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". This is also described in MFC's Pharmacy Policy 205: Non-formulary Medications. 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. 4. All clinically appropriate formulary alternatives should be exhausted before approval of a branded product is granted.	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	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.

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	who 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	2. Approval Duration: up to 12 months, not intended to last longer than the final infusion completing 24 months of therapy.

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	of cumulative use of parathyroid hormone analogs (e.g., Teriparatide, Forteo, Tymlos) during the patient's lifetime. 10. Approval Duration: up to 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**	**Note: this applies to any combination of albuterol MDIs and levalbuterol MDIs.** If patient has exceeded 6 inhalers per 365 days: • Provider must show that patient has been prescribed appropriate controller therapy for indication (asthma, 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. 2. Approval for asthma indication is for one inhaler, one fill only. 3. Approval for COPD may be longer depending upon documented COPD severity, concurrent therapy, compliance with COPD regimen, and oversight by a pulmonologist.	

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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**	
Allogeneic processed thymus tissue–agdc (**Rethymic**)	**USE MFC High-Cost Medication PA Criteria**	
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 ▪ 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	1. Documentation of positive clinical response to therapy. 2. Authorization Duration: 12 months.

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	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. Approval Duration: 6 months.	
Antihemophil FVIII, B-dom del (**Xyntha**), J7185	**USE MFC High-Cost Medication PA Criteria**	
Avalglucosidase alfa-ngpt (**Nexviazyme**), J0219	**USE MFC High-Cost Medication PA Criteria**	
Avapritinib (**Ayvakit**) tablets 100mg, 200mg, 300mg	1. Ordered for an approved indication for use: • <u>Gastrointestinal Stromal Tumor (GIST)</u> ○ Treatment of adults with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. • <u>Advanced Systemic Mastocytosis (AdvSM)</u>	1. No evidence of disease progression. 2. Approval Duration: 12 months.

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	○ Treatment of adult patients with AdvSM. AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), and mast cell leukemia (MCL). • <u>Indolent Systemic Mastocytosis (ISM)</u> Treatment of adult patients with ISM. 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: 12 months.	
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.	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.

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	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 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**	
Azacitadine (**Onureg**) tablets 200mg, 300mg	1. Ordered for an approved indication for use: • Continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and are not able to complete intensive curative therapy. 2. Patient is not able to complete intensive curative therapy (i.e., transplant-ineligible). 3. Medication ordered by an Oncologist.	1. Patient does not show evidence of progressive disease while on Onureg therapy. 2. Approval duration: 12 months.
Azelaic Acid GEL (Finacea) 15%	1. Ordered for Acne Vulgaris in adults.	

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STEP THERAPY	2. Patient has had an adequate trial (30 days) of at least two types of formulary, topical acne products. Two types meaning, two different active ingredients. 3. Acceptable formulary precursor ingredients include: adapalene, benzoyl peroxide, benzoyl peroxide-erythromycin combination products, clindamycin, clindamycin-benzoyl peroxide combination products, erythromycin, tretinoin. 4. If patient's claims data supports the completion of the step-therapy, the claim will adjudicate without manual review. 5. Approval Duration: 12 months.	
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.	1. Prescriber attestation of continued clinical benefit. 2. Approval Duration: 6 months.

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	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. 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:	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

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	• 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: • 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.	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., Tezpire (Tezepelumab)). 4. Approval Duration: 12 months.
Beremagene geperpavec (**Vyjuvek**), J3401	**USE MFC High-Cost Medication PA Criteria**	
berotralstat (**Orladeyo**) capsules	**USE MFC High-Cost Medication PA Criteria**	

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J3490, J8499		
Betibeglogene autotemcel (**Zynteglo**), J3590	**USE MFC High-Cost Medication PA Criteria**	
blinatumomab (**Blincyto**) Injection 35mcg, J9039	**USE MFC High-Cost Medication PA Criteria**	
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**	
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. • Ordered for treatment when the indication has been recognized by the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a category of Evidence and Consensus of 1, 2A, or 2B. **<u>Non-Small Cell Lung Cancer (NSCLC):</u>** • The tumor is anaplastic lymphoma kinase (ALK)-positive. • The cancer is either: metastatic, recurrent, or advanced.	1. Patient does not show evidence of progressive disease while on Alunbrig therapy. 2. Approval Duration: 12 months.

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	Soft Tissue Sarcoma/Uterine Neoplasms: • Diagnosis of inflammatory myofibroblastic tumor (IMT); and • Presence of ALK translocation. **Histiocytic Neoplasms:** • Diagnosis of symptomatic Erdheim-Chester Disease; and • Used as targeted therapy ALK-fusion; and • Disease is either relapsed or refractory. **Central Nervous System (CNS) Cancers:** • Diagnosis of metastatic brain cancer from NSCC; and • Tumor is ALK-positive. 2. Medication ordered by or in consultation with an Oncologist. 3. Approval Duration: 12 months.	
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. Submission of kidney biopsy results confirming the diagnosis of primary immunoglobulin A nephropathy (IgAN). 3. Lab results/chart notes indicating that the patient has proteinuria ≥ 1 gm/day or baseline urine protein-to-creatinine ratio (UPCR) ≥ 0.8 gm/gm based on 24-hour urine collection. 4. History of failure, contraindication or intolerance to a glucocorticoid.	1. All patients requesting authorization for continuation of therapy must meet all initial authorization criteria.

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	5. 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. 6. Medication ordered by a nephrologist. 7. Approval Duration: 10 months.	
burosumab-twza (**Crysvita**) injection; J0584	**USE MFC High-Cost Medication PA Criteria**	
c1 Inhibitor [Human] **cinryze** sol; J0598 500 unit **haegarda** injection 2000unit, 3000unit; J0599	**USE MFC High-Cost Medication PA Criteria**	
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: 2 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

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cabotegravir and rilpivirine extended-release (**Cabenuva**) injectable suspension 600mg-900mg ***Note the Cabenuva 400/600 mg strength is non-formulary.*** ***Requests for 400/600 mg strengths will be redirected to the every-two-months dosing regimen, 600mg/900mg strength.***	1. Ordered for an approved indication for use: • Treatment of HIV-1 infection in adults and adolescents 12 years of age and older and 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. Patient is antiretroviral treatment-experienced and has been virologically suppressed (HIV RNA < 50 copies/ml) for at least three months; AND 4. Patient has no history of treatment failure. 5. May not be approved for pre-exposure prophylaxis (PrEP) or any other indication. 6. Injection Quantity Limits: • Cabenuva 600mg/900 mg kit – 1 kit per 2 months • Allowance of one additional Cabenuva 600mg/900mg kit in the first two months of initiation of injection therapy. 7. Authorization Duration: 12 months	1. Patient has previously received treatment with Cabenuva. 2. Laboratory documentation of maintained viral suppression (HIV-1 RNA <50 copies per ml within previous 3 months. 3. Patient has not experienced a virologic failure while on Cabenuva. This is defined as **2 consecutive** plasma HIV-1 RNA levels ≥ 200 copies per ml. 4. Renewal duration: 12 months.
cabozantinib (**Cabometyx)** tablets 20mg, 40mg, 60mg	**USE MFC High-Cost Medication PA Criteria**	
caplacizumab-yhdp (**Cablivi**) kit 11mg; C9047	**USE MFC High-Cost Medication PA Criteria**	
casimersen (**Amondys 45**) injection; J1426	**USE MFC High-Cost Medication PA Criteria**	

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Cerliponase alpha (**Brineura**) J0567	**USE MFC High-Cost Medication PA Criteria**	
Ciltacabtagene autoleucel (**Carvykti**); Q2056	**USE MFC High-Cost Medication PA Criteria**	
Coagulation factor IX (**Benefix**) recombinant; J7195	**USE MFC High-Cost Medication PA Criteria**	
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. • Ordered for treatment when the indication has been recognized by the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a category of Evidence and Consensus of 1, 2A, or 2B. **<u>Non-Small Cell Lung Cancer (NSCLC):</u>** • The cancer is either: metastatic, recurrent, or	1. Patient does not show evidence of progressive disease while on Xalkori therapy. 2. Approval Duration: 12 months.

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	advanced.
	• The tumor is one of the following:
	  ○ ALK-positive
	  ○ ROS1-positive
	  ○ Positive for mesenchymal-epithelial transition (MET) amplification
	  ○ Positive for MET exon 14 skipping mutation
	Soft Tissue Sarcoma/Uterine Neoplasms:
	• Diagnosis of inflammatory myofibroblastic tumor (IMT); and
	• Presence of ALK translocation.
	Histiocytic Neoplasms:
	• Diagnosis of one of the following:
	  ○ Erdheim-Chester Disease
	  ○ Langerhans Cell Histiocytosis
	  ○ Rosai-Dorfman Disesase
	• Used as targeted therapy ALK-fusion.
	Central Nervous System (CNS) Cancers:
	• Diagnosis of metastatic brain cancer from NSCLC; and
	• Tumor is ALK-positive OR ROS1-positive.
	Anaplastic Large Cell Lymphoma:
	• Tumor is ALK-positive; and
	• Disease is relapsed or refractory
	Melanoma:
	• Diagnosis of metastatic or unresectable cutaneous melanoma; and
	• Disease is ROS1 gene fusion-positive; and
	• Used as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of	

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	progression with BRAF-targeted therapy. 2. Medication ordered by an Oncologist. 3. Approval Duration: 12 months.	
cysteamine bitartrate (**Procysbi**) capsules/granules; J8499	**USE MFC High-Cost Medication PA Criteria**	
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.	**Limitations of use:** • Tafinlar is not indicated for treatments of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. • Tafinal is not indicated for treatment of patients with wild-type BRAF solid tumors. • The indication for treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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	2. Medication ordered by an Oncologist. 3. Approval Duration: 12 months.	
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. 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.	1. Improvement in walking speed as demonstrated by T25FW as compared with baseline. 2. Approval duration: 12 months.
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	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

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	stimulating agents. 7. Maximum daily dose 24 mg per day. 8. Initial approval duration: 6 months.	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). • Metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel. 2. Patient is ≥ 18 years of age, AND 3. The medication is concurrently used with docetaxel OR the patient has completed docetaxel therapy. 4. The patient meets ONE of the following: • The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) agonist, or • The medication is used concurrently with degarelix SQ injection; or • Patient has bilateral orchiectomy. 5. Medication ordered by an Oncologist or Urologist. 6. Approval Duration: 12 months.	1. Patient has not shown disease progression. 2. Patient has not experienced unacceptable toxicity. 3. Patient should also receive a GnRH analog concurrently OR have had a bilateral orchiectomy. 4. Treatment may continue even if a cycle of docetaxel is delayed, interrupted, or discontinued. 5. Approval Duration: 12 months.
Deflazacort (Emflaza) J8499, J3490	**USE MFC High-Cost Medication PA Criteria**	
Delandistrogene moxeparvovec (**Elevidys**); J1413	**USE MFC High-Cost Medication PA Criteria**	
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)	1. Documentation of positive clinical response to therapy. 2. Approval Duration: up to 12 months. **<u>Limitations of Use:</u>**

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
	• 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.	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. • 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. Baseline calcium and vitamin D level results, with plan to correct any identified deficiencies before treatment	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.**

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
	initiation. 5. Baseline dental exam completed, and any preventative dentistry performed before treatment initiation. 6. Limited to 1 syringe every 6 months. 7. Concomitant use of calcium and vitamin D supplement required. 8. For patients with advanced kidney disease (eGFR <30 mL/minute/1.73 m^2), including dialysis-dependent patients: evaluation for presence of chronic kidney disease-mineral disorder (CKD-MBD) must be completed prior to denosumab initiation. Treatment with denosumab in these patients should be supervised by a health care provider with expertise in the diagnosis and management of CKD-MBD. 9. Authorization duration: 12 months.	
deutetrabenzine (**Austedo**) tablets titration kit 6mg, 9mg, 12mg **NOTE:** ***Austedo XR is covered ONLY for the titration pak.*** ***Maintenance doses must be converted to the IR tablets.*** ***Total daily dose is equivalent on a mg-to-mg basis, but the IR should be administered in 2 divided doses if the total***	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	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. Dose administered is optimized by tablet strength to achieve target dose as described in this table: Total Daily | Regimen to Approve AFTER

<table>
<tr><th>Generic Medication (Brand Name)
Bolded medication specifies whether Brand or Generic is on Formulary with PA requirement</th><th>Approval Criteria & Submission Requirements</th><th>Additional Considerations and Renewal Criteria</th></tr>
<tr><td>dose is ≥ 12 mg per day. See table under renewal criteria.</td><td>and renewal PA requests.
7. Patient must not be suicidal or have untreated/inadequately treated depression.
8. Approval Duration: 1 fill of starter dose (XR formulation)</td><td><table><tr><th>Dose</th><th>starter kit completed</th></tr><tr><td>12 mg</td><td>IR 6 mg BID</td></tr><tr><td>18 mg</td><td>IR 9 mg BID</td></tr><tr><td>24 mg</td><td>IR 12 mg BID</td></tr><tr><td>30 mg</td><td>IR 12 mg x 2 tabs + IR 6 mg QD</td></tr><tr><td>36 mg</td><td>IR 12 mg x 3 tabs QD</td></tr><tr><td>42 mg</td><td>IR 12 mg x 3 tabs + 6 mg IR QD</td></tr><tr><td>48 mg</td><td>12 mg IR x 2 BID</td></tr></table>6. Approval duration: 12 months.</td></tr>
<tr><td>Dinutuximab (Unituxin)
J9999</td><td>USE MFC High-Cost Medication PA Criteria</td><td></td></tr>
<tr><td>Dulaglutide (Trulicity)
0.75 mg, 1.5 mg, 3 mg, 4.5 mg</td><td>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.
• 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).
2. A1c or TIR% report within past 3 months.
3. Baseline A1c is ≥ 8.0, for patients WITHOUT CVD OR Baseline A1c is ≥ 7.0, for patients WITH CVD defined as: Patient is considered high or very high risk for ASCVD-risk as evidenced by <u>one</u> of the following:</td><td>Cannot be approved for indication of weight management.
1. Chart notes with A1c or CGM report with TIR% within previous 3 months.
2. Documented positive clinical response defined as one of the following:
• Dose titration is occurring at expected monthly intervals which applies only to the first 6 months of treatment or until A1c labs are available, or
• A1c goal has been reached on requested dose; or
• A1c has decreased by ≥ 1% since onset of therapy; or
• Patient is at maximum tolerated dose and used as part of a comprehensive diabetes regimen in combination with</td></tr>
</table>

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
	• Acute coronary syndrome • History of myocardial infarction • Stable or Unstable angina • Coronary or other arterial revascularization • Stroke • Transient ischemic attack • Peripheral arterial disease • ≥ 20% 10-year CVD risk according to the AHA Prevent Calculator: https://professional.heart.org/en/guidelines-and-statements/prevent-calculator 3. May not be concurrently using: • Any other GLP1 or GLP1/GIP combination drug (e.g., Mounjaro, Rybelsus, Trulicity, Victoza, Xultrophy or Soliqua). • Any DPP4i (e.g., alogliptin, Januvia (sitagliptin), Tradjenta (Linagliptin), Onglyza (saxagliptin)). • Agents for severe constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 4. No history of pancreatitis. 5. Not approved for use in Type 1 Diabetes mellitus. 6. Starter doses are limited and require dose escalation. Trulicity 0.75 mg is a starter dose and is limited to one, 28-day supply and then must be dose escalated UNLESS Trulicity renewal criteria are met (i.e. 0.75 mg dose can be continued if therapeutic benefit meets renewal criteria). 7. Approval Duration: up to 12 months	other anti-hyperglycemic medications. 3. Patient has not had medical intervention for pancreatitis OR severe gastrointestinal events. (e.g., hospitalization or new start GI motility agent). These patients will be directed to other anti-hyperglycemic agents. 4. May not be concurrently using: • any other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus, Trulicity, Victoza, Xultrophy or Soliqua) AND/OR • a DPP4i (e.g., alogliptin, Januvia (sitagliptin), Onglyza, or Tradjenta (linagliptin)). • Agents for *severe* constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 5. PBM claims data shows consistent adherence as shown by no instance of a drug-free interval greater than 2 months at which time the patient would need to satisfy the initial criteria.

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
		6. Approval Duration: up to 12 months
Eculizumab (**Soliris**) injection - 10mg/ml; J1300	**USE MFC High-Cost Medication PA Criteria**	
Elacestrant (**Orserdu**) J3490; J9999	**USE MFC High-Cost Medication PA Criteria**	
Efgartigimod alfa-fcab (**Vyvgart**) injection; J9332 **Vyvgart Hytrulo** (efgartigimod alfa and hyaluronidase) SQ J9334	**USE MFC High-Cost Medication PA Criteria**	
elapegademase-lvlr (**Revcovi**) Injection; J3490, J3590	**USE MFC High-Cost Medication PA Criteria**	
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). 5. Provider justification of necessity of medication change if currently stable on another CF regiment and asymptomatic. 6. Medication ordered by a Pulmonologist.	1. Provider attestation of continued benefit without adverse drug effects. 2. Provider attestation of continued monitoring as appropriate. 3. 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
	7. Approval duration: 12 months.	
Elivaldogene autotemecel (**Skysona**); J3590	**USE MFC High-Cost Medication PA Criteria**	
Elosulfase alfa (**Vimizim**) injection; J1322	**USE MFC High-Cost Medication PA Criteria**	
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. 2. Request is for the 200/25 mg strength. 3. Approval Duration: 12 months	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).
Elranatamab-bcmm (**Elrexfio**)	**USE MFC High-Cost Medication PA Criteria**	
Enzalutamide (**Xtandi**) capsules 40mg	1. Ordered for an approved indication for use: • castration-resistant prostate cancer for patients > 18 years of age. • Metastatic, castration-sensitive prostate cancer (mCRPC) for patients > 18 years of age. 2. Patient is ≥ 18 years of age, AND 3. The patient meets ONE of the following: • The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) agonist, or • Patient has bilateral orchiectomy; or • Patient has non-metastatic, castration-sensitive cancer and a biochemical recurrence and at high-	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).

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
	risk for metastasis (PSA doubling time ≤ 9 months. 4. Medication ordered by an Oncologist or Urologist. 2. Approval Duration: 12 months. 3. Medication ordered by an Oncologist or urologist	
Epocoritamab-bysp (**Epkinly**) J9321	**USE MFC High-Cost Medication PA Criteria**	
Etranacogene dezaparvocec (**Hemgenix**); J1411	**USE MFC High-Cost Medication PA Criteria**	
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**	
Exagamglogene autolemcel (**Casgevy**); J3590	**USE MFC High-Cost Medication PA Criteria**	

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factor VIIa, recombinant human (**NovoSeven RT**) injection: J7189	**USE MFC High-Cost Medication PA Criteria**	
factor VIII, recombinant human pegylated (**Jivi**) injection: J7208	**USE MFC High-Cost Medication PA Criteria**	
Factor VIII, recombinant human with VWF fusion (**Altuviiio**); J7214	**USE MFC High-Cost Medication PA Criteria**	
Factor VIII recombinant human, with Fc fusion (**Eloctate**); J7205	**USE MFC High-Cost Medication PA Criteria**	
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: o At least 3 unformed stools per day for 2 consecutive days o Stool test confirming the presence of *C. difficile* toxin or toxigenic *C. difficile*. o 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:	**Limitations of Use:** VOWST is not indicated for treatment of CDI.

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	○ 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 ○ 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,	1. Ordered for an approved indication for use: • management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment	All opioids require prior authorization (PA). The PA request form can be access using the following links:

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62.5mcg/hr, 75mcg/hr, 87.5mcg/hr, 100mcg/hr	options are inadequate. Patients considered opioid-tolerant are those taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid. 2. Fully completed opioid PA form submitted. 3. Submission of clinical documentation from last office visit, dated within 3 months of the request. 4. Maximum approval duration is 6 months but may be reduced based on any of the criteria as outlined in Pharmacy Policy 219: Opioid Prescription Prior Authorization.	OPIOID PRIOR AUTH FORM-MD
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,	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

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
	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 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:	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

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
	• Serum potassium ≤ 5.0 mEq/L • eGFR ≥ 25 mL/min/1.73 m2 • Urine albumin-to-creatinine ratio ≥ 30 mg/g • Concomitant use with maximum tolerated doses of ACE-Inhibitor or ARB unless intolerant to or contraindicated. 3. Failed trial or contraindication to one formulary SGLT2i. 4. Approval duration: 3 months	3. Approval duration: 12 months
Fosdenopterin (**Nulibry**) injection 9.5mg; J3490	**USE MFC High-Cost Medication PA Criteria**	
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	**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

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
	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 ○ 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.	

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	2. Medication ordered by an Oncologist	
Givosiran (**Givlaari**); J0223	**USE MFC High-Cost Medication PA Criteria**	
Glofitamab (**Columvi**); J9286	**USE MFC High-Cost Medication PA Criteria**	
glycerol phenylbutyrate (**Ravicti**) Liquid; J8499	**USE MFC High-Cost Medication PA Criteria**	
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. Patient age ≥ 9 years. 3. Must have tried and failed OTC Clinical Strength antiperspirants and at least one prescription strength antiperspirant (ex: Drysol or Xerac AC) for at least 4 weeks and experienced inadequate efficacy 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. Qbrexza is not intended for application to areas other than the axillae. 5. Patient does not have any of the following conditions: • Glaucoma • Paralytic ileus • Unstable cardiovascular status in acute hemorrhage • Severe ulcerative colitis • Toxic megacolon • Myasthenia gravis • Sjogren's syndrome 6. Limited to 30 cloths per 30 days.	1. Patient has experienced positive clinical response to treatment. 2. 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
	7. Approval Duration: 12 months.	
Golodirsen (**Vyondys 53**) injection; J1429	**USE MFC High-Cost Medication PA Criteria**	
Goserelin (**Zoladex**) implant 3.6mg, 10.8mg	1. Ordered for an approved indication for use: • 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	**Endometriosis:** • Can not be administered for more 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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	• 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 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	Ordered for an approved indication for use: **Treatment of children with central precocious puberty (CPP):**	**Central Precocious Puberty:** • Patient is currently receiving therapy for central precocious puberty; and

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	• 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
	  • 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
		• 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 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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	experienced in transgender hormone therapy. • Approval Duration: 12 months	
Human plasma-derived plasminogen (**Ryplazim**); J2998	**USE MFC High-Cost Medication PA Criteria**	
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. 2. Medication ordered by an Oncologist. 3. Quantity limit: 4 tablets per day.	**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 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. Patient age ≥ 18 years. 3. Prescribed for the treatment of acute HAE attacks. 4. Member has a C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets one of the following: • C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing	1. Patient meets initial approval criteria. 2. Submission of chart notes showing that Patient has experienced a reduction in severity and/or duration of attacks. 3. Prophylaxis should be considered based on the frequency and severity of attacks, comorbid conditions, and patient's quality of life. 4. Approval Duration: 6 months.

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	the test; OR • Normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test). 5. If not the criteria in #4 above, the patient has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria: • Patient has an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation as confirmed by genetic testing; or • Patient has a documented family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy (i.e. cetirizine at 40 mg per day or the equivalent) for at least 30 days. 6. Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g. Berinert, Kalbitor, or Ruconest). 7. Medication ordered by an Allergist or ENT. 8. Approval Duration: 6 months.	
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	1. Used for cardiovascular risk reduction. 2. Documentation of positive clinical response to therapy 3. Patient is receiving maximally tolerated statin therapy. 4. 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
	○ 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 **<u>one</u>** of the following: ○ Acute coronary syndrome ○ History of myocardial infarction ○ Stable or Unstable angina ○ Coronary or other arterial revascularization ○ 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	

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	○ 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** BOTH OF THE FOLLOWING: • 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 tolerated statin therapy. 8. Approval duration: 12 months.	
idecabtagene vicleucel (**Abecma**) injection; Q2055	**USE MFC High-Cost Medication PA Criteria**	
idursulfase (**Elaprase**) injection 6mg/3ml; J1743	**USE MFC High-Cost Medication PA Criteria**	
imiglucerase (**Cerezyme**) injection 400 unit; J1786	**USE MFC High-Cost Medication PA Criteria**	
immune globulin subcutaneous (human) (**Cutaquig**) solution 1gm, 1.65gm, 2gm, 3.3gm, 4gm, 8gm	1. Ordered for an approved indication for use: • Replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients ≥ 2 years of age. • Prevention of bacterial infection in patients with hypogammaglobulinemia and/or recurrent bacterial	

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	infections with malignancy (e.g., B-cell chronic lymphocytic leukemia) or primary humoral immunodeficiency disorders. 2. Medication ordered by an Immunologist.	
interferon gamma-1b (**Actimmune)** injection; J9216	**USE MFC High-Cost Medication PA Criteria**	
Ipilimumab (**Yervoy**) injection 50mg, 200mg; J9228	**USE MFC High-Cost Medication PA Criteria**	
ivacaftor (**Kalydeco**) 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 3mg	1. Ordered for an approved indication for use:	**Limitations for use:**

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	• 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).
Lanadelumab-flyo (**Takhzyro**) injection 300mg/2ml; J0593	**USE MFC High-Cost Medication PA Criteria**	
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. The patient is being treated for one of the following solid tumors: soft tissue sarcoma, salivary gland, infantile fibrosarcoma, thyroid, lung, or gastrointestinal stromal tumors; and 3. The tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion; AND 4. The tumor is metastatic OR surgical resection of tumor will likely result in severe morbidity. 5. Medication ordered by an Oncologist. 6. Approval Duration: 6 months for first authorization.	1. Patient continues to meet initial criteria. 2. Patient has documented positive response to therapy as defined by stabilization of disease or decrease in tumor size or tumor spread. 3. Absence of unacceptable toxicity from the drug (e.g. severe neurotoxicity, hepatotoxicity etc.) 4. Approval Duration: 12 months.
Lecanemab-irmb (**Leqembi)** 200 mg/2 ml Intraveneous solution	1. Ordered for an approved indication: • Treatment of Alzheimer disease; to be initiated in patients with mild cognitive impairment or mild dementia stage of disease, with confirmed presence of	1. Patient continues to meet criteria for initial approval. 2. Absence of unacceptable toxicity from drug AND

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	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.	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 5. 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)	1. Patient has previously received treatment with Sunlenca.

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	in adult patients. 2. Patient age ≥ 18 years. 3. Confirmed diagnosis of HIV-1 infection. 4. Provider attestation that patient has multi-drug resistant HIV-1 infection and is failing a current antiretroviral regiment for HIV; AND 5. The patient has resistance to two or more agents from at least THREE of the following antiviral classes: • Nucleoside reverse transcriptase inhibitor, e.g., abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumerate, tenofovir alafenamide, zidovudine. • Non-nucleoside reverse transcriptase inhibitors, e.g., delaviridine, efavirenz, etravirine, nevirapine, nevirapine XR, rilpivirine. • Protease inhibitors, e.g., atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir. • Intefrase strand transfer inhibitors e.g., raltegravir, dolutegravir, elvitegravir. AND 6. The medication will be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND 7. Dosing is in accordance with FDA-approved prescribing information. 8. Prescribed by or in consultation with a physician who specializes in the treatment of HIV infection. 9. Maximum Approval Duration: 12 months.	2. Patient has responded to a Sunlenca-containing regimen, as determined by the prescriber. Examples of a response are HIV RNA, 50 cells/mm^3, HIV-1 RNA ≥ 0.5 log_{10} reduction from baseline in viral load. 3. Provider confirms that patient has achieved a clinically significant viral response to therapy. 4. Provider confirms that patient will continue to take an optimized background antiretroviral regimen in combination with Sunlenca. 5. Maintenance dosing is in accordance with FDA-approved prescribing guidance. 6. Authorization Duration: 12 months.
Leniolisib (**Joenja**); J8499	**USE MFC High-Cost Medication PA Criteria**	

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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:** 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,	**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:** • 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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	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. **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	

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	• 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; Q2054	**USE MFC High-Cost Medication PA Criteria**	
lomitapide (**Juxtapid**) capsules 5mg, 10mg, 20mg, 30mg	1. Ordered for an approved indication for use: • An adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce LDL-C, total cholesterol, apolipoprotein B, and non-HDL-C in patients with homozygous familial hypercholesterolemia. 2. 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.	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. 4. Renewal Duration: 12 months

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Loncastuximab tesirine-lpyl (**Zynlonta**) solution; J9359	**USE MFC High-Cost Medication PA Criteria**	
Lotilaner 0.25% solution (**Xdemvy**)	1. Ordered for an approved indication for use: • Treatment of Demodex blepharitis in adults 1. Patient aged ≥ 18 years of age. 2. Diagnosis of Demodex blepharitis, AND 3. Patient demonstrates one of the following signs of Demodex infestation: • Cylindrical cuff at the root of the eyelashes. • Lid margin erythema • Eyelash anomalies (eyelash misdirection); AND 4. Patient demonstrates two of the following symptoms of manifestation: • Itching/burning • Foreign body sensation • Crusting/matter lashers • Blurry vision • Discomfort/irritation; AND 5. Patient is practicing good eye-lid hygiene (e.g., non-prescription tree-tea oil). 6. Patient has not undergone more than one, 6-week treatment in the previous 12 months. 7. Written by or in consultation with an ophthalmologist or optometrist. 8. Approval limited to 1 bottle (10 ml) per 12 months.	At this time, there is no clinical evidence to show benefit beyond 6 weeks of treatment and shall not be approved for more than one treatment per 12 months.
Lumacaftor/ivacaftor (**Orkambi**) Tablets	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.	1. Provider attestation of continued benefit without adverse drug effects. 2. Provider attestation of continued monitoring as appropriate.

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100mg-125mg, 200mg-125mg	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	3. Renewal Duration: 12 months.
lumasiran (**Oxlumo**) injection 94.5mg/0.5ml; J0224	**USE MFC High-Cost Medication PA Criteria**	
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. 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.	**Each treatment course requires a separate PA request. Initial criteria apply to all requests.**
Maralixibat (**Livmarli**); J8499	**USE MFC High-Cost Medication PA Criteria**	
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.	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

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	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.	of these medications should be submitted.
Mecasermin (**Increlex**) J2170	**USE MFC High-Cost Medication PA Criteria**	
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. 2. Approval is indication specific: **Asthma:** • Patient is ≥ 6 years or age; AND • Patient has blood eosinophil level ≥ 150 cells/microliter within previous 6 weeks or within 6 weeks prior to treatment with Nucala or another monoclonal antibody therapy that reduces blood eosinophil levels, (e.g. Cinqair, Dupixent, Fasenra, Nucala, Tezspire or Xolair); AND • Patient has received at least three consecutive months of combination therapy with BOTH an inhaled	**Asthma:** • Patient has already received 6 months of therapy with Nucala. • Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler. • Patient has responded to therapy (e.g. decreased asthma exacerbations, symptoms, hospitalizations, ER visits, urgent care visits, or decreased requirement for oral corticosteroid therapy. **Chronic Rhinosinusitis with Nasal Polyps:** • Patient has received at least 6 months of therapy with Nucala. • Patient continues to receive therapy with an intranasal corticosteroid; and

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	corticosteroid AND at least one additional asthma controller or asthma maintenance medication; AND
	• Patient has asthma that is controlled or was uncontrolled at baseline as defined by one of the following:
	  ○ Patient experienced 2 or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
	  ○ Patient experienced at least one asthma exacerbation requiring hospitalization, an emergency department visit, or urgent care visit in the previous year; OR
	  ○ Patient has a forced expiratory volume in1 second (FEV_1) < 80% predicted; or
	  ○ Patient has an FEV_1)/forced vital capacity (FVC) < 0.80; OR
	  ○ Patient has asthma that worsens upon tapering of oral (systemic) corticosteroid therapy.
	• Medication ordered by an Allergist, Immunologist or Pulmonologist.
	• Approval Duration: 6 months.
	<u>Chronic Rhinosinusitis with Nasal Polyps:</u>
	• Patient is ≥ 18 years of age; and
	• Patient has chronic rhinosinusitis with nasal polyps as evidenced by direct examination, endoscopy, or cinus computed tomography (CT) scan; and
	• Has had two or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction or loss of smell; AND
		• Patient has responded to therapy (e.g. reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, improved sense of smell.

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	• Patient has received at least 4 wee4ks of therapy with an intranasal corticosteroid; AND
	• Patient will continue to receive therapy with an intranasal corticosteroid concomitantly with Nucala; and
	• Patient meets one of the following:
	  ○ Patient has had at least one course of treatment with systemic corticosteroid for 5 days or more within the previous 2 years; or
	  ○ Patient has a contraindication to systemic corticosteroid therapy, or
	  ○ Patient has prior history of surgery for nasal polyps; AND
	• Prescribedf by or in consultation with an allergist, immunologist, or otolaryngologist/ENT.
	• Approval Duration: 6 months.
	3. Indications excluded from coverage include:
	• Atopic Dermatitis
	• COPD
	• Concurrent use of another monoclonal antibody therapy.
	• Eosinophillic esophagitis, eosinophilic gastroenteritis, or eosinophilic colitis.	

Methadone (for Pain) Concentrate 10mg/ml Solution 5mg/5ml, 10mg/5ml,	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.	All opioids require Prior Authorization (PA). The PA form can be accessed using the following link: 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
Tablets 5mg, 10mg	3. Submission of clinical documentation from last office visit, dated within 3 months of the request. 4. Maximum approval duration is 6 months but may be reduced based on any of the criteria as outlined in Pharmacy Policy 219: Opioid Prescription Prior Authorization.	
Metreleptin (**Myalept**) injection; J3490, J3590	**USE MFC High-Cost Medication PA Criteria**	
Mifepristone (Korlym) tablets Korlym-300mg ONLY; J8499	**USE MFC High-Cost Medication PA Criteria**	
Mirabegron (Myrbetriq) tablets 25mg, 50mg **STEP THERAPY**	1. Ordered for an approved indication for use: • Overactive bladder (OAB) in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency, either alone or in combination with the muscarinic antagonist solifenacin succinate. 2. Pediatric neurogenic detrusor overactivity (NDO) in patients weighing ≥ 35 kg. 3. OAB: adequate trial (30 days), or intolerance to at least 2 preferred bladder agents. 4. NDO: Adequate trial (30 days), or intolerance to oxybutynin IR or ER OR the patient is ≥ 5 years of age. 5. No concurrent diagnosis of severe hepatic impairment (Child-Pugh Class C). 6. No step therapy or prior authorization is required for patients aged ≥ 65 years. 7. If computer claims data supports the Step Therapy requirement, the claim will adjudicate without manual review.	**Limitations for use:** Extended-release tablets and granules are not bioequivalent and cannot be substituted on a mg:mg basis. Do not combine dosage forms to achieve a specific dose.

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	• An adequate trial of two formulary preferred ingredients that include: oxybutynin, solifenacin, tolterodine, and/or trospium. An adequate trial is 30 days. 8. Approval Duration: 12 months.	
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 not 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 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.	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.
Mirvetuximab (**Elahere**); J9063	**USE MFC High-Cost Medication PA Criteria**	

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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: • Patient has been on Pyrukynd for > 52 weeks and has maintained positive clinical response to therapy; OR • 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 • 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. 2. Authorization duration: 12 months 3. If documentation does not provide evidence of positive clinical response to Pyrukynd therapy, allow for dose titration with discontinuation of therapy. 4. **In this case, authorization duration is for 4 weeks.**
Mogamulizumab-kpkc (**Poteligeo**) injection; J9204	**USE MFC High-Cost Medication PA Criteria**	

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
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 an opioid prior authorization form. 3. Submission of clinical documentation from last office visit, dated within 3 months of the request. 4. Maximum approval duration is 6 months but may be reduced or denied based on the criteria as outlined in Pharmacy Policy 219: Opioid Prescription Prior Authorization.	All opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-MD
Mosunetuzumab-axgb (**Lunsumio**), J**9350**	**USE MFC High-Cost Medication PA Criteria**	
Nanoparticle albumin bound sirolimus (**Fyarro**); J9331	**USE MFC High-Cost Medication PA Criteria**	
Naxitamab (**Danyelza**); J9348	**USE MFC High-Cost Medication PA Criteria**	
Nintedanib (**Ofev**) capsule 100mg, 150mg	1. Ordered for an approved indication for use: • Treatment of adults for idiopathic pulmonary fibrosis. • Treatment of adults for chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype. • To slow the rate of decline in pulmonary function in patients with systemic sclerosis associated interstitial lung disease (SSc-ILD). 2. Documentation that patient does not smoke. 3. Medication ordered by a pulmonologist. 4. Authorization Duration: 12 months.	1. All initial criteria are met. 2. Documentation of positive clinical response to Ofev therapy. 3. Approval Duration: 12 months
Niraparib (**Zejula**) tablets 100mg, 200 mg, 300 mg	1. Ordered for an approved indication for use:	

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	• 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. • 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. 2. Patient has advanced (Stage II-IV) disease and Zejula will be used as a single agent or in combination with bevacizumab; OR 3. Patient has recurrent disease with a deleterious or suspected deleterious germline BRCA mutation and the agent will be used as monotherapy. 4. Medication ordered by an Oncologist. 5. Approval Duration: 12 months.	
Nirogacestat (**Ogsiveo**) tablets 50 mg	**USE MFC High-Cost Medication PA Criteria**	
Nitisinone (Orfadin) capsules **Orfadin** brand preferred for 20 mg dose; J8499	**USE MFC High-Cost Medication PA Criteria**	ORFADIN PRIOR AUTH FORM
Nusinersen (**Spinraza**); J2326	**USE MFC High-Cost Medication PA Criteria**	
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**	
Olipudase alfa- (**Xenpozyme**); J0218	**USE MFC High-Cost Medication PA Criteria**	
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. Patient age ≥ 18 years. 3. Member must have tried and failed a 30-day trial of OTC fish oil. 4. Approval Duration: 12 months.	1. The patient has achieved or maintained a reduction in triglyceride levels from baseline. 2. Approval Duration: 12 months.

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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 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.	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. 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.	**<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
	• Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting ≥ 4 hours a day. • Spasticity in adult patients. • Cervical dystonia in adult patients to reduce the severity of abnormal head position and neck pain. • Severe axillary hyperhidrosis of adults inadequately managed by topical agents. • Treatment of blepharospasm associated with dystonia in patients 12 years of age and older. • Treatment of strabismus in patients 12 years of age and older. 2. Medication ordered by a Neurologist, Urologist, Ophthalmologist, or applicable specialist.	
Onasemnogene abeparvovec-xioi (**Zolgensma**) injection; J3399	**USE MFC High-Cost Medication PA Criteria**	
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 the previous 3 months. 4. Maximum approval duration is 6 months but may be approved for a shorter duration based on any of the criteria as outlined in Pharmacy Policy 219: Opioid Prescription Prior Authorization.	All opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-MD

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oxycodone ER and IR capsules, tablets, oral solution/concentrate 5 mg capsules 100mg/5mL oral concentrate 5mg/5mL oral solution IR tablets 5, 10, 13, 20, 30 mg ER tablets 10, 20, 40 mg	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 the opioid prior authorization form. 3. Submission of supporting clinical documentation for last office visit dated within previous 3 months. 4. Maximum approval duration is 6 months but may be reduced or denied based on any of the criteria as outlined in Pharmacy Policy 219: Opioid Prescription Prior Authorization.	All opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-MD
oxycodone/APAP tablets, oral solution tablets 5-325, 7.5-325, 10-325 mg oral solution 5-325mg/5mL	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. Maximum approval duration is 6 months but may be reduced or denied based on any of the criteria as outlined in Pharmacy Policy 219: Opioid Prescription Prior Authorization.	All opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-MD
oxymorphone extended release 12-hour (Opana) tablets 5mg, 7.5mg, 10mg, 15mg, 20mg, 30mg, 40mg,	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.	All opioids require Prior Authorization (PA). The PA form can be accessed using the following link: 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
	3. Submission of supporting clinical documentation for last office visit, dated within previous 3 months. 4. Maximum approval duration is 6 months but may be reduced or denied based on any of the criteria as outlined in Pharmacy Policy 219: Opioid Prescription Prior Authorization.	
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.	1. Initial approval criteria continue to be met. 2. 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: ○ Stool frequency

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	7. <u>Additional Criteria for Multiple Sclerosis</u> • 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	○ 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) 3. 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.	1. Patient shows evidence of positive response to therapy. 2. Approval Duration: 12 months.

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	2. Patient age ≥ 18 years. 3. Patient has recurrent or metastatic disease; and 4. Patient has hormone receptor positive (HR+) either estrogen receptor positive and/or progesterone receptor positive disease; and 5. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND 6. Patient meets one of the following: • Patient is post-menopausal; or • Patient is pre/peri-menopausal and has had either surgical bilateral oophorectomy or ovarian irradiation OR is receiving ovarian suppression/ablation with a GnRH. 7. Ibrance will be used in combination with one of the following: anastrozole, exemestance, letrozole, or fulvestrant. 8. Medication ordered by an Oncologist 9. Approval Duration: 12 months.	
Patisiran (**Onpattro**) Solution 10mg/5ml; J0222	**USE MFC High-Cost Medication PA Criteria**	
Pegcetacoplan (**Empaveli**) injection 1080mg; J3490, J3590	**USE MFC High-Cost Medication PA Criteria**	
pegloticase (**Krystexxa**) injection 8mg/ml; J2507	**USE MFC High-Cost Medication PA Criteria**	
Pegunigalsidase alfa (**Elfabrio**) J2508	**USE MFC High-Cost Medication PA Criteria**	
Ravulizumab-cwvz (**Ultomiris**) injection; J1303	**USE MFC High-Cost Medication PA Criteria**	
Resmetirom (**Rezdiffra**)	1. Ordered for an approved indication for use:	1. Patient meets ONE of the following:

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80 mg, 100 mg tablets **(60 mg is non-formulary)**	• Treatment of adults with nonalcoholic steatohepatitis (NASH/MASH) with moderate to advanced (F2 or F3) liver fibrosis. 2. Patient age ≥ 18 years, AND 3. Prior to treatment, the diagnosis of MASH/NASH is confirmed by one of the following: • Patient has had a liver biopsy AND meets both of the following: ○ Liver biopsy was performed within the 6 months preceding treatment with Rezdiffra; AND ○ Liver biopsy shows non-alcoholic fatty liver disease activity score ≥ 4 with a score > 1 in ALL of the following: steatosis, ballooning, and lobular inflammation OR • Patient has had ONE of the following imaging exams performed within the 3 months preceding treatment with Rezdiffra: ○ Elastography (e.g. Fibroscan, transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, or shear wave elastography); OR ○ Computed tomography; OR ○ Magnetic resonance imaging. 4. Patient meets ONE of the following prior to treatment with Rezdiffra: • Patient has Stage F2 fibrosis; **OR** • Patient has Stage F3 fibrosis; **AND THREE** or more of the following metabolic risk factors that are managed according to Standards of Care: ○ Central obesity	• Completed ≥ 1 year and < 2 years of therapy with Rezdiffra AND the patient has derived benefit from treatment as demonstrated by at least ONE of the following: MASH/NASH resolution AND no worsening of fibrosis OR • No worsening of MASH/NASH AND improvement in fibrosis by ≥ 1 stage; **OR** • Patient has completed ≥ 2 years of treatment AND the patient has not had worsening of fibrosis or MASH/NASH AND according to the prescriber, the patient has not progressed to stage F4 (cirrhosis). 2. Metabolic risk factors are managed according to standard of care; **AND** 3. According to the prescriber, the patient meets ONE of the following: • <u>Female patients</u>: Alcohol consumption < 20 grams per day; OR • <u>Male patients</u>: Alcohol consumption < 30 grams per day. *Note: One standard drink (or one alcoholic drink equivalent) contains ~14 grams of pure alcohol, which is found in*

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	○ Hypertriglyceridemia ○ Reduced high-density lipoprotein cholesterol, ○ Hypertension ○ Elevated fasting plasma glucose indicative of diabetes or pre-diabetes; AND 5. According to the prescriber, the patient meets ONE of the following: • Female patients: Alcohol consumption < 20 grams per day; OR • Male patients: Alcohol consumption < 30 grams per day. *Note: One standard drink (or one alcoholic drink equivalent) contains ~14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits*. 6. Other causes of liver disease or hepatic steatosis have been ruled out (e.g., alcoholic steatohepatitis, acute fatty liver, autoimmune hepatitis, Hepatitis A, B, or C, hemochromatosis, drug-induced liver disease, etc.), AND 7. Provider attestation that member has adopted liver-protective lifestyle interventions such as optimizing weight loss, dietary changes, and exercise, AND 8. Member does not have evidence of cirrhosis, hepatic decompensation, or hepatocellular carcinoma (HCC). 9. All other indications are excluded from coverage as experimental. 10. Prescribed by, or in consultation with an endocrinologist, hepatologist or gastroenterologist. 11. Approval Duration: 12 months	*12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits*. 4. 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. 5. Approval Duration: 12 months.

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Rozanolixizumab (**Rystiggo**); J3333	**USE MFC High-Cost Medication PA Criteria**	
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. 2. Medication ordered by Hematologist or Oncologist. 3. Approval Duration: 12 months.	**<u>Limitations of Use:</u>** • 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.
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>**	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)).

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	• 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). **Nonsegmental Vitiligo:** • 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., 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	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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	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	
Sastralizumab-mwge (**Enspryng**) injection; J3590	**USE MFC High-Cost Medication PA Criteria**	
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. 3. Approval Duration: 12 months.	1. Patient does not show evidence of progressive disease while on Retevmo therapy. 2. Approval Duration: 12 months.
Semaglutide (**Ozempic, Rybelsus**)	1. Ordered for an approved indication for use: • As adjunct to diet and exercise to improve glycemic	**Cannot be approved for indication of weight management.**

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Ozempic 2mg/3 ml (0.25 mg or 0.5 mg/week; 4mg/3ml (1 mg per week) 8mg/3ml (2 mg per week) Rybelsus 3mg, 7mg, 14mg	control in adults with type 2 diabetes mellitus. 2. Patient age ≥ 18 years. **NOTE: Semaglutide is only approved in adolescents for weight loss and is not a covered benefit.** 3. A1c or TIR% report within previous 3 months. 4. **Baseline A1c is ≥ 8.0,** for patients WITHOUT CVD **OR** **Baseline A1c is ≥ 7.0,** for patients WITH CVD defined as: Patient is considered high or very high risk for ASCVD-risk as evidenced by **one** of the following: • Acute coronary syndrome • History of myocardial infarction • Stable or Unstable angina • Coronary or other arterial revascularization • Stroke • Transient ischemic attack • Peripheral arterial disease • ≥ 20% 10-year CVD risk according to the AHA Prevent Calculator: https://professional.heart.org/en/guidelines-and-statements/prevent-calculator 5. May not be concurrently using: • Any other GLP1 or GLP1/GIP combination drug (e.g., Mounjaro, Trulicity, Victoza, Xultrophy or Soliqua). • Any DPP4i (e.g., alogliptin, Januvia (sitagliptin), Tradjenta (Linagliptin), Onglyza (saxagliptin). • Agents for severe constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 6. No history of pancreatitis.	1. Chart notes with A1c or CGM report with TIR% within previous 3 months. **2.** Documented positive clinical response defined as one of the following: • Dose titration is occurring at expected monthly intervals which applies only to the first 6 months of treatment or until A1c labs are available, **or** • A1c goal has been reached on the requested dose, **or** • A1c has decreased by ≥ 1% since onset of therapy; **or** • Patient is at maximum tolerated dose and used as part of a comprehensive diabetes regimen in combination with other anti-hyperglycemic medications. **3.** Patient has not had medical intervention for pancreatitis OR severe gastrointestinal events. (e.g., hospitalization or new start GI motility agent). These patients will be directed to other anti-hyperglycemic agents. 4. May not be concurrently using: • any other GLP1 or GLP1/GIP combination drug (e.g.,

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	7. Not approved for use in Type 1 Diabetes mellitus. 8. Starter doses are limited and require dose escalation. Starter doses are defined as: • Ozempic: the 0.25/0.5 mg strength combines the starter-dose and titration-dose and is limited to two, 28-day dispenses before requiring clinical review. • Rybelsus 3 mg is a starter dose and limited to one, 30-day dispense. 9. Maximum approval duration: 12 months.	Ozempic, Rybelsus, Trulicity, Victoza, Xultrophy or Soliqua) AND/OR • a DPP4i (e.g., alogliptin, Januvia (sitagliptin), Onglyza, or Tradjenta (linagliptin)). • Agents for *severe* constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). **5.** PBM claims data shows consistent adherence as shown by no instance of a drug-free interval greater than 2 months at which time the patient would need to satisfy the initial criteria. **6.** Approval Duration: 12 months
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. 3. Approval duration: 12 months	**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**	
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:**

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		• Ngenla will not be approved for idiopathic short stature (ISS), athletic enhancement, central precocious puberty, congenital adrenal hyperplasia, constitutional delay of growth and puberty, or anti-aging purposes.
Somatropin [recombinant human growth hormone] (**Norditropin FlexPro; Serostim**) injection **Norditropin** 5/1.5ml, 10/1.5ml, 15/1.5ml, 30mg/3ml **Serostim** 4mg, 5mg, 6mg	1.Ordered for an approved indication: **<u>Growth failure in pediatric patients:</u>** ○ Due to inadequate endogenous growth hormone secretion; short stature associated with Turner Syndrome [Norditropin FlexPro] ○ 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] **<u>Growth hormone deficiency in adults:</u>** • replacement of endogenous growth hormone in adults with growth hormone deficiency [Norditropin FlexPro] • Treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance [Serostim ONLY] 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.	**<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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		1. Clinical documentation indicating positive clinical response during previous 12 months. 2. Approval duration: 12 months
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. 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. 3. Envarsus XR will be used in combination with other immunosuppressant medications to prevent kidney transplant rejection. 4. Patient has not been diagnosed with congenital long Qt-syndrome. 5. Prescribed by a Nephrologist and Transplant Specialist. 6. Approval Duration: 12 months	1. Patient has continued care with a nephrologist or transplant specialist. 2. Patient continues to meet the initial approval criteria. 3. No clinical evidence of organ failure. 4. Individual has not developed any significant adverse drug effects that may exclude continued use such as: • Pure red cell aplasia (PRCA) • Posterior reversible encephalopathy syndrome (PRES) • Torsades de points 5. Approval duration: 12 months
tadalafil (Adcirca; Alyq) tablets 20mg PAH: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 nitrate-containing medication (e.g. Nitrodur, NitroStat). 3. BPH-specific requirements: • Ordered for generic Cialis (tadalafil) 5 mg tablets • Ordered by a urologist.	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. • If using tadalafil and finasteride, max recommended duration of tadalafil is ≤26 weeks (manufacturer's labeling).

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	4. PAH-specific requirements: • Ordered for generic Adcirca (tadalafil PAH) 20 mg tablets. 5. Medication ordered by a Pulmonologist, Cardiologist, or Rheumatologist. 6. **Erectile dysfunction is not a covered indication for use.** 7. Approval Duration: 12 months.	PAH: • Tadalafil is contraindicated in patients taking guanylate cyclase stimulators (e.g. riociguat) due to potentially severe hypotension.
Talquetamab-tgvs **(Talvey)**	**USE MFC High-Cost Medication PA Criteria**	
Tebentafusp (**Kimmtrak**); J9274	**USE MFC High-Cost Medication PA Criteria**	
Teclistamab (**Tecvayli**) J9380	**USE MFC High-Cost Medication PA Criteria**	
Teduglutide (**Gattex**); J3490	**USE MFC High-Cost Medication PA Criteria**	
Tenofovir alafenamide (**Vemlidy**) tablets 25mg	1. Ordered for an approved indication for use: • Treatment of chronic hepatitis B virus infection in adults and pediatric patients, ≥ 6 years of age and weighing at least 25 kg, with compensated liver disease 2. Baseline test results prior to treatment start. • Confirmed negative HIV test result prior to starting medication. • HBV DNA • 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 and tenofovir disoproxil fumarate (generic Viread) **OR** meets one of the following criteria: • Patient age < 20 years.	1. Documentation of a positive clinical response to Vemlidy therapy. 2. Patient is not a suitable candidate for entecavir or tenofovir disoproxil fumarate (generic Viread). 3. Approval duration: 12 months.

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	• 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. In patients with renal impairment, patients who are not receiving chronic hemodialysis must have an estimated creatinine clearance > 15 ml/minute. 5. Medication ordered or in consultation with an Infectious Disease specialist, Gastroenterologist, or Hepatologist. 6. Authorization Duration: 12 months.	
Teplizumab (**Tzield**); J9381	**USE MFC High-Cost Medication PA Criteria**	
Teprotumumab-trbw (**Tepezza**) injection; J3241	**USE MFC High-Cost Medication PA Criteria**	
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.	**<u>Osteoporosis</u>** 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.

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	• 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. • 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.	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 **<u>Glucocorticoid-induced osteoporosis:</u>** 1. Documentation supports positive response to therapy. 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

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		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. 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).	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 • 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

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	• 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.	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. **Baseline A1c is ≥ 8.0,** for patients WITHOUT CVD **OR** **Baseline A1c is ≥ 7.0,** for patients WITH CVD defined as: Patient is considered high or very high risk for ASCVD-risk as evidenced by **one** of the following: • Acute coronary syndrome • History of myocardial infarction • Stable or Unstable angina • Coronary or other arterial revascularization • Stroke • Transient ischemic attack • Peripheral arterial disease • ≥ 20% 10-year CVD risk according to the AHA Prevent Calculator: https://professional.heart.org/en/guidelines-and-statements/prevent-calculator 4. May not be concurrently using or taking: • Any other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus, Trulicity, Victoza, Xultrophy or Soliqua) AND/OR	**Cannot be approved for indication of weight management.** 1. Chart notes with A1c or CGM report with TIR% within previous 3 months. **2.** Documented positive clinical response defined as one of the following: • Dose titration is occurring at expected monthly intervals which applies only to the first 6 months of treatment or until A1c labs are available, **or** • A1c goal has been reached on requested dose, **or** • A1c has decreased by ≥ 1% since onset of therapy, **or** • Patient is at maximum tolerated dose and used as part of a comprehensive diabetes regimen in combination with other anti-hyperglycemic medications. **3.** Patient has not had medical intervention for pancreatitis **OR**

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	• a DPP4i (e.g., alogliptin, Januvia (sitagliptin), Onglyza, or Tradjenta (linagliptin)). • Agents for *severe* constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 5. No history of pancreatitis. 6. Not approved for use in Type 1 Diabetes mellitus. 7. Starter doses are limited and require dose escalation. Mounjaro 2.5 mg is a starter dose and is limited to one, 28-day supply and then must be dose escalated UNLESS Mounjaro renewal criteria are met (i.e. 2.5 mg dose can be continued if therapeutic benefit meets renewal criteria). 8. **Cannot be approved for indication of weight management.** 9. Maximum Approval Duration: up to 12 months	severe gastrointestinal events. (e.g., hospitalization or new start GI motility agent). These patients will be directed to other anti-hyperglycemic agents. 4. May not be concurrently using: • any other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus, Trulicity, Victoza, Xultrophy or Soliqua) AND/OR • a DPP4i (e.g., alogliptin, Januvia (sitagliptin), Onglyza, or Tradjenta (linagliptin)). • Agents for *severe* constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 5. PBM claims data shows consistent adherence as shown by no instance of a drug-free interval greater than 2 months at which time the patient would need to satisfy the initial criteria. 6. Approval Duration: up to 12 months.
Tisotumab vedotin-tftv (**Tivdak**) injection J9273	**USE MFC High-Cost Medication PA Criteria**	

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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. Patient has relapsed or Stage IV disease; AND 3. Patient has tried at least two other systemic regiments (i.e. Inlyta + Keytruda; Cabometyx + Opdivo; Lenvima + Keytruda; Yervoy + Opdivo, sunitinib, pazopaniv, or Lenvima + everolimus. 4. Medication order by Hematology/oncology. 5. Approval Duration: 12 months.	1. Patient does not show evidence of disease progression while on Fotivda therapy. 2. Approval Duration: 12 months.
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 for last office visit, dated within the previous 3 months. 4. Maximum approval duration is 6 months but may be reduced or denied based on any of the criteria as outlined in Pharmacy Policy 219: Opioid Prescription Prior Authorization	All 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.
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:**	1. **Prostate Cancer:** • Patient is experiencing clinical benefit (e.g., serum testosterone < 50 ng/dl) • Patient has not experienced unacceptable toxicity.

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	• 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 • Gender affirming care: 12 months	**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 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**	
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. * examples of contraindications include: a history	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.

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	of coronary artery disease, cardiac accessory pathway disorders, history of stroke or TIA, or hemiplegic or basilar migraine, peripheral vascular disease, ischemic bowel disease, uncontrolled hypertension, or severe hepatic impairment. 4. Quantity limits: 16 tablets per 30 days, 200 mg max daily dose. 5. 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. 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 biosimilars) 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.	**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, adalimumab, Risankizumab, gueslkumab, secukinumab, ixekizumab, brodalumab, tildrakizumab, rofacitinib, baricitinib, upadacitinib, apremilast, or similar). 3. Approval Duration: 12 months.

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	• Must have trialed and failed 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: o Corticosteroids o Vitamin D analogs (calcitriol, calcipotriene) o Tacrolimus or pimecrolimus. • 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.	

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
	• 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. • 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, 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	

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
	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 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	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. 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

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
	hypoglycemia. 9. Approval Duration: 12 months.	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**	
Vamorolone (**Agamree**)	**USE MFC High-Cost Medication PA Criteria**	
Velmanase alfa (**Lamzede**); J0217	**USE MFC High-Cost Medication PA Criteria**	
viltolarsen (**Viltepso**) 50 mg/ml solution; J1427	**USE MFC High-Cost Medication PA Criteria**	
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. 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	1. All initial criteria continue to be met. 2. Documentation provided or attestation of therapeutic benefit. 3. Approval Duration: 6 months.
Vestronidase alpha (**Mepsevii**) J3397	**USE MFC High-Cost Medication PA Criteria**	

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Voretigene neparvovec (**Luxturna**) J3398	**USE MFC High-Cost Medication PA Criteria**	
Vutrisiran (**Amvuttra**) J0225	**USE MFC High-Cost Medication PA Criteria**	
Zilucoplan (**Zilbrysq**) J3490, J3590, C9399	**USE MFC High-Cost Medication PA Criteria**	