapy. • <u>Prostate Cancer</u> o 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. 2. Medication ordered by an Oncologist	
ruxulitinib (**Jakafi**) tablets 5mg, 10mg, 15mg, 20mg, 25mg	1. Ordered for an approved indication for use: • Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults.	**<u>Limitations of Use:</u>** • Avoid concomitant use with fluconazole doses greater than

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	• Polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea. • Steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older. • Chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older. 2. Medication ordered by Hematologist or Oncologist.	200 mg. Reduce Jakafi dosage with fluconazole doses ≤ 200 mg. • Strong CYP3A4 Inhibitiors: Reduce, interrupt, or discontinue Jakafi doses as recommended except in patients with acute or chronic graft-versus-host-disease.
sacituzumab govitecan-hziy (**Trodelvy**) solution 180mg	1. Ordered for an approved indication for use: • metastatic triple-negative breast cancer who have received at least two prior therapies for metastatic disease. • 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. 2. Medication ordered by an Oncologist	**Limitations of Use:** • Withhold Trodelvy for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood counts periodically during treatment Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.
safinamide (**Xadago**) tablets 50mg, 100mg	1. Ordered for an approved indication for use: • as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes. 2. Medication ordered by a neurologist	**Limitations of Use:** • Contraindicated with concomitant use of the following drugs: o Other monoamine oxidase inhibitors or drugs that are potent inhibitors of monoamine oxidase (e.g. linezolid). o Opioid drugs; serotonin-norepinephrine reuptake inhibitors, tri-or tetra-cyclic or triazolopyridine antidepressants, cyclobenzaprine,

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		methylphenidate, amphetamine or their derivatives, St John's wort, dextromethorphan. • Severe hepatic impairment (Child-Pugh C) • Hypersensitivity to safinamide.
sastralizumab-mwge (**Enspryng**) injection	1. Ordered for an approved indication for use: • Treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. 2. Age ≥ 18 years. 3. Prescriber attests that baseline evaluation has been done and there are no contraindications to use (e.g. Hep B, TB, LFT's, live or live-attenuated vaccines 4 weeks prior or 2 weeks for non-live vaccines. 4. Prescriber attests that subsequent appropriate evaluation and monitoring will be done based on the package insert (e.g. infections, LFT's, CBCs – neutrophils) 5. Medication ordered by neurologist, immunologist, or ophthalmologist.	Requires MFC Physician or Pharmacist review prior to approval. • Contraindicated in patients with active hepatitis B infection or active or untreated latent tuberculosis. • Use in caution if ALT/AST > 1.5 x ULN.c • Approval duration is 12 months **Renewal Criteria:** • Meets all initial criteria, AND • Provider attestation of continued benefit • 12 months authorization period
selinexor (**Xpovio**) Pak 40mg, 50mg, 60mg, 80mg 100mg	1. Ordered for an approved indication for use: • In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. • in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.	• Continued approval for treatment of DLBCL may be contingent upon verification and description of clinical benefit in confirmatory trials.

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	• Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after a least 2 lines of systemic therapy. 2. Medication ordered by an Oncologist	
selpercatinib (**Retevmo**) capsules 40mg, 80mg	1. Ordered for an approved indication for use: • Adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during tranfection (RET) gene fusion, as detected by an FDA-approved test. • Adult and pediatric patients ≥ 12 years of age with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, who require systemic therapy. • adult and pediatric patients ≥ 12 years of age with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). • Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. 2. Medication ordered by an Oncologist	
semaglutide (**Ozempic**) injection 2mg/1.5ml, 2mg/3ml, 4mg/3ml, 8mg/3ml (**Rybelus**) tablets 3mg, 7mg, 14mg	1. Ordered for an approved indication for use: • As adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. • To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease. 2. A1C lab within past 3 months OR Recent CGM report if applicable with 70% utilization 3. Dispense quantity limited to 30-day supply per dispense. 4. May not be taking a DPP4i (e.g. alogliptin, januvia, tradjenta)	**Cannot be approved for indication of weight management.** **Titration doses will be approved for a maximum of 60-days supply per year** **<u>Limitations of Use:</u>** • Contraindicated in patients with personal or family history of medullary thyroid carcinoma

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		(MTC) and in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2). • Not for the treatment of type 1 diabetes or diabetic ketoacidosis. • Not for patients with pre-existing severe gastrointestinal disease • Not studied in patients with history of pancreatitis, consider alternate therapy.
seracycline (**Seysara**) tablet 60mg, 100mg, 150mg	1. Ordered for an approved indication for use: • treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients ≥ 9 years of age. 2. Failure of at least one other oral tetracycline antibiotic. Medication ordered by a Dermatologist.	**Limitations of Use:** • Efficacy of Seysara beyond 12 weeks and safety beyond 12 months have not been established. • Seysara has not been evaluated in the treatment of infections and should only be used as indicated.
sildenafil (Revatio) tablet 20mg	1. Ordered for an approved indication for use: • treatment of pulmonary arterial hypertension (PAH) (WHO Group I) in adults to improve exercise ability and delay clinical worsening. 2. Medication ordered by a cardiologist or pulmonologist.	**Limitations of Use:** • Medication will not be covered for use to treat erectile dysfunction (ED). • Viagra and generic product strengths (25 mg, 50 mg, 100 mg) are not covered.
sodium oxybate (**Xyrem**) solution 500mg/ml	1. Ordered for an approved indication for use: • treatment of cataplexy or excessive daytime sleepiness (EDS) in patients ≥ 7 years of age with narcolepsy. • alternative diagnoses must have been excluded 2. for cataplexy, must have failed tricyclic or SSRIs 3. for excessive daytime sleepiness, must have failed at least one formulary stimulant treatment (ex: methylphenidate or	**Limitations of Use:** • Xyrem is available only through a restricted program called the Xyrem REMS or Xyway REMS. • Contraindicated in combination with sedative hypnotics or alcohol • Contraindicated in patients with

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	dextroamphetamine) 4. 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) 5. Medication ordered by a Neurologist	succinic semialdehyde dehydrogenase deficiency.
sodium phenylbutyrate/taurours odiol (**Relyvrio**) pak 3-1GM	1. Ordered for an approved indication for use: • Treatment of adults with amyotrophic lateral sclerosis (ALS) 2. Medication ordered by a Neurologist.	
somatropin [recombinant human growth hormone] (**Norditropin FlexPro; Serostim**) injection Norditropin 5/1.5ml, 10/1.5ml, 15/1.5ml, 30mg/3ml Serostim 4mg, 5mg, 6mg	1. Ordered for an approved indication for use: • **Norditropin** -- Pediatric: growth failure due to inadequate secretion of endogenous growth hormone (GH), short stature associated with Noonan syndrome, short stature associated with Turner syndrome, short stature born small for gestational age (SGA) with no catch-up growth by age 2 to 4 years, Idiopathic Short Stature (ISS), and growth failure due to Prader-Willi Syndrome. • **Norditropin** -- Adult: Replacement of endogenous GH in growth hormone deficiency. • **Serostim** – treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance. 2. Medication ordered by an Endocrinologist or Infectious disease specialist.	**<u>Contraindications:</u>** • Acute critical illness • Pediatric patients with Prader-Willi syndrome who are severely obese, have history of severe upper airway obstruction, or have severe respiratory impairment due to risk of sudden death. • Active malignancy • Active proliferative or severe non-proliferative diabetic retinopathy • Pediatric patients with closed epiphyses.
sotorasib (**Lumakras**) tablet 120mg	1. Ordered for an approved indication for use: • 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 2. Medication ordered by Oncologist	• 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.
tadalafil (Adcirca; Alyq) tablets	1. Ordered for an approved indication for use:	• BPH:

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20mg BPH:5mg (Cialis) PAH:20 mg	• To treat signs and symptoms of benign prostatic hyperplasia (BPH). • To treat pulmonary arterial hypertension (World Health Organization group 1) to improve exercise ability. 2. Confirmation the patient is not currently taking any forms of nitrate-containing medication (e.g. Nitrodur, NitroStat). 3. BPH-specific requirements: • Ordered for generic Cialis (tadalafil) 5 mg tablets • Ordered by a urologist. 4. PAH-specific requirements: • Ordered for generic Adcirca (tadalafil PAH) 20 mg tablets 5. Medication ordered by a Pulmonologist, Cardiologist, or Rheumatologist	a. Tadalafil should not be used concurrently with an alpha-1 blocker (e.g. tamsulosin) due to minimal added benefit and higher adverse effect likelihood. b. If using tadalafil and finasteride, max recommended duration of tadalafil is ≤26 weeks (manufacturer's labeling). • PAH: c. Tadalafil is contraindicated in patients taking guanylate cyclase stimulators (e.g. riociguat) due to potentially severe hypotension. • Erectile dysfunction is not a covered indication for use.
tagraxofusp-erzs (**Elzonris**) sol 1000mcg	1. Ordered for an approved indication for use: 6. The treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients ≥ 2 years of age. 2. Medication ordered by an Oncologist	
talazoparib (**Talzenna**) capsules 0.5mg, 0.25mg, 0.75mg, 1mg	1. Ordered for an approved indication for use: • treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer. 2. Medication ordered by an Oncologist	
tazemetostat (**Tazverik**) tablets 200mg	1. Ordered for an approved indication for use:	

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	• adults and pediatric patients aged ≥ 16 years with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection. • 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. • adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options. 2. Medication ordered by an Oncologist	
tenofovir (**Vemlidy**) tablets 25mg	1. Ordered for an approved indication for use: • Treatment of chronic hepatitis B virus infection in adults and pediatric patients ≥ 12 years of age with compensated liver disease. 2. Baseline test results prior to treatment start: • Confirmed negative HIV test result prior to starting medication. • Hepatitis B e antigen (HBeAg) status. • Liver function tests. 3. Medication ordered or recommended by an Infectious Disease specialist.	**Limitations of Use:** • Use of Vemlidy is not recommended in patients with Child-Pugh Class B or C hepatic impairment. • Should not be used as a single agent for the treatment of HIV-1 due to risk of development of resistance. • Use is not recommended in patients with Crcl < 15 ml/min who are not receiving hemodialysis.
tesamorelin (**Egrifta SV**) injection 2mg	1. Ordered for an approved indication for use: • Reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy.	**Limitations of use:** • Long-term cardiovascular safety of EGRIFTA SV has not been established. • Not indicated for weight loss management. • There are no data to support improved

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		compliance with anti-retroviral therapies in HIV-positive patients taking EGRIFTA SV.
tetrabenazine (Xenazine) tablets 12.5mg, 25mg	1. Ordered for an approved indication for use: • the treatment of chorea associated with Huntington's disease. 2. Medication ordered by a Neurologist.	**Contraindications:** • In patients with untreated or inadequately treated depression or who are actively suicidal. • Patients with hepatic impairment • Patients taking monoamine oxidase inhibitors (MAOIs) or within a minimum of 14-days of discontinuing therapy with MAOIs. • Patients taking reserpine, deutetrabenazine or valbenazine.
tirzepatide (**Mounjaro**) injection 2.5mg/0.5ml, 5mg/0.5ml, 7.5mg/0.5ml, 10mg/0.5ml, 12.5mg/0.5ml, 15mg/0.5ml	1. Ordered for an approved indication for use: • Treatment of Type 2 Diabetes mellitus. 2. Documented ≥4-week trial of other formulary GLP-1 receptor agonist medication. 3. Must have tried and failed or have a contraindication to a formulary GLP-1 agonist (e.g., Ozempic, Rybelsus, Trulicity, or Victoza). 4. Include recent CGM report if applicable. 5. Limited to 30-day supply 6. May not be concurrently taking a DPP4i (e.g. alogliptin, januvia, or tradjenta)	**Cannot be approved for indication of weight management.** **Titration dose 2.5 mg limited to 8 pens per year** **Limitations of Use:** • Mounjaro is not indicated for use in patients with type 1 diabetes mellitus • The ASCVD benefit of Mounjaro is under investigation; other GLP-1 medications are preferred in patients with DM2 and high ASCVD risk.
tivozanib (**Fotivda**) capsules 0.89mg, 1.34mg	1. Ordered for an approved indication for use: • the treatment of adult patients with relapsed or refractory	

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	advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. 2. Medication order by Hematology/oncology	
tobramycin inh (Bethkis) sol 300mg/4ml	1. Ordered for an approved indication for use: • Management of cystic fibrosis patients with Pseudomonas aeruginosa. 2. Medication ordered by a Pulmonologist.	**Limitations of Use:** • Safety and efficacy have not been demonstrated in patients under the age of six years, patients with a forced expiratory volume in one second (FEV1) less than 40% or greater than 80% predicted, or patients colonized with Burkholderia cepacian.
tolvaptan (**Jynarque**) pak 15mg, 30-15mg, 45-15mg, 60-30mg, 90-30mg, Tab 15mg, 30mg,	1. Ordered for an approved indication for use: • Slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease. 2. Medication ordered by provider registered in Jynarque REMS program. 3. Medication ordered by nephrologist	• Contraindicated in history of signs or symptoms of significant liver impairment or injury.
topotecan (**Hycamtin**) capsules 0.25mg, 1mg	1. Ordered for an approved indication for use: • Treatment of patients with relapsed small cell lung cancer (SCLC). 2. Medication ordered by an Oncologist	
trametinib (**Mekinist**) tablets 0.5mg, 2mg	1. Ordered for an approved indication for use: • Monotherapy for BRAF-inhibitor treatment-naïve patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA approved test. • In combination with dabrafenib, for: 2. Treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations.	**Limitations of Use:** • MEKINIST is not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. • The indication for patients ≥ 6 years of age with unresectable or

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	3. Adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations and involvement of lymph node(s), following complete resection. 4. Treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation. 5. Treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and no satisfactory locoregional treatment options. 6. Treatment of adult and pediatric patients ≥ 6 years of age with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. • Treatment of pediatric patients ≥ 1 year of age with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.	metastatic solid tumors with BRAF V600E mutation without satisfactory treatment options 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 a confirmatory trial.
trilaciclib (**Cosela**) injection 300mg	1. Ordered for an approved indication for use: • 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. 2. Medication ordered by an Oncologist.	
tucatinib (**Tukysa**) tablets 50mg, 150mg	1. Ordered for an approved indication for use: • in combination with trastuzumab and capecitabine for treatment of adult patients with locally 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. 2. Medication ordered by an Oncologist.	
ubrogepant (**Ubrelvy**) tablets 50mg, 100mg	1. Ordered for an approved indication for use:	

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	• the acute treatment of migraine with or without aura in adults. 2. Member must have tried and failed NSAIDs and Triptans or have a contraindication to taking either of these medications.	
V-go wearable insulin delivery system 20, 30, 40	1. Ordered for an approved indication for use: • Wearable insulin device indicated for use in adult patients requiring insulin. 2. Medication ordered by an Endocrinologist. 3. Patient meets all Policy #1413 criteria.	Please click link below for External Insulin Pump Policy: External Insulin Pump Policy-DC
vemurafenib (**Zelboraf**) tablet 240mg	1. Ordered for an approved indication for use: • the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. • the treatment of patients with Erdheim Chester Disease with BRAF V600 mutation. 2. Medication ordered by an Oncologist or dermatologist	**Limitations of Use:** • Zelboraf is not indicated for use in patients with wild-type BRAF melanoma. • The safety and efficacy of Zelboraf in combination with ipilimumab have not been established.
venetoclax (**Venclexta**) tablet 10mg, 50mg, 100mg	1. Ordered for an approved indication for use: • for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). • 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. 2. Medication ordered by an Oncologist	
vigabatrin (Sabril) 500 mg powder pack; 500mg tablets	1. Ordered for an approved indication for use: • treatment of Refractory Complex Partial Seizures as adjunctive therapy in patients ≥ 2 years of age who have responded inadequately to several alternative treatments.	**Limitations of Use:** • Vigabatrin is not indicated as a first line agent.

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	• Infantile Spasms - monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss. 2. Medication prescribed by a provider registered in the vigabatrin REMS program. 3. Medication prescribed by a Neurologist.	
viloxazine extended release (**Qelbree**) capsules 100mg, 150mg, 200mg	1. Ordered for an approved indication for use: • treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients ≥ 6 years of age. 2. No diagnosis of biopolar disorder within prior 365 days. 3. No diagnosis of suicidal ideation or suicide attempt within previous 180 days. 4. Treatment failure or contraindication to formulary preferred agents (e.g., guanfacine ER, atomoxetine, clonidine ER, amphetamine salts or methylphenidate product). 5. Single dose does not exceed 400 mg per day for patients 17 years of age or younger; 600 mg per day max for ages ≥ 18 years. 6. Ordered by a psychiatrist	**Contraindications:** • Concomitant administration of a monoamine oxidase inhibitor (MAOI) or within 14 days of discontinuing an MAOI • Concomitant administration of sensitive CYP1A2 or CYP1A2 substrates with a narrow therapeutic range.
viltolarsen (**Viltepso**) 50 mg/ml solution	1. Ordered for an approved indication for use: • of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. 2. Genetic testing must confirm patient's DMD gene is amenable to exon 53 skipping. 3. Current patient weight, including date weight was obtained and within 30 days of requested date. 4. Baseline renal function test (GFR) and Urine protein-to-creatinine ratio prior to starting treatment. 5. Documented baseline function testing using a tool to demonstrate physical functions, including, but not limited to:	Requires MFC Physician or Pharmacist review prior to approval. • Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. **Limitations of Use:** • Can not be used concomitantly with other exon-skipping therapies for DMD.

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	Brooke Upper Extremity Scale, Baseline 6-minute walk test, Pediatric Evaluation of Disability Inventory. 6. Stable dose of glucocorticoid for at least 3 months. 7. Prescribed by a neurologist. 8. Approval duration: 6 months	• Studied only in males from ages 4-10, Vyondy's 53 has been studied in children aged 6-13 years of age. • Should not be continued as treatment for individuals who experience decreasing physical function while on medication. **<u>Renewal Criteria:</u>** • Documentation and provider attestation of continued benefit, including respiratory status assessment, without adverse effects • Not receiving another antisense therapy or gene therapy • Approval duration: 12 months
voclosporin (**Lupkynis**) capsule 7.9mg	1. Ordered for an approved indication for use: • in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis.	**<u>Limitations of Use:</u>** • Safety and efficacy of Lupkynis have not been established in combination with cyclophosphamide and is not recommended.
vorapaxar (**Zontivity**) tablet 2.08mg	1. Ordered for an approved indication for use: • reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD) 2. Medication ordered by Cardiology, Neurology or Vascular Surgery	• Contraindicated in patients with history of stroke, TIA, or ICH and/or active pathologic bleeding.

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vosoritide (**Voxzogo**) injection 0.4mg, 0.56mg, 1.2mg	1. Ordered for an approved indication for use: • to increase linear growth in pediatric patients with achondroplasia who are ≥ 5 years of age with open epiphyses. 2. Genetic test confirming a mutation in the fibroblast growth factor receptor 3 (FGFR3) gene. 3. Patient age ≥ 5 years but < 18 years of age. 4. Documentation of radiographic evidence indicating open epiphyses (growth plates) 5. Documentation of baseline annualized growth velocity, calculated based on standing height measured over the course of 6 months prior to request 6. Voxzogo is not prescribed concurrently with any human growth hormone products (e.g., Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Saizen®, Zomacton®) 7. Medication ordered by or in consultation with a pediatric endocrinologist	• This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).