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** medication specifies whether Brand or Generic is on Formulary with PA requirement	**Approval Criteria & Submission Requirements**	**Additional Considerations and Renewal Criteria**
ANY BRAND NAME DRUG REQUESTED WHEN A THERAPEUTICALLY EQUIVALENT GENERIC IS AVAILABLE.	1. To comply with amendments to COMAR 10.09.03.07 H (3), prescribers are required to complete a DHMH Medwatch form. A copy of the form must be forwarded to the Maryland Pharmacy Program for its review and approval before the Program will reimburse at the brand rate for prescriptions dispensed as "Brand Medically Necessary". 2. To request an over-ride for a "brand medically necessary" prescription, the prescriber must complete and sign the DHMH Medwatch form and include with the Prior Authorization request. Mere submission of the form is no guarantee that the request will be honored. If a generic version of the drug made by a different manufacturer is available, a trial with the other generic drug may be required before approving the brand name product. A copy of a DHMH Medwatch form and instructions are available at the links in the column to the right. 3. In the event of a market shortage for generic products, a brand drug may be approved through the duration of the anticipated drug shortage.	1. Instructions for Completing MDH Medwatch Form 2. MDH Medwatch Form
Abaloparatide **(Tymlos)**	1. Prescribed for an approved indication for use: • Treatment of postmenopausal women with osteoporosis at high risk for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. • Treatment to increase bone density in men with osteoporosis at high risk for fracture, or patients who	1. Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide, Forteo, Tymlos) during the patient's lifetime. 2. Approval Duration: up to 12 months, not intended to last longer than the

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	have failed or intolerant to other available osteoporosis therapy. 2. Patient has diagnosis of post-menopausal osteoporosis and is at high risk for bone fracture. 3. Patient is female, age ≥ 18 years of age. 4. Patient does not have increased baseline risk for osteosarcoma (e.g., Paget's disease of the bone, bone metastases, or skeletal malignancies). 5. T-score ≤ -2.5 based on BMD measurements from the lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) **OR** • History of one of the following resulting from minimal trauma: vertebral compression fracture, fracture of the hip, fracture of the distal radius, fracture of the pelvis, fracture of the proximal humerus. 6. If the criteria in #2 are not met, approval may be granted for patients with both of the following: • BMD T-score between -1 and -2.5 based on BMD measurements from lumbar spine, hip, or radius; AND • ONE of the following FRAX 10-year fracture probabilities: o Major osteoporotic fracture ≥ 20% o Hip fracture ≥ 3% 7. Documented trial of teriparatide (Forteo). 8. Documented intolerance, ineffectiveness, contraindication, and/or treatment failure of a minimum trial of 12 weeks of an oral bisphosphonate product. 9. Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g.,	final infusion completing 24 months of therapy.

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	Teriparatide, Forteo, Tymlos) during the patient's lifetime. 10. Approval Duration: up to 12 months	
acalabrutinib (**Calquence**) tablets 100mg	1. Ordered for an approved indication for use: • Treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). • Treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. 2. Confirmation that requested indication continues to carry FDA-approval. 3. Patient aged 18 years or older. 4. Prescriber agrees to monthly monitoring of CBC. 5. Medication ordered by an Oncologist. 6. Maximum Approval Duration: 12 months	1. Confirmation that medication still carries FDA-approval for intended indication. 2. Prescriber has documented monthly CBC monitoring, labs submitted. 3. No documented disease progression or unacceptable toxicity. 4. Approval Duration: 12 months
adagrasib (**Krazati)** tablets 200mg	1. Ordered for an approved indication for use: • To treat *KRAS* G12C-mutated locally advanced or metastatic non–small cell lung cancer (NSCLC), as determined by an approved test, in adults who have received at least 1 prior systemic therapy. 2. Test results confirming presence of *KRAS* G12C mutation in tumor or plasma specimens. 3. Patient has had at least one prior systemic therapy. 4. Medication ordered by an Oncologist. 5. Approval Duration: 12 months.	1. Confirmation that medication still carries FDA-approval for intended indication. 2. Prescriber has submitted documentation showing periodic monitoring of AST, ALT, alkaline phosphatase, and total bilirubin. 3. No documentation of disease progression or unacceptable toxicity. 4. Approval Duration: 12 months
Albuterol inhalers **Levalbuterol inhalers**	1. If patient has exceeded 6 inhalers per 365 days: **Note: this applies to any combination of albuterol MDIs and levalbuterol MDIs.** • Provider must show that patient has been prescribed appropriate controller therapy for indication (asthma,	

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	COPD). • Provider must provide documentation of treatment plan and patient follow-up that will occur. • Patient must be referred for follow up with MFC Case Management. • Approval for asthma indication is for one inhaler, one fill only. 2. Approval for COPD may be longer depending upon concurrent therapy and oversight by a pulmonologist.	
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. Patient ≥ 18 years of age. 3. Patient has advanced or metastatic disease. 4. Patient has anaplastic lymphoma kinase (ALK)- positive disease as detected by an approved test. 5. Medication ordered by an Oncologist. 6. Maximum Approval Duration: 12 months.	1. No documentation of disease progression or unacceptable toxicity. 2. Approval duration: 12 months
Alglucosidase alfa (**Lumizyme**)	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Allogeneic processed thymus tissue–agdc (**Rethymic**)	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Alosetron (**Lotronex**) 0.5 mg, 1 mg	1. Ordered for an approved indication for use: • For females with severe diarrhea-predominant irritable bowel syndrome (IBS) who have: ▪ Chronic IBS symptoms lasting ≥ 6 months. ▪ Had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and	1. Documentation of positive clinical response to therapy. 2. Authorization Duration: 12 months.

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	▪ Not responded adequately to conventional therapy (e.g., loperamide, antispasmodics) Diarrhea-predominant IBS is defined as severe if it includes diarrhea and one or more of the following criteria: • Frequent and severe abdominal pain/discomfort • Frequent bowel urgency or fecal incontinence • Disability or restriction of daily activities due to IBS 2. Prescribed for a female patient with a diagnosis of severe diarrhea-predominant IBS syndrome AND 3. Chronic IBS symptoms lasting at least 6 months. 4. Gastrointestinal tract abnormalities have been ruled out 5. There has been an inadequate response to conventional therapy. 6. The patient does not have a history of any of the following conditions: • Chronic or severe constipation or sequelae from constipation • Intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions • Ischemic colitis • Impaired intestinal circulation, thrombophlebitis, or hypercoagulable state • Crohn's disease or ulcerative colitis • Diverticulitis • Severe hepatic impairment 7. Dose is limited to 2 tablets per day. 8. Initial authorization is for 6 months.	
Antihemophil FVIII, B-dom del (**Xyntha**), J7185	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.

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Avalglucosidase alfa-ngpt (**Nexviazyme**), J0219	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Avapritinib (**Ayvakit**) tablets 100mg, 200mg, 300mg	1. Ordered for an approved indication for use: • Gastrointestinal Stromal Tumor (GIST) ○ Treatment of adults with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. • Advanced Systemic Mastocytosis (AdvSM) ○ 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). • Indolent Systemic Mastocytosis (ISM) Treatment of adult patients with ISM. 2. Patient age ≥ 18 years. 3. Patient has experienced treatment failure to first-line therapy. 4. Patient's platelet count is ≥ 50 x 10^9/L; AND 5. Patient meets one of the following criteria: • Diagnosis of indolent systemic mastocytosis OR • Patient has one of the following subtypes of advanced systemic mastocytosis: ○ Aggressive systemic mastocytosis; or ○ Systemic mastocytosis with an associated hematological neoplasm; or ○ Mast cell leukemia. 6. Approval Duration: 1 year	1. No evidence of disease progression. 2. Approval Duration: 12 months.

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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. Patient age ≥ 18 years. 3. A recent (less than 1 month old) platelet count must be supplied with documentation submitted. 4. Medication ordered by a Hematologist. When prescribed for thrombocytopenia in patients with chronic liver disease-associated thrombocytopenia scheduled to undergo a procedure: • Approval limited to 15 tablets per treatment course. • Approval Duration: one month. When prescribed to patients with chronic immune thrombocytopenia with insufficient response to previous treatment: • Diagnosis of chronic immune thrombocytopenia (ITP). • Patient experienced insufficient response to a previous treatment (e.g., corticosteroids, immunoglobulins, thrombopoietin receptor agonists, splenectomy). • Approval duration: 12 months.	When prescribed for thrombocytopenia in chronic liver disease with procedure scheduled: • must meet initial use criteria for each request. • Maximum approval duration: 1 month • Maximum of 15 tablets per treatment. When prescribed to patients with chronic immune thrombocytopenia with insufficient response to previous treatment: • Documented positive response to treatment. • Approval Duration: 12 months.
Axicabtagene ciloleucel (**Yescarta**) Injection, Q2041	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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	1. Patient does not show evidence of progressive disease while on Onureg therapy. 2. Approval duration: 12 months.

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	following intensive induction chemotherapy and are not able to complete intensive curative therapy. 2. Patient is not able to complete intensive curative therapy (i.e., transplant-ineligible). 3. Medication ordered by an Oncologist.	
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. 3. Approval duration: 24 weeks	
Belumosudil (**Rezurock**) tablets 200mg	1. Ordered for an approved indication for use: • 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. 3. Patient age ≥ 12 years. 4. Provider attestation: Drug specific baseline evaluation and monitoring completed (CBC/CMP including total bilirubin, AST, ALT). Patient is not pregnant and is using effective contraception, concurrent use of CYP3A inducers and proton pump inhibitors is contraindicated. 5. Life expectancy is > 6 months.	1. Prescriber attestation of continued clinical benefit. 2. Approval Duration: 6 months.

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	6. Quantity limited to 30 tablets per 30 days. 7. Approval duration: 6 months.	
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. Diagnosis of severe, uncontrolled asthma as defined by at least ONE of the following: • Poor symptom control (e.g., Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20). • Two or more bursts of systemic corticosteroids for at least 3 days each in previous 12 months. • Asthma-related emergency treatment (ER visit, hospital admission, or unscheduled OV for nebulizer or emergency treatment). • Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted. • Patient is currently dependent on oral corticosteroids for the treatment of asthma. 3. Submission of medical records documenting one of the following: • Asthma is eosinophilic phenotype as defined by baseline (pre-benralizumab treatment) peripheral blood eosinophil level ≥ 150 cells/uL within the past 6 weeks; OR • Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma. 4. Fasenra will be used in combination with ONE of the following:	1.Documentation of positive clinical response to Fasenra therapy as demonstrated by at least one of the following: • Reduction in frequency of exacerbations • Decreased utilization of rescue medications • Increase in percent predicted FEV1 from pretreatment baseline. • Reduction in severity or frequency of asthma-related symptoms • Reduction in oral corticosteroid requirements. 2. Used in combination with inhaled corticosteroid (ICS)-containing controller medication. 3. Patient is not receiving treatment in combination with ANY of the following: • Anti-interleukin-5 therapy (e.g., Cinqair (resilizumab), Nucala (mepolizumab). • Anti-IgE therapy (e.g., Xolair (omalizumab).

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	• One high-dose combination inhaled corticosteroid (ICS/LABA); OR • Combination therapy with BOTH one high dose inhaled corticosteroid and one additional asthma controller medication. 5. Patient is not receiving treatment in combination with ANY of the following: • Anti-interleukin-5 therapy (e.g., Cinqair (resilizumab), Nucala (mepolizumab)). • Anti-IgE therapy (e.g., Xolair (omalizumab). • Anti-interleukin-4 therapy (e.g., Dupixent (dupilumab). • Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., Tezspire (Tezepelumab)). 6. Medication ordered by a Pulmonologist, Immunologist, or Allergist. 7. Approval Duration: 12 months.	• Anti-interleukin-4 therapy (e.g., Dupixent (dupilumab). • Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., Tezpire (Tezepelumab)). 4. Approval Duration: 12 months.
Beremagene geperpavec (**Vyjuvek**), J3401	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
berotralstat (**Orladeyo**) capsules J3490, J8499	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Betibeglogene autotemcel (**Zynteglo**), J3590	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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	

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blinatumomab (**Blincyto**) Injection 35mcg, J9039	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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. 3. Authorization Duration: 12 months.	1.Patient does not show evidence of disease progression while on Bosulif therapy. 2. Approval Duration: 12 months.
brentuximab (**Adcetris**) injection 50mg, J9042	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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.	
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.

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burosumab-twza (**Crysvita**) injection **Not on MDH list, J0584	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
c1 Inhibitor [Human] **cinryze** sol; J0598 500 unit **haegarda** injection 2000unit, 3000unit; J0599	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
cabotegravir sodium (**Apretude ER**); suspension 600mg/3 ml	1. Ordered for an approved indication for use: • At-risk adults and adolescents weighing at least 35 kg for PrEP to reduce the risk of sexually acquired HIV-1 infection. 2. Individuals must have a negative HIV-1 test prior to initiating APRETUDE and prior to each injection. 3. Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection; AND 4. Patient is not an appropriate candidate for oral PrEP (e.g., difficulty with adherence to prior oral PrEP, significant renal disease); AND 5. Provider attests that patient demonstrates treatment readiness by BOTH of the following: 6. Patient understands the risks of missed doses. 7. Patient has ability to adhere to the required every 2 months injection and testing appointments. 8. Dosing is in accordance with FDA-approved labeling. 9. Approval Duration: 12 months	1. Patient has previously received treatment with Apretude 2. Patient has a negative HIV-1 test 3. Provider confirms that the patient will be tested for HIV-1 with each subsequent injection; and 4. Dosing is in accordance with FDA-approved labeling. 5. Approval Duration: 2 months
cabotegravir and rilpivirine extended-release (**Cabenuva**) injectable suspensions	1. Ordered for an approved indication for use: • A complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and	1. Patient has previously received treatment with Cabenuva 2. Laboratory documentation of maintained viral suppression (HIV-1 RNA

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400mg-600mg, 600mg-900mg	weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine. 2. Documentation of clinical appropriateness is required and MUST include the following: • Most recent office note (<3 months old) • Lab test showing HIV-1 RNA less than 50 copies per ml (< 3 months old). 3. Authorization Duration: 3 months	<50 copies per ml. 3. Renewal duration: 3 months.
cabozantinib (**Cabometyx)** tablets 20mg, 40mg, 60mg (**meets MFC high-cost med criteria, status pending** J8999	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
caplacizumab-yhdp (**Cablivi**) kit 11mg **Not on MDH list; C9047	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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; J1426	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Cerliponase alpha (**Brineura**) J0567	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.

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Ciltacabtagene autoleucel (**Carvykti**) **Not on MDH list; Q2056	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Coagulation factor IX (**Benefix**) recombinant; J7195	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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.	
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: **Unless patient age < 2 years of age.** 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. • 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. 2. 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.

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cysteamine bitartrate (**Procysbi**) capsules/granules; J8499	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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. • 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	**Limitations of use:** • Tafinlar is not indicated for treatments of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. • Tafinlar 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.
dalfampridine (Ampyra) ER tablets 10mg	1. Ordered for an approved indication for use: • To Improve walking in adult patients with multiple sclerosis (MS). 2. Patient age ≥ 18 years.	1. Improvement in walking speed as demonstrated by T25FW as compared with baseline. 2. Approval duration: 12 months.

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	3. Patient is currently receiving therapy with an agent to reduce progression of multiple sclerosis. 4. Patient does not have history of seizure. 5. Patient has appropriate renal function; CrCl > 50 ml/min. 6. Must be able to walk 25 feet within 8 to 45 seconds at baseline. 7. Must have a baseline gait assessment by PT within 90 days of beginning Ampyra. 8. Limited to 2 tablets per day. 9. Medication ordered by a Neurologist. 10. **Initial approval for 3 months only** after 3 months, must show improvement in walking speed must be documented to obtain continued approval.	
Daprodustat (**Jesduvroq**) tablets 1 mg, 2 mg, 4 mg, 6 mg, 8 mg	1. Ordered for an approved indication for use: • Treatment of anemia that is caused by chronic kidney disease (CKD) in adults who have been on dialysis for at least 4 months. 2. Patient age ≥ 18 years. 3. Patient on dialysis. 4. Pre-treatment hemglobin level is < 11 g/dL. 5. Serum transferrin saturation (TSAT) ≥ 20% within prior 3 months. 6. Cannot use concomitantly with other erythropoiesis stimulating agents. 7. Maximum daily dose 24 mg per day. 8. Initial approval duration: 6 months.	1. Can not increase dose more frequently than once every 4 weeks. 2. Serum transferrin saturation (TSAT) ≥ 20% within prior 3 months. 3. May not use concomitantly with other erythropoiesis stimulating agents. 4. After 24 weeks, if hemoglobin has not increased by ≥ 1 g/dL, then therapy should be discontinued and cannot be approved. 5. Approval duration: 6 months.
darolutamide (**Nubeqa**) tablets 300mg	1. Ordered for an approved indication for use: • treatment of non-metastatic castration-resistant prostate cancer (mmCRPC).	

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	• Metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel. 2. Medication ordered by an Oncologist or Urologist	
Deflazacort (**Emflaza**)	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Delandistrogene moxeparvovec (**Elevidys**); J1413	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Dextromethorphan/Quinidine (**Nuedexta**) tablets	1. Ordered for an approved indication for use: • Treatment of pseudobulbar affect (PBA) 2. Patient age ≥ 18 years. 3. Patient has been diagnosed with ONE of the following: • Amyotrophic lateral sclerosis (ALS) • Alzheimer's disease • Multiple sclerosis (MS) • Parkinson's disease • Stroke • Traumatic brain injury 4. The baseline Center for Neurologic Study-Lability Scale (CNS-LS) score must be > 13. 5. Dose must not exceed 2 capsules per day. 6. Prescribed by or in consultation with a neurologist. 1. Initial Authorization period is limited to 6 months.	1. Documentation of positive clinical response to therapy. 2. Authorization period is up to 12 months. **<u>Limitations of Use:</u>** The following indications are considered experimental and cannot be approved: • Heroin detoxification • Levodopa-induced Dyskinesia in Parkinson's Disease • Neuropathic pain • Psychosis-Related Aggression • Treatment Resistant Depression
Denosumab (**Prolia**; **Xgeva**) injection 60mg/ml	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.	1. All initial criteria met. 2. Approval Duration: 12 months. **3. NOTE: drug discontinuation conveys an increased risk of fractures and would require transition to alternative agent based on clinical guidance.**

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	• 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. Patient age ≥ 18 years of age. 3. Tried and failed, had adverse reaction to, or contraindication to formulary preferred products (e.g., alendronate, calcitonin nasal spray). 4. Patients must not be on dialysis. 5. Limited to 1 syringe every 6 months. 7. Concomitant use of calcium and vitamin D supplement required. 8. Authorization duration: 12 months.	
deutetrabenzine (**Austedo XR**) tablets titration kit 6mg, 9mg, 12mg	1. Ordered for an approved indication for use: • Chorea associated with Huntington's disease. (HD) • Tardive dyskinesia (TD) in adults. 2. Patient age ≥ 18 years. 3. Patient is not receiving other VMAT2 inhibitors (tetrabenazine or valbenazine), MAOI's or reserpine. 4. Patient does not have hepatic impairment. 5. Tardive dyskinesia: • AIMS score sheet along with the progress note must be provided for initial and renewal PA requests. 6. Huntington's disease: • Description of functional impairment, including Total Maximal Chorea (TMC) score sheet along with progress notes must be provided for both initial and	1. Prescriber attestation of continued clinical benefit and subsequent evaluation and monitoring performed. 2. TD: AIMS score must show improvement over initial score. 3. HD: TMC score must show improvement over the initial score and functional impairment must show improvement from baseline. 4. All initial criteria must be met. 5. Approval duration: 12 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is on Formulary with PA requirement	Approval Criteria & Submission Requirements	Additional Considerations and Renewal Criteria
	renewal PA requests. 7. Patient must not be suicidal or have untreated/inadequately treated depression. 8. Approval Duration: 3 months.	
Dinutuximab (**Unituxin**) J9999	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Dulaglutide (**Trulicity**) 0.75 mg, 1.5 mg, 3 mg, 4.5 mg	1. Ordered for an approved indication for use: • As an adjunct to diet and exercise to improve glycemic control in adults or pediatric patients **≥ 10 years** of age with type 2 diabetes mellitus. • In adult patients with T2DM for risk reduction of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors. 2. Use in patients aged ≥10 years to < 18 years of age with type 2 DM is limited to those who are ≥3 months post-diagnosis with an HbA_{1c} of ≥6.5% while on metformin therapy (maximized). **3. Titration dose (0.75 mg) limited to 8 pens in 365 days without medical director review.** • To continue at initiation dose, must show A1c < 8.0 **OR** TIR > 50% within the past 3 months. 4. Maximum 30-day supply per dispense. 5. A1c or TIR% report within past 3 months. 6. May not be concurrently using any other GLP1 or GLP1/GIP combination drug (e.g., Mounjaro, Rybelsus, Trulicity, Victoza, Xultrophy or Soliqua).	**Cannot be approved for indication of weight management.**

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	7. May not be concurrently taking a DPP4i (e.g., alogliptin, Januvia (sitagliptin), Tradjenta (Linagliptin), Onglyza (saxagliptin)). 8. Maximum Approval Duration: 12 months	
Eculizumab (**Soliris**) injection - 10mg/ml; J1300	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Elacestrant (**Orserdu**) **Not on MDH list; J3490; J9999	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Efgartigimod alfa-fcab (**Vyvgart**) injection; J9332 **Vyvgart Hytrulo** (efgartigimod alfa and hyaluronidase) SQ **Not on MDH list; J9334	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
elapegademase-lvlr (**Revcovi**) Injection; J3490, J3590	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Elexacaftor, ivacaftor, and tezacaftor (**Trikafta**) tablets 150mg	1. Ordered for an approved indication for use: • 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. Patient age ≥ 2 years. 4. Provider attestation of baseline and subsequent evaluation and monitoring as appropriate and indicated by the FDA-approved product labeling (provider must submit documentation).	1. Provider attestation of continued benefit without adverse drug effects. 2. Provider attestation of continued monitoring as appropriate. 3. Approval Duration: 12 months.

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	5. Provider justification of necessity of medication change if currently stable on another CF regiment and asymptomatic. 6. Medication ordered by a Pulmonologist. 7. Approval duration: 12 months.	
Elivaldogene autotemecel (**Skysona**); J3590	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Elosulfase alfa (**Vimizim**) injection; J1322	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
emtricitabine and tenofovir alafenamide (**Descovy**) tablet 200mg/25mg	1. Ordered for an approved indication for use: • Combination with other antiretroviral agents for the treatment of HIV- 1 infection in adults and pediatric patients weighing at least 35 kg. • Combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 14 kg and less than 35 kg.	Although Descovy is FDA approved for pre-exposure prophylaxis, MFC does not cover it for this indication. Descovy is covered for HIV treatment only. [MFC covers emtricitabine tenofovir disoproxil (generic Truvada) for pre-exposure prophylaxis]. Descovy is covered only if there is a documented intolerance to or medical contraindication to emtricitabine tenofovir disoproxil (generic Truvada).
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:	

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	• 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.	
Enzalutamide (**Xtandi**) capsules 40mg	1. Ordered for an approved indication for use: • castration-resistant prostate cancer for patients > 18 years of age. 2. Metastatic, castration-sensitive prostate cancer (mCRPC) for patients > 18 years of age. 3. Medication ordered by an Oncologist or urologist	Patients receiving Xtandi should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).
Epocoritamab-bysp (**Epkinly**)	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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-	

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	containing chemotherapy. 2. Medication ordered by an Oncologist.	
Etranacogene dezaparvocec (**Hemgenix**); J1411	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Etrasimod (**Velsipity**) tablets 2 mg	1.Ordered for an approved indication for use: • Treatment of ulcerative colitis (UC), in adults with moderately to severely active disease. 2. Patient is ≥ 18 years of age. 3. Patient has had a trial of one systemic agent for ulcerative colitis. (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone). Note: a trial of one biologic is considered a trial of systemic agent for ulcerative colitis. 4. Patient is not being treated concurrently with a biologic or targeted synthetic disease-modifying antirheumatic drug (DMARD) for UC. (e.g., adalimumab, infliximab, sarilumab, abatacept, rituximab, mirkizumab, ustekinumab, apremilast, ozanimod, or similar). 5. Medication is prescribed by or in consultation with a gastroenterologist. 6. Initial Approval Duration: 12 months.	1. Patient exhibits a positive clinical response by at least one objective measure from baseline. (e.g., fecal calprotectin levels, C-reactive protein, endoscopic assessment, and/or decreased utilization of corticosteroids **OR** 2. Patient has a documented clinical improvement in at least one subjective measure from baseline (e.g., decreased pain, fatigue, stool frequency, and/or rectal bleeding). 3. Approval duration: 12 months.
evinacumab-dgnb (**Evkeeza**) injection; J1305	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Exagamglogene autolemcel (**Casgevy**)	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
factor VIIa, recombinant human (**NovoSeven RT**) injection: J7189	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
factor VIII, recombinant human pegylated (**Jivi**) injection	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.

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**Not on MDH list; J7208		
Factor VIII, recombinant human with VWF fusion (**Altuviiio**); J7214	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Factor VIII recombinant human, with Fc fusion (**Eloctate**); J7205	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Fecal microbiota capsules, oral (**Vowst**)	1. Ordered for an approved indication for use: • To prevent recurrence of *Clostridioides difficile* infection (CDI) in individuals ≥ 18 years of age following antibacterial treatment for recurrent CDI. 2. Patient has had three or more episodes of CDI within previous 12 months (including most recent episode). 3. Patient has recent episode of recurrent CDI with all of the following: ○ At least 3 unformed stools per day for 2 consecutive days ○ Stool test confirming the presence of *C. difficile* toxin or toxigenic *C. difficile.* ○ An adequate clinical response (i.e., resolution of symptoms) following standard of care antibiotic therapy (e.g., vancomycin + metronidazole, fidaxomicin) 4. Patient does not have ANY of the following: ○ Known or suspected toxic megacolon and/or known small bowel ileus OR ○ Admitted to, or expected to be admitted to an ICU for medical reasons, OR ○ Absolute neutrophil count < 500 cells/mL[3]	**Limitations of Use:** VOWST is not indicated for treatment of CDI.

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	○ History of major GI surgery within 3 months before treatment start (not including appendectomy or cholecystectomy) OR ○ History of total colectomy or bariatric surgery that disrupted the GI lumen OR ○ History of active inflammatory bowel disease (e.g. ulcerative colitis, Crohn's disease, microscopic colitis) with diarrhea believed to be cause by active inflammatory bowel disease in the past 3 months. ○ History of fecal microbiota transplantation (FMT) within 3 months 5. The patient will not be using the requested agent in combination with Rebyota or Zinplava for the requested indication. 6. Provider attests that patient will follow the bowel preparation protocol outlined in the package insert. 7. Patient will not be taking a concurrent antibiotic. 8. Prescribed by or in consultation with an infectious disease specialist. 9. Approval is limited to 12 capsules per dispense; maximum of 24 capsules lifetime.	
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: 2. 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,	All long-acting opioids require prior authorization (PA). The PA request form can be access using the following links: OPIOID PRIOR AUTH FORM-MD

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	or an equianalgesic dose of another opioid. 3. Fully completed opioid PA form submitted. 4. Submission of clinical documentation from last office visit, dated within 3 months of the request. 5. If daily MME > 90, and patient does not meet exclusion criteria based on diagnosis or treatment status; a gradual tapering plan and adjuvant therapy may be required for approval. 6. Maximum approval duration is 6 months but may be reduced or denied if total daily MME > 90.	
Fezolinetant **(Veozah)**	1. Ordered for an approved indication for use: • Treatment of moderate to severe vasomotor symptoms due to menopause. 2. Patient must be a perimenopausal or post-menopausal female 3. Documentation of baseline bloodwork to evaluate for hepatic function and injury including ALT, AST and serum bilirubin (total and direct) before initiation of treatment. 4. Provider attests to monitoring liver function tests at 3-months, 6-months, and 9-months after starting therapy. 5. Patient must not have cirrhosis. 6. Patient does not have severe renal impairment (GFR < 30 ml/min) or end-stage renal disease. 7. The medication must not be used concomitantly with CYP1A2 inhibitors (e.g., acyclovir, allopurinol, amiodarone, cimetidine, clarithromycin, duloxetine, famotidine, fluoroquinolones, fluvoxamine, mexiletine, oral contraceptives, verapamil, zafirlukast, zileuton). 8. Patient must have treatment failure, intolerance, or contraindication to at least one menopausal hormone	1. All criteria listed for initial approval AND: 2. Documented improvement of symptoms 3. Documentation of liver function tests monitoring during first year of treatment with labs within previous 3 months. 4. Renewal duration: 12 months

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	therapy. 9. Initial approval period: 9 months	
finasteride/tadalafil (**Entadfi**) capsules-5mg/5mg	1. Ordered for an approved indication for use: • Treatment of signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks. 2. Patient age ≥ 18 years. 3. Adequate trial (30 days) and inadequate response, or intolerance to, at least two preferred BPH agents. 4. History of finasteride use in the past one year. 5. No previous full course of therapy with Entadfi. 6. No concomitant use of organic nitrate, either regularly or intermittently. 7. No concomitant use of guanylate cyclase stimulators (e.g., Riociguat (Adempas®). 8. CrCl ≥ 50 ml/minute. 9. Quantity limit: 1 capsule per day 10. Approval Duration: 26 weeks of therapy.	**Renewal Criteria: not applicable. Lifetime treatment duration is limited to 26 weeks.**
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 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-	1. All initial criteria for approval; AND 2. Dosing appropriate based on 4-week potassium laboratory check. • 20 mg daily if Potassium ≤ 4.8 • 10 mg daily if K+ between 4.8-5.5 • Interrupt therapy if K+ > 5.5, may restart at 10 mg daily when potassium is ≥ 5.0 3. Approval duration: 12 months

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	Inhibitor or ARB unless intolerant to or contraindicated. 3. Failed trial or contraindication to one formulary SGLT2i. 4. Approval duration: 3 months	
Fosdenopterin (**Nulibry**) injection 9.5mg; J3490	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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. Patient age ≥ 18 years. 3. Patient is not on hemodialysis. 4. Max dose: 150 mg 2 times daily with goal platelets ≥ 50 x 10^9/mmcp/L. 5. Medication ordered by a Hematologist. 6. Initial Approval Duration: 3 months.	1. Documentation of improved symptoms and attestation of lab parameters. 2. Renewal approval duration: 12 months
Furosemide subcutaneous device (**Furoscix**)	1. Ordered for the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure. 2. Patient has CrCl > 30 ml/min OR eGFR > 20 ml/min 3. Patient has been stable and is refractory to at least one of the following loop diuretics, at up to maximally indicated doses: ○ Furosemide oral tablets; 40-160 mg/day ○ Torsemide oral tablets; 50-100 mg/day ○ Bumetanide oral tablets; 3-10 mg/day 4. Documentation that member is a candidate for parenteral diuresis outside of the hospital, as defined by all of the following: ○ Oxygen saturation ≥ 90% on exertion ○ Respiratory rate < 24 breaths per minute ○ Resting heart rate < 100 beats per minute	**Limitations of Use:** • Furoscix is not indicated for emergency situations or in patients with acute pulmonary edema. • The On-Body Infusor will deliver only an 80-mg dose of Furoscix. • Patients must meet initial approval criteria for each request

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	○ Systolic blood pressure > 100 mmHg 5. Patient does not have anuria. 6. Patient does not allergy to medical adhesives or furosemide. 7. Patient does not have hepatic cirrhosis or ascites. 8. Dose does not exceed 80 mg (1 cartridge) per day. 9. Prescribed by cardiologist. 10. Limited to 8 kits every 30 days 11. Approval requires that patient is referred for MFC Case Management 12. Authorization Duration: 3 months	
gabapentin extended-release (Gralise) tablets 300mg, 600mg **note, this is not the same as gabapentin enacarbil which is non-formulary.*	1. Ordered for an approved indication for use: • the management of Postherpetic Neuralgia (PHN). Not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect dosing frequency. 2. Patient age ≥ 18 years. 3. Patient CrCl > 30 ml/min; patient is not on hemodialysis. 4. Dose does not exceed 1800 mg per day. 5. Approval Duration: 12 months	1. Initial criteria continue to be met. 2. Approval duration: 12 months.
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	
Givosiran (**Givlaari**); J0223	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
glecaprevir and pibrentasvir (**Mavyret**) tablets 100mg-40mg	1. Ordered for an approved indication for use: • treatment of adult and pediatric patients 3 years and older with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infections without cirrhosis or with compensated cirrhosis (Child-Pugh A).	For a full listing of all Prior Authorization requirements, please click the link below: HEPC CRITERIA & PRIOR AUTH FORM-MD

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	• treatment of adult and pediatric patients 3 years and older, weighing at least 45 kg with HCV genotype 1 infection, previously treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. 2. Submission of a completed Hepatitis C Prior Authorization form and supporting documentation. 3. Patient treatment plan aligns with MDH Clinical Criteria recommendations. 4. Approval Duration: limited to 12 weeks.	• Contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation. • Contraindicated with coadministration of atazanavir or rifampin. Concomitant use with carbamazepine, efavirenz containing regimens and St. John's wort may decrease concentrations of Mavyret and is not recommended.
Glofitamab (**Columvi**); J9286	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
glycerol phenylbutyrate (**Ravicti**) Liquid; J8499	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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. 4. Approval Duration: 12 months.	• 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.)
Golodirsen (**Vyondys 53**) injection; J1429	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Goserelin (**Zoladex**) implant 3.6mg, 10.8mg	1. Ordered for an approved indication for use:	**Endometriosis:** • Can not be administered for more

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	• palliative treatment of advanced carcinoma of the prostate. (3.6 mg and 10.8 mg) • in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. (3.6 mg and 10.8 mg) • management of endometriosis (3.6 mg) • palliative treatment of advanced breast cancer in pre- and peri-menopausal women. (3.6 mg) • to cause endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. (3.6 mg) • management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. **Endometriosis:** 1. Contraindication, intolerance, or failure of initial treatment to BOTH of the following: • Oral contraceptives or depot medroxyprogesterone; AND • Non-steroidal anti-inflammatory drugs; OR • Patient has had surgical ablation to prevent recurrence. 2. Approval Duration: Limited to 6 months. **Endometrial Thinning/Dysfunctional Uterine Bleeding:** • For use prior to endometrial ablation; AND • Other causes of symptoms of bleeding are ruled out; AND • Patient has been prescribed the 3.6 mg implant; and • Approval duration is for a maximum of 2 depots. **Fertility Preservation:** Clinical studies do not support use for this indication, and cryopreservation is clinically preferred. Please attempt to redirect to cryopreservation. Only clinically appropriate as a potential	than 6 months lifetime maximum. **Endometrial thinning:** • Can not be administered for more than 6 months lifetime maximum. **Fertility Preservation:** • Patient currently receiving GnRH analog therapy for purpose of fertility preservation; and • Patient continues to receive a cytotoxic agent associated with primary ovarian insufficiency; and • Authorization duration: 12 months **Gender Affirming Care – Adolescents OR Gender Affirming Care – Transgender Adults:** • Approval Duration: 12 months.

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	adjunct to cryopreservation. May be medically necessary for treatment of fertility preservation when both of the following criteria are met: • Patient is a pre-menopausal female. • Patient is receiving a cytotoxic agent associated with causing primary ovarian insufficiency, e.g., cyclophosphamide, procarbazine, vinblastine, cisplatin. • Approval Duration: 12 months. **Gender Affirming Care – Adolescents** • Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy. • Approval Duration: 12 months **Gender Affirming Care – Transgender Adults** • Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy. • Approval Duration: 12 months	

Histrelin implant (**Supprelin LA**) Kit 50mg	1. Ordered for an approved indication for use:
	Treatment of children with central precocious puberty (CPP):
	• Onset of secondary sexual characteristics in one of the following:
	  ○ Females ≤ 8 years of age; or
	  ○ Males ≤ 9 years of age.
	• Confirmation of diagnosis as defined by one of the following:
	  • Pubertal basal level of luteinizing hormone (based on laboratory reference ranges); OR
	  • A pubertal luteinizing hormone response to a GnRH stimulation test; OR
		Central Precocious Puberty:
		• Patient is currently receiving therapy for central precocious puberty; and
		• Documented positive response to therapy.
		• Patient is currently younger than the appropriate age for the onset of puberty, i.e., Females < 11 years of age, Males < 12 years of age.
		• Approval Duration: 12 months.
		Fertility Preservation:
		• Patient currently receiving GnRH analog therapy for purpose of

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	• Bone age advanced one year beyond chronological age • Medication ordered by pediatric endocrinologist. • Approval Duration: 12 months. **Fertility Preservation:** May be medically necessary for treatment of fertility preservation when both of the following criteria are met: • Patient is a pre-menopausal female. • Patient is receiving a cytotoxic agent associated with causing primary ovarian insufficiency, e.g., cyclophosphamide, procarbazine, vinblastine, cisplatin. • Approval Duration: 12 months. **Gender Affirming Care – Adolescents** • Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy. • Approval Duration: 12 months **Gender Affirming Care – Transgender Adults** • Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy. • Approval Duration: 12 months	fertility preservation; and • Patient continues to receive a cytotoxic agent associated with primary ovarian insufficiency; and • Authorization duration: 12 months **Gender Affirming Care – Adolescents OR Gender Affirming Care – Transgender Adults:** Approval Duration: 12 months.
Human plasma-derived plasminogen (**Ryplazim**); J2998	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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 • Adult and pediatric patients ≥ 1 year of age with chronic graft versus host disease after failure of one or more lines of systemic therapy.	**Limitations for use:** • Indications for Mantle Cell Lymphoma and Marginal Zone Lymphoma were voluntarily withdrawn, April 2023 **New dose modification guidelines adopted in December 2022:** Therapy should be withheld for any new

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	2. Medication ordered by an Oncologist. 3. Quantity limit: 4 tablets per day.	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.
Icosapent ethyl (E-EPA) (Vascepa)	1. Ordered for an approved indication for use: • As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) AND ○ Established cardiovascular disease OR ○ Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease • As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. 2. Age ≥ 45 years 3. Diagnosis of hypertriglyceridemia (pre-treatment TG level ≥ 150 mg/dl) AND 4. Patient is considered high or very high risk for cardiovascular disease (CVD) as evidenced by **one** of the following: ○ Acute coronary syndrome ○ History of myocardial infarction ○ Stable or Unstable angina ○ Coronary or other arterial revascularization	**Renewal Criteria:** • Used for cardiovascular risk reduction. • Documentation of positive clinical response to therapy • Patient is receiving maximally tolerated statin therapy. • Approval duration: 12 months

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is on Formulary with PA requirement	Approval Criteria & Submission Requirements	Additional Considerations and Renewal Criteria
	○ Stroke ○ Transient ischemic attack ○ Peripheral arterial disease 5. **<u>OR, if not the criteria in #4:</u>** ○ Type 2 Diabetes diagnosis **AND TWO of the following:** ○ Men ≥ 55 years and women ≥ 65 years ○ Cigarette smoker or stopped within past 3 months ○ Hypertension diagnosis ○ HDL-C ≥ 40 mg/dL for men or ≥ 50 mg/dL for women ○ High-sensitivity C-reactive protein > 3.0 mg/L ○ Creatinine clearance > 30 and < 60 ml/min ○ Retinopathy ○ Micro- or macro-albuminuria ○ Ankle-brachial index (ABI), 0.9 without symptoms of intermittent claudication 6. Patient has received at least 12 consecutive weeks of high-intensity statin therapy (Atorvastatin 40-80 mg; rosuvastatin 20-40 mg) **OR** <u>BOTH OF THE FOLLOWING:</u> • Intolerance to high-intensity statin as evidenced by ≥ 2 weeks of myalgia and/or myositis AND • at least 12 consecutive weeks of low/moderate intensity statin therapy 7. Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy, or contraindication or intolerance to ezetimibe OR has LDL-C less than 100 mg/dL while on maximally	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is on Formulary with PA requirement	Approval Criteria & Submission Requirements	Additional Considerations and Renewal Criteria
	tolerated statin therapy. 8. Approval duration: 12 months.	
idecabtagene vicleucel (**Abecma**) injection **Not on MDH list; Q2055	**USE MFC High-Cost Medication PA Criteria**	• Requires MFC Physician or Pharmacist review prior to approval.
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. 5. Ordered through a Specialty Pharmacy	**Limitations of use:** • 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.
idursulfase (**Elaprase**) injection 6mg/3ml **Not on MDH list; J1743	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
imiglucerase (**Cerezyme**) injection 400 unit **Not on MDH list; J1786	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is on Formulary with PA requirement	Approval Criteria & Submission Requirements	Additional Considerations and Renewal Criteria
	infections with malignancy (e.g., B-cell chronic lymphocytic leukemia) or primary humoral immunodeficiency disorders. 2. Medication ordered by an Immunologist.	
interferon gamma-1b (**Actimmune)** injection; J9216	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Ipilimumab (**Yervoy**) injection 50mg, 200mg Not on MDH list; J9228	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
ivacaftor (**Kalydeco**) Packets 25mg, 50mg, 75mg Tablets 150mg	1. Ordered for an approved indication for use: • Treatment of cystic fibrosis (CF) in patients ≥ 4 months who have one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or *in vitro* assay data. 2. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. 3. Patient is not homozygous in the CFTR gene. 4. Patient age ≥ 4 months. 5. Provider attestation of baseline and subsequent evaluation and monitoring as appropriate and as indicated in the FDA-approved labeling (provider must submit documentation). 6. Provider justification of necessity of medication change if currently stable on another CF regimen and asymptomatic. 7. Medication ordered by Pulmonologist. 8. Approval Duration: 12 months.	1. Provider attestation of continued benefit without adverse drug effects. 2. Provider attestation of continued monitoring as appropriate. 3. Approval Duration: 12 months.
Ivermectin (Stromectol) tablets	1. Ordered for an approved indication for use:	**Limitations for use:**

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3mg	• Strongyloidiasis of the intestinal tract (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis. • Onchocerciasis due to the nematode parasite Onchocerca volvulus. 2. **Cannot be used for outpatient COVID-19 treatment**.	• 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: • Acute Myeloid Leukemia (AML), newly diagnosed who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy. • Relapsed or refractory AML • Locally Advanced or Metastatic Cholangiocarcinoma who have been previously treated. 2. Medication ordered by an Oncologist	
Lanadelumab-flyo (**Takhzyro**) injection 300mg/2ml; J0593	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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)**	1. Ordered for an approved indication: • Treatment of Alzheimer disease; to be initiated in patients	**Renewal Criteria:**

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200 mg/2 ml Intraveneous solution	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. 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.	1. Patient continues to meet criteria for initial approval. 2. Absence of unacceptable toxicity from drug AND 3. 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 4. 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.
Lenacapavir (**Sunlenca**)	1. Ordered for an approved indication for use; treatment of multi-drug resistant human immunodeficiency virus (HIV) in	1. Patient has previously received treatment with Sunlenca.

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	adult patients. 2. Confirmed diagnosis of HIV-1 infection. 3. Provider attestation that patient has multi-drug resistant HIV-1 infection. 4. Provider confirms that patient has been prescribed an optimized background antiretroviral regimen, containing at least one antiretroviral agent that demonstrates full viral sensitivity or susceptibility. 5. Dosing is in accordance with FDA-approved prescribing information. 6. Maximum Approval Duration: 12 months.	2. Provider confirms that patient has achieved a clinically significant viral response to therapy. 3. Provider confirms that patient will continue to take an optimized background antiretroviral regimen in combination with Sunlenca. 4. Maintenance dosing is in accordance with FDA-approved prescribing guidance. 5. Authorization Duration: 12 months.
Leniolisib (**Joenja**); J8499	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Leuprolide **Eligard Injection 45mg** **Lupron Depot Injection 3.75mg, 7.5mg, 11.25mg, 22.5mg, 30mg, 45mg** **Lupron Depot-PED Injection 7.5mg, 11.25mg 15mg, 30mg, 50mg**	1.Ordered for an approved indication for use: • palliative treatment of advanced carcinoma of the prostate. • in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. • management of endometriosis • palliative treatment of advanced breast cancer in pre- and peri-menopausal women. • to cause endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. • management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. **Endometriosis:**	**Endometriosis:** • Can not be administered for more than 6 months lifetime maximum. **Fertility Preservation:** • Patient currently receiving GnRH analog therapy for purpose of fertility preservation; and • Patient continues to receive a cytotoxic agent associated with primary ovarian insufficiency; and • Authorization duration: 12 months **Gender Affirming Care – Adolescents OR Gender Affirming Care – Transgender Adults:** • Approval Duration: 12 months. **Oncology Indications:**

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	1. Contraindication, intolerance, or failure of initial treatment to BOTH of the following: • Oral contraceptives or depot medroxyprogesterone; **AND** • Non-steroidal anti-inflammatory drugs; **OR** • Patient has had surgical ablation to prevent recurrence. • Approval Duration: Limited to 6 months. **Fertility Preservation:** May be medically necessary for treatment of fertility preservation when both of the following criteria are met: • Patient is a pre-menopausal female. • Patient is receiving a cytotoxic agent associated with causing primary ovarian insufficiency, e.g., cyclophosphamide, procarbazine, vinblastine, cisplatin. • Approval Duration: 12 months. **Gender Affirming Care – Adolescents** • Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy. • Approval Duration: 12 months **Gender Affirming Care – Transgender Adults** • Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy. • Approval Duration: 12 months **Oncology Indications:** • Prescribed by a hematologist/oncologist AND • The requested use is supported by the National Comprehensive Cancer Network (NCCN) clinical practice guidelines with a recommendation category level of 1 or 2A.	• Patient has positive clinical response and absence of unacceptable toxicity **Uterine Leiomyomata (Fibroids) –** • Can not be administered for greater than 3 months.

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	Oncology Approval duration: • Prostate cancer: up to 90 mg per 12 months. • Breast/ovarian cancer: up to 22.5 mg per 6 months; approval duration is up to 6 months. **Uterine Leiomyomata (Fibroids) –** • Lupron Depo formulation prescribed • Prescribed for use prior to surgery to reduce the size of fibroids to facilitate surgical procedure; OR • For the treatment of uterine leiomyomata related anemia; AND • Patient do not respond to iron therapy of one month duration; AND • For use prior to surgery • Approval Duration: 3 months total.	
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). 3. Approval Duration: 12 months.	
lisocabtagene maraleucel (**Breyanzi**) injection **Not on MDH list; Q2054	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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-	1. Meets all initial approval criteria. 2. Attestation of continued benefit without significant adverse drug effects. 3. Laboratory data (full lipid panel) submitted to support continued use.

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	HDL-C in patients with homozygous familial hypercholesterolemia. 2. Patient age ≥ 18 years. 3. Documentation of baseline LFTs (including ALT, AST, alkaline phosphatase and total bilirubin) prior to initiation of treatment. 4. Prescriber attestation that a low-fat diet (<20% of energy from fat) has been initiated. 5. Prior trial, failure, insufficient response, and/or documented intolerance to preferred lipid lowering treatments including statin + ezetimibe, or Praluent. 6. Medication ordered by a REMS registered cardiologist or endocrinologist. 7. Approval Duration: 12 months.	4. Renewal Duration: 12 months
Loncastuximab tesirine-lpyl (**Zynlonta**) solution **Not on MDH list; J9359	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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.
Lotilaner 0.25% solution (**Xdemvy**)	1. Ordered for an approved indication for use: • Treatment of Demodex blepharitis in adults 2. Patient aged ≥ 18 years of age. 3. Diagnosis of Demodex blepharitis based on presence of clinical signs such as collarettes, lid erythema, madarosis and/or misdirected lashes.	At this time, there is no clinical evidence to show benefit beyond 6 weeks of treatment.

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	4. Documentation indicating that the patient has symptoms attributable to Demodex blepharitis in at least one eye (e.g., itching, foreign body sensation, burning, etc.); and 5. Patient has not undergone more than 1 6-week treatment in the previous 12 months. 6. Written by or in consultation with an ophthalmologist or optometrist. 7. Approval limited to 1 bottle (10 ml) per 12 months.	
Lumacaftor/ivacaftor (**Orkambi**) Granules 75mg-94mg, 100mg-125mg, 150mg-188mg Tablets 100mg-125mg, 200mg-125mg	1. Ordered for an approved indication for use: a. 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. Patient age ≥ 2 years. 4. Provider justification of necessity of medication change if currently stable on another CF regimen and asymptomatic. 5. Patient has not undergone an organ transplant. 6. Medication ordered by Pulmonologist. 7. Approval Duration: 12 months	1. Provider attestation of continued benefit without adverse drug effects. 2. Provider attestation of continued monitoring as appropriate. 3. Renewal Duration: 12 months.
lumasiran (**Oxlumo**) injection 94.5mg/0.5ml; J0224	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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. 2. Patient age ≥ 18 years.	**Each treatment course requires a separate PA request. Initial criteria applies to all requests.**

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	3. Not being ordered for patient with chronic liver disease to normalize platelet counts. 4. Dose: 3 mg (1 tablet) daily for 7 days. 5. Approval Duration: one treatment course.	
Maralixibat (**Livmarli**); J8499	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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. 2. Medication is not prescribed in conjunction with ganciclovir or valganciclovir. 3. Medication is prescribed by or in consultation with a hematologist, infectious disease specialist, oncologist or physician affiliated with a transplant center. 4. Approval Duration: not to exceed 8 weeks.	If a patient has a paid claim in the MFC system for ganciclovir, valganciclovir, cidofovir, or foscarnet, Livtencity will process at the pharmacy without PA. If there is no evidence of a paid claim for ganciclovir, valganciclovir, cidofovir, or foscarnet, a PA is required, and documentation of previous use of one of these medications should be submitted.
Mepolizumab (**Nucala**) Injection 40mg/0.4ml, 100mg, 100mg/ml	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. • Add-on treatment of adult patients with chronic rhinosinusitis with nasal polyps. • Treatment of eosinophilic granulomatosis with polyangiitis (EGPA) in adults. • 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.	

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	2. Medication ordered by an Allergist or Pulmonologist.	
Mecasermin (**Increlex**) J2170	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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. 2. Completion of an opioid prior authorization form. 3. Submission of clinical documentation from last office visit, dated within 3 months of the request. 4. If daily MME > 90, and patient does not meet exclusion criteria based on diagnosis or treatment status; a gradual tapering plan and adjuvant therapy may be required for approval. 5. Maximum approval duration is 6 months but may be reduced or denied if total daily MME > 90.	All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-MD **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.
Metreleptin (**Myalept**) injection; J3490, J3590	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Mifepristone (Korlym) tablets Korlym-300mg ONLY **Not on MDH list; J8499	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Mirabegron (**Myrbetriq**) tablets 25mg, 50mg	1. Ordered for an approved indication for use:	**Limitations for use:**

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	• 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) 6. Approval Duration: 12 months.	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.
Mirikizumab (**Omvoh**) injection 100 mg/1 ml	1. Ordered for an approved indication for use: • Maintenance treatment of ulcerative colitis (UC) in adults with moderate to severe active disease. 2. Patient is ≥ 18 years of age, and **3.** Patient has had a trial of one systemic agent for UC (e.g., 6-MP, azathioprine, cyclosporine, tacrolimus or a corticosteroid. Note that trial of a mesalamine product does <u>not</u> count as a systemic therapy for UC) **OR** 4. Patient has both: • Pouchitis AND • Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema 5. Patient is not being treated concurrently with a biologic or targeted synthetic disease-modifying antirheumatic drug (DMARD) for UC. (e.g., adalimumab, infliximab, sarilumab, abatacept, rituximab, ustekinumab, apremilast, ozanimod, or	1. Patient exhibits a positive clinical response by at least one objective measure from baseline. (e.g., fecal calprotectin levels, C-reactive protein, endoscopic assessment, and/or decreased utilization of corticosteroids **OR** 2. Patient has a documented clinical improvement in at least one subjective measure from baseline (e.g., decreased pain, fatigue, stool frequency, and/or rectal bleeding). 3. Approval duration: 12 months.

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	similar). 6. Medication is prescribed by or in consultation with a gastroenterologist. 7. Initial Approval Duration: 6 months; if patient has already received > 6 months of subcutaneous therapy, then approval duration is 12 months.	
Mirvetuximab (**Elahere**) **Not on MDH list; J9063	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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. Patient is not homozygous for the c.1436G>A (p.R479H) variant. 4. Patient does not have two non-missense variants (without the presence of another missense variant) in the PKLR gene. 5. Baseline hemoglobin less than or equal to 10 g/dL. 6. Prescribed by or in consultation with a Hematologist. 7. Initial Approval Duration limited to 6 months.	1. Documentation of positive clinical response to Pyrukynd therapy based on ONE of the following: 8. Patient has been on Pyrukynd for > 52 weeks and has maintained positive clinical response to therapy; OR 9. Reduction in transfusions of ≥ 33% in the number of red blood cell units transfused during the initial 24-week period compared with the patient's historical transfusion burden; OR 10. A ≥ 1.5 g/dL increase in hemoglobin from baseline sustained at 2 or more scheduled assessments 4 weeks apart during the initial 24-week period without any transfusions. 11. Authorization duration: 12 months 12. If documentation does not provide evidence of positive clinical response to Pyrukynd therapy, allow for dose titration with discontinuation of

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		therapy. In this case, authorization duration is for 4 weeks.
Mogamulizumab-kpkc (**Poteligeo**) injection **Not on MDH list; J9204	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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. 2. Completion of opioid prior authorization form. 3. Submission of clinical documentation from last office visit, dated within 3 months of the request. 4. If total daily MME > 90, and patient does not meet exclusion criteria based on diagnosis or treatment status; a gradual tapering plan and adjuvant therapy may be required for PA renewal. 5. Maximum approval duration is 6 months but may be reduced or denied if total daily MME > 90.	All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: **OPIOID PRIOR AUTH FORM-MD**
Mosunetuzumab-axgb (**Lunsumio**), **J9350**	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Nanoparticle albumin bound sirolimus (**Fyarro**) **Not on MDH list; J9331	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Naxitamab (**Danyelza**); J9348	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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.	1. All initial criteria are met. 2. Documentation of positive clinical response to Ofev therapy. 3. Approval Duration: 12 months

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	• To slow the rate of decline in pulmonary function in patients with systemic sclerosis associated interstitial lung disease (SSc-ILD). 2. Documentation that patient does not smoke. 3. Medication ordered by a pulmonologist. 4. Authorization Duration: 12 months.	
Niraparib (**Zejula**) tablets 100mg, 200 mg, 300 mg	1. Ordered for an approved indication for use: • maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy. 2. 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.	Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA.
Nitisinone (Orfadin) capsules **Orfadin** brand preferred for 20 mg dose. **Not on MDH list; J8499	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval. ORFADIN PRIOR AUTH FORM
Nusinersen (**Spinraza**); J2326	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Ocrelizumab (**Ocrevus**) injection 300mg/10ml	1. Ordered for an approved indication for use: • Primary progressive multiple sclerosis (MS); • Relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. 2. Age is ≥18 years and <55 years of age.	1. All initial criteria continue to be met. 2. Documentation of positive clinical response to Ocrevus therapy. 3. Approval duration: 12 months.

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	3. Patient has one of the following: • Ineffective treatment response due to continued clinical relapse, intolerance, or contraindication to two or more MS drugs; • Patient is not a candidate for any other preferred first-line treatments due to MS severity; • Patient is at higher risk of poor long-term outcome (spinal cord involvement, highly active disease, poor relapse recovery), as determined by their neurologist. 4. Not being used in combination with other immune-modulating or immunosuppressive therapies, including immunosuppressant doses of corticosteroids. 5. Not being used in combination with another MS disease modifying agent [Avonex, Betaseron, dalfampridine, dimethyl fumarate, Extavia, fingolimod, glatiramer, glatopa, Kesimpta, Mayzent, Rebif, teriflunomide, Vumerity]. 6. Medication ordered by a neurologist. 7. Approval duration: 12 months.	
Odevixibat (**Bylvay**); J8499	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Olipudase alfa- (**Xenpozyme**); J0218	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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: • Diabetes mellitus in persons requiring insulin. 2. Medication ordered by an Endocrinologist or practitioner who	1. Office visit notes from last two encounters with prescribing provider support of Medical Necessity.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is on Formulary with PA requirement	Approval Criteria & Submission Requirements	Additional Considerations and Renewal Criteria
	specializes in diabetes. 3. Office visit notes from last two encounters with prescribing provider to support Medical Necessity. 4. Evidence of face-to-face visit within past 3 months. 5. Documentation of uncontrolled diabetes on multiple daily injections. 6. Documentation that patient has been educated on device. 7. Documentation of self-blood-glucose monitoring (30-day blood glucose log or CGM report). 8. May not be used if patient needs to make insulin adjustments of less than 2-unit increments due to risk of hypoglycemia. 9. Approval Duration: 12 months.	2. Prescribed by Endocrinologist or practitioner who specializes in diabetes with evidence of face-to-face visit within the past 3 months. 3. Documentation of self-blood glucose monitoring (30-day blood glucose log or CGM report). 4. Approval duration: 12 months.
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.	**<u>Limitations for Use:</u>** • **Botox will NOT be approved for cosmetic purposes** • Safety and effectiveness have <u>not</u> 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.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is on Formulary with PA requirement	Approval Criteria & Submission Requirements	Additional Considerations and Renewal Criteria
	• 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.	
Onasemnogene abeparvovec-xioi (**Zolgensma**) injection; J3399	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Opioids IR: ER:	Ordered for an approved indication for use: 1. The management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 2. Completion of the opioid prior authorization form. 3. Submission of supporting clinical documentation for the last office visit, dated within previous 3 months. 4. If daily MME > 90, and patient does not meet exclusion criteria based on diagnosis or treatment status; a gradual tapering plan and adjuvant therapy may be required for approval. 5. Maximum approval duration is 6 months but may be approved for a shorter duration if total daily MME > 90.	The Opioid PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-MD
oxycodone ER and IR tablets	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.	OPIOID PRIOR AUTH FORM-MD

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is on Formulary with PA requirement	Approval Criteria & Submission Requirements	Additional Considerations and Renewal Criteria
	2. Completion of the opioid prior authorization form. 3. Submission of supporting clinical documentation for last office visit, dated within previous 3 months. 4. If daily MME > 90, and patient does not meet exclusion criteria based on diagnosis or treatment status; a gradual tapering plan and adjuvant therapy may be required for approval. 5. Maximum approval duration is 6 months but may be reduced or denied if total daily MME > 90.	
oxycodone/APAP 5-325mg/5ml Solution (Roxicodone)	1. Ordered for an approved indication for use: • management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 2. Completion of the opioid prior authorization form. 3. Submission of supporting clinical documentation for last office visit, dated within previous 3 months. 4. If daily MME > 90, and patient does not meet exclusion criteria based on diagnosis or treatment status; a gradual tapering plan and adjuvant therapy may be required for approval. 5. Maximum approval duration is 6 months but may be reduced or denied if total daily MME > 90.	OPIOID PRIOR AUTH FORM-MD
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: • management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 2. Completion of opioid prior authorization form. 3. Submission of clinical documentation from last office visit, dated within 3 months of the request.	All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-MD

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	4. If daily MME > 90, and patient does not meet exclusion criteria based on diagnosis or treatment status; a gradual tapering plan and adjuvant therapy may be required for approval. 5. Maximum approval duration is 6 months but may be reduced or denied if total daily MME > 90.	
Ozanimod (**Zeposia**) capsules 7-day starting pack 0.92 mg capsules; Capsule starting kit which includes 0.23 mg, 0.46 mg, and 0.92 mg capsules.	1. Ordered for an approved indication for use: • Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. • Treatment of moderately to severely active ulcerative colitis (UC) in adults. 2. Patient has not received a manufacturer supplied sample or any form of assistance from the manufacturer coupon or sample card as a means to establish as a current user of Zeposia. 3. Baseline evaluation of the following labs before starting treatment: CBC, ECG, LFT's 4. No history (within previous 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure. 5. No severe untreated sleep apnea 6. Zeposia will not be used in combination with either a biologic DMARD (e.g. adalimumab, Simponi (golimumab), Stelara (ustekinumab) OR a Janus kinase inhibitor (e.g. Xeljanz (tofacitinib), Rinvoq (upadacitinib), OR other S1P agent (e.g., Velsipity (etrasimod). Note: Ampyra and Nuedexta are not disease modifying. **7. <u>Additional Criteria for Multiple Sclerosis</u>**	**<u>Renewal Criteria:</u>** • Initial approval criteria continue to be met. • Patient is not receiving in combination a biologic DMARD or janus kinase inhibitor **<u>Multiple Sclerosis:</u>** • Patient experiencing disease stability or improvement while receiving Zeposia. • Maximum approval Duration: 12 months **<u>Ulcerative Colitis:</u>** • Patient has achieved or maintained remission. • Patient shows positive clinical response as evidenced by low disease activity or improvement in signs/symptoms of the condition when there is improvement in any ONE of the following from baseline:

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	• Prescribed by or within consultation with a neurologist. **8. <u>Additional Criteria for Ulcerative Colitis</u>** • Diagnosis of moderately to severely active UC • Patient has failed, contraindication or intolerance to a course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, or 6-mercaptopurine) OR • Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of UC as documented by claims history or submission of medical records. (e.g., adalimumab, Entyvio (vedolizumab), Stelara (ustekinumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)). **AND** • Patient has trialed and failed treatment with Velsipity (etrasimod). • Prescribed by or in consultation with a gastroenterologist. 9. Approval duration: 12 months	○ Stool frequency ○ Rectal bleeding ○ Urgency of defecation ○ C-reactive protein (CRP) ○ Fecal calprotectin (FC) ○ Endoscopic appearance of the mucosa ○ Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity (UCEIS, Mayo score) • Approval Duration: 12 months
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	

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Patisiran (**Onpattro**) Solution 10mg/5ml **Not on MDH list; J0222	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Pegcetacoplan (**Empaveli**) injection 1080mg **Not on MDH list; J3490, J3590	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
pegloticase (**Krystexxa**) injection 8mg/ml; J2507	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Pegunigalsidase alfa (**Elfabrio**) **Not on MDH list; J2508	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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.
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	
Pretomanid tablets	1. Ordered for an approved indication for use:	**Limitations of Use:**

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200mg	• as part of a combination regimen with bedaquiline and linezolid for the treatment of adults with pulmonary extensively drug resistant (XDR), treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB). 2. Medication ordered by a Pulmonologist.	• Pretomanid is not indicated in patients with drug-sensitive TB. • Not indicated Latent infection due to Mycobacterium tuberculosis or extra-pulmonary infection due to Mycobacterium tuberculosis. • TB with known resistance to any component of the combination therapy. • Safety and effectiveness has not been established for its use in combination with drugs other than bedaquiline and linezolid. • Risk for significant drug-drug interactions.
Ravulizumab-cwvz (**Ultomiris**) injection **Not on MDH list; J1303	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
ripretinib (**Qinlock**) tablet 50mg	1. Ordered for an approved indication for use: • the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib. 2. Medication ordered by Oncologist	
Rozanolixizumab (**Rystiggo**); J3333	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Rucaparib (**Rubraca**) tablets 200mg, 250mg, 300mg	1. Ordered for an approved indication for use: • **Ovarian Cancer** ○ for the maintenance treatment of adult patients with	

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	recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. ○ for the treatment of adult patients with 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. • **Prostate Cancer** • 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	
Ruxolitinib (**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. • 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.	**Limitations of Use:** • Avoid concomitant use with fluconazole doses greater than 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.

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	2. Medication ordered by Hematologist or Oncologist.	
Ruxolitinib (**Opzelura**) For systemic Ruxolitinib (**Jakafi**) see above	1. Ordered for an approved indication for use: • The topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in Non-immunocompromised patients ≥ 12 years of age whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. • The topical treatment of nonsegmental vitiligo in patients ≥ 12 years of age. 2. Patient is ≥ 12 years of age. **3. <u>Atopic Dermatitis:</u>** • Patient has inadequate treatment response, intolerance, or contraindication to at least two classes of formulary drugs (medium/high potency corticosteroid and a topical calcineurin inhibitor (e.g., tacrolimus or pimecrolimus) Adequate trial is considered 2 months AND • Treatment failure, intolerance, or contraindication to Eucrisa. • The drug will not be applied to affected areas greater than 20% of body surface area (BSA). **<u>Nonsegmental Vitiligo:</u>** • The drug will not be applied to affected areas greater than 10% of body surface area (BSA). • Patient has inadequate treatment response, intolerance, or contraindication to at least two classes of formulary drugs (medium/high potency corticosteroid and a topical calcineurin inhibitor (e.g.,	**1.** Documented positive clinical response to therapy. 2. Patient is not receiving Opzelura in combination with another biologic medication (e.g. Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)) OR JAK inhibitor (e.g. Jakafi (ruxolitinib, Xeljanz (tolacitinib), Rinvoq (upadacitinib)). 3. Patient is not receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine). 4. Approval Duration: 12 months

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	tacrolimus or pimecrolimus). An adequate trial is considered 6 months. 4. Patient is not receiving Opzelura in combination with another biologic medication (e.g. Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)) OR JAK inhibitor (e.g. Jakafi (ruxolitinib, Xeljanz (tolacitinib), Rinvoq (upadacitinib)). 5. Patient is not receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine). 6. Prescribed by a Dermatologist 7. Patient has not received a sample or coupon trial supply to establish themselves as a current user for authorization under continuity-of-care. **8. <u>Initial authorization duration:</u>** • Atopic dermatitis: 2 months • Nonsegmental vitiligo: 6 months 9. Quantity limits: 60 gm per week or 180 gm per 28-days	
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	**<u>Limitations of Use:</u>** • Contraindicated with concomitant use of the following drugs: • Other monoamine oxidase inhibitors or drugs that are potent inhibitors of monoamine oxidase (e.g. linezolid). • Opioid drugs; serotonin-norepinephrine reuptake inhibitors, tri-or tetra-cyclic

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		or triazolopyridine antidepressants, cyclobenzaprine, methylphenidate, amphetamine or their derivatives, St John's wort, dextromethorphan. • Severe hepatic impairment (Child-Pugh C) Hypersensitivity to safinamide.
Sastralizumab-mwge (**Enspryng**) injection **Not on MDH list; J3590	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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. • 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	Continued approval for treatment of DLBCL may be contingent upon verification and description of clinical benefit in confirmatory trials.

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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, Rybelsus**) Ozempic 2mg/1.5ml, 2mg/3ml, 4mg/3ml, 8mg/3ml Rybelus 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. • **NOTE: Semaglutide is only approved in adolescents for weight loss and is not a covered benefit for patients aged < 18 years**. 2. Patient age ≥ 18 years. 3. Not indicated for Type 1 Diabetes. 4. Within past 3 months: A1c OR CGM report with TIR%.	**Cannot be approved for indication of weight management.** **Titration doses will be approved for a maximum of 60-days supply per year.** 1. A1c or CGM report with TIR% within previous 3 months. 2. All initial approval criteria met. 3. Approval Duration: 12 months.

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	5. May not be concurrently using any other GLP1 or GLP1/GIP combination drug (e.g., Mounjaro, Trulicity, Victoza, Xultrophy or Soliqua). 6. May not be concurrently taking a DPP4i (e.g., alogliptin, Januvia (sitagliptin), Tradjenta (Linagliptin), Onglyza (saxagliptin). 7. Rybelsus 3 mg is limited to 60-days supply, then may be approved only for 7 mg or 14 mg doses. 8. Limited to 30-day supply per dispense, maximum of one capsule per day regardless of strength. 9. Maximum approval duration: 12 months.	
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. 3. Medication ordered by a Dermatologist. 4. Approval duration: 3 months only.	**Not eligible for renewal because efficacy beyond 12 weeks has not been proven effective.**
sildenafil (Revatio) 20 mg tablets 10 mg/ml solution	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 phenylbutyrate (**Olpruva**) Suspension; J8499	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Sofosbuvir and Velpatasvir (Epclusa)	1. Ordered for an approved indication for use: • Treatment of patient with chronic HCV genotype (GT) 1, 2, 3, 4, 5, or 6 infections without cirrhosis and with	**Hepatitis C Medication Prior Authorization Form**

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	compensated cirrhosis (Child-Pugh A) and with decompensated cirrhosis for use in combination with ribavirin (Child-Pugh B or C). • Treatment of adult and pediatric patients aged 6 years or older, weighing at least 17 kg, with HCV GT 1, 2, 3, 4, 5, or 6 infections, who previously were treated with a regimen containing an HCV NS5A inhibitor or an NS5B protease inhibitor, but not both. 2. A **fully** completed Hepatitis C Prior-Authorization Form with supporting clinical documents. 3. Patient treatment plan aligns with MDH Clinical Criteria recommendations. 4. Authorization is for a maximum of 24 weeks.	
somatrogon (**Ngenla**) solution pen-injector 24mg/1.2ml; 60mg/1.2ml	1. Ordered for an approved indication for use: • Treatment of growth failure in children due to inadequate secretion of endogenous growth hormone (GH) 2. Age 3 < 18 years 3. Medication ordered by or in consultation with an Endocrinologist. 4. Initial approval: • Confirmation of open epiphysial growth plates • Patient meets at least one of the following: o Height is at least TWO standard deviations (SD) below the mean height for normal children of same age and gender; o Height velocity less than 25th percentile for age. 5. Approval duration: 12 months	1. Confirmation of open epiphysial growth plates as above, OR the patient has not completed prepubertal growth 2. Patient meets at least one of the following: • Has an annual growth velocity of at least 2 cm during most recent approval year; • Is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm during the most recent approval year. 3. Approval duration: 12 months **Limitations of Use:** • Ngenla will not be approved for

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		idiopathic short stature (ISS), athletic enhancement, central precocious puberty, congenital adrenal hyperplasia, constitutional delay of growth and puberty, or angi-aging purposes.

Somatropin [recombinant human growth hormone] (**Norditropin FlexPro; Nutropin AQ; 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:
	
	• **<u>Growth failure in pediatric patients:</u>**
	  ○ Due to inadequate endogenous growth hormone secretion; short stature associated with Turner Syndrome [Norditropin FlexPro; Nutropin AQ]
	  ○ Idiopathic Short Stature (ISS); short stature born small for gestational age (SGA) with no catch-up growth by age 2 to 4 years; Prader-Willi syndrome; short stature associated with Noonan syndrome [Norditropin ONLY]
	  ○ Growth failure associated with chronic kidney disease until time of renal transplant [Nutropin ONLY].
	• **<u>Growth hormone deficiency in adults:</u>**
	• replacement of endogenous growth hormone in adults with growth hormone deficiency [Norditropin FlexPro, Nutropin AQ]
	• Treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance [Serostim ONLY]
		<u>Growth failure in pediatric patients:</u>
		
		1. Confirmation of open epiphysial growth plates as above, OR the patient has not completed prepubertal growth
		2. Patient meets at least one of the following:
		  ○ Has an annual growth velocity of at least 2 cm during most recent approval year;
		  ○ Is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm during the most recent approval year.
		3. Approval duration: 12 months.
		
		<u>Adult indications for use:</u>

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	2. Medication ordered by an Endocrinologist or Infectious disease specialist (Serostim ONLY). 3. For pediatric patients with growth failure: Confirmation of open epiphysial growth plates. 4. Approval duration: 12 months.	1. Clinical documentation indicating positive clinical response during previous 12 months. 2. Approval duration: 12 months
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.
tacrolimus extended-release (**Envarsus XR**) tablets 0.75mg, 1mg, 4mg	1. Ordered for an approved indication for use: • prophylaxis of organ rejection in kidney transplant in adult patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants. 2. Evidence that the patient had at least three-month trial and failure or intolerance to immediate-release tacrolimus. 3. Documented evidence that the patient is unable to achieve or maintain an appropriate therapeutic drug level with immediate-release tacrolimus---Lab values must be submitted. 4. Prescribed by a Nephrologist and Transplant Specialist.	**Limitations of use:** Not interchangeable or substitutable with other tacrolimus products.
tadalafil (Adcirca) tablets 20 mg	1. Ordered for an approved indication for use: • 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	**BPH:** • Tadalafil should not be used concurrently with an alpha-1 blocker (e.g., tamsulosin) due to minimal added benefit and higher adverse effect likelihood.

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	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. 6. Approval Duration: 12 months.	• If using tadalafil and finasteride, max recommended duration of tadalafil is ≤26 weeks (manufacturer's labeling). **PAH:** • 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.
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: • 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. 1. Medication ordered by an Oncologist	

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Tebentafusp (**Kimmtrak**); J9274	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Teclistamab (**Tecvayli**) **Not on MDH list; J9380	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Teduglutide (**Gattex**); J3490	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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 Be antigen (HBeAg) status. • Liver function tests. Not recommended for Child-Pugh class B or C hepatic impairment. 3. Patient has a history of adverse event, intolerance to or contraindication to treatment with entecavir OR meets one of the following criteria: • Patient age < 20 years. • Documentation of osteopenia or osteoporosis as defined by a T-score ≤ 1 and supported by clinical documentation of DEXA scan results. • Submission of medical records documenting a prior low-trauma or non-traumatic fracture. 4. Medication ordered or in consultation with an Infectious Disease specialist, Gastroenterologist, or Hepatologist. 5. Initial authorization period: 12 months.	1. Documentation of a positive clinical response to Vemlidy therapy. 2. Patient is not a suitable candidate for entecavir. 3. Approval duration: 12 months.

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Teplizumab (**Tzield**); J9381	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist prior to approval.
Teprotumumab-trbw (**Tepezza**) injection **Not on MDH list; J3241	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist prior to approval.
Teriparatide (Forteo) 630 mcg/2.4 ml Pen-injector	1. Ordered for an approved indication for use: • Treatment of postmenopausal women with osteoporosis at high risk for fracture. • To increase bone mass in men with primary or hypogonadal osteoporosis at high risk of fracture. • Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dose equivalent to ≥ 5 mg of prednisone) at high risk for fracture. 2. Age ≥ 18 years or documentation of closed epiphyses on X-ray. 3. Patient is at very high fracture risk as evidenced by one of the following: • Recent osteoporotic fracture within the past 12 months. • Bone mineral density (BMD) T-score at hip or spine ≤ -3.0 • BMD T-score at hip or spine ≤ -2.5 AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus). 4. Patient has completed a 3-year trial of bisphosphonate therapy at up to maximally indicated doses, UNLESS one of the following: • All bisphosphonates are contraindicated.	**Osteoporosis** 1. Patient previously met initial approval criteria. 2. Documentation supports positive response to therapy. 3. If request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture) and that the risk versus benefit of continued therapy has been reviewed with the member. 4. If request is for a dose increase, the new dose does not exceed 20 mcg per day (1 per per 28 days). 5. Approval duration: 12 months **Glucocorticoid-induced osteoporosis:** 1. Documentation supports positive response to therapy.

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	• Clinically adverse effects are experienced to both IV and PO formulations. • Patient has experienced a loss of- or a lack of increase in- BMD while receiving bisphosphonate therapy. • Patient experienced an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy. 5. If request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture) and that the risk versus benefit of continued therapy has been reviewed with the member. 6. Dose does not exceed 20 mcg per day (1 pen every 28 days) 7. Approval Duration: 6 months.	2. If request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture) and that the risk versus benefit of continued therapy has been reviewed with the member. 3. Approval duration: not to exceed 6 months.
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. 2. Approval Duration: 6 months.	1.Documentation of positive clinical response (e.g., improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance). 2. Approval Duration: 12 months.
Tezepelumab-ekko (**Tezspire**) sol 210mg	1. Ordered for an approved indication for use: • the add-on maintenance treatment of adult and pediatric patients aged ≥ 12 years with severe asthma. 2. Patient has refractory Type 2 airway inflammation (i.e., allergic asthma) OR has refractory non-Type 2 airway inflammation (i.e., non-allergic asthma). 3. Tezspire is being used in combination with an inhaled corticosteroid containing controller medication.	1. Documentation of positive clinical response to Tezspire therapy as demonstrated by at least one of the following: • Reduction in the frequency of exacerbations • Decreased utilization of rescue medications

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	4. Patient is not receiving Tezspire in combination with ANY of the following: • Anti-interleukin-5 therapy (e.g., Fasenra, Nucala) • Anti-EgE-therapy (e.g., Xolair) • Anti-interleukin-4-therapy (e.g., Dupixent) 5. Classification of asthma as uncontrolled or inadequately controlled as defined by at least one of the following: • Poor symptom control (e.g. Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently < 20. • Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months. • Asthma-related emergency treatment (e.g. ER visit, urgent care visit or unscheduled office visit for nebulizer treatment). • Airflow limitation (e.g., FEV1 < 80% predicted) • Dependent on oral steroids for treatment of asthma. 6. Medication ordered by an Allergist, Immunologist or Pulmonologist 7. Maximum Approval Duration: 12 months.	• Increase in the percent predicted FEV1 from pretreatment baseline • Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.) 2. Patient is not receiving Tezspire in combination with ANY of the following: • Anti-interleukin-5 therapy (e.g., Fasenra, Nucala) • Anti-EgE-therapy (e.g., Xolair) • Anti-interleukin-4-therapy (e.g., Dupixent). 3. Tezspire is being used in combination with an inhaled corticosteroid containing controller medication. 4. Prescribed by an allergist, pulmonologist, or immunologist. 5. Approval Duration: 12 months
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 adult patients with Type 2 Diabetes mellitus. 2. Patient age ≥ 18 years. 3. A1c or TIR% report within past 3 months. 4. May not be concurrently taking a DPP4i (e.g., alogliptin, Januvia (sitagliptin), Onglyza, or Tradjenta (linagliptin)).	**Cannot be approved for indication of weight management.** 1. A1c or CGM report with TIR% within previous 3 months. 2. All initial approval criteria met. 3. Approval Duration: 12 months.

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	5. May not be concurrently using any other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus, Trulicity, Victoza, Xultrophy or Soliqua). 6. Not approved for use in Type 1 Diabetes mellitus. **7. Titration dose 2.5 mg limited to 8 pens per year.** **8.** Maximum Approval Duration: 12 months	
Tisotumab vedotin-tftv (**Tivdak**) injection **Not on MDH list; J9273	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
tivozanib (**Fotivda**) capsules 0.89mg, 1.34mg	1. Ordered for an approved indication for use: • the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. 2. Medication order by Hematology/oncology 3. Approval Duration: 12 months.	1.Patient does not show evidence of disease progression while on Fotivda therapy. 2. Approval Duration: 12 months.
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	
tramadol hydrochloride extended release (Ultram) capsules (biphasic release) 100mg, 150mg, 200mg, 300mg Tablets 100mg, 200mg, 300mg Tablets (biphasic release) 100mg, 200mg, 300m	1.Ordered for an approved indication for use: • in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. 2. Completion of the opioid prior authorization form. 3. Submission of supporting clinical documentation from the last office visit, dated within previous 3 months. 4. If daily MME > 90, and patient does not meet exclusion criteria based on diagnosis or treatment status; a gradual tapering plan and adjuvant therapy may be required for approval.	All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-MD **Limitations of Use:** Not indicated as an as-needed (prn) analgesic.

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	5. Maximum approval duration is 6 months but may be reduced or denied if total daily MME > 90.	
trientine (Syprine) capsules 250mg	1. Ordered for an approved indication for use: • the treatment of patients with Wilson's disease who are intolerant of penicillamine.	**Limitations of Use:** Syprine and penicillamine cannot be considered interchangeable. Syprine is not recommended in cystinuria or rheumatoid arthritis.
Triptorelin (**Trelstar**) intramuscular injection 3.75 mg; 11.25 mg; 22. 5 mg	1. Ordered for an approved indication for use: • Palliative treatment of advanced prostate cancer • Preservation of ovarian function • Breast cancer (ovarian suppression) • Gender affirming care. 2. **Prostate Cancer:** • Prescribed by an oncologist. **Preservation of ovarian function:** • Patient is premenopausal and undergoing chemotherapy. **Breast cancer:** • Patient is premenopausal with hormone-receptor positive breast cancer at high-risk for recurrence using in combination with endocrine therapy. **Gender affirming care:** • Patient has diagnosis of gender dysphoria and meets MDH regulatory requirements for care. • Patient has reached Tanner stage ≥ 2 of puberty. 3. **Approval Durations:** • Prostate Cancer: 12 months • Preservation of ovarian function: 3 months • Breast cancer (ovarian suppression): 12 months	1. **Prostate Cancer:** • Patient is experiencing clinical benefit (e.g., serum testosterone < 50 ng/dl) • Patient has not experienced unacceptable toxicity. **Preservation of ovarian function:** • Patient meets all initial criteria. **Breast cancer:** • Patient was premenopausal at diagnosis and is still undergoing treatment with endocrine therapy. • Total treatment with triptorelin does not exceed 5 years. **Gender affirming care:** • Patient has reached Tanner stage ≥ 2 of puberty. 2. Approval Durations: • Prostate Cancer: 12 months • Preservation of ovarian function: up to 12 months ***providing that*

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	• Gender affirming care: 12 months	*cumulative treatment course is < 5 years.* • Breast cancer: 12 months • Gender affirming care: 12 months
Trofinetide (**Daybue**); J8499	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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: • the acute treatment of migraine with or without aura in adults. 2. Patient age ≥ 18 years. 3. Member must have tried and failed or have contraindication to NSAIDs **and** at least **TWO** formulary triptans. 4. Quantity limited to 16 tablets per 30 days, 200 mg max daily dose. 5. Approval Duration: 12 months.	1. Meets all initial clinical criteria. 2. Documentation of positive clinical response to treatment. 3. Quantity limited to 16 doses per 30 days, 200 mg max daily dose. 4. Approval Duration: 12 months.
Ustekinumab (**Stelara**) Injection, 45 mg; 90 mg	1. The criteria for Stelara are **indication specific**. Please review criteria for the patient-specific diagnosis. 2. **Stelara induction therapy requires Prior Authorization and must meet the prior authorization criteria below.** 3. Patient has been screened for Hepatitis B and Tuberculosis prior to initiation of therapy.	**ALL INDICATIONS:** 1. Documented positive clinical response. 2. Patient is not receiving in combination with any other targeted immunomodulator (e.g., etanercept, certolizumab, golimumab, abatacept,

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	4. Patient is not receiving in combination with any other targeted immunomodulator (e.g., etanercept, certolizumab, golimumab, abatacept, adalimumab, Risankizumab, gueslkumab, secukinumab, ixekizumab, brodalumab, tildrakizumab, rofacitinib, baricitinib, upadacitinib, apremilast, or similar). **Hidradenitis suppurative**: excluded from coverage; off-label indication. Note: Humira (or biosimilar) is first line therapy. Remicade (infliximab) is the MFC recommended alternate. **Crohn's disease**: • Diagnosis of moderately to severely active Crohn's disease • Patient is currently on Stelara therapy for moderately to severely active Crohn's disease as documented by claims history or submission of medical records. • Must have trialed and failed first line therapy with adalimumab, this includes patients who have failed infliximab. (1A recommendation from AGA Practice Guidelines 2021). • Approved dose: 90 mg/ml • Approval Duration: 12 months **Plaque psoriasis**: • Diagnosis of moderate to severe plaque psoriasis • ≥ 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis; AND • History of failure to one of the following topical therapies: Corticosteroids o Vitamin D analogs (calcitriol, calcipotriene) o Tacrolimus or pimecrolimus.	adalimumab, Risankizumab, gueslkumab, secukinumab, ixekizumab, brodalumab, tildrakizumab, rofacitinib, baricitinib, upadacitinib, apremilast, or similar). 3. Approval Duration: 12 months.

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	• History of failure to a 3-month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced. The trial must be documented in chart notes with date and duration of trial; OR • Patient has been previously treated with a targeted immunomodulator indicated for the treatment of plaque psoriasis as documented by claims history or submission of medical records that include drug name, date, and duration of therapy. (e.g., adalimumab, certolizumab, apremilast, Risankizumab, gueslkumab or similar). • Must be prescribed by or in consultation with a dermatologist. • Approved dose: 45 mg/ml for patient weight ≤ 100 kg • Approved dose: 90 mg/ml for patient weight > 100 kg • Approval duration: 12 months. **Psoriatic arthritis**: • Diagnosis of active psoriatic arthritis; AND • History of failure to a 3-month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced. The trial must be documented in chart notes with date and duration of trial; OR • Patient has been previously treated with a targeted immunomodulator indicated for the treatment of plaque psoriasis as documented by claims history or submission of medical records that include drug name, date, and duration of therapy. (e.g., adalimumab, certolizumab,	

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	apremilast, golimumab, gueslkumab, tofacitinib, upadacitinib, or similar). • Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Janssen sponsored CarePath Savings program shall be required to meet initial authorization criteria as if the patient were new to therapy. • Prescribed by or in consultation with a rheumatologist or dermatologist. • Approved dose: 45 mg/ml for patient weight ≤ 100 kg • Approved dose: 90 mg/ml for patient weight > 100 kg • Approval duration: 12 months **<u>Ulcerative colitis, moderate to severe:</u>** • Must show treatment failure or contraindication to first-line therapies: Remicade (infliximab) or Entyvio (vedolizumab). • Prescribed by or in consultation with a gastroenterologist. • Approved dose: 90 mg/ml • Approval Duration: 12 months	
V-go wearable insulin delivery system 20, 30, 40	1. Ordered for an approved indication for use: • Diabetes mellitus in persons requiring insulin. 2. Medication ordered by an Endocrinologist or practitioner who specializes in diabetes. 3. Office visit notes from last two encounters with prescribing provider to support Medical Necessity. 4. Evidence of face-to-face visit within past 3 months. 5. Documentation of uncontrolled diabetes on multiple daily	1. Office visit notes from last two encounters with prescribing provider support of Medical Necessity. 2. Prescribed by Endocrinologist or practitioner who specializes in diabetes with evidence of face-to-face visit within the past 3 months.

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	injections. 6. Documentation that patient has been educated on device. 7. Documentation of self-blood-glucose monitoring (30-day blood glucose log or CGM report). 8. May not be used if patient needs to make insulin adjustments of less than 2-unit increments due to risk of hypoglycemia. 9. Approval Duration: 12 months.	3. Documentation of self-blood glucose monitoring (30-day blood glucose log or CGM report). 4. May not be used if patient needs to make insulin adjustments of less than 2-unit increments should not use V-GO as it may result in hypoglycemia. 5. Approval duration: 12 months.
Valoctocogene roxaparvovec (**Roctavian**); J1412	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Vamorolone (**Agamree**)	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Velmanase alfa (**Lamzede**); J0217	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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. • 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.
viltolarsen (**Viltepso**) 50 mg/ml solution; J1427	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
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. (mycophenolate mofetil and corticosteroids). 2. Patient age ≥ 18 years.	1. All initial criteria continue to be met. 2. Documentation provided or attestation of therapeutic benefit. 3. Approval Duration: 6 months.

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	3. Not taking concurrently with cyclophosphamide. 4. Prescriber specialty: immunologist, nephrologist, rheumatologist, or provider experienced in treatment of lupus nephritis. 5. Prescriber attestation that all baseline evaluations have been done, and not contraindications to use are present (strong 3A4 inhibitor contraindicated, live vaccines, pregnancy/breastfeeding negative, assessment of renal function). 6. Quantity Limit: 6 tablets per day (23.7 mg twice daily). 7. Approval Duration: 6 months	
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	
Vestronidase alpha (**Mepsevii**) J3397	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Voretigene neparvovec (**Luxturna**) J3398	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Vutrisiran (**Amvuttra**) **Not on MDH list; J0225	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.
Zilucoplan (**Zilbrysq**) J3490, J3590, C9399	**USE MFC High-Cost Medication PA Criteria**	Requires MFC Physician or Pharmacist review prior to approval.