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. All clinically appropriate formulary (preferred) alternatives should be exhausted before approval of a branded product is considered. 2. To request an override for a "brand medically necessary" prescription, the prescriber must complete and sign the DHMH MedWatch form and include with the Prior Authorization request. Mere submission of the form is no guarantee that the request will be honored. If a generic version of the drug made by a different manufacturer is available, a trial with the other generic drug may be required before approving the brand name product. A copy of a DHMH MedWatch form and instructions are available at the links in the column to the right. 3. In the event of a market shortage for generic products, a brand drug may be approved through the duration of the anticipated drug shortage.	1. Instructions for Completing MDH Medwatch Form 2. MDH Medwatch Form
abaloparatide **(Tymlos)**	1. Prescribed for an approved indication for use: • Treatment of postmenopausal women with osteoporosis at high risk for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. • Treatment to increase bone density in men with osteoporosis at high risk for fracture, or patients who have failed or intolerant to other available osteoporosis therapy. 2. Patient has diagnosis of post-menopausal osteoporosis	1. Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide, Forteo, Tymlos) during the patient's lifetime. 2. Approval Duration: up to 12 months, not intended to last longer than the final infusion completing 24 months of therapy.

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

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	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
ADAMTS13 recombinant (**Adzynma**)	**USE MFC High-Cost Medication PA Criteria**	
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. **Asthma indication:** One inhaler, One time only. **COPD indication:** Duration determination is dependent upon: • Oversight by a Pulmonologist,	

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	• documented COPD severity, • concurrent therapy with appropriate escalation based on current guidelines (e.g, LABA+LAMA+ICS if eos ≥ 100 cells/uL or LABA+LAMA if eos < 100 cells/uL, roflumilast, PDE4 inhibitor etc.) • compliance with COPD regimen • Note that LABAs/LAMAs are preferred over SABAs/SAMAs • Maximum approval duration: 6 months.	
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) including one or more of the following: frequent and severe abdominal pain	1. Documentation of positive clinical response to therapy. 2. Authorization Duration: 12 months.

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	or discomfort, frequent bowel urgency or fecal incontinence, or disability or restriction of daily activities due to IBS. 2. Prescribed for a female patient with diagnosis of severe diarrhea-predominant IBS syndrome, **AND** 3. Chronic IBS symptoms lasting at least 6 months. 4. Gastrointestinal tract abnormalities have been ruled out. 5. There has been an inadequate response to conventional therapy (e.g., loperamide, antispasmodics). 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**	
Atazanavir sulfate (Reyataz) 300 mg capsules **All other strengths or formulations are non-formulary*	1. Ordered for an approved indication for use: • Treatment of HIV-1 infection in combination with other antiretroviral agents in pediatric or adult patients.	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days.

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	2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least **ONE** of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Patient age ≥ 3 months and ≥ 5 kg; **OR** Patient age ≥ 6 years and ≥ 20 kg. 5. Not prescribed concurrently with Crixivan (indinavir), Kaletra (lopinavir-ritonavir), or Norvir (ritonavir). 6. Approval Duration: continuous if no gaps in therapy > 90-days occur.	3. Approval Duration: continuous if no gaps in therapy > 90 days occur.
Avalglucosidase alfa-ngpt (**Nexviazyme**), J0219	**USE MFC High-Cost Medication PA Criteria**	
Avatrombopag (**Doptelet**) 20mg tablets	1. Ordered for an approved indication for use: • thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. • thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure. 2. Patient age ≥ 18 years. 3. May not be treated concurrently with other thrombopoietin receptor agonists (e.g. Alvaiz, Nplate, Mulpleta, Promacta) or with spleen tyrosine kinase	1. **<u>Chronic Immune Thrombocytopenia</u>** • Documented positive response to treatment (e.g. increased platelet counts, maintenance of platelet counts, and/or decreased frequency of bleeding episodes; **AND** • Patient remains at risk for bleeding complications. • Approval Duration: 12 months.

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	inhibitors (e.g. Tavalisse). **Chronic Immune Thrombocytopenia (ITP):** • Patient has undergone a splenectomy **OR** Patient has tried at least **ONE** other therapy (e.g. systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Promacta (eltrombopag tablets/suspension), Alvaiz (eltrombopag choline), Nplate (romiplostim SQ injection), Tavalisse (fostamatinib tablets), or rituximab); **AND** • Patient has platelet count < $30*10^9$/L (<30,000/mcL) **OR** Patient has platelet count < $50*10^9$/L (<50,000/mcL) **AND** according to prescriber has an increased risk of bleeding. • A platelet count obtained within the previous 30 days must be supplied with documentation submitted. • Medication ordered by a or in consultation with a Hematologist. • **Approval Duration: 6 months** **Thrombocytopenia in a patient with Chronic Liver Disease:** • Patient has a current platelet count < $50*10^9$/L (<50,000/mcL); AND • Patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. • Approval Duration: 5 days, a maximum of 15 tablets per treatment.	2. **Thrombocytopenia in a patient with Chronic Liver Disease:** • must meet initial use criteria for each request. • Approval Duration: 5 days, a maximum of 15 tablets per treatment
Axicabtagene ciloleucel (**Yescarta**) Injection, Q2041	**USE MFC High-Cost Medication PA Criteria**	

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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 ≥ 18 years of age. 3. Patient does not have diagnosis of Myelodysplastic Syndrome (MDS). 4. Patient does not have severe hepatic impairment (i.e. total bilirubin > 3 times the upper limit of normal. 5. Onureg will be used as a single agent. 6. Patient is not able to complete intensive curative therapy (i.e., transplant-ineligible) OR patient is ≥ 60 years of age and has declined/is not fit for allogeneic hematopoietic stem cell transplant. 7. Medication ordered by an Oncologist. 8. Limited to 14 tablets per 28 days. 9. Approval Duration: 6 months.	1. Patient shows treatment response as defined by stabilization or improvement that is evidenced by: • A complete response, or • A complete hematologic response, or • A partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH. 2. Patient has not experienced unacceptable toxicity from the drug (e.g., severe myelosuppression). 3. Approval duration: 6 months.
Azelaic Acid GEL (Finacea) 15% **STEP THERAPY FOR ACNE ONLY, SEE ROSACEA SPECIFIC CRITERIA IN CENTER COLUMN**	1. Ordered for an approved indication for use: • Acne Vulgaris in adults • Rosacea 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. • Acceptable formulary precursor ingredients for acne treatment include: adapalene, benzoyl peroxide, benzoyl peroxide-erythromycin combination	1. Treatment for rosacea to be renewed for 12 months upon documentation of beneficial clinical effect.

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	products, clindamycin, clindamycin-benzoyl peroxide combination products, erythromycin, tretinoin. 3. If patient's claims data supports the completion of the step-therapy for the treatment of acne, the claim will adjudicate without manual review. **Rosacea:** *Step Therapy automation is not in place for the indication of Rosacea.* • Rosacea indication requires a 30-day trial and failure of topical metronidazole. • Approval Duration: 12 months.	
Baricitinib (**Olumiant**) tablets 2 mg, 4 mg (1 mg non-formulary)	1. Ordered for an approved indication for use: • Treatment of patients with severe alopecia areata • Treatment of patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF blockers. 2. Patient age ≥ 18 years. **Alopecia Areata:** • Diagnosis of moderate to severe alopecia areata, with a current episode of alopecia areata with at least 50% scalp hair loss, **AND** • Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecias, secondary syphilis, tinea capitis, triangular alopecia, and trichotillomania); **AND** • Patient is not receiving Olumiant concurrent with **ANY** of the following: o A targeted immunomodulator e.g., adalimumab, Cimzia, Enbrel, Simponi, Orencia, Xeljanz, Rinvoq or Litfulo OR	**Renewal Criteria applies to both Alopecia Areata and Rheumatoid Arthritis indications:** 1. Documentation of positive clinical response to Olumiant therapy; **AND** 2. Patient is not receiving Olumiant concurrent with ANY of the following: • A targeted immunomodulator e.g. Adalimumab, Cimzia, Enbrel, Simponi, Orencia, Xeljanz, Rinvoq or Litfulo **OR** • A potent immunosuppressant (e.g. azathioprine or cyclosporine). 3. Approval Duration: 12 months.

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	○ A potent immunosuppressant (e.g., azathioprine or cyclosporine). • Prescribed by, or in consultation with a Dermatologist. • Limitations: 1 tablet per day (i.e. if 4 mg dose needed, use 4 mg tablets rather than 2 x 2 mg tablets). • Approval Duration: 12 months **Rheumatoid Arthritis (RA):** • Diagnosis of moderately to severely active RA; **AND** • **One** of the following: ○ History of failure to a 3-month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) (e.g. methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial), **OR** ○ Patient has previously been treated with a targeted immunomodulator FDA-approved for the treatment of RA as documented by claims history or medical records that include drug, date and duration of therapy. (e.g., adalimumab, Enbrel, Cimzia, Simponi, Orencia, Xeljanz, Rinvoq); **AND** • **One** of the following: ○ History of failure, contraindication or intolerance to at least **two** preferred products with documentation of drug, date, and	

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	duration of trial: adalimumab, Enbrel, Cimzia, Simponi, Rinvoq, Xeljanz; **OR** ○ Patient is currently on Olumiant therapy as documented by claims history or submission of medical records **AND** the patient has not received a manufacturer supplied sample at no cost as a means to establish themselves as a current user of Olumiant; **AND** • Patient is not receiving Olumiant concurrent with **ANY** of the following: ○ A targeted immunomodulator e.g., adalimumab, Cimzia, Enbrel, Simponi, Orencia, Xeljanz, Rinvoq or Litfulo OR ○ A potent immunosuppressant (e.g., azathioprine or cyclosporine). • Prescribed by or in consultation with a Rheumatologist. • Dose is limited to one, 2 mg per day. • 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. Patient is ≥ 5 years of age; **AND** 3. Patient weighs ≥ 15 kg; **AND** 4. Patient has Mycobacterium tuberculosis resistant to rifampin and isoniazid; **AND** 5. Sirturo is prescribed as part of a combination regimen	1. Must meet initial approval criteria. 2. Manufacturer labelling limits therapy to a maximum duration of 6 months, however, longer durations may be necessary to treat infection. 3. Approval Duration: 6 months.

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	with other anti-tuberculosis agents (i.e., pretomanid and linezolid); **AND** 6. Medication ordered by or in consultation with an infectious disease specialist. 7. Approval duration: 6 months.	
belimumab (**Benlysta**) Inj 200mg/ml	1. Ordered for an approved indication for use: • patients ≥ 5 years of age with active systemic lupus erythematosus (SLE) who are receiving standard therapy. • Patients ≥ 18 years of age with active lupus nephritis who are receiving standard therapy. 2. Not prescribed for patients with severe active central nervous system lupus as use of Benlysta is not recommended for those patients. 3. Must be currently taking **OR** has tried and failed or had intolerance/contraindication to at least one standard therapy for SLE (e.g., corticosteroids, antimalarials, NSAIDS or immunosuppressives) or lupus nephritis (e.g., corticosteroids, mycophenolate, cyclophosphamide, azathioprine) 4. Prescriber attestation that all baseline evaluations have been done and no contraindications to use are present including counseling/assessment of recent live vaccine use and depression/suicide risk. 5. Prescriber attests that subsequent appropriate evaluation, and monitoring will be done based on the package insert. 6. Patient is not receiving Benlysta in combination with **ANY** of the following: • Targeted Immunomodulator (e.g.,	1. All initial criteria continue to be met. 2. Documentation demonstrating clinical benefit and tolerance. 3. Patient is not receiving Benlysta in combination with **ANY** of the following: • Targeted Immunomodulator (e.g., Adalimumab, etanercept, certolizumab, anakinra) • Lupkynis (voclosporin) • Saphnelo (anifrolumab) 4. Approval Duration: 12 months.

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	Adalimumab, etanercept, certolizumab, anakinra) • Lupkynis (voclosporin) • Saphnelo (anifrolumab) 7. Prescribed by an immunologist, nephrologist, rheumatologist, or provider experienced in the treatment of SLE or lupus nephritis. 8. Approval Duration: 12 months.	
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. Patient age ≥ 12 years. 3. Member must have tried and failed, have intolerance or medical contraindication to at least three of these medications: cyclosporine, methotrexate, mycophenolate, sirolimus, and glucocorticoids. 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.	1. Prescriber attestation of continued clinical benefit. 2. Approval Duration: 6 months.
benralizumab (**Fasenra**) Pen 30mg/ml	1. Ordered for an approved indication for use: • add-on maintenance treatment of severe asthma in adults and pediatric patients ≥ 6 years of age with an eosinophilic phenotype.	**Asthma:** 1. Documentation of positive clinical response to Fasenra therapy as demonstrated by at least one of the

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	• Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA) (formerly known as Churg-Strauss Syndrome). 2. May not be covered for the indication of COPD. **<u>Eosinophilic Asthma:</u>** 1. Patient age ≥ 6 years. 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); or • Two or more bursts of systemic corticosteroids for at least 3 days each in previous 12 months; or • Asthma-related emergency treatment (ER visit, hospital admission, or unscheduled OV for nebulizer or emergency treatment); **OR** • Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted; **AND** • Patient is currently dependent on oral corticosteroids for the treatment of asthma. 3. Submission of medical records documenting one of the following: • Asthma is eosinophilic phenotype as defined by baseline (pre-benralizumab treatment) peripheral blood eosinophil level ≥ 150 cells/uL within the past 6 weeks: **OR** • Patient is currently dependent on maintenance	following: • Reduction in frequency of exacerbations • Decreased utilization of rescue medications • Increase in percent predicted FEV1 from pretreatment baseline. • Reduction in severity or frequency of asthma-related symptoms • Reduction in oral corticosteroid requirements. 2. Used in combination with inhaled corticosteroid (ICS)-containing controller medication. 3. Patient is not receiving treatment in combination with **ANY** of the following: • Anti-interleukin-5 therapy (e.g., Cinqair (resilizumab), Nucala (mepolizumab). • Anti-IgE therapy (e.g., Xolair (omalizumab). • Anti-interleukin-4 therapy (e.g., Dupixent (dupilumab). • Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., Tezpire (Tezepelumab)).

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	therapy with oral corticosteroids for the treatment of asthma. 4. Fasenra will be used in combination with **<u>ONE</u>** 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: **6 months**. **<u>EGPA:</u>** 1. Patient age ≥ 18 years. 2. Chart documentation of pre-treatment blood eosinophil count of more than 1000 cells per microliter or a blood eosinophil level > 10%. 3. Patient is currently taking oral corticosteroids, unless contraindicated or not tolerated. 4. Patient has at least two of the following disease characteristics of EGPA:	4. Approval Duration: 12 months. **<u>EGPA:</u>** 1. Patient has a beneficial response to treatment as demonstrated by any of the following: • A reduction in the frequency of relapses. • A reduction or discontinuation of daily oral corticosteroid dose • No active vasculitis 2. Approval Duration: 12 months

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	• Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation. • Neuropathy, mono or poly (motor deficit or nerve conduction abnormality). • Pulmonary infiltrates, non-fixed • Sino-nasal abnormality • Cardiomyopathy (established by echocardiography or magnetic resonance imaging) • Glomerulonephritis (hematuria, red cell casts, proteinuria) • Alveolar hemorrhage (by bronchoalveolar lavage) • Palpable purpura • Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3). 5. Patient has had at least one relapse (i.e., requiring an increase in oral corticosteroid dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within the 2 years prior to starting treatment with Fasenra or has refractory disease. 6. Medication ordered by a Pulmonologist, Immunologist, or Allergist. 7. 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**	
Bictegravir, emtricitabine and tenofovir alafenamide (**Biktarvy**) **only 50/200/25 mg tablets are formulary*	1. Ordered for an approved indication for use: • Treatment of HIV-1 infection (as a complete regimen) in adults and pediatric patients ≥ 14 kg as an initial therapy in those with no antiretroviral treatment history; OR to replace a stable antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen and no known or suspected substitutions associated with resistance to bictegravir and tenofovir. 2. Use of Biktarvy for **PrEP** is off-label and not approved for coverage (Use CDC-approved PrEP formulary alternatives: generic Truvada or Apretude). 3. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 4. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 5. Not used concurrently with any of the following: Epivir (lamivudine), Cimduo (lamivudine-tenofovir), Combivir (lamivudine-zidovudine), Delstrigo (doravirine-lamivudine-tenofovir), Dovato (dolutegravir-lamivudine),	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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	Epzicom (lamivudine-abacavir), Symfi or Symfi LO (efavirenz-lamivudine-tenofovir), Temixys (abacavir-dolutegravir-lamivudine), Trizivir (abacavir-lamivudine-zidovudine). 6. Approval Duration: continuous if no gaps in therapy > 90-days occur.	
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. If patient < 19 years of age, shall be approved. 3. For patients ≥ 19 years of age, approved for one of the following: • Chronic Myelogenous/Myeloid Leukemia • Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia • Myeloid/Lymphoid Neoplasms WITH the presence of an ABL1 rearrangement • Any NCCN Recommended Regimen with a Drug and Biologics Compendium with a Category of Evidence and Consensus rating of 1, 2A, or 2B. 4. Medication ordered by an Oncologist. 5. Authorization Duration: 12 months.	1. Patient does not show evidence of disease progression while on Bosulif therapy. 2. Approval Duration: 12 months.
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.	1. Patient does not show evidence of progressive disease while on Alunbrig therapy. 2. Approval Duration: 12 months.

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	• 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. **Non-Small Cell Lung Cancer (NSCLC):** • The tumor is anaplastic lymphoma kinase (ALK)-positive. • The cancer is either: metastatic, recurrent, or advanced. **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 loss of kidney function in adults with primary immunoglobulin A nephropathy (igAN) who are at risk for disease progression.	1. All patients requesting authorization for continuation of therapy must meet all initial authorization 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
	2. Diagnosis of primary immunoglobulin A (IgAN) confirmed by renal biopsy, AND 3. Laboratory report and/or chart notes indicating that the patient has proteinuria ≥ 1 gm/day or baseline urine protein-to-creatinine ratio (UPCR) ≥ 0.8 g/g based on 24-hour urine collection, AND 4. Patient is at risk for disease progression, AND 5. The estimated glomerular filtration rate (eGFR) ≥ 35 ml/min, AND 6. 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, OR • Patient has an allergy, contraindication or intolerance to ACEI and ARB, AND 7. Patient has a history of failure, contraindication, or intolerance to a 30-day trial of a glucocorticoid (e.g. methylprednisolone, prednisone). 8. Medication ordered by a nephrologist. 9. Approval Duration: 9 months.	
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: • PrEP for at-risk adults and adolescents weighing at least 35 kg for to reduce the risk of sexually acquired HIV-1 infection. 2. Individuals must have a negative HIV-1 test prior to initiating Apretude.	1. Patient has previously received treatment with Apretude 2. Patient has a negative HIV-1 test within previous 3 months. 3. Provider confirms that the patient will be tested for HIV-1 with each

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. 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: • Patient understands the risks of missed doses. • Patient has ability to adhere to the required every 2 months injection and testing appointments. 6. Dosing is in accordance with FDA-approved labeling. 7. Approval Duration: 12 months	subsequent injection; and 4. Dosing is in accordance with FDA-approved labeling. 5. Approval Duration: 12 months
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. May NOT be approved for pre-exposure prophylaxis (PrEP) or any off-label indication.** 3. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 4. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative	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.

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
	• HIV P24 antigen • HIV Western blot • HIV genotype 3. 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). 4. Patient is antiretroviral treatment-experienced and has been virologically suppressed (HIV RNA < 50 copies/ml) for at least three months; AND 5. Patient has no history of treatment failure. 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	
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**	
Cerliponase alpha (**Brineura**) J0567	**USE MFC High-Cost Medication PA Criteria**	
Ciltacabtagene autoleucel (**Carvykti**); Q2056	**USE MFC High-Cost Medication PA Criteria**	
Cipaglucosidase alfa (**Pombiliti**); J1203	**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
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.** • Trial and failure to: o At least one medium- or high-potency topical steroid **AND** o A six-week trial of topical tacrolimus **OR** pimecrolimus, **OR** a four-week trial of Zoryve. 3. Quantity Limit: 60 gm per 25 days or 180 gm per 75 days. 4. Additional quantity requests may be granted if the affected area is greater than 5% of BSA. 5. Approval Duration: 12 months	1. Patient has achieved or maintained a positive clinical response as evidenced by improvement or resolution of any of the following: • Erythema, edema, xerosis, erosions, excoriations, oozing and crusting, lichenification or pruritus. 2. Approval Duration: 12 months.
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	1. Patient does not show evidence of progressive disease while on Xalkori therapy. 2. Approval Duration: 12 months.

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	Consensus of 1, 2A, or 2B. **Non-Small Cell Lung Cancer (NSCLC):** • The cancer is either: metastatic, recurrent, or advanced. • The tumor is one of the following: o ALK-positive o ROS1-positive o Positive for mesenchymal-epithelial transition (MET) amplification o 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: o Erdheim-Chester Disease o Langerhans Cell Histiocytosis o Rosai-Dorfman Disease • 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	

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	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 progression with BRAF-targeted therapy. 2. Medication ordered by an Oncologist. 3. Approval Duration: 12 months.	
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.	1. Patient does not show signs of disease progression or unacceptable toxicity. 2. Patient is not using Tafinlar for adjuvant treatment of cutaneous melanoma. This indication is limited to a total of 12 months cumulative treatment and may not be approved for additional supply. 3. All other indications may be approved for up to 12 months per 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
	• Treatment of pediatric patients ≥ 1 year of age with low-grade glioma (LGG) with BRAF V600E mutation who require systemic therapy. **Cutaneous Melanoma:** • Patient has either unresectable melanoma or metastatic melanoma; **AND** • Tafinlar is prescribed as adjuvant therapy involving the lymph nodes; **AND** • Will be used in combination with Mekinist (trametinib); **AND** • Cancer is positive for a BRAF V600 mutation. **Central Nervous System Cancers (CNS):** • Patient has metastatic brain lesions AND Tafinlar is active against the primary (melanoma) tumor; OR • Patient has glioma AND the cancer is positive for BRAF V600E mutation AND will be used in combination with Mekinist (trametinib). **Non-Small Cell Lung Cancer (NSCLC):** • Diagnosis of metastatic, advanced or recurrent NSCLC; AND • Cancer is positive for BRAF V600E mutation. **Thyroid Cancer that is positive for BRAF V600E mutation:** • Diagnosis of Anaplastic Thyroid Cancer (ATC): o disease is metastatic, locally advanced, or unresectable OR prescribed as adjuvant therapy following resection; and o Will be used in combination with Mekinist (trametinib). • Diagnosis of one of the following carcinomas:	

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
	follicular, oncocytic, or papillary; and • Disease if unresectable locoregional recurrent disease, or persistent disease, or metastatic disease; AND • Patient has symptomatic or progressive disease; AND • Disease is refractory to radioactive iodine treatment. Hepatobiliary Cancers: • Diagnosis of BRAF V600E mutation positive, gallbladder, extrahepatic cholangiocarcinoma, or intrahepatic cholangiocarcinoma; AND • Used as a subsequent treatment after progession on or after systemic treatment; AND • Disease is unresectable or metastatic; AND • Used in combination with Mekinist (trametinib) **Histiocytic Neoplasms:** • Diagnosis of eith Langerhans Cell Histiocytosis or Erdheim-Chester Disease that is positive for BRAF V600E mutation **Solid Tumors:** • Presence of solid tumor positive for BRAF V600E mutation; and • Used as subsequent treatment after progression on or after systemic treatment; and • Disease is unresectable or metastatic; and • Will be used in combination with Mekinist (trametinib). Any other NCCN Recommended Regimen with a Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.	

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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 hemoglobin 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 cannot be approved.

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
	stimulating agents. 7. Maximum daily dose 24 mg per day. 8. Initial approval duration: 6 months.	5. Approval duration: 6 months.
Darunavir (Prezista) tablets 600 mg, 800 mg **all other dosages are non-formulary*	1. Ordered for an approved indication for use: • Treatment of HIV-1 infection, coadministered with ritonavir and other antiretroviral agents in adults and pediatric patients aged ≥ 3 years. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Can not be taken concurrently with Symtuza (darunavir-cobicistat-emtricitabine-tenofovir) OR Prezcobix (darunavir-cobicistat). 5. Approval Duration: continuous if no gaps in therapy > 90 days occur.	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.
Darunavir and cobicistat 800 mg/150 mg tablets **(Prezcobix)**	1. When ordered for the following indications: • Treatment of HIV-1 infection in treatment-naïve and treatment-experienced adults and pediatric patients weighing at least 40 kg with no darunavir resistance-associated substitutions • Compendial use as part of an alternative Post-exposure Prophylaxis (PEP) treatment in combination	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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
	with other antiretroviral medications. **<u>When prescribed as treatment for PEP:</u>** Requests shall be redirected to a preferred PEP therapy shown to have either greater efficacy or adherence to therapy per current CDC PEP guidelines. **<u>When prescribed for the treatment of HIV-infections:</u>** 1. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 2. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 3. Can not be taken concurrently with the following medications which are either therapeutic duplications or combinations of drugs that reduce the effectiveness of the requested drug: Evotaz (atazanavir-cobicistat), Genvoya (elvitegravir-cobicistat-emtricitabine-tenofovir), Prezista (darunavir), Stribild (cobicistat-elvitegravir-emtricitabine-tenofovir), Symtuza (darunavir-cobicistat-emtricitabine-tenofovir), Tybost (cobicistat). 4. Approval Duration: continuous if no gaps in therapy > 90 days occur.	

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
Darunavir, cobicistat, emtricitabine, tenofovir alafenamide (**Symtuza**)	1. Ordered for an approved indication for use: • Treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg with no prior antiretroviral treatment history or who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen for at least 6 months and have no known substitutions associated with resistance to darunavir or tenofovir as a complete regimen. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14%) are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Can not be taken concurrently with the following medications which are either therapeutic duplications or combinations of drugs that reduce the effectiveness of the requested drug: Atripla, Biktarvy, Cimduo, Complera, Delstrigo, Emtriva, Evotaz, Genvoya, Odefsey, Prezcobix, Prezista, Stribild, Symfi or Symfi LO, Temixys, Tybost, or Viread. 5. Approval Duration: continuous if no gaps in therapy > 90 days occur.	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.
darolutamide (**Nubeqa**) tablets 300mg	1. Ordered for an approved indication for use: • treatment of non-metastatic castration-resistant	1. Patient has not shown disease progression.

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
	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 a gonadotropin-releasing hormone (GnRH) analog (e.g. leuprolide, goserelin, triptorelin, histrelin, or degarelix). • Patient has bilateral orchiectomy. 5. Medication ordered by an Oncologist or Urologist. 6. Approval Duration: 12 months.	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**	
Denosumab (**Prolia**) 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.	1. All initial criteria met. 2. Approval Duration: 12 months. **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
	• 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 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:**	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.	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

<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>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 dose is ≥ 12 mg per day. See table under renewal criteria.</td><td>4. Patient does not have hepatic impairment.
5. Tardive dyskinesia:
• AIMS score sheet along with the progress note must be provided for initial and renewal PA requests.
6. Huntington’s disease:
• Description of functional impairment, including Total Maximal Chorea (TMC) score sheet along with progress notes must be provided for both initial and 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>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 the table below:
<table><tr><th>Total Daily Dose</th><th>Regimen to Approve AFTER 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>Dextromethorphan/Quinidine (Nuedexta) tablets</td><td>1. Ordered for an approved indication for use:
• Treatment of pseudobulbar affect (PBA)
2. Patient age ≥ 18 years.
3. Patient has been diagnosed with ONE of the following:
• Amyotrophic lateral sclerosis (ALS)
• Alzheimer’s disease
• Multiple sclerosis (MS)
• Parkinson’s disease
• Stroke
• Traumatic brain injury
4. The baseline Center for Neurologic Study-Lability Scale (CNS-LS) score must be > 13.</td><td>1. Documentation of positive clinical response to therapy.
2. Approval Duration: up to 12 months.</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
	5. NOTE: 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 6. Dose must not exceed 2 capsules per day. 7. Prescribed by or in consultation with a neurologist. 8. Initial Authorization period is limited to 6 months.	
Dinutuximab (**Unituxin**) J9999	**USE MFC High-Cost Medication PA Criteria**	
Dolutegravir (**Tivicay**) 50 mg tablets. **note Tivicay PD is non-formulary*	1. Ordered for an approved indication for use: • Treatment of HIV-1 infection in adults (treatment naïve or experienced) and in pediatric patients (naïve or -experienced but INSTI-naïve) aged at least 4 weeks and weighing at least 3 kg in combination with other antiretroviral agents. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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. Can not be taken concurrently with the following medications which are either therapeutic duplications or combinations of drugs that reduce the effectiveness of the requested drug: Dovato (dolutegravir-lamivudine), Juluca (dolutegravir-rilpivirine), or Triumeq (abacavir-dolutegravir-lamivudine). 5. Approval Duration: continuous if no gaps in therapy > 90 days occur.	
Dolutegravir, abacavir, and lamivudine (**Triumeq**)	1. Ordered for an approved indication for use: • Treatment of HIV-1 infection in adults and pediatric patients aged at least 3 months and weighing at least 6 kg. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Patient does not have resistance-associated integrase substitutions or clinically suspected INSTI resistance. 5. Can not be taken concurrently with the following medications which are either therapeutic duplications or combinations of drugs that reduce the effectiveness of the requested drug: Cimduo, Combivir, Delstrigo,	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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
	Dovato, Epivir, Epzicom, Juluca, Symfi or Symfi Lo, Temixys, Tivicay, Trizivir, Ziagen. 6. Approval Duration: continuous if no gaps in therapy > 90 days occur.	
Dolutegravir and lamivudine (**Dovato**) tablets	1. Ordered for an approved indication for use: • As a complete regimen for the treatment of HIV-1 infection in adults and adolescents ≥ 12 years of age and weighing at least 25 kg with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history or treatment failure and no known substitutions associated with resistance to the individual components of Dovato. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Can not be taken concurrently with the following medications which are either therapeutic duplications or combinations of drugs that reduce the effectiveness of the requested drug: Cimduo, Combivir, Delstrigo, Epivir,	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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	Epzicom, Juluca, Symfi or Symfi Lo, Temixys, Tivicay, Triumeq, Trizivir. 5. Approval Duration: continuous if no gaps in therapy > 90 days occur.	
Doravirine (**Pifeltro**) 100 mg tablets	1. Ordered for an approved indication for use: • In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg with no prior antiretroviral treatment history OR 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 no known substitutions associated with resistance to doravirine. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Can not be taken concurrently with the following medications which are either therapeutic duplications or combinations of drugs that reduce the effectiveness of the requested drug: Delstrigo (doravirine-lamivudine-tenofovir).	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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
	5. Approval Duration: continuous if no gaps in therapy > 90 days occur.	
Doravirine, lamivudine, tenofovir DF (**Delstrigo**)	1. Ordered for an approved indication for use: • In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg with no prior antiretroviral treatment history OR 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 no known substitutions associated with resistance to doravirine. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Can not be taken concurrently with the following medications which are either therapeutic duplications or combinations of drugs that reduce the effectiveness of the requested drug: Atripla, Biktarvy, Cimduo, Combivir, Complera, Dovato, Epivir, Epzicom, Genvoya, Odefsey, Pifeltro, Stribild, Symfi or Symfi Lo, Symtuza, Temixys, Triumeq, Trizivir, Viread.	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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	5. Approval Duration: continuous if no gaps in therapy > 90 days occur.	
Dulaglutide (**Trulicity**) 0.75 mg, 1.5 mg, 3 mg, 4.5 mg	1. Ordered for an approved indication for use: • As an adjunct to diet and exercise to improve glycemic control in adults or pediatric patients **≥ 10 years** of age with type 2 diabetes mellitus. • In adult patients with T2DM for risk reduction of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors. 2. Patient is aged ≥ 10 years of age. 3. Patient has Type 2 Diabetes Mellitus ******NOTE:** Type 1 DM does **NOT** qualify for coverage**** 4. A1c or CGM Time In Range% (TIR) report within past 3 months. 5. A urine albumin-to-creatinine ratio (uACR) within the previous 12 months. **Treatment of Type 2 Diabetes without regard to CVD risk factors:** The patient has an A1c (hemoglobin A1c) of ≥ 7.5 (TIR ≤ 60%) **OR** **Treatment of Type 2 Diabetes with CVD as defined below:** • Pre-treatment A1c is ≥ 6.5 (TIR ≤ 70%) **AND** • BMI ≥ 27 kg/m^2 (documentation within previous 90 days of current height and weight) **AND** Documentation submitted to show that the patient has at least **ONE of the following:** • History of myocardial infarction; **OR**	**Cannot be approved for indication of weight management.** 1. Chart notes with A1c or CGM report with TIR% within previous 3 months. 2. A urine albumin-to-creatinine ratio (uACR) within the previous 12 months. 3. Documented positive clinical response defined as one of the following: **Baseline (pre-GLP-1) A1c was ≥ 8.0 and:** • A1c has decreased by ≥ 1% since onset of therapy or TIR% was ≤ 55% and has increased ≥ 10% **OR** **Baseline (pre-GLP-1) A1c was ≥ 6.5 but < 8.0 and:** • A1c or TIR% has improved • Not eligible for renewal if A1c is unchanged or has increased or TIR% has decreased. • Patient has not had medical intervention for ○ Pancreatitis; or ○ Severe gastrointestinal events. (e.g., hospitalization or new start GI motility agent). 4. May not be concurrently using:

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	• Prior Stroke (ischemic or hemorrhagic stroke); **OR**
	• Peripheral arterial disease as evidenced by:
	  ○ Intermittent claudication with ankle-branchial index (ABI) less than 0.85 (at rest); **OR**
	  ○ Peripheral arterial revascularization procedure; **OR**
	  ○ Amputation due to atherosclerotic disease.
	6. May not be concurrently using:
	• Any other GLP1 or GLP1/GIP combination drug (e.g., Mounjaro, Ozempic, Rybelsus, Saxenda, Soliqua, Victoza [liraglutide], Xultrophy or Zepbound).
	• 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).
	7. Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all contraindications.
	8. May not be approved for patients with:
	• Any personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN 2).
	• A history of confirmed pancreatitis, **and/or**
	• Current pregnancy
	9. **Cannot be approved for indication of weight management.**
		• **ANY** other GLP1 or GLP1/GIP combination drug (e.g., Mounjaro, Ozempic, Rybelsus, Saxenda, Soliqua, Trulicity, Victoza (liraglutide), Xultrophy or Zepbound)
		• **ANY** DPP4i (e.g., alogliptin, Januvia (sitagliptin), Onglyza (saxagliptin), 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

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	10. Trulicity 0.75 mg is a starter dose and is limited to one, 28-day supply and then must be dose escalated to 1.5 mg per week dose **UNLESS** A1c ≤ 7.0 or TIR ≥ 65% 11. Approval Duration: up to 12 months	
Dupilumab (**Dupixent**) SQ inj Pen-injector – 200 mg/1.14 ml Pen-injector – 300 mg/2 ml Prefilled syringe – 200mg/1.14 ml Prefilled syringe – 300 mg/2 ml	1. Prescribed for an FDA-approved indication for use. 2. The dosage and frequency requested are aligned with FDA and manufacturer guidelines for patient-specific parameters: • Patient age • Patient weight • Indication for use 3. The criteria for Dupixent are **indication specific**. Please review criteria for the patient-specific diagnosis. **Atopic Dermatitis:** • Diagnosis of moderate-to-severe chronic atopic dermatitis; **AND** • History of failure, contraindication, or intolerance to **TWO** of the following therapeutic **classes** of topical therapies (document drug, date of trial, and/or contraindication to medication). ○ Medium-high, or very-high potency topical corticosteroid (e.g. mometasone, fluocinolone acetonide, fluocinonide). ○ Topical calcineurin inhibitor (e.g., tacrolimus or pimecrolimus). ○ Phosphodiesterase-4 Enzyme Inhibitor, e.g. Zoryve (roflumilast), Eucrisa (crisaborole); **AND** • Patient is not receiving Dupixent concurrent with either of the following:	Renewal criteria are indication specific. Please review criteria for the patient-specific diagnosis. **Atopic Dermatitis:** • Documentation of a positive clinical response to therapy; **AND** • Patient is not Dupixent concurrent with either of the following: ○ Biologic immunomodulator (e.g., Adbry (tralokinumab-ldrm), Ebglyss (lebrikizumab), etc.) ○ Janus kinas inhibitor (e.g., Rinvoq (Upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib); **AND** • Prescribed by a Dermatologist, Allergist, or Immunologist. • Approval Duration: 12 months. **Asthma:** • Documentation of positive clinical response as demonstrated by at least **ONE** of the following: ○ Reduction in frequency of

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	○ Biologic immunomodulator (e.g., tralokinumab-ldrm); ○ Janus kinas inhibitor (e.g., Ebglyss (lebrikizumab), Rinvoq (Upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib) • **<u>UNLESS</u>** Patient has ≥ 25% skin involvement and topical management is not feasible. • Prescribed by or a Dermatologist, Allergist or Immunologist. • Approval Duration: 12 months. **<u>Asthma, moderate to severe eosinophilic:</u>** • Diagnosis of moderate-to-severe asthma; **AND** • 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 > 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, hospital admission, or unscheduled physicians' office visit for nebulizer or other urgent treatment ○ Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] < 80% predicted	exacerbations. ○ Decreased utilization of rescue medications. ○ Increased in % predicted FEV1 from pre-treatment baseline. ○ Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, SOB, coughing) ○ Reduction in oral corticosteroid requirements; **AND** ○ Dupixent is being used in combination with an ICS-containing maintenance medication (e.g.fluticasone/salmeterol, Breo Ellipta, budesonide/formoterol, Trelegy); **AND** ○ Patient is not receiving Dupixent in combination with any of the following: Anti-interleukin-5 therapy (e.g. mepolizumab, resilizumab, benralizumab); Anti-IgE therapy (e.g. omalizumab); and/or Thymic stromal

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	○ Patient is currently dependent on oral corticosteroids for the treatment of asthma; **AND** • **ONE** of the following: ○ Submission of medical records documenting that asthma is an eosinophilic phenotype as defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level ≥ 150 cells/µL; **OR** ○ Patient is currently dependent on oral corticosteroids for the treatment of asthma; **AND** ○ Dupixent will be used in combination with **ONE** of the following: ▪ On maximally dosed combination inhaled ICS/LABA inhaler (e.g., Advair, AirDuo, Symbicort, Breo, etc); OR ○ Combination therapy including **BOTH** of the following: ▪ One maximally dosed ICS product (e.g. Alvesco, Asmanex, Qvar, etc); **AND** ▪ One additional asthma controller medication (e.g., LABA, montelukast or theophylline); **AND** • Patient is not receiving Dupixent in combination with **ANY** of the following: ○ Anti-interleukin-5 therapy (e.g. Nucala, Cinqair, Fasenra). ○ Anti-IgE therapy (e.g., Xolair).	lymphopoietin (TSLP) inhibitor (e.g. Tezepelumab); **AND** • Prescribed by an Allergist, Immunologist, or Pulmonologist. • Approval Duration: 12 months. **<u>Chronic Obstructive Pulmonary Disease (COPD)</u>** • Documentation of positive clinical response to therapy as defined by at least **<u>one</u>** of the following criteria: ○ A reduction in moderate exacerbations (i.e., those requiring systemic steroids and/or antibiotics). ○ A reduction of severe exacerbations (i.e. those requiring hospitalization and requiring more than one day of observation in an emergency department or urgent care facility). ○ An improvement in baseline lung function as assessed by pre-bronchodilator forced expiratory volume (FEV1). • Approval Duration: 12 months.

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	○ Thymic stromal lymphopoietin (TSLP) inhibitor (e.g. Tezspire); **AND** • Prescribed by or a Dermatologist, Allergist, Immunologist or Pulmonologist. • Approval Duration: 12 months. **Chronic Obstructive Pulmonary Disease (COPD)** • May be approved as add-on therapy in refractory disease who are inadequately controlled on standard therapies. • Patient age ≥ 18 years. • Diagnosis of COPD confirmed by spirometry (FEV1/FVC < 0.7). • Patient is actively using a triple therapy inhaler (e.g. Breztri or Trelegy). Active use is confirmed by pharmacy claims data showing ≥ 65% of utilization over time in the previous 6 months. • Patient has had 2 or more moderate exacerbations (i.e. symptoms requiring treatment with systemic glucocorticosteoids) **OR** at least 1 hospitalization for COPD exacerbation in previous 12 months, **AND** • Pre-treatment blood eosinophil count ≥ 300 cells/microliter. • Prescribed by or in consultation with a Pulmonologist. • Approval Duration: 12 months. **Chronic Rhinosinusitis with Nasal Polyposis** • Diagnosis with chronic rhinosinusitis with nasal polyposis (CRSwNP) defined by **ALL** of the following: ○ **TWO** or more of the following symptoms for longer than a 12-week duration:	**Chronic Rhinosinusitis with Nasal Polyposis** • Documentation of positive clinical response to Dupixent therapy; **AND** • Patient will continue to receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids; **AND** • Patient is not receiving Dupixent in combination with **ANY** of the following: Anti-interleukin-5 therapy (e.g. mepolizumab, resilizumab, benralizumab); Anti-IgE therapy (e.g. omalizumab); and/or Thymic stromal lymphopoietin (TSLP) inhibitor (e.g. Tezepelumab); **AND** • Prescribed by an Allergist, Immunologist, or Pulmonologist. • Approval Duration: 12 months. **Eosinophilic Esophagitis:** • Documentation of positive clinical response to Dupixent therapy as evidenced by improvement in at least **ONE** of the following from baseline: ○ Symptoms ○ Histologic measures ○ Endoscopic measures;

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	▪ Nasal mucopurulent discharge ▪ Nasal obstruction, blockage or congestion ▪ Facial pain, pressure and/or fullness ▪ Reduction or loss of sense of smell; **AND** ○ **ONE** of the following findings using nasal endoscopy and/or sinus computed tomography: ▪ Purulent mucus or edema in the middle meatus or ethmoid regions ▪ Polyps in the nasal cavity or the middle meatus ▪ Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses; **AND** ○ **ONE** of the following: ▪ Prescence of bilateral nasal polyposis ▪ Patient has previously required surgical removal of bilateral nasal polyps; **AND** ○ **ONE** of the following: ▪ Patient has required prior sinus surgery ▪ Patient has required systemic corticosteroids for CRSwNP in the previous 2 years ▪ Patient has been unable to obtain symptom relief after trial of **TWO** of the following classes of agents: ➢ Nasal saline irrigations	**AND** • Patient is not receiving Dupixent in combination with **ANY** of the following: Anti-interleukin-5 therapy (e.g. mepolizumab, resilizumab, benralizumab); Anti-IgE therapy (e.g. omalizumab); and/or Thymic stromal lymphopoietin (TSLP) inhibitor (e.g. Tezepelumab); **AND** • Prescribed by a Gastroenterologist or Allergist. • Approval Duration: 6 months. **<u>Prurigo Nodularis</u>** • Documentation of positive clinical response to Dupixent therapy; **AND** • Patient is not receiving Dupixent in combination with **EITHER** of the following: ○ Biologic immunomodulator (e.g., Adbry) **OR** ○ Janus kinase inhibitor (e.g., Rinvoq, Xeljanz/XR, Opzelura, Cinginqo); **AND** • Prescribed by a Dermatologist, an Allergist, or an Immunologist. • Approval Duration: 12 months.

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	➢ Intranasal corticosteroids ➢ Antileukotriene agents; **AND** • Patient will receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids; **AND** • Patient is **NOT** receiving Dupixent in combination with **ANY** of the following: o Anti-interleukin-5 therapy (e.g. mepolizumab, resilizumab, benralizumab); o Anti-IgE therapy (e.g. omalizumab); and/or o Thymic stromal lymphopoietin (TSLP) inhibitor (e.g. Tezepelumab); **AND** • Prescribed by an Allergist, an Immunologist, an Otolaryngologist, or a Pulmonologist. • Approval Duration: 12 months. **<u>Eosinophilic Esophagitis:</u>** • Diagnosis of Eosinophilic Esophagitis; **AND** • Patient aged ≥ 2 years of age; **AND** • Patient is experiencing symptoms related to esophageal dysfunction (e.g., dysphagia, food impaction, chest pain that is centrally located and may not respond to antacids, gastroesophageal reflux disease-like symptoms/refractory heartburn, upper abdominal pain); **AND** • Submission of clinical documentation indicating eosinophil-predominant inflammation on esophageal biopsy, consisting of a peak value of ≥15 intraepithelial eosinophils per high-power field (HPF) or 60 eosinophils per mm^2; **AND**	

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	• Secondary causes of esophageal eosinophilia have been ruled out; **AND**
	• Mucosal eosinophilia is isolated to the esophagus and symptoms have persisted after an 8-week trial of at least **ONE** of the following:
	  ○ Proton pump inhibitor
	  ○ Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone); **AND**
	• Patient is **not** receiving Dupixent in combination with any of the following:
	  ○ Anti-interleukin-5 therapy (e.g. mepolizumab, resilizumab, benralizumab);
	  ○ Anti-IgE therapy (e.g. omalizumab); and/or
	  ○ Thymic stromal lymphopoietin (TSLP) inhibitor (e.g. Tezepelumab); **AND**
	• Prescribed by either a Gastroenterologist or Allergist.
	• Approval Duration: 6 months.
	<u>Prurigo Nodularis</u>
	• Diagnosis of prurigo nodularis; **AND**
	• Patient has ≥ 20 nodular lesions; **AND**
	• History of failure, contraindication, or intolerance to previous prurigo nodularis treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin); **AND**
	• Patient is not receiving Dupixent with **EITHER** of the following:
	  ○ Biologic immunomodulator (e.g. Adbry); **OR**
	  ○ Janus kinase inhibitor (e.g., Rinvoq, Xeljanz/XR, Opzelura, Cibinqo); **AND**	

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	• Prescribed by a Dermatologist, Allergist, or Immunologist. • Approval Duration: 6 months.	
Eculizumab (**Soliris**) injection 10mg/ml; J1300	**USE MFC High-Cost Medication PA Criteria**	
Efavirenz, emtricitabine, tenofovir DF 600/200/300 mg tablets (Atripla)	1. Ordered for an approved indication for use: • A complete regimen or in combination with other antiretroviral agents for the treatment of HIV-1 infections in adults and pediatric patients weighing at least 40 kg. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Can not be taken concurrently with the following medications which are either therapeutic duplications or combinations of drugs that reduce the effectiveness of the requested drug: Biktarvy, Cimduo, Complera, Delstrigo, Emtriva, Genvoya, Odefsey, Stribild, Sustiva, Symfi or Symfi Lo, Symtuza, Temixys, Viread. 5. Approval Duration: continuous if no gaps in therapy > 90-days occur.	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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Efgartigimod alfa-fcab (**Vyvgart**) injection; J9332 **Vyvgart Hytrulo** (efgartigimod alfa and hyaluronidase) SQ J9334	**USE MFC High-Cost Medication PA Criteria**	
Elagolix, estradiol, and norethindrone (**Oriahnn**) 300/1/0.5 mg capsule pack	1. Ordered for an approved indication for use: • Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. 2. The patient is biologically female and premenopausal. 3. Must have tried and failed or have a contraindication to using: • Combined estrogen/progestin-containing contraceptives (oral pills, transdermal patch, vaginal ring); OR • Levonorgestrel-releasing intrauterine device (IUD; e.g. Kyleena, Liletta, Mirena, Skyla); OR • Progestin-only oral contraceptive pills; OR • Tranexamic acid tablets. 4. The patient has not exceeded 24 cumulative months of treatment with an elagolix-containing product (e.g. Orilissa) or a relugolix-containing product (e.g., Myfembree). 5. The patient is not concurrently using another GnRH antagonist drug (e.g. Orilissa, Myfembree). 6. Quantity Limits: 56 capsules for 28 days, lifetime limit of 24 fills. 7. Approval Duration is the lesser of 12 months OR 24 minus the number of months of cumulative therapy as listed above in criteria #4.	1. Patient has not exceeded 24 cumulative months of treatment with an elagolix-containing product (e.g., Oriahnn, Orilissa) or a relugolix-containing product (e.g., Myfembree). 2. Approval Duration is the lesser of 12 months OR (24-minus the total number of months of therapy as listed in the criteria above).

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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. 7. 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.
Elivaldogene autotemecel (**Skysona**); J3590	**USE MFC High-Cost Medication PA Criteria**	
Eltrombopag (**Promacta**) 12.5 mg, 25 mg packets for oral suspension; 12.5 mg, 25 mg, 50 mg, 75 mg tablets ***note that Alvaiz (eltrombopag choline) is non-formulary***	1. Ordered for an approved indication for use: • Treatment of thrombocytopenia in patients aged 1 year and older with persistent or chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. • Treatment of thrombocytopenia in patients with chronic Hepatitis C to allow the initiation and maintenance of interferon-based therapy.	May not be treated concurrently with other thrombopoietin receptor agonists (e.g. Alvaiz, Doptelet, Nplate, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g. Tavalisse). **Chronic Immune Thrombocytopenia (ITP):** 1. Documentation of positive clinical response to Promacta.

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	• First-line treatment of severe aplastic anemia in patients ≥ 2 years of age in combination with standard immunosuppressive therapy. • Treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy. 2. Pre-treatment platelet count lab results. 3. May not be treated concurrently with other thrombopoietin receptor agonists (e.g. Alvaiz, Doptelet, Nplate, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g. Tavalisse). 4. Promacta should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding and should not be used in an attempt to normalize platelet counts. **Chronic Immune Thrombocytopenia (ITP):** 1. Diagnosis of ITP; AND 2. Patient has had an insufficient response to a previous treatment (e.g. corticosteroids, immunoglobulins, thrombopoietin receptor agonists, splenectomy). 3. Pre-treatment platelet counts. 4. Untransfused platelet count at any point prior to the initiation of Promacta less than $30*10^9$/L or $30*10^9$/L to $50*10^9$/L with symptomatic bleeding (e.g. significant mucous membrane bleeding, GI bleeding or trauma) or risk factors for bleeding. 5. Ordered by or in consultation with a hematologist or oncologist. 6. Approval Duration: 6 months. **Chronic Hepatitis C-associated Thrombocytopenia:** 1. Diagnosis of chronic hepatitis C-associated thrombocytopenia; AND 2. One of the following:	2. Current platelet count. 3. **Approval Duration: 3 months** for patients with current platelet counts less than $50*10^9$/L for whom the platelet count is not sufficient to prevent clinically important bleeding and who have not received a maximal dose of Promacta for at least 4 weeks. 4. **Approval Duration: 12 months** for patients: • with current platelet counts less than $50*10^9$/L for whom the platelet count is sufficient to prevent clinically important bleeding OR • for current platelet counts of $50*10^9$/L to $200*10^9$/L, OR • patients with current platelet count > $200*10^9$/L to ≤ $400*10^9$/L for whom dosing Promacta will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding. **Chronic Hepatitis C-associated Thrombocytopenia:** 1. Documentation of positive clinical response to Promacta; AND 2. Patient is currently on antiviral interferon therapy for treatment of chronic hepatitis C. 3. Approval Duration: 6 months **Aplastic Anemia:**

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	• Planning to initiate and maintain interferon-based treatment, OR • Currently receiving interferon-based treatment. • Ordered by or in consultation with a provider specializing in infectious disease, gastroenterology, hepatology, or transplant. • Approval Duration: 6 months. **<u>Aplastic Anemia:</u>** 1. Diagnosis of severe aplastic anemia; AND 2. Patient aged ≥ 2 years; AND 3. ONE of the following: • Used in combination with standard immunosuppressive therapy (e.g., Atgam [antithymocyte globulin equine], Thymoglobulin [antithymocyte globin rabbit], cyclosporine), OR • History of failure, contraindication, or intolerance to at least one course of immunosuppressive therapy (e.g. cyclosporine, Atgam, Thymoglobulin). 4. Approval Duration: 6 months.	1. Documentation of positive clinical response to Promacta. 2. Current platelet counts. 3. Approval Durations: • Up to 4 months total for patients with current platelet counts less than $50*10^9$/L who have not received appropriately titrated therapy with Promacta for at least 16 weeks. • Up to 4 months total for patients with current platelet counts < $50*10^9$/L who are transfusion-independent. • 12 months for patient with current platelet counts of $50*10^9$/L to $200*10^9$/L. • 12 months for patients with current platelet count > $200*10^9$/L to ≤ $400*10^9$/L for whom dosing Promacta when dose adjusted to achieve and maintain the appropriate target platelet count.
Elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide (**Genvoya**)	1. Ordered for an approved indication for use: • A complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 25 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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	the individual components of Genvoya. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Can not be taken concurrently with the following medications which are either therapeutic duplications or combinations of drugs that reduce the effectiveness of the requested drug: Atripla, Biktarvy, Cimduo, Complera, Delstrigo, Emtriva, Evotaz, Odefsey, Prezcobix, Stribild, Symfi or Symfi Lo, Symtuza, Temixys, Tybost, Viread. 5. Approval Duration: continuous if no gaps in therapy > 90-days occur.	
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. Patients assigned female gender at birth **may not be** approved for coverage for the indication of PrEP as this is	1. All initial criteria are met 2. Renewal or prior authorization is on required for gaps in therapy > 90 days. 3. Approval Duration is continuous if no gaps in therapy > 90 days occur.

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	contraindicated by treatment guidelines. **3. Although Descovy is approved for PrEP, MFC does not provide coverage for this indication and will redirect these requests to formulary preferred alternatives: tenofovir disoproxil fumarate and emtricitabine (generic Truvada) OR Apretude (cabotegravir).** 4. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 5. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Request is for the 200/25 mg strength. 5. Approval Duration: continuous if no gaps in therapy > 90 days.	
Elranatamab-bcmm (**Elrexfio**)	**USE MFC High-Cost Medication PA Criteria**	
Elvitegravir, cobicistat, emtricitabine, tenofovir DF (**Stribild**)	1. Ordered for an approved indication for use: • A complete treatment regimen for the treatment of HIV-1 infection in adults and pediatric patients aged ≥12 years of age and weighing at least 35 kg who have no antiretroviral treatment history or to replace a current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen for at least 6 months	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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	with no history of treatment failure and no known substitutions associated with resistance to the individual components of Stribild. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Can not be taken concurrently with the following medications which are either therapeutic duplications or combinations of drugs that reduce the effectiveness of the requested drug: Atripla, Biktarvy, Cimduo, Complera, Delstrigo, Emtriva, Evotaz, Genvoya, Odefsey, Prezcobix, Symfi or Symfi Lo, Symtuza, Temixys, Tybost, Viread. 5. Approval Duration: continuous if no gaps in therapy > 90-days occur.	
Emicizumab (**Hemlibra**) J7170	**USE MFC High-Cost Medication PA Criteria**	
Enzalutamide (**Xtandi**) 80 mg tablets	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	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

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	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-risk for metastasis (PSA doubling time ≤ 9 months. 4. Medication ordered by an Oncologist or Urologist. 5. Dose limited to 2 tablets per day 6. Approval Duration: 12 months.	(leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).
Epocoritamab-bysp (**Epkinly**) J9321	**USE MFC High-Cost Medication PA Criteria**	
Etanercept (**Enbrel**)	1. Ordered for an approved indication for use and following the indication-specific criteria listed below: **Rheumatoid Arthritis (RA):** 1. Diagnosis of moderately to severely active RA. 2. Patient meets one of the following: • Has history of failure to a 3-month trial of one non-biologic disease modifying anti-rhematic drug (DMARD) (e.g. methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial). **OR** • Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of RA as documented by claims history or submission of medical records. (document drug, date and duration of therapy). (e.g. Cimzia, adalimumab, Simponi,	**Renewal Criteria applies to all approved indications described in the initial criteria column:** 5. Documentation of positive clinical response to therapy. 6. Patient is not receiving Enbrel concurrently with another targeted immunomodulator (e.g. Cimzia, adalimumab, Simponi, Olumiant, Rinvoq, Xeljanz). 7. Approval Duration: 12 months.

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	Olumiant, Rinvoq, Xeljanz), OR 2. Patient is not receiving Enbrel in combination with another targeted immunomodulator (as listed in #2). 3. Prescribed by or in consultation with a rheumatologist. 4. Approval Duration: 12 months. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** 1. Diagnosis of moderately to severely active PJIA. 2. Patient is not receiving Enbrel concurrently with another targeted immunomodulator. 3. Prescribed by or in consultation with a rheumatologist. 4. Approval Duration: 12 months **Psoriatic Arthritis (PsA)** 1. Diagnosis of Psoriatic Arthritis. 2. The patient meets **ONE** of the following: • Patient has history of failure to a 3-month trial of methotrexate a maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (with documentation of trial dates and details), **OR** • Patient has been previously treated with a targeted immunomodulator that is FDA-approved for the treatment of PsA as documented in claims history or submission of medical records that include the name of the drug, dates, and duration of therapy, **OR** 3. Prescribed by or in consultation with a rheumatologist or dermatologist. 4. Approval Duration: 12 months. **Plaque Psoriasis:** 1. Diagnosis of moderate to severe plaque psoriasis. 2. Patient has greater than or equal to 3% body surface area	

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	involvement, palmoplantar, facial, genital involvement or severe scalp psoriasis, **AND** • History of failure to one of the following topical therapies unless contraindicated or clinically significant adverse effects are experienced with documentation included: o Topical corticosteroids o Vitamin D analogs (calcitriol, calcipotriene) o Tazarotene o Calcineurin inhibitors (tacrolimus/pimecrolimus) o Anthralin o Coal tar; **AND** • History of failure to a 3-month trial of methotrexate at maximally indicated dose unless contraindicated or clinically adverse effects occurred, OR 3. Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records that include the name of the drugs, dates and duration of therapy. 4. Prescribed by or in consultation with a dermatologist. 5. Approval Duration: 12 months.	
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	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

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	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.	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**	
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**	

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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: o Known or suspected toxic megacolon and/or known small bowel ileus OR o Admitted to, or expected to be admitted to an ICU for medical reasons, OR o Absolute neutrophil count < 500 cells/mL[3] o History of major GI surgery within 3 months before treatment start (not including appendectomy or cholecystectomy) OR o History of total colectomy or bariatric surgery that disrupted the GI lumen OR o History of active inflammatory bowel disease (e.g. ulcerative colitis, Crohn's disease, microscopic colitis) with diarrhea believed to be cause by	1. Use is limited to two treatment courses per lifetime. 2. Patient must meet the initial criteria for use. **Limitations of Use:** VOWST is not indicated for treatment of CDI.

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	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, 50mcg/hr, 75mcg/hr, 100mcg/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 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.	All opioids require prior authorization (PA). The PA request form can be access using the following links: OPIOID PRIOR AUTH FORM-MD

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	4. Patient must be considered opioid-tolerant which is defined as patients who have been taking for one week or longer, at least 60 mg morphine daily, or at least 30 mg of oral oxycodone daily or at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid. 5. 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.	
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. The labs as listed in #3 are needed for each of the FDA-labelled testing frequencies at month 1, 2, 3, 6 and 9 after starting therapy. 5. Patient must not have cirrhosis. 6. Patient does not have severe renal impairment (GFR < 30 ml/min) or end-stage renal disease. 7. The medication must not be used concomitantly with CYP1A2 inhibitors (e.g., acyclovir, allopurinol, amiodarone, cimetidine, clarithromycin, duloxetine, famotidine, fluoroquinolones, fluvoxamine, mexiletine,	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 1-3 months depending upon how long patient has received treatment, reference criteria #4 of initial approval criteria. 4. Renewal duration is dependent on how long patient has been Veozah and shall only be for as long as needed to reach the next lab monitoring checkpoint. Once patient has been monitored for 9 months of initial therapy, approval duration may be extended to 12 months.

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	oral contraceptives, verapamil, zafirlukast, zileuton). 8. Patient must have treatment failure, intolerance, or contraindication to a 12-week trial of at least one menopausal hormone therapy. 9. Initial approval period: 1 month.	
finerenone (**Kerendia**) tablets 10mg, 20mg	1. Ordered for approved indication: • to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). 2. PA SUBMISSION REQUIREMENTS: • Serum potassium ≤ 5.0 mEq/L • eGFR ≥ 25 mL/min/1.73 m2 • Urine albumin-to-creatinine ratio ≥ 30 mg/g • Concomitant use with maximum tolerated doses of ACE-Inhibitor or ARB unless intolerant to or contraindicated. 3. Failed trial or contraindication to one formulary SGLT2i. 4. Approval duration: 3 months	1. All initial criteria for approval; AND 2. Dosing appropriate based on 4-week potassium laboratory check. • 20 mg daily if Potassium ≤ 4.8 • 10 mg daily if K+ between 4.8-5.5 • Interrupt therapy if K+ > 5.5, may restart at 10 mg daily when potassium is ≥ 5.0 3. Approval duration: 12 months
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 had an inadequate response to a previous treatment (e.g. corticosteroids, immunoglobulins,	1. Documentation of positive clinical response as defined by one of the following: • Increased platelet count. • Reduction in bleeding events. 2. Patient is not receiving concurrent treatment with thrombopoietin receptor agonists (e.g. Alvaiz,

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	thrombopoietin receptor agonists or splenectomy). 4. Documentation of pre-treatment platelet count of ≤ $30*10^9$/L. 5. Patient has documented trial and failure to, or an intolerance or contraindication to ALL of the following: • 4-day trial of corticosteroid therapy • IVIG therapy • 60-day trial of Promacta (or equivalent e.g. Nplate). 6. Patient has relapsed after splenectomy, or has a contraindication to splenectomy. 7. Patient is not on hemodialysis. 8. Patient not being concurrently treated with thrombopoietin receptor agonists (e.g. Alvaiz, Doptelet, Nplate, Mulpleta, Promacta). 9. Max dose: 150 mg 2 times daily with goal platelets ≥ 50 x 10^9/L. 10. Ordered by or in consultation with a Hematologist. 11. Initial Approval Duration: 3 months.	Doptelet, Nplate, Mulpleta, Promacta). 3. Approval duration: 12 months.
Fostemsavir (**Rukobia**) 600 mg tablets	1. Ordered for an approved indication for use: • Treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following:	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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	• HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Approval Duration: continuous if no gaps in therapy > 90-days occur.	
Furosemide subcutaneous device (**Furoscix**)	1. Ordered for an approved indication for use: • treatment of congestion due to fluid overload in adults with chronic heart failure. 2. Patient has CrCl > 30 ml/min **OR** eGFR > 20 ml/min 3. Patient has been stable and is refractory to at least one of the following loop diuretics, at up to maximally indicated doses: ○ Furosemide oral tablets; 40-160 mg/day ○ Torsemide oral tablets; 50-100 mg/day ○ Bumetanide oral tablets; 3-10 mg/day 4. Documentation that member is a candidate for parenteral diuresis outside of the hospital, as defined by meeting **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: • Hepatic cirrhosis or ascites • Acute pulmonary edema • Anuria 6. Dose does not exceed 80 mg (1 cartridge) per day.	1. Patients must meet initial approval criteria for each request. 2. Dose has not exceeded 8 cartridges in the previous 30 days.

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	7. Prescribed by a cardiologist. 8. <u>Limitations:</u> • Dose limited to 80 mg (1 cartridge) per day. • Not to exceed 8 cartridges in 30 days. 9. Approval requires that patient is referred to MFC Case Management, AND 10. Authorization Duration: 3 months	
gabapentin extended-release (Gralise) tablets 300mg, 600mg **note, this is not the same as gabapentin enacarbil which is non-formulary.*	1. Ordered for an approved indication for use: • the management of Postherpetic Neuralgia (PHN). Not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect dosing frequency. 2. Patient age ≥ 18 years. 3. Patient CrCl > 30 ml/min; patient is not on hemodialysis. 4. Dose does not exceed 1800 mg per day. 5. Approval Duration: 12 months	1. Initial criteria continue to be met. 2. Approval duration: 12 months.
Gilteritinib (**Xospata**) tablets 40mg	1. Ordered for an approved indication for use: • the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test. 2. Medication ordered by an Oncologist. 3. Approval Duration: 12 months	1. Patient does not show evidence of disease progression while on Xospata therapy. 2. Approval Duration: 12 months.
Givosiran (**Givlaari**); J0223	**USE MFC High-Cost Medication PA Criteria**	
Glofitamab (**Columvi**); J9286	**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 of age, **AND**	1. All initial criteria continue to be met. 2. The patient's HDSS score has improved by at least 2 points since starting treatment with glycopyrronium (documentation required). 3. Limited to 30 cloths per 30 days.

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	3. Symptomatic hyperhidrosis occurs more than once weekly, and the symptoms cease at night; **AND** 4. Must have tried and failed: • OTC Clinical Strength antiperspirants **AND** • At least one prescription strength antiperspirant (e.g. 20% aluminum chloride hexahydrate, 15% aluminum chloride hexahydrate) **for at least 4 weeks** and experienced inadequate efficacy unless a documentation is submitted to support a contraindication. 5. Hyperhidrosis Severity Scale (HDSS) score of 3 or 4. 6. Qbrexza is not intended for application to areas other than the axillae and may **NOT** be approved for Primary Focal Hyperhidrosis or any indication requiring application to areas other than the axillae. 7. 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 8. Limited to 30 cloths per 30 days. **9. Approval Duration: 2 months.**	4. Approval Duration: 12 months. Hyperhidrosis Disease Severity Scale
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)	**Endometriosis:** • Can not be administered for more than 6 months lifetime maximum. **Endometrial thinning:** • Can not be administered for more

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	• in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. (3.6 mg and 10.8 mg) • management of endometriosis (3.6 mg) • palliative treatment of advanced breast cancer in pre- and peri-menopausal women. (3.6 mg) • to cause endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. (3.6 mg) • management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. **Endometriosis:** 1. Contraindication, intolerance, or failure of initial treatment to BOTH of the following: • Oral contraceptives or depot medroxyprogesterone; AND • Non-steroidal anti-inflammatory drugs; OR • Patient has had surgical ablation to prevent recurrence. 2. Approval Duration: Limited to 6 months. **Endometrial Thinning/Dysfunctional Uterine Bleeding:** • For use prior to endometrial ablation; AND • Other causes of symptoms of bleeding are ruled out; AND • Patient has been prescribed the 3.6 mg implant; and • Approval duration is for a maximum of 2 depots. **Fertility Preservation:** Clinical studies do not support use for this indication, and	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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	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):
	• Onset of secondary sexual characteristics in one of the following:
	  ○ Females ≤ 8 years of age; or
	  ○ Males ≤ 9 years of age.
		Central Precocious Puberty:
		• Patient is currently receiving therapy for central precocious puberty; and
		• Documented positive response to therapy.
		• Patient is currently younger than the appropriate age for the onset of puberty, i.e., Females < 11 years

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	• 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 experienced in transgender hormone therapy.
	• Approval Duration: 12 months
		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.

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
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 the test; OR • Normal C1-INH antigenic level and a low C1-INH	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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	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 ○ Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease	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
	• 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: o Acute coronary syndrome o History of myocardial infarction o Stable or Unstable angina o Coronary or other arterial revascularization o Stroke o Transient ischemic attack o Peripheral arterial disease 5. **<u>OR, if not the criteria in #4:</u>** o Type 2 Diabetes diagnosis **AND TWO of the following:** o Men ≥ 55 years and women ≥ 65 years o Cigarette smoker or stopped within past 3 months o Hypertension diagnosis o HDL-C ≤ 40 mg/dL for men or ≤ 50 mg/dL for women o High-sensitivity C-reactive protein > 3.0 mg/L o Creatinine clearance > 30 and < 60 ml/min o Retinopathy o Micro- or macro-albuminuria o Ankle-brachial index (ABI), 0.9 without	

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
	symptoms of intermittent claudication 6. Patient has received at least 12 consecutive weeks of high-intensity statin therapy (Atorvastatin 40-80 mg; rosuvastatin 20-40 mg) **OR** <u>BOTH OF THE FOLLOWING:</u> • Intolerance to high-intensity statin as evidenced by ≥ 2 weeks of myalgia and/or myositis AND • at least 12 consecutive weeks of low/moderate intensity statin therapy 7. Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy, or contraindication or intolerance to ezetimibe OR has LDL-C less than 100 mg/dL while on maximally tolerated statin therapy. 8. Approval duration: 12 months.	
idecabtagene vicleucel (**Abecma**) injection; Q2055	**USE MFC High-Cost Medication PA Criteria**	
interferon gamma-1b (**Actimmune)** injection; J9216	**USE MFC High-Cost Medication PA Criteria**	
Iptacopan (**Fabhalta**)	**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	1. Provider attestation of continued benefit without adverse drug effects. 2. Provider attestation of continued monitoring as appropriate. 3. Approval Duration: 12 months.

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	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.	
Ivermectin (Stromectol) tablets 3mg	1. Ordered for an approved indication for use: • Strongyloidiasis of the intestinal tract (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis. • Onchocerciasis due to the nematode parasite Onchocerca volvulus. 2. **Cannot be used for outpatient COVID-19 treatment**. 3. **Approval Duration and Quantity is indication specific and for most indications is limited to 2 doses**.	**Limitations for use:** • Ivermectin has no activity against adult *Onchocerca volvulus* parasites. Ivermectin is not active against *L. loa* (adult worms).
Lamivudine and tenofovir DF (**Cimduo**) 300 mg/300 mg tablets	1. Ordered for an approved indication for use: • Treatment of HIV-1 infection in combination with other antiretroviral agents in adult and pediatric patients weighing ≥ 35 kg. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following:	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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
	• HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Not prescribed concurrently with Atripla (efavirenz-emtricitabine-tenofovir), Biktarvy (bictegravir-emtricitabine-tenofovir), Complera (rilpivirine-emtricitabine-tenofovir), Emtriva (emtricitabine), Genvoya (elvitegravir-cobicistat-emtricitabine-tenofovir), Odefsey (emtricitabine-rilpivirine-tenofovir), Stribild (cobicistat-elvitegravir-emtricitabine-tenofovir), Symtuza (darunavir-cobicistat-emtricitabine-tenofovir). 5. Approval Duration: continuous if no gaps in therapy > 90-days occur.	
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	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.

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	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.	
Lebrikizumab (**Ebglyss**)	1. Ordered for an approved indication: • Treatment of patients ≥ 12 years of age who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical therapies or when those therapies are not advisable. **2.** Diagnosis of moderate-to-severe chronic atopic dermatitis; **AND** 3. Patient age is ≥ 12 years 4. Patient weight is ≥ 40 kg. 5. History of failure, contraindication, or intolerance to **TWO** of the following therapeutic **classes** of topical therapies (document drug, dates of trial, and/or contraindication to medication). • Medium-high, or very-high potency topical corticosteroid (e.g. mometasone, fluocinolone acetonide, fluocinonide). • Topical calcineurin inhibitor (e.g. tacrolimus or pimecrolimus) • Phosphodiesterase-4 Enzyme Inhibitor (e.g. Zoryve (roflumilast), Eucrisa (crisaborole)). **AND** 6. Patient is not receiving Ebglyss concurrent with any of the following: • Biologic immunomodulators (e.g. Adbrey (tralokinumab-ldrm), or Dupixent).	1. Documentation of a positive clinical response to therapy; **AND** 2. Patient is not using Ebglyss concurrent with any of the following: • Biologic immunomodulator (e.g., Dupixent (dupilumab), Adbry (tralokinumab-ldrm); and/or • Janus kinase inhibitor (e.g., Rinvoq (Upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (ruxolitinib), Cibinqo (abrocitinib); **AND** 3. Prescribed by or in consultation with a Dermatologist, Allergist, or Immunologist. 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
	• Janus kinase inhibitors (e.g. Rinvoq (Upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (ruxolitinib), Cibinqo (abrocitinib)). 7. Prescribed by or in consultation with a Dermatologist, Allergist, or Immunologist. 8. Approval Duration: 6 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 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. Submission of records documenting the presence of beta-amyloid protein deposition, as evidenced by one of the following: • Positive amyloid positron emission tomography (PET) brain scan, OR • CSF biomarker testing documents abnormalities suggestive of beta-amyloid accumulation in the brain (e.g. Aβ42: 40 ratio, p-tau 181/Aβ42, CSF t-tau/Aβ42) 7. Functional Assessment Staging Test Stage score of 2 to 4. 8. Mini-Mental State Examination score greater than 20, or St. Louis University Mental Status (SLUMS) score/ Montreal Cognitive Assessment (MoCA) score of greater	1. Patient continues to meet criteria for initial approval. 2. Absence of unacceptable toxicity from drug AND 3. Patient has responded to therapy compared to pretreatment as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment in one or more of the following (not all-inclusive): ADAS-Cog 13; ADCS-ADL-MCI; MMSE: CDR-SB etc, AND 4. Patient has not progressed to moderate or severe AD; AND 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. 6. Approval Duration: 12 months.

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	than 17. 9. 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. 10. Approval Duration: 6 months.	
Lenacapavir (**Sunlenca**)	1. Ordered for an approved indication for use; treatment of multidrug-resistant human immunodeficiency virus (HIV) in adult patients. 2. Patient age ≥ 18 years. 3. Confirmed diagnosis of HIV-1 infection. 4. Provider attestation that patient has multidrug-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.,	1. Patient has previously received treatment with Sunlenca. 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.

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	abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, 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. May not be approved for Pre-Exposure Prophylaxis (PrEP) of HIV injections or for the treatment of HIV in treatment naïve patients. 9. Prescribed by or in consultation with a physician who specializes in the treatment of HIV infection. 10. Maximum Approval Duration: 12 months.	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**	
Leuprolide **Eligard Injection 45mg**	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.	**<u>Central Precocious Puberty (CPP)</u>** • Patient is currently receiving therapy for CPP; and • Documentation of positive clinical response to therapy; and • Patient is currently younger than the appropriate time point for the

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
Lupron Depot Injection 3.75mg, 7.5mg, 11.25mg, 22.5mg, 30mg, 45mg **Lupron Depot-PED Injection 7.5mg, 11.25mg 15mg, 30mg, 50mg**	• 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. • Treatment of pediatric patients with central precocious puberty. **Central Precocious Puberty (CPP)** 1. Diagnosis of CPP (idiopathic or neurogenic), AND 2. Onset of secondary sexual characteristics in one of the following: • Females ≤ 8 years of age, OR • Males ≤ 9 years of age, AND 3. 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 the chronological age. 4. Approval Duration: no longer than 12 months. **Endometriosis:** 1. Contraindication, intolerance, or failure of initial treatment to BOTH of the following:	onset of puberty, for example: ○ Females ≤ 11 years of age ○ Males ≤ 12 years of age • Approval Duration: for no more than 12 months. **Endometriosis:** • A single retreatment course of a maximum duration of 6-months of leuprolide in combination with norethindrone acetate may be considered if symptoms recur. • Monotherapy is not recommended for retreatment. • Total duration of therapy (initial treatment plus re-treatment for symptom recurrence) should not exceed 12 months. • Quantity Limits: ○ 3.75 mg monthly for up to 6 months. ○ 11.25 mg every 3 months for up to 2 doses. • Approval Duration: Maximum of 6 months for 1st renewal request • May not exceed 12 cumulative months lifetime. **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 • Drug should be discontinued at

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	• Oral contraceptives or depot medroxyprogesterone; **AND**
	• Non-steroidal anti-inflammatory drugs; **OR**
	• Patient has had surgical ablation to prevent recurrence.
	• Quantity Limits:
	  ○ 3.75 mg every month for up to 6 months or
	  ○ 11.25 mg every 3 months for up to 2 doses.
	• Approval Duration: Limited to 6 months.
	Fertility Preservation:
	May be medically necessary for treatment of fertility preservation when both of the following criteria are met:
	• Patient is a pre-menopausal female.
	• Patient is receiving a cytotoxic agent associated with causing primary ovarian insufficiency, e.g., cyclophosphamide, procarbazine, vinblastine, cisplatin.
	• Quantity Limits: 3.75 mg dose every 28 days beginning at least 1 week prior to the initiation of chemotherapy.
	• Approval Duration: up to 12 months, should not exceed the duration of chemotherapy.
	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
		conclusion of chemotherapy treatment.
		• 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 cumulative.

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	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 did not respond to a one-month trial of iron monotherapy; **AND** • For use prior to surgery • Approval Duration: 3 months total.	
Lifitegrast ophthalmic (**Xiidra**) Drop 5%	1. Ordered for an approved indication for use: • the treatment of the signs and symptoms of dry eye disease (DED). 2. Must have tried and failed artificial tears AND cyclosporine emulsion 0.05% (generic of Restasis). 3. Approval Duration: 12 months.	

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Liraglutide (Victoza) 1.2 mg/day 2-pack pens (6 ml) 1.8 mg/day 3-pack pens (9 ml)	5. Ordered for an approved indication for use: • An adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes • To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease. 6. Patient is aged 7. Patient has Type 2 Diabetes Mellitus ******NOTE**: Type 1 DM does **NOT** qualify for coverage**** 8. A1c or CGM Time in Range% (TIR) report within past 3 months. 9. A urine albumin-to-creatinine ratio (uACR) within the previous 12 months. **Treatment of Type 2 Diabetes without regard to CVD risk factors:** The patient has an A1c (hemoglobin A1c of ≥ 7.5 (TIR ≤ 60%) **OR** Treatment of Type 2 Diabetes with CVD as defined below: • Pre-treatment A1c is ≥ 6.5 (TIR ≤ 70%) **AND** • BMI ≥ 27 kg/m2 (documentation within previous 90 days current height and weight); **AND** Documentation submitted to show that the patient has at least one of the following: • History of myocardial infarction; or • Prior stroke (ischemic or hemorrhagic); or • Symptomatic peripheral arterial disease (PAD) as evidenced by: ○ Intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest); OR	**Cannot be approved for the indication of weight management.** 1. Chart notes with A1c or CGM report with TIR% within previous 3 months. 2. A urine albumin-to-creatinine ratio (uACR) within the previous 12 months. 3. Documented positive clinical response defined as one of the following: **Baseline (pre-GLP1) A1c was ≥ 8.0 and:** • A1c has decreased by ≥ 1% since onset of therapy or TIR% was ≤ 55% and has increased ≥ 10% or • A1c is ≤ 7.0 at initiation dose. **Baseline (pre-GLP1) A1c was ≥ 6.5 but < 8.0 and:** • A1c or TIR% has improved. **NOT** eligible for renewal if A1c has increased or TIR% has decreased. 4. May not be concurrently using: • **ANY** other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus, Saxenda, Soliqua, Trulicity, Victoza, Xultrophy or Zepbound) AND/OR • **ANY** DPP4i (e.g., alogliptin, Januvia (sitagliptin), Onglyza (saxagliptin), or Tradjenta (linagliptin)). • Agents for *severe* constipation: metoclopramide, Amitiza (lubiprostone), Linzess

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	○ Peripheral arterial revascularization procedure; OR ○ Amputation due to atherosclerotic disease. 6. May not be concurrently using: • **ANY** other GLP1 or GLP1/GIP combination drug (e.g., Mounjaro, Ozempic, Rybelsus, Saxenda, Soliqua, Trulicity, Wegovy, Xultrophy or Zepbound). • **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). 7. Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all contraindications. 8. May not be approved for patients with: • Personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). • Current pregnancy; and/or • A history of confirmed pancreatitis. **9. Cannot be approved for indication of weight management.** 10. Dose escalation in accordance with manufacturer guidelines required. Initial dose is 0.6 mg once daily for 1 week, then must increase to 1.2 mg daily as the 0.6 mg dose does not provide effective glycemic control. 11. Quantity Limits: • 1.2 mg daily dose is limited to one-pack containing 2	(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

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	pens (6 ml) per 30 days. • 1.8 mg daily dose is limited to one pack containing 3 pens (9 ml) per 30 days. 12. Maximum Approval Duration: 12 months.	
lisocabtagene maraleucel (**Breyanzi**) injection; Q2054	**USE MFC High-Cost Medication PA Criteria**	
lomitapide (**Juxtapid**) capsules 5mg, 10mg, 20mg, 30mg	**USE MFC High-Cost Medication PA Criteria**	
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 2. Patient aged ≥ 18 years of age. 3. Diagnosis of Demodex blepharitis, AND 4. 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** 5. Patient demonstrates two of the following symptoms of manifestation: • Itching/burning • Foreign body sensation • Crusting/matter lashers • Blurry vision • Discomfort/irritation; **AND** 6. Patient is practicing good eye-lid hygiene (e.g., non-prescription tree-tea oil).	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.

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	7. Patient has not undergone more than one, 6-week treatment in the previous 12 months. 8. Written by or in consultation with an ophthalmologist or optometrist. 9. Approval limited to 1 bottle (10 ml) per 12 months.	
Lumacaftor/ivacaftor (**Orkambi**) Tablets 100mg-125mg, 200mg-125mg	1. Ordered for an approved indication for use: a. the treatment of cystic fibrosis (CF) in patients aged 1 year and older who are homozygous for the F508del mutation in the CFTR gene. 2. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of the F508del mutation on both alleles of the CFTR gene. 3. Patient age ≥ 2 years. 4. Provider justification of necessity of medication change if currently stable on another CF regimen and asymptomatic. 5. Patient has not undergone an organ transplant. 6. Medication ordered by Pulmonologist. 7. Approval Duration: 12 months	1. Provider attestation of continued benefit without adverse drug effects. 2. Provider attestation of continued monitoring as appropriate. 3. Renewal Duration: 12 months.
lumasiran (**Oxlumo**) injection 94.5mg/0.5ml; J0224	**USE MFC High-Cost Medication PA Criteria**	
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.**

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Macitentan (**Opsumit**) 10 mg tablets	1. Ordered for an approved indication for use: • Treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to reduce risks of disease progression and hospitalization. 2. Patient age ≥ 18 years. 3. Pulmonary arterial hypertension is symptomatic. 4. Diagnosis is confirmed by right heart catheterization. 5. Prescribed as monotherapy or concurrently with endothelin receptor antagonist or phosphodiesterase type 5 inhibitor. 6. Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist. 7. Quantity Limits: 30 tablets per 30 days 8. Approval Duration: 12 months.	1. Documentation of positive clinical response. 2. Approval Duration: 12 months.
Macitentan and tadalafil (**Opsynvi**) 10-20 mg, 10-40 mg tablets	1. Ordered for an approved indication for use: • Treatment of chronic pulmonary arterial hypertension (PAH, WHO Group I) in adult patients of WHO functional class II-III. 2. Patient age ≥ 18 years. 3. Pulmonary arterial hypertension is symptomatic. 4. Diagnosis is confirmed by right heart catherterization. 5. Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist. 6. Quantity Limits: 30 tablets per 30 days 7. Approval Duration: 12 months.	1. Documentation of positive clinical response to therapy. 2. Approval Duration: 12 months.
Maralixibat (**Livmarli**); J8499	**USE MFC High-Cost Medication PA Criteria**	
Maraviroc (Selzentry) 150 mg, 300 mg tablets	1. Ordered for an approved indication for use: • Combination antiretroviral treatment of adults infected with only CCR5-tropic HIV-1 detectable, who	1. All initial criteria are met.

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	have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Approval Duration: continuous if no gaps in therapy > 90-days occur.	2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.
Maribavir (**Livtencity**) tablets 200mg	1. Ordered for an approved indication for use: • treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet. 2. Medication is not prescribed in conjunction with ganciclovir or valganciclovir. 3. Medication is prescribed by or in consultation with a hematologist, infectious disease specialist, oncologist or physician affiliated with a transplant center. 4. Approval Duration: not to exceed 8 weeks.	If a patient has a paid claim in the MFC system for ganciclovir, valganciclovir, cidofovir, or foscarnet, Livtencity will process at the pharmacy without PA. If there is no evidence of a paid claim for ganciclovir, valganciclovir, cidofovir, or foscarnet, a PA is required, and documentation of previous use of one of these medications should be submitted.
Mecasermin (**Increlex**) J2170	**USE MFC High-Cost Medication PA Criteria**	

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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. 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., Tezpire (Tezepelumab)). **3. Indications excluded from coverage include:** • Atopic Dermatitis • COPD **4.** Eosinophilic esophagitis, eosinophilic gastroenteritis, or eosinophilic colitis. **Approval is indication specific:** **<u>Asthma, severe eosinophilic:</u>**	1. Patient has not been concurrently prescribed any of the agents as described in initial criteria #2. **<u>Asthma, severe eosinophilic:</u>** • 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. • Approval Duration: 12 months. **<u>Chronic Rhinosinusitis with Nasal Polyps:</u>** • Patient has received at least 6 months of therapy with Nucala. • Patient continues to receive therapy with an intranasal corticosteroid; and • Patient has responded to therapy (e.g. reduced nasal polyp size, improved nasal congestion, reduced sinus opacification,

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	• 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 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: o Patient experienced 2 or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR o Patient experienced at least one asthma exacerbation requiring hospitalization, an emergency department visit, or urgent care visit in the previous year; OR o Patient has a forced expiratory volume in1 second (FEV_1) < 80% predicted; or o Patient has an FEV_1)/forced vital capacity (FVC) < 0.80; OR o Patient has asthma that worsens upon tapering of oral (systemic) corticosteroid therapy.	decreased sino-nasal symptoms, improved sense of smell. • Approval Duration: 12 months. **Eosinophilic granulomatosis with polyangiitis (EGPA) (previously known as Churg-Strauss syndrome):** Patient has a beneficial response to treatment as demonstrated by any of the following: • A reduction in the frequency of relapses. • A reduction or discontinuation of daily oral corticosteroid dose • No active vasculitis Approval Duration: 12 months. **Hypereosinophilic Syndrome (HES):** • Patient shows positive clinical response to therapy. • Approval Duration: 12 months.

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	• Prescribed by or in consultation with an Allergist, Immunologist or Pulmonologist.
	• Approval Duration: 6 months.
	<u>Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):</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 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
	• Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist/ENT.
	• Approval Duration: 6 months.	

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	<u>Eosinophilic granulomatosis with polyangiitis (EGPA) (previously known as Churg-Strauss syndrome):</u>
	• Patient age ≥ 18 years.
	• Chart documentation of pre-treatment blood eosinophil count of more than 1000 cells per microliter or a blood eosinophil level > 10%.
	• Patient is currently taking oral corticosteroids, unless contraindicated or not tolerated.
	• Patient has at least two of the following disease characteristics of EGPA:
	  • Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation.
	  • Neuropathy, mono or poly (motor deficit or nerve conduction abnormality).
	  • Pulmonary infiltrates, non-fixed
	  • Sino-nasal abnormality
	  • Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
	  • Glomerulonephritis (hematuria, red cell casts, proteinuria)
	  • Alveolar hemorrhage (by bronchoalveolar lavage)
	  • Palpable purpura
	  • Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3).
	• Patient has had at least one relapse (i.e., requiring an increase in oral corticosteroid dose,	

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	initiation/increased dose of immunosuppressive therapy or hospitalization) within the 2 years prior to starting treatment with Fasenra or has refractory disease. • Medication ordered by a Pulmonologist, Immunologist, or Allergist. • Approval Duration: 12 months. **Hypereosinophilic Syndrome (HES):** • Diagnosis of HES ≥ 6 months prior to request. • The is no identifiable non-hematologic secondary cause of the patient's HES (e.g. drug sensitivity, parasitic helminth infection, HIV-infection, non-hematologic malignancy). • Approval Duration: 12 months.	
Methadone (for Pain) Concentrate 10mg/ml Solution 5mg/5ml, 10mg/5ml, Tablets 5mg, 10mg	1.Ordered for an approved indication for use: • The management of chronic pain severe enough to require daily, around-the- clock, long-term opioid treatment and for which alternative treatment options are inadequate. 2. Completion of an opioid prior authorization form. 3. Submission of clinical documentation from last office visit, dated within 3 months of the request. 4. 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.	All opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-MD
Mifepristone (Korlym) tablets Korlym-300mg ONLY; J8499	**USE MFC High-Cost Medication PA Criteria**	
Mirikizumab (**Omvoh**) injection	1. Ordered for an approved indication for use:	1. Patient exhibits a positive clinical

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100 mg/1 ml	• 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.	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**	
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.	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

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	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.	• 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.**
Morphine sulfate extended-release (MS Contin) tablets 15mg, 30mg, 60mg 100mg, 200mg	1. Ordered for an approved indication for use: 2. The management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 3. Completion of an opioid prior authorization form. 4. Submission of clinical documentation from last office visit, dated within 3 months of the request. 5. Opioid naïve adult patients (no opioid use within previous 30-days) are limited to a 7-day supply with an MME ≤ 50	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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	MME per day, patients under age 18 are limited to a 3-day supply. 6. 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.	
Nanoparticle albumin bound sirolimus (**Fyarro**); J9331	**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
Nirogacestat (**Ogsiveo**) tablets 150 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
Ocrelizumab (**Ocrevus**) injection long infusion 300mg/10ml Ocrevus Zunovo injection, SQ 920 mg/23,000 units/23 ml	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 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 one or more intermediate efficacy MS drugs, e.g. Bafiertam (monomethyl fumarate), dimethyl fumarate, fingolimod, Zeposia (ozanimod). • 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**	
Omalizumab (**Xolair**) Injection 75mg/0.5ml, 150mg/ml Solution for injection 150mg	1. Ordered for an approved indication for use: • moderate to severe persistent asthma in patients ≥ 6 years of age with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms	Renewal criteria applicable to all indications in addition to indication specific criteria outlined below: 1. Patient is not receiving treatment in combination with ANY of the

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	that are inadequately controlled with inhaled corticosteroids. • chronic spontaneous urticaria (CSU) in adults and adolescents ≥ 12 years of age who remain symptomatic despite H1 antihistamine treatment. • Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients ≥ 18 years of age with inadequate response to nasal corticosteroids, as add-on maintenance treatment. • IgE-mediated food allergy and patients ≥ 1 year of age for the reduction of Type I allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more foods, in conjunction with food allergen avoidance. 2. **NOT** eligible for coverage for the treatment/management of: • Acute bronchospasm or status asthmaticus, or • Emergency treatment of allergic reactions, including anaphylaxis, or • Other forms of urticaria. 3. Patient is not receiving treatment in combination with **ANY** of the following: • Anti-interleukin-4 therapy (e.g. Dupixent (dupilumab)). • Anti-interleukin-5 therapy (e.g., Cinqair (resilizumab), Fasenra, (benralizumab), Nucala (mepolizumab)). • Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., Tezspire (Tezepelumab)).	following: • Anti-interleukin-5 therapy (e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)). • Anti-interleukin-4 therapy (e.g., Dupixent (dupilumab). • Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., Tezspire, (Tezepelumab)). **Asthma:** 1. Documentation of positive clinical response (e.g. reduction in frequency of exacerbations, decreased use of rescue medications, increase in percent predicted FEV1 from pre-treatment baseline or reduction in symptom severity or frequency), AND 2. Xolair is being used in combination with an ICS-containing maintenance medication – **NOT** covered as monotherapy. 3. Approval Duration: 12 months. **IgE-mediated Food Allergy:** 1. Documentation of positive clinical response to Xolair therapy, e.g. reduction in type I allergic reactions, and

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	Asthma: 1. Patient aged ≥ 6 years of age. 2. Positive skin test or in-vitro reactivity to a perennial aeroallergen, AND 3. Submission of clinical documentation showing the baseline (pre-treatment) serum total IgE level ≥ 30 IU/ml and ≤ 1300 IU/ml, AND 4. Diagnosed with moderate to severe asthma inadequately controlled with inhaled corticosteroids 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); or • Two or more bursts of systemic corticosteroids for at least 3 days each in previous 12 months; or • Asthma-related emergency treatment (ER visit, hospital admission, or unscheduled OV for nebulizer or emergency treatment); **OR** • Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted; **OR** • Patient is currently dependent on oral corticosteroids for the treatment of asthma; **AND,** 5. Xolair will be used in combination with one maximally dosed combination ICS/LABA inhaler **OR** with an ICE inhaler and one additional asthma controller medication (e.g. montelukast, theophylline). 6. Prescribed by an allergist, immunologist or pulmonologist.	2. Used in conjunction with food allergen avoidance, and 3. Patient has access to epinephrine, and 4. Prescribed by an allergist or immunologist. 5. Approval Duration: 12 months. **Rhinosinusitis, chronic, with nasal polyps (CRSwNP):** 1. Documentation of positive clinical response to Xolair therapy. 2. Patient continues to use add-on maintenance therapy with intranasal corticosteroids – **NOT** covered as monotherapy. 3. Approval Duration: 12 months. **Urticaria (chronic spontaneous):** 1. Documentation of positive clinical response to Xolair therapy (e.g. reduction in exacerbations, itch severity, hives). 2. Approval Duration: 12 months.

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	7. Approval Duration: 12 months. **<u>IgE-mediated Food Allergy:</u>** 1. Patient aged ≥ 1 year of age. 2. Diagnosis of IgE-mediated food allergy to one or more foods, AND 3. Diagnosis has been confirmed by BOTH of the following: • History of type I allergic reactions (e.g., nausea, vomiting, cramping, diarrhea, flushing, pruritus, urticaria, swelling of lips, face, or throat, wheezing, lightheadedness, syncope), AND • ONE of the following: o Food specific skin prick testing (SPT) o IgE antibody in vitro testing o Oral food challenge (OFC) 4. Xolair will be used in conjunction with food allergen avoidance, AND 5. Patient has access to epinephrine, AND 6. Prescribed by an allergist or immunologist. 7. Approval Duration: 12 months. **<u>Rhinosinusitis, chronic, with nasal polyps (CRSwNP):</u>** 1. Patient aged ≥ 18 years of age. 2. Prescribed as add-on maintenance treatment to nasal corticosteroids (NOT covered as monotherapy). 3. Diagnosis of nasal polyps, AND 4. Patient has TWO or more of the following symptoms for ≥ 12 weeks: • Nasal mucopurulent discharge • Nasal obstruction, blockage, or congestion • Facial pain, pressure and/or fullness • Reduction or loss of sense of smell; AND	

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	5. ONE of the following findings using nasal endoscopy and/or sinus computed tomography (CT): • Purulent mucus or edema in the middle meatus or ethmoid regions, or • Polyps in the nasal cavity or the middle meatus, or • Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses; AND 6. ONE of the following: • Patient has not obtained relief after a trial of BOTH intranasal corticosteroids and one other therapy used in the management of nasal polyps (e.g. nasal saline irrigations, antileukotriene agents); OR • Patient has required systemic corticosteroids for nasal polyps in the previous 2 years; OR • Patient has required prior sinus surgery, AND 7. Patient will receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids. 8. Prescribed by an allergist, immunologist, otolaryngologist, or pulmonologist. 9. Approval Duration: 12 months. **<u>Urticaria (chronic spontaneous):</u>** 1. Patient is aged ≥ 12 years of age. 2. Patient remains symptomatic following: • at least a 2-week trial of, contraindication, or intolerance to TWO H1-antihistamines (e.g. fexofenadine, diphenhydramine, loratadine **OR**	

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	• a two-week trial of taking a second-generation H1-antihistamines in combination with:
	  ○ a different second generation H1 antihistamine, or
	  ○ a first generation H1 antihistamine (e.g. hydroxyzine, diphenhydramine, or chlorpheniramine), or
	  ○ an H2 antihistamine (e.g. famotidine or cimetidine), or
	  ○ a leukotriene modifier (e.g. montelukast).
	3. Prescribed by an allergist, dermatologist or immunologist
	4. Approval Duration: 12 months.	

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.	6. The patient has achieved or maintained a reduction in triglyceride levels from baseline. 7. 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.
		1. Documentation of positive clinical response.
		2. Approval Duration: 12 months.

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	• Neurogenic detrusor overactivity (NDO) in pediatric patients ≥ 5 years of age who have an inadequate response to or are intolerant of anticholinergic medication.
	• Prophylaxis of headaches in adult patients with chronic migraine (**≥15** days per month with headache lasting ≥ 4 hours a day; AND
	  ○ Patient has failed a minimum of a two-week trial of TWO different classes of migraine prevention therapies including: ACEI or ARB therapy, beta blockers, antiepileptic drugs, or antidepressants.
	  ○ **NOTE:** Coverage for prophylaxis of episodic migraines ≤ 14 headaches per month is not permitted.
	• Spasticity in patients ≥ 2 years of age.
	• 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; **AND**
	  ○ Patients must have a Hyperhidrosis Disease Severity Scale Score of 3 or 4.
	  ○ **NOTE**: treatment of hyperhidrosis in any other area besides the axilla is **NOT** covered.
	• 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. Ordered for a MedStar Family Choice approved compendial use:	

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	• Chronic anal fissure failing conventional non-surgical treatment. • Chronic sialorrhea • Focal dystonia • Hirschsprung Disease • Primary esophageal achalasia • Treatment of cholinergic-mediated secretions associated with a fistula refractory to pharmacotherapy. • Treatment of disabling essential tremor • Treatment of hemifacial spasms, seventh cranial nerve palsy (Bell's palsy) or Gaze palsies causing persistent pain or vision impairment. 3. Not prescribed for a cosmetic indication. 4. Requested volume of units and dosing frequency are aligned with FDA and manufacturer labeling for applicable indication. 5. Medication ordered by a Neurologist, Urologist, Ophthalmologist, or applicable specialist. 6. Approval Duration: 12 months.	
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. Opioid naïve adult patients (no opioid use within previous 30-days) are limited to a 7-day supply with an MME ≤ 50	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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	MME per day, patients under age 18 are limited to a 3-day supply. 5. 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.	
oxycodone 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 Oxycontin tablets 10, 15, 20, 30, 40 mg	1. Ordered for an approved indication for use: 2. The management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 3. Completion of the opioid prior authorization form. 4. Submission of supporting clinical documentation for last office visit dated within previous 3 months. 5. Opioid naïve adult patients (no opioid use within previous 30-days) are limited to a 7-day supply with an MME ≤ 50 MME per day, patients under age 18 are limited to a 3-day supply. 6. 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 5-325, 7.5-325, 10-325 mg	1. Ordered for an approved indication for use: 2. management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 3. Completion of the opioid prior authorization form. 4. Submission of supporting clinical documentation for last office visit, dated within previous 3 months.	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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	5. Opioid naïve adult patients (no opioid use within previous 30-days) are limited to a 7-day supply with an MME ≤ 50 MME per day, patients under age 18 are limited to a 3-day supply. 6. 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.	
oxymorphone extended release 12-hour (Opana) tablets 5mg, 7.5mg, 10mg, 15mg, 20mg, 30mg, 40mg,	1. Ordered for an approved indication for use: 2. management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 3. Completion of the opioid prior authorization form. 4. Submission of supporting clinical documentation for last office visit, dated within previous 3 months. 5. Opioid naïve adult patients (no opioid use within previous 30-days) are limited to a 7-day supply with an MME ≤ 50 MME per day, patients under age 18 are limited to a 3-day supply. 6. 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
Ozanimod (**Zeposia**) capsules 7-day starting pack 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.	1. Initial approval criteria continue to be met. 2. Patient is not receiving in combination a biologic DMARD or janus kinase inhibitor

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Capsule starting kit which includes 0.23 mg, 0.46 mg, and 0.92 mg capsules.	• 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. Patient is ≥ 18 years of age. 4. Baseline evaluation of the following labs before starting treatment: CBC, ECG, LFT's 5. No history (within previous 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure. 6. No severe untreated sleep apnea 7. 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. **8. <u>Additional Criteria for Multiple Sclerosis</u>** • Patient has failed a 4-week trial of one of the following agents: bafiertam (monomethyl fumarate), Gilenya (fingolimod), or Tecfidera (dimethyl fumarate). • Prescribed by or within consultation with a neurologist. • Approval Duration: 12 months. **9. <u>Additional Criteria for Ulcerative Colitis</u>** • Diagnosis of moderately to severely active UC	**<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 ○ 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

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	• 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. • Approval duration: 12 months	
Palbociclib (**Ibrance**) capsules 75mg, 100mg, 125mg	1. Ordered for an approved indication for use: • Treatment of adult patients with hormone receptor positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer in combination with: a. An aromatase inhibitor as initial endocrine based therapy. b. Fulvestrant in patients with disease progression following endocrine therapy. 2. 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	3. Patient shows evidence of positive response to therapy. 4. Approval Duration: 12 months.

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	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, exemestane, letrozole, or fulvestrant. 8. Medication ordered by an Oncologist 9. Approval Duration: 12 months.	
Palopegteriparatide (**Yorvipath**) 168 mcg/0.56 ml 294 mcg/0.98 ml 420 mcg/1.4 ml	1. Ordered for an approved indication for use: • Treatment of hypoparathyroidism in adults. 2. Patient has had hypoparathyroidism for ≥ 6 months. 3. Patient has documentation or claims history supporting treatment with a vitamin D metabolite/analog therapy with calcitriol ≥ 0.5 mcg per day or alfacalcidol ≥ 1.0 mcg per day. 4. Patient is treated with elemental calcium at doses ≥ 800 mg per day. 5. Serum 25-hydroxyvitamin D concentration is above the lower limit of normal laboratory range. 6. Laboratory results confirming albumin-corrected serum calcium is ≥ 7.8 mg/dL prior to initiation of therapy. 7. Laboratory results confirming magnesium level is within normal laboratory limits. 8. Not prescribed for acute post-surgical hypoparathyroidism (within six months of surgery) and expected recovery from hypoparathyroidism. 9. Approval Duration: 12 months.	1. Documentation of positive clinical benefit from therapy as evidenced by the maintenance or normalization of calcium levels compared to baseline. 2. Approval Duration: 12 months.

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Palovarotene (**Sohonos**) J8499	**USE MFC High-Cost Medication PA Criteria**	
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**	
ponatinib (**Iclusig**) tablets 10mg, 15mg, 30mg, 45mg	1. Ordered for an approved indication for use: • Chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least 2 prior kinase inhibitors. • Accelerated phase (AP) or blast phase (BP) CML or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other kinase inhibitors are indicated. • T315I-positive CML (chronic-, accelerated-, or blast phase) or T315I-positive Ph+ ALL. 1. Medication ordered by an Oncologist. **<u>Acute Lymphoblastic Leukemia:</u>** 1. Patient is ≥ 15 years of age; AND 2. Patient has Philadelphia chromosome-positive acute lymphoblastic leukemia; AND 3. Patient meets ONE of the following: • The drug will be used in combination with chemotherapy; or	1. Patient shows positive clinical response to therapy. 2. Patient has not experienced any severe adverse effects from therapy. 3. Approval Duration: 12 months.

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	• The acute lymphoblastic leukemia is T315I-positive; OR • The patient has tried at least one other tyrosine kinase inhibitor that is used for Ph+ ALL (e.g., Sprycel (dasatinib)). 4. Approval Duration: 12 months. **Chronic Myeloid Leukemia (CML):** 1. Patient is ≥ 18 years; AND 2. Patient has Philadelphia chromosome-positive chronic myeloid leukemia; AND 3. Patient meets ONE of the following: • The chronic myeloid leukemia is T315I-positive; OR • Patient has tried at least two other tyrosine kinase inhibitors indicated for use in Ph+ CML (e.g., imatinib, dasatinib, nilotinib); OR • Patient meets BOTH of the following: o Patient has accelerated-phase CML or blast-phase CML; AND o No other tyrosine kinase inhibitor is indicated. 4. Approval Duration: 12 months. COVERED COMPENDIAL USES: **Gastrointestinal Stromal Tumor:** 1. Patient age ≥ 18 years; and 2. Patient has tried each of the following four therapies: • One of either imatinib or avapritinib; AND • One of either sunitinib or dasatinib; AND • Stivarga (regorafenib); AND • Qinlock (repretinib).	

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	3. Approval Duration: 1 year. **Myeloid/Lymphoid Neoplasms with Eosinophilia:** 1. Patient age ≥ 18 years; and 2. Patient meets ONE of the following: • The tumor has an ABL1 rearrangement, OR • The tumor has an FGFR1 rearrangement. 2. Approval Duration: 12 months.	
Posaconazole (Noxafil) 40 mg/ml suspension 100 mg tablets ***Note: dosage forms are approved for different indications and are not substitutable.* Injection: indicated for persons aged 2 years and older Tablets: persons aged 2 years and older who weigh greater than 40 kg Oral Suspension: persons aged 13 years and older Powder mix or delayed-release oral suspension: persons aged 2 years and older weighing less than 40 kg.	1. Ordered for an approved indication for use: • Treatment of invasive aspergillosis in adults and pediatric patients ≥ 13 years of age. (Injection and tablets). • Treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adults or pediatric patients ≥ 13 years of age. • Prophylaxis of invasive Aspergillus and Candida infections in patients at high risk of infection development due to being severely **Oropharyngeal Candidiasis:** 1. Prescribed for the treatment of moderate to severe oropharyngeal candidiasis when all of the following are met: • The request is for Noxafil oral suspension (immediate-release). • The patient is aged 13 years or older. • The patient has experienced an inadequate treatment response, intolerance to, or has a contraindication to fluconazole AND itraconazole oral solution.	

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	2. Approval Duration: 1 month **<u>Prevention of Invasive Aspergillus and Candida Infections:</u>** 1. The patient is being prescribed for the treatment for the prevention of invasive aspergillus and/or candida infections in a patient who is at high risk of developing these infections due to being severely immunocompromised. 2. Approval Duration: 6 months. **<u>Treatment of Invasive Aspergillus Infections:</u>** 1. The patient is being prescribed injection or delayed-release tablets for the treatment of invasive aspergillosis. 2. Approval Duration: 3 months.	
Pozelimab (**Veopoz**) J3590	**USE MFC High-Cost Medication PA Criteria**	
Raltegravir (**Isentress**) 400 mg, HD 600 mg tablets **100 mg strength is non-formulary and will be evaluated individually if requested.*	When ordered for one of the following indications: • Treatment of HIV-1 infections in combination with other antiretroviral agents. • As part of the CDC-preferred Post Exposure Prophylaxis (PEP) treatment regimen. **<u>Information for use as part of a PEP-regimen:</u>** • Requests for Isentress 400 mg BID that are part of a PEP treatment protocol shall be approved for 56 tablets. • Expected use in combination with tenofovir DF/emtricitabine (generic Truvada). • Note that PEP initiation is not recommended for exposures occurring > 72 hours prior to treatment or for non-blood contaminated exposures from secretions such as urine, saliva, sweat, tears, or nasal	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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	secretions. **When prescribed as part of an HIV-1 treatment regimen:** 1. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 2. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 3. Isentress HD 600 mg formulation only should not be used concurrently with Intelence (etravirine) or Aptivus (tipranavir). 4. Approval Duration: continuous if no gaps in therapy > 90-days occur.	
Ravulizumab-cwvz (**Ultomiris**) injection; J1303	**USE MFC High-Cost Medication PA Criteria**	
Resmetirom (**Rezdiffra**) 80 mg, 100 mg tablets **(60 mg is non-formulary)**	1. Ordered for an approved indication for use: • 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:	1. Patients who have received < 1 year of therapy or who is restarting therapy should be evaluated based on the initial approval criteria. 2. Patient is currently receiving Rezdiffra and completed ≥ 1 year and < 2 years of therapy with Rezdiffra AND • patient has derived benefit from treatment as demonstrated by at least ONE of the following:

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	○ Liver biopsy was performed within the 6 months preceding treatment with Rezdiffra; (documentation required), 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 (documentation required): ○ 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 F3 fibrosis, **OR** • Patient has Stage F2 fibrosis; **AND THREE** or more of the following metabolic risk factors that are managed according to Standards of Care: ○ Central obesity ○ 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:	MASH/NASH resolution AND no worsening of fibrosis OR • No worsening of MASH/NASH AND improvement in fibrosis by ≥ 1 stage; **OR** 3. 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). 4. Metabolic risk factors are managed according to standard of care; **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.** 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

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	• 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	verification and description of clinical benefit in confirmatory trials. 7. Approval Duration: 12 months.
Rilpivirine (**Edurant**) 25 mg tablets	1. Ordered for an approved indication for use: • In combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve patients aged ≥ 2 years of age and weighing at least 14 kg with HIV-1 RNA ≤ 100,000 copies/mL. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status).	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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	3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Can not be taken concurrently with the following medications which are either therapeutic duplications or combinations of drugs that reduce the effectiveness of the requested drug: Cabenuva, Complera, Juluca, Odefsey, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifapentine, any proton pump inhibitor, systemic dexamethasone (> 1 dose). 5. Approval Duration: continuous if no gaps in therapy > 90-days occur.	
Rilpivirine, emtricitabine, tenofovir DF (**Complera**)	1. Ordered for an approved indication for use: • Treatment of HIV-1 infections. 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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	4. Can not be taken concurrently with the following lamivudine or lamivudine containing combination products. 5. Approval Duration: continuous if no gaps in therapy > 90-days occur.	
Riociguat (**Adempas**) 0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg tablets	1. Ordered for an approved indication for use: • Persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class. • Pulmonary Arterial Hypertension (PAH) (WHO Group 1) to improve exercise capacity, improve WHO functional class and to delay clinical worsening. **CTEPH:** 1. Patient is diagnosed with inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH); AND 2. CTEPH is symptomatic; AND 3. Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist. 4. Approval Duration: 12 months. **PAH:** 1. Patient has symptomatic PAH. 2. Diagnosis of PAH is confirmed by right heart catheterization. 3. Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist. 4. Approval Duration: 12 months.	1. Clinical documentation supports that the patient is receiving clinical benefit from Adempas therapy. 2. Approval Duration: 12 months.

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Ripivirine, emtricitabine, tenofovir alafenamide (**Odefsey**)	1. Ordered for an approved indication for use: • Treatment of HIV-1 infection 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable) • HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Can not be taken concurrently with the following medications which are either therapeutic duplications or combinations of drugs that reduce the effectiveness of the requested drug: 5. Approval Duration: continuous if no gaps in therapy > 90-days occur.	1. All initial criteria are met. 2. Renewal of prior authorization is only required when patient has had a gap in therapy > 90 days. 3. Approval Duration: continuous if no gaps in therapy > 90 days occur.
Ritonavir 100 mg tablets (Norvir)	1. Ordered for an indication for use listed below: • Treatment of HIV-1 infection in combination with other protease inhibitors. • Compendial treatment of Post-Exposure Prophylaxis (PEP) in combination with other retrovirals 2. Diagnosis date(s) of opportunistic infection(s) OR CD4 laboratory test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). 3. Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following: • HIV RNA/DNA quantitative (if detectable)	1. All initial criteria are met. 2. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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	• HIV RNA/DNA qualitative • HIV P24 antigen • HIV Western blot • HIV genotype 4. Can not be taken concurrently with the following medications which are either therapeutic duplications or combinations of drugs that reduce the effectiveness of the requested drug: Kaletra (lopinavir-ritonavir). 5. Approval Duration: continuous if no gaps in therapy > 90-days occur.	
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.	**Limitations of Use:** • Avoid concomitant use with fluconazole doses greater than 200 mg. Reduce Jakafi dosage with fluconazole doses ≤ 200 mg. • Strong CYP3A4 Inhibitiors: Reduce, interrupt, or discontinue Jakafi doses as recommended except in patients with acute or chronic graft-versus-host-disease.

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Sastralizumab-mwge (**Enspryng**) injection; J3590	**USE MFC High-Cost Medication PA Criteria**	
Secukinumab (**Cosentyx**) 75 mg SOSY, 150 mg SOSY, Sensoready 150 mg pens Unoready 300 mg pens	1. Ordered for an approved indication for use following the indication-specific criteria as outlined below. Please note that the following indications are **NOT** approved for coverage: Crohn's Disease, Rheumatoid Arthritis, or Uveitis. 2. May not be ordered for concurrent use with a biologic or targeted synthetic oral small molecule drug (e.g., TNF inhibitors, Inhibitors of interleukin types 1, 6, 12, 17, 17A, 23, or combinations thereof, CD20-directed cytolytic antibodies, JAKs, PDE4s, Sphingosine 1 phosphate receptor modulators due to increased risk of adverse effects and lack of clinical data supporting additive efficacy. **<u>Ankylosing Spondylitis:</u>** • Patient age ≥ 18 years; AND • Prescribed by or in consultation with a rheumatologist • Approval Duration: 6 months. **<u>Enthesitis-Related Arthritis:</u>** • Patient age ≥ 4 years of age; AND • Prescribed by or in consultation with a rheumatologist • Approval Duration: 6 months. **<u>Hidradenitis Suppurativa:</u>** • Patient age ≥ 18 years; AND • Patient has tried at least one other therapy (e.g. corticosteroids, systemic antibiotics, or isotretinoin). • Prescribed by or in consultation with a dermatologist. • Approval Duration: 3 months.	**<u>Ankylosing Spondylitis:</u>** • Patient has been established on Cosentyx SQ or IV for at least 6 months; AND • Patient shows positive clinical response by way of at least one objective measure or improvement in at least one symptom. • Approval Duration: 12 months. **<u>Enthesitis-Related Arthritis:</u>** • Patient has been established on Cosentyx SQ for at least 6 months; AND • Patient shows positive clinical response by way of at least one objective measure; AND • Patient shows positive clinical response or improvement in at least one symptom. • Approval Duration: 12 months. **<u>Hidradenitis Suppurativa:</u>** • Patient has been established on Cosentyx SQ for at least 3 months; and • Patient has experienced positive clinical response to at least one

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	Non-Radiographic Axial Spondylarthritis:
	• Patient age ≥ 18 years; AND
	• Patient has objective signs of inflammation, defined as at least ONE of the following:
	  ○ C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory, OR
	  ○ Sacroiliitis reported on magnetic resonance imaging; AND
	• Prescribed by or in consultation with a rheumatologist
	• Approval Duration: 6 months.
	Plaque Psoriasis:
	• Patient age ≥ 6 years; AND
	• Patient meets ONE of the following conditions:
	  ○ Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant (e.g. methotrexate, cyclosporine, or acitretin or a 3-month trial of psoralen plus ultraviolet light unless patient has already had a 3-month trial or previous intolerance to at least one biologic other than Cosentyx/biosimilar); OR
	  ○ Patient has a contraindication to methotrexate
	• Prescribed by or in consultation with a dermatologist.
	• Approval Duration: 3 months.
	Psoriatic Arthritis:
	• Patient age ≥ 2 years; AND
	• Prescribed by or in consultation with a rheumatologist or dermatologist.
	• Approval Duration: 6 months.
		objective measure from baseline (e.g. Hurley staging, Sartorius score, Physician Global Assessment, and Hidradenitis Suppurativa Severity index); AND
		• Patient has experienced positive clinical response in at least one symptom (e.g. decreased pain or drainage of lesions, nodules, or cysts).
		• Approval Duration: 12 months.
		Non-Radiographic Axial Spondylarthritis:
		• Patient has been established on Cosentyx SQ or IV for at least 6 months; AND
		• Patient shows positive clinical response by way of at least one objective measure or improvement in at least one symptom.
		• Approval Duration: 12 months.
		Plaque Psoriasis:
		• Patient has been established on Cosentyx SQ for at least 3 months.
		• Patient has experienced a positive clinical response defined as improvement from baseline in at least one of the following: estimated affected BSA, erythema,

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		induration/thickness and/or scale of areas affected by psoriasis. • Patient has experienced a positive clinical response in at least one symptom such as decreased pain, itching, and/or burning. • Approval Duration: 12 months. **Psoriatic Arthritis:** • Patient has been established on Cosentyx SQ or IV for at least 6 months; AND • Patient shows positive clinical response by way of at least one objective measure or improvement in at least one symptom. • Approval Duration: 12 months.
Selexipag (**Uptravi**) tablets 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, 1600 mcg	1. Ordered for an approved indication for use: • Treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to delay disease progression and reduce the risk for hospitalization for PAH. 2. Patient aged ≥ 18 years. 3. Patient diagnosed with pulmonary hypertension WHO group 1. 4. Patient has had a right heart catheterization and the diagnosis of WHO Group 1 PAH is confirmed. 5. Patient meets one of the following criteria (a or b): a. Patient has tried or is currently receiving at least one oral medication for PAH from one of the three following different categories (either alone or in	2. Patient meets initial approval criteria. 3. Approval Duration: 12 months.

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	combination) each for ≥ 60 days: one phosphodiesterase type 5 (PDE5) inhibitor (i.e sildenafil or tadalafil), one endothelin receptor antagonist (ERA) (i.e., bosentan, ambrisentan or macitentan), or Adempas (riociguat) OR b. Patient is currently receiving, or has a history of receiving, one prostacyclin therapy for PAH (i.e., Tyvaso or Orenitram, (Treprostinil), Ventavis (iloprost), or epoprostenol). 6. May not concurrently be prescribed Orenitram, inhaled prostacyclin products, or parenteral prostacyclin agents used for PAH (e.g. Tyvaso, Ventavis, epoprostenol, Treprostinil SQ or IV [Remodulin, generics]). 7. May not have Child-Pugh Class C or D liver disease. 8. May not be on dialysis or have eGFR < 15 ml/min 9. Prescribed by or in consultation with a cardiologist or pulmonologist. 10. Quantity Limits: 1 titration/starter pack per 365 days Max 2 tablets per day and total daily dose of 3200 mcg 11. Approval Duration: 12 months.	
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	4. Patient does not show evidence of progressive disease while on Retevmo therapy. 5. Approval Duration: 12 months.

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	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.	
Semaglutide (**Ozempic, Rybelsus**) **WEGOVY CRITERIA LISTED SEPARATELY BELOW** 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	1. Ordered for an approved indication for use: • As adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. • Treatment of adult patients with Type 2 diabetes mellitus for risk reduction of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) who have established CVD or multiple cardiovascular risk factors. 2. Patient age ≥ 18 years. ***NOTE**: Semaglutide is approved in adolescents for weight loss only and is **not** a covered benefit.* 3. Patient must have Type 2 Diabetes Mellitus ******NOTE**: Type 1 DM does **NOT** qualify for coverage**** 4. A1c or CGM Time in Range% (TIR%) report within previous 3 months. 5. A urine albumin-to-creatinine ratio (uACR) within the previous 12 months. **Treatment of Type 2 Diabetes without regard to CVD risk factors:**	**Cannot be approved for indication of weight management.** 1. Rybelsus 3 mg dose may not be renewed and must be escalated to 7 mg or 14 mg dose. 2. Chart notes with A1c or CGM report with TIR% within previous 3 months. 3. A urine albumin-to-creatinine ratio (uACR) within the previous 12 months. 4. Documented positive clinical response defined as one of the following: **Baseline (pre-GLP-1) A1c was ≥ 8.0 and:** • A1c has decreased by ≥ 1% since onset of therapy or • TIR% was ≤ 55% and has increased ≥ 10% **Baseline (pre-GLP-1) A1c was ≥ 6.5 but < 8.0 and:**

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	The patient has an A1c (hemoglobin A1c) of ≥ 7.5 (TIR ≤ 60%). **OR** **<u>Treatment of Type 2 Diabetes with CVD as defined below:</u>** • Pre-treatment A1c is ≥ 6.5 (TIR ≤ 70%) **AND** • BMI ≥ 27 kg/m2 (documentation within previous 90 days of current height and weight); **AND** Documentation submitted to show that the patient has at least **<u>ONE</u>** of the following: • Prior myocardial infarction; **OR** • Prior stroke (ischemic or hemorrhagic); **OR** • Symptomatic peripheral arterial disease (PAD) as evidenced by: o Intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest); **OR** o Peripheral arterial revascularization procedure; **OR** o Amputation due to atherosclerotic disease. 7. May not be concurrently using: • **ANY** other GLP1 or GLP1/GIP combination drug (e.g., Mounjaro, Ozempic, Rybelsus, Saxenda, Soliqua, Trulicity, Victoza (liraglutide), Wegovy, Xultrophy or Zepbound). • **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). 8. Prescriber attests that medication is prescribed in accordance with prescribing information, including	• A1c or TIR% has improved. • Not eligible for renewal if A1c has not changed or has increased or TIR% has decreased. 5. Patient has not had medical intervention for: • Pancreatitis, or • Severe gastrointestinal events (e.g., hospitalization or new start GI motility agent). 6. May not be concurrently using: • **ANY** other GLP1 or GLP1/GIP combination drug (e.g., liraglutide, Ozempic, Rybelsus, Saxenda, Soliqua, Trulicity, Victoza, Xultrophy or Zepbound) AND/OR • **ANY** DPP4i (e.g., alogliptin, Januvia (sitagliptin), Onglyza (saxagliptin), or Tradjenta (linagliptin)). • Agents for *severe* constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 7. 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

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	screening for any black box warnings and all contraindications. 9. May not be approved for patients with: • Personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). • Current pregnancy; and/or • A history of confirmed pancreatitis, and/or • Suicidal ideation or new onset depression. 10. 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 and then must be dose escalated to 1 mg per week dose **UNLESS** A1c ≤ 7.0 or TIR ≥ 65%. • **Rybelsus 3 mg** is a starter dose and limited to one, 30-day dispense then must be dose escalated to 7 mg. 11. Ozempic: Limited to a maximum of 1 pen per 28 days. Rybelsus: Limited to 30 capsules per 30 days. 12. Maximum approval duration: 12 months.	criteria. 8. Approval Duration: 12 months
Semaglutide (**Wegovy**) 0.25 mg, 0.5 mg, 1 mg, 1.7 mg and 2.4 mg pens Wegovy Prior Authorization Form	1. Ordered **ONLY** for the indication: • To reduce the risk of Major Adverse Cardiovascular Events (MACE), in combination with a reduced calorie diet and increased physical activity, for adults with established cardiovascular disease and who are either obese or overweight. 2. Patient age ≥ 18 years. 3. Patient does **NOT** have Type 1 or Type 2 diabetes.	**May not be renewed if BMI < 27** 1. **ALL** initial criteria continue to be met. 2. Patient's weekly dose is: • 1.7 mg or 2.4 mg per week. • Renewal criteria is **not** met for weekly doses < 1.7 mg. 3. **Approval Duration: 6 months.**

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	• Persons with T2DM may be redirected to Ozempic. • Persons with T1DM are **not** eligible for coverage. 4. Documentation submitted to show that patient is either obese or overweight. • Obesity/Overweight is defined as ≥ 27 kg/m^2. • Documentation of current BMI, height, **and** weight within last 90 days is **required;** **AND** 5. Documentation submitted to show that the patient has established atherosclerotic cardiovascular disease (ASCVD) as defined below: The patient has **one** or more of the following: ○ Prior myocardial infarction; **OR** ○ Prior stroke (ischemic or hemorrhagic); **OR** ○ Symptomatic peripheral arterial disease (PAD) as evidenced by **one** of the following: ▪ Intermittent claudication with ankle-brachial index (ABI) < 0.85 (at rest); **OR** ▪ Peripheral arterial revascularization procedure; **OR** ▪ Amputation due to atherosclerotic disease. 6. May not be concurrently using or taking **ANY** of the below: • ANY GLP1 or GLP1/GIP combination drug (e.g., Mounjaro, Ozempic, Rybelsus, Saxenda, Soliqua, Trulicity, Victoza, Xultrophy, or Zepbound). • ANY DPP4i (alogliptin, Januvia [sitagliptin], Onglyza [saxagliptin], Tradjenta [linagliptin]). • Agents for severe constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide),	

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	Motegrity (prucalopride) or Trulance (plecanatide). 7. Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all contraindications. 8. May **not** be approved in patients with: • Current pregnancy • History of confirmed pancreatitis • Suicidal thoughts or new onset depression 9. Must be administered according to most current FDA guidelines for dosage and timing. • **Per FDA-approved labeling, if patient cannot tolerate 1.7 mg weekly dose, Wegovy should be discontinued.** • Dose titration is expected every 4 weeks until patient reaches a minimum weekly dose of 1.7 mg. • Expected titration schedule: ○ 0.25 mg dose for 4 weeks, then ○ 0.5 mg dose for 4 weeks, then ○ 1.0 mg dose for 4 weeks, then ○ 1.7 mg dose for 4 weeks, then ○ 2.4 mg dose thereafter (if tolerated). • Dose titration is expected every 4 weeks until patient reaches a minimum weekly dose of 1.7 mg (2.4 mg per week is recommended weekly maintenance dose). 10. Limited to 4 pens of any strength per 24 days. 11. **Approval Duration: 6 months.**	
sildenafil (Revatio)	1. Ordered for an approved indication for use:	1. All initial criteria continue to be met.

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20 mg tablets 10 mg/ml solution ***NOTE: sildenafil 25 mg, 50 mg and 100 mg dosage forms are indicated for erectile dysfunction <u>only</u> and are not covered by the formulary.*	• treatment of pulmonary arterial hypertension (PAH) (WHO Group I) in adults to improve exercise ability and delay clinical worsening. 2. Patient is not concurrently on organic nitrates (i.e. isosorbide mononitrate, isosorbide dinitrate, nitroglycerin) or Adempas (riociguat), OR tadalafil, AND 3. The diagnosis of PAH is documented by right-heart catheterization with ALL of the following: • Mean pulmonary artery pressure (mPAP) > 20 mmHg, • Pulmonary arterial wedge pressure (PAWP) ≤ 15 mmHg; AND • Pulmonary vascular resistance (PVR) ≥ 3 wood units. 4. Prior Authorization not required for solution for children less than 6 years of age. Tablets are preferred dosage form; solution should only be utilized when tablets cannot satisfy medical necessity. **5. May not be approved for the treatment of erectile dysfunction (ED).** 6. Medication ordered by a cardiologist or pulmonologist. 7. Total daily dosage does not exceed 60 mg. 8. Approval duration: 12 months.	2. Has documented positive clinical response to sildenafil treatment as determined by one or more of the following: • Progress towards improvement in WHO functional class status, • Improvement in right-ventricular function (based on echocardiogram or cardiac MRI), • Improvement from baseline on the 6-minute walk distance (6MWD), • Improvement in B-type natriuretic peptide plasma levels (NT-proBNP) 3. Approval Duration: 12 months.
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 compensated cirrhosis (Child-Pugh A) and with decompensated cirrhosis for use in combination with ribavirin (Child-Pugh B or C).	**Hepatitis C Medication Prior Authorization Form**

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
	• 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 between 3 < 18 years 3. Medication ordered by or in consultation with an Endocrinologist. 4. Initial approval: • Confirmation of open epiphysial growth plates • Patient meets at least one of the following: o Height is at least TWO standard deviations (SD) below the mean height for normal children of same age and gender; o Height velocity less than 25th percentile for age. 5. Approval duration: 12 months	1. Confirmation of open epiphysial growth plates as above, OR the patient has not completed prepubertal growth 2. Patient meets at least one of the following: • Has an annual growth velocity of at least 2 cm during most recent approval year; • Is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm during the most recent approval year. 3. Approval duration: 12 months **Limitations of Use:** • Ngenla will not be approved for idiopathic short stature (ISS), athletic enhancement, central precocious puberty, congenital

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		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>** 1. Clinical documentation indicating positive clinical response during previous 12 months. 2. Approval duration: 12 months
Setmelanotide (**Imcivree**)	1. Ordered for an approved indication for use:	**May not be renewed if BMI ≤ 24**

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10 mg/ml solution for SQ administration Imcivree Prior Authorization Form	• Chronic weight management in patients aged ≥ 6 years with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency that has been confirmed by genetic testing demonstrating variants in *POMC*, *PCSK1*, or *LEPR* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance. 2. Patient age ≥ 6 years and ≤ 64 years. 3. *POMC*, *PCSK1*, or *LEPR* deficiency is confirmed by genetic test **AND** the patient's genetic variants are interpreted as pathogenic, likely pathogenic, or of uncertain significance, **OR** 4. The patient has Bardet-Biedl syndrome (BBS) as defined by: • Patient having at least FOUR of the following primary features of Bardet-Biedl Syndrome: Rod-cone dystrophy, polydactyly, obesity, learning disability, renal abnormalities, or male hypogonadism; **OR** • Patient having at least THREE primary features from the list above **in addition to** at least TWO secondary features of BBS: Speech disorder/delay, strabismus/cataracts/astigmatism, brachydactyly, developmental delays, polyuria or polydipsia, ataxia, diabetes, dental crowding, congenital heart disease, or hepatic fibrosis. 5. Body Mass Index (BMI) meets one of the following: • Adults: > 30 kg/m^2	1. Patient meets initial authorization criteria. 2. Patient meets indication specific criteria listed below. <u>For patients treated for obesity attributed to *POMC*, *PCSK1*, or *LEPR* deficiency:</u> • Evaluation of weight loss should occur 12 to 16 weeks following initiation of therapy and approved only if weight loss ≥ 5% of baseline body weight has occurred. • Approval Duration: 6 months. <u>For patients diagnosed with BBS:</u> • Evaluation of weight loss after 1 year, may be approved only if weight loss of ≥ 5% of baseline body weight has been achieved. • 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
	• A BMI > 97th percentile using growth chart assessments for pediatric patients for obesity due to Bardet-Biedl syndrome (BBS) • A BMI > 95th percentile on pediatric growth chart for pediatric patients for obesity due to *POMC*, *PCSK1*, or *LEPR* deficiencies. 6. The patient has an eGFR > 15 ml/min/1.73m^2 7. Attestation by the prescriber that Imcivree will not be used concurrently with another weight loss drug which includes prescription, over-the-counter, and herbal preparations. 8. Documentation that a medical work up has excluded organic causes of obesity (i.e. hypothyroidism). 9. Prescribed by, or in consultation with an endocrinologist or geneticist. 10. **NOTE:** Other genetic obesity syndromes are **NOT** covered. This includes patient with Alstrom syndrome, Prader-Willi syndrome and any other form of obesity not specifically described above. 11. Approval Duration: for BBS diagnosis **ONLY**: 12 months. Approval Duration: 4 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.	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)

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	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	• Posterior reversible encephalopathy syndrome (PRES) • Torsades de points 5. Approval duration: 12 months
tadalafil (Adcirca; Alyq) PAH: 20 mg tablets *Tadalafil for treatment of BPH is non-formulary. If medically necessary, must be requested under a non-formulary exception PA request.*	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. Patient is not concurrently on organic nitrates (i.e., isosorbide mononitrate, isosorbide dinitrate, nitroglycerin), OR sildenafil, OR Adempas (riociguat); AND 3. IF patient is also prescribed macitentan (Opsumit), please **redirect** to Opsynvi (macitentan + tadalafil). 4. **Erectile dysfunction is not a covered indication for use.** 5. Ordered for generic Adcirca (tadalafil PAH) 20 mg tablets. 6. The diagnosis of PAH is documented by right-heart catheterization with ALL of the following: o Mean pulmonary artery pressure (mPAP) > 20 mmHg, and o Pulmonary arterial wedge pressure (PAWP) ≤ 15 mmHg, and o Pulmonary vascular resistance (PVR) ≥ 3 wood units.	1. All initial criteria continue to be met. 2. IF patient is also prescribed macitentan (Opsumit), please **redirect** to Opsynvi (macitentan + tadalafil). 2. Patient has documented positive clinical response to tadalafil treatment. 3. Approval Duration: 12 months.

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	7. Medication ordered by a Pulmonologist, Cardiologist, or Rheumatologist. 8. Quantity Limits: 2 tablets per day. 9. Approval Duration: 12 months.	
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**	
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. • Documentation of osteopenia or osteoporosis as defined by a T-score ≤ 1 and supported by clinical documentation of DEXA scan results.	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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	• 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.	
Tenofovir disoproxil fumarate (Viread)	1. Ordered for an approved indication for use: • Treatment of chronic hepatitis B virus (HBV) in patients ≥ 2 years of age weighing ≥ 10 kg. • Treatment of HIV-1 infection in patients ≥ 2 years of age weighing ≥ 10 kg, in combination with other antiretroviral agents. • Treatment of Hepatitis B/HIV coinfection in combination with lamivudine or emtricitabine and other appropriate antiretrovirals. • OR for compendial use, when ordered as part of combination therapy for either occupational or non-occupational post-exposure prophylaxis. 2. Prior to initiation of chronic therapy with tenofovir disoproxil fumarate, patients should be tested for both HBV and HIV-1 infections. **HIV-1 infection treatment:** • Diagnosis date(s) of opportunistic infection(s) OR CD4 test results (CD4 counts < 200 or < 14% are indicative of HIV+ status). • Confirmation of HIV diagnosis by laboratory documentation of at least ONE of the following:	1. All initial criteria are met. 2. Approval Duration for HIV, Hep B, or HIV with Hep B coinfection: Automated for continuous approval unless gaps in therapy > 90 days occur.

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	○ HIV RNA/DNA quantitative (if detectable) ○ HIV RNA/DNA qualitative ○ HIV P24 antigen ○ HIV Western blot ○ HIV genotype • Tenofovir disoproxil fumarate should not be used as a single-agent treatment of HIV-1 infections. 3. May not be taken concurrently with any of the following: Atripla, Biktarvy, Cimduo, Complera, Delstrigo, Genvoya, Odefsey, Stribild, Symfi/Symfi LO, Symtuza, Temixys. 4. **Approval Duration:** • <u>For HIV or Hepatitis B infections</u> (individually or as co-infections): ○ Continuous if no gaps in therapy > 90 days occur • <u>For Post Exposure Prophylaxis:</u> ○ 28 days	
Teplizumab (**Tzield**); J9381	**USE MFC High-Cost Medication PA Criteria**	
Teriparatide (Forteo) 600 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.	**<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

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	3. Patient is at very high fracture risk as evidenced by one of the following: • Recent osteoporotic fracture within the past 12 months. • Bone mineral density (BMD) T-score at hip or spine ≤ -3.0 • BMD T-score at hip or spine ≤ -2.5 AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus). 4. Patient has completed a 3-year trial of bisphosphonate therapy at up to maximally indicated doses, UNLESS one of the following: • All bisphosphonates are contraindicated. • 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.	fracture or multiple risk factors for fracture) and that the risk versus benefit of continued therapy has been reviewed with the member. 4. If request is for a dose increase, the new dose does not exceed 20 mcg per day (1 per per 28 days). 5. Approval duration: 12 months **<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.

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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. Diagnosis of HIV-associated lipodystrophy. 3. Patient age ≥ 18 years and ≤ 65 years. 4. Patient meets ONE of the following: • If male, waist circumference is ≥ 95 cm (37.4 inches) and waist-to-hip ratio is ≥ 0.94; OR • If female, waist circumference is ≥ 94 cm (37 inches) and waist-to-hip ratio is ≥ 0.88; AND 5. Patient has been stable on antiretroviral regimen for at least 8 weeks; AND 6. Medication is prescribed by or in consultation with an endocrinologist or physician specializing in the treatment of HIV-infection. 7. Approval Duration: 6 months.	1. Documentation of positive clinical response (e.g., improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance). 2. Approval Duration: 12 months.
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 the covered indication: • Treatment of adult patients with Type 2 Diabetes mellitus (T2DM). 2. Patient age ≥ 18 years. 3. Patient has diagnosis of T2DM. ***NOTE:*** *this product is not indicated for use in T1DM.* 4. A1c **or** Time in Range% (TIR%) CGM-report within past 3 months. 5. A urine albumin-to-creatinine ratio (uACR) within the previous 12 months. **Treatment of Type 2 Diabetes without regard to CVD risk factors:** The patient has an A1c (hemoglobin A1c) of ≥ 7.5 (TIR ≤ 60%). **OR**	**Cannot be approved for indication of weight management.** 1. Chart notes with A1c or CGM report with TIR% within previous 3 months. 2. A urine albumin-to-creatinine ratio (uACR) within the previous 12 months. 3. Documented positive clinical response defined as one of the following: **Baseline (pre-GLP-1) A1c was ≥ 8.0 and:** • A1c has decreased by ≥ 1% since onset of therapy **or** TIR% was ≤ 55% and has increased ≥ 10% **or** • A1c is ≤ 7.0 at initiation dose.

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	<u>Treatment of Type 2 Diabetes with CVD as defined below:</u> • Pre-treatment A1c is ≥ 6.5 (TIR ≤ 70%) **AND** • BMI ≥ 27 kg/m2 (documentation within previous 90 days of current height and weight); **AND** Documentation submitted to show that the patient has at least **<u>one</u>** of the following: • History of myocardial infarction; **or** • Prior stroke (ischemic or hemorrhagic); **or** • Symptomatic peripheral arterial disease (PAD) as evidenced by: ○ Intermittent claudication with ankle-brachial index (ABI) < 0.85 (at rest); **or** ○ Peripheral arterial revascularization procedure; **or** ○ Amputation due to atherosclerotic disease. 6. May not be concurrently using or taking **ANY** of the following: • ANY other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus, Saxenda, Soliqua, Trulicity, Victoza (liraglutide), Xultrophy, or Zepbound) • **ANY** DPP4i (e.g., alogliptin, Januvia (sitagliptin), Onglyza (saxagliptin) or Tradjenta (linagliptin)). • Agents for *severe* constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 7. Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all	**<u>Baseline (pre-GLP-1) A1c was ≥ 6.5 but < 8.0 and:</u>** • A1c or TIR% has improved. Not eligible for renewal if A1c has increased **or** TIR% has decreased. 4. Patient has not had medical intervention for: ○ Pancreatitis; or ○ Severe gastrointestinal events. (e.g., hospitalization or new start GI motility agent). 5. May not be concurrently using **ANY** of the following: • **ANY** other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus, Saxenda, Soliqua, Trulicity, Victoza, Xultrophy or Zepbound) • **ANY** DPP4i (e.g., alogliptin, Januvia (sitagliptin), Onglyza (saxagliptin), or Tradjenta (linagliptin)). • Agents for *severe* constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 6. PBM claims data shows consistent adherence as shown by no instance of a drug-free interval greater than 2

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	contraindications. 8. May **not** be approved for patients with: • Any personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN 2). • Current pregnancy • History of confirmed pancreatitis 9. 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 to 5 mg per week dose **UNLESS** A1c ≤ 7.0 or TIR ≥ 65% on 2.5 mg dose. 10. **Cannot be approved for indication of weight management.** 11. Maximum Approval Duration: up to 12 months	months at which time the patient would need to satisfy the initial criteria. 7. Approval Duration: up to 12 months.
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	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.	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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Tablets 100mg, 200mg, 300mg Tablets (biphasic release) 100mg, 200mg, 300m	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. Opioid naïve adult patients (no opioid use within previous 30-days) are limited to a 7-day supply with an MME ≤ 50 MME per day, patients under age 18 are limited to a 3-day supply. 5. 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	**Limitations of Use:** Not indicated as an as-needed (prn) analgesic.
Treprostinil (**Orenitram**) 0.125 mg, 0.25 mg, 1 mg, 2.5 mg, 5 mg tablets	1. Ordered for an approved indication for use: • To delay disease progression and improve exercise capacity in patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue disease. 2. Patient aged ≥ 18 years. 3. Patient has a diagnosis of World Health Organization (WHO) Group I pulmonary arterial hypertension (PAH); **AND** 4. Documentation is submitted showing that the patient has had a right heart catheterization that confirms the diagnosis of WHO Group I PAH; **AND** 5. Patient meets one of the following conditions: • Patient has tried **TWO** oral therapies for PAH from two of the three different categories (either alone or in combination) of each for ≥ 60 days:	1. Patient has a diagnosis of World Health Organization (WHO) Group I pulmonary arterial hypertension (PAH); **AND** 2. Patient has had a right heart catheterization; **AND** 3. The results of the right heart catheterization confirm the diagnosis of WHO Group I PAH; **AND** 4. The patient is experiencing a positive clinical response to treatment with Orenitram as evidenced by any of the following: reduced pulmonary vascular resistance and/or pressure, improved symptoms, and/or improved patient activity. 5. Not prescribed concurrently with Uptravi (selexipag), inhaled prostacyclin products (e.g. Tyvaso [Treprostinil], Tyvaso DPI, Ventavis [iloprost], epoprostenol).

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	○ One phosphodiesterase type 5 (PDE5) inhibitor (e.g. sildenafil or tadalafil); or ○ One endothelin receptor antagonist (ERA) (e.g. bosentan, ambrisentan or Opsumit [macitentan]), or Adempas (riociguat); **OR** ○ Patient has history of treatment with one PAH prostacyclin therapy or a prostacyclin receptor agonist 6. Patient does not have severe hepatic impairment (Child Pugh Class C). 7. Not prescribed concurrently with Uptravi (selexipag), inhaled prostacyclin products (e.g. Tyvaso [Treprostinil], Tyvaso DPI, Ventavis [iloprost], epoprostenol). 8. Prescribed by or in consultation with a cardiologist or pulmonologist. 9. Quantity Limit: 2 tablets per day. Use appropriate tablet strength to reach desired total daily dose. 10. Approval Duration: 12 months.	6. Orenitram is prescribed by, or in consultation with a cardiologist or pulmonologist. 7. Approval Duration: 12 months.
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. **<u>Prostate Cancer:</u>** • Prescribed by an oncologist. **<u>Preservation of ovarian function:</u>** • Patient is premenopausal and undergoing chemotherapy. **<u>Breast cancer:</u>**	1. **<u>Prostate Cancer:</u>** • Patient is experiencing clinical benefit (e.g., serum testosterone < 50 ng/dl) • Patient has not experienced unacceptable toxicity. **<u>Preservation of ovarian function:</u>** • Patient meets all initial criteria. **<u>Breast cancer:</u>** • Patient was premenopausal at diagnosis and is still undergoing treatment with endocrine therapy.

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	• Patient is premenopausal with hormone-receptor positive breast cancer at high-risk for recurrence using in combination with endocrine therapy. **<u>Gender affirming care:</u>** • Patient has diagnosis of gender dysphoria and meets MDH regulatory requirements for care. • Patient has reached Tanner stage ≥ 2 of puberty. 3. **<u>Approval Duration:</u>** • Prostate Cancer: 12 months • Preservation of ovarian function: 3 months • Breast cancer (ovarian suppression): 12 months • Gender affirming care: 12 months	• Total treatment with triptorelin does not exceed 5 years. **<u>Gender affirming care:</u>** • Patient has reached Tanner stage ≥ 2 of puberty. 2. **<u>Approval Duration:</u>** • 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 at least one NSAID. 4. Member must have tried and failed at least **TWO** formulary triptans or have a contraindication to triptan therapy. *Examples of contraindications include: a history 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. 5. Quantity limits: 16 tablets per 30 days, 200 mg max daily	1. Meets all initial clinical criteria. 2. Documentation of positive clinical response to treatment (e.g., reduction in migraine frequency). 3. Quantity limited to 16 doses per 30 days, 200 mg max daily dose. 4. Approval Duration: 12 months.

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	dose. 6. 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 under the Medical Benefit 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). 5. Requested dose and frequency are aligned with FDA and manufacturer labeling. **Hidradenitis suppurative**: **excluded** from coverage; off-label indication. Note: Humira (or biosimilars) is first line therapy. Remicade (infliximab) is the MedStar Family Choice recommended alternate. **Crohn's disease**: • Diagnosis of moderately to severely active Crohn's disease • Patient is currently on Stelara therapy for moderately to severely active Crohn's disease as documented by claims history or submission of medical records. • Must have trialed and failed therapy with adalimumab, this includes patients who have failed	**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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	infliximab. (1A recommendation from AGA Practice Guidelines 2021).
	• Approved dose: 90 mg/ml
	• Approval Duration: 12 months
	Plaque psoriasis:
	• Diagnosis of moderate to severe plaque psoriasis
	• ≥ 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis; AND
	• History of failure to one of the following topical therapies:
	  ○ Corticosteroids
	  ○ Vitamin D analogs (calcitriol, calcipotriene)
	  ○ 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.	

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	• 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	

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	be required to meet initial authorization criteria as if the patient were new to therapy. • Prescribed by or in consultation with a rheumatologist or dermatologist. • Approved dose: 45 mg/ml for patient weight ≤ 100 kg • Approved dose: 90 mg/ml for patient weight > 100 kg • Approval duration: 12 months **Ulcerative colitis, moderate to severe:** • 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	
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.	1. All initial criteria continue to be met. 2. Documentation provided or attestation of therapeutic benefit. 3. Approval Duration: 6 months.

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	3. Not taking concurrently with cyclophosphamide. 4. Prescriber specialty: immunologist, nephrologist, rheumatologist, or provider experienced in treatment of lupus nephritis. 5. Prescriber attestation that all baseline evaluations have been done, and not contraindications to use are present (strong 3A4 inhibitor contraindicated, live vaccines, pregnancy/breastfeeding negative, assessment of renal function). 6. Quantity Limit: 6 tablets per day (23.7 mg twice daily). 7. Approval Duration: 6 months	
Vestronidase alpha (**Mepsevii**) J3397	**USE MFC High-Cost Medication PA Criteria**	
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**	