MedStar Family Choice MD Prior Authorization and Step Therapy Table

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	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	1. Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide, Forteo, Tymlos) during the patient's lifetime. 2. Approval Duration: up to 12 months, not intended to last longer than the

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	osteoporosis therapy. 2. Patient has diagnosis of post-menopausal osteoporosis and is at high risk for bone fracture. 3. Patient is female, age ≥ 18 years of age. 4. Patient does not have increased baseline risk for osteosarcoma (e.g., Paget's disease of the bone, bone metastases, or skeletal malignancies). 5. T-score ≤ -2.5 based on BMD measurements from the lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) OR • History of one of the following resulting from minimal trauma: vertebral compression fracture, fracture of the hip, fracture of the distal radius, fracture of the pelvis, fracture of the proximal humerus. 6. If the criteria in #2 are not met, approval may be granted for patients with both of the following: • BMD T-score between -1 and -2.5 based on BMD measurements from lumbar spine, hip, or radius; AND	final infusion completing 24 months of therapy.

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	• ONE of the following FRAX 10-year fracture probabilities:
	  ○ Major osteoporotic fracture ≥ 20%
	  ○ 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.
	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.	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.

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	3. Patient has had at least one prior systemic therapy. 4. Medication ordered by an Oncologist. 5. Approval Duration: 12 months.	3. No documentation of disease progression or unacceptable toxicity. 4. Approval Duration: 12 months
Adalimumab **(Humira Biosimilar)** Single-dose prefilled autoinjector: 40 mg/0.8ml Single-dose prefilled glass syringe: 40 mg/0.8 ml Single -dose prefilled autoinjector: 40 mg/0.4 ml **ADALIMUMAB-AATY, ADALIMUMAB-FKJP, HADLIMA**	Indication (FDA Approved Uses) **Rheumatology** • Moderately to severely active Rheumatoid Arthritis (RA) • Active Psoriatic Arthritis (PsA) • Active Ankylosing Spondylitis (AS) • Active Non-radiographic Axial Spondyloarthritis (nr-axSpA) • Moderately to severely active Polyarticular Juvenile Idiopathic Arthritis (pJIA ≥2 years) **Dermatology** • Moderate to severe Plaque Psoriasis (PsO) • Moderate to severe Hidradenitis Suppurativa (HS) **Gastroenterology** • Moderately to severely active Crohn's Disease (CD) (adult and pediatric ≥6 years) • Moderately to severely active Ulcerative Colitis (UC)	REAUTHORIZATION CRITERIA • Documented clinical improvement • Continued adherence No serious adverse events Approval Duration: 12 Months

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	(adult and pediatric ≥5 years)
	Ophthalmology
	Non-infectious Uveitis (intermediate, posterior, or panuveitis)
	
	• Must be prescribed by or in consultation with:
	  ○ Rheumatologist (RA, PsA, AS, nr-axSpA, pJIA)
	  ○ Dermatologist (PsO, HS)
	  ○ Gastroenterologist (CD, UC)
	  ○ Ophthalmologist (uveitis)
	
	GENERAL COVERAGE CRITERIA
	
	(ALL REQUIRED)
	
	• Diagnosis consistent with FDA labeling
	• Documentation of disease severity (e.g., DAS28, BSA/PASI, CDAI, Mayo score, HS staging)
	• Negative TB screening prior to initiation
	• No concurrent biologic or JAK inhibitor therapy	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• Use consistent with FDA-approved dosing STEP THERAPY REQUIREMENTS A. **Rheumatoid Arthritis (RA)** Patient has tried and failed one of the following conventional DMARDs (eg: Methotrexate, Leflunomide, Sulfasalazine) for at least 12 weeks or have a contraindication/intolerance or no adequate response. B. **Psoriatic Arthritis (PsA)** Patient has tried and failed one of the following conventional DMARDs (eg: Methotrexate, Leflunomide, Sulfasalazine) for at least 12 weeks or have a contraindication/intolerance or no adequate response. C. **Ankylosing Spondylitis / nr-axSpA** Patient has tried and failed NSAIDs (eg: Ibuprofen, naproxen, meloxicam, … etc) for at least 4 weeks or have a contraindication/intolerance or no adequate response.	

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	D. **Plaque Psoriasis (PsO)** History of failure to one of the following topical therapies for 12 weeks : ○ Corticosteroids ○ Vitamin D analogs (calcitriol, calcipotriene) ○ Tacrolimus or pimecrolimus. **AND** History of failure to Phototherapy. **AND** Patient has tried and failed one of the following systemic therapies (eg: Methotrexate, cyclosporine, acitretin) for at least 12 weeks or have a contraindication/intolerance or no adequate response. E. **Hidradenitis Suppurativa (HS)** Patient has tried and failed one of the following antibiotics (eg: doxycycline, clindamycin/rifampin) for at least 90 days or have a contraindication/intolerance or no adequate response.	

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	F. **Crohn's Disease (CD) / Ulcerative Colitis (UC)** Patient has had an inadequate response for at least 12 weeks to conventional therapies (such as anti- inflammatory drugs, corticosteroids, or oral immunosuppressive agents) G. **Uveitis** Patient has had an inadequate response for at least 12 weeks to conventional therapies (such as corticosteroids, or oral immunosuppressive agents) 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.	

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	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.
	<u>Asthma indication</u>: One inhaler, One time only.
	
	<u>COPD indication:</u>
	Duration determination is dependent upon:
	• Oversight by a Pulmonologist,
	• 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	

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	• Note that LABAs/LAMAs are preferred over SABAs/SAMAs • Maximum approval duration: 6 months.	
	1. , metoprolol, nadolol, propranolol, timolol), candesartan, divalproex sodium, Botox, SNRI therapy (duloxetine, venlafaxine), topiramate, or tricyclic antidepressants (amitriptyline, nortriptyline). 2. Requested medication will not be used concurrently with another CGRP antagonist or inhibitor intended for migraine prevention **Approval duration**: 12 months	1. Patient demonstrates clinical improvement, Including reduction in migraine frequency and/ or severity 2. Medication will not be used concurrently with another CGRP antagonist or inhibitor intended for migraine prevention **Approval duration**: 12 months

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alectinib (**Alecensa**) capsule 150mg	1. Ordered for an approved indication for use: • Treatment of patients with anaplastic lymphoma kinase (ALK)- positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. 2. Patient ≥ 18 years of age. 3. Patient has advanced or metastatic disease. 4. Patient has anaplastic lymphoma kinase (ALK)- positive disease as detected by an approved test. 5. Medication ordered by an Oncologist. 6. Maximum Approval Duration: 12 months.	1. No documentation of disease progression or unacceptable toxicity. 2. Approval duration: 12 months.
alglucosidase alfa (**Lumizyme**)	USE **MFC High-Cost Medication PA Criteria**	
allogeneic processed thymus tissue–agdc (**Rethymic**)	USE **MFC High-Cost Medication PA Criteria**	
alosetron (**Lotronex**) 0.5 mg, 1 mg	1. Ordered for an approved indication for use: • For females with severe diarrhea-predominant irritable bowel syndrome (IBS) including one or more of the following: frequent and severe abdominal pain or discomfort, frequent bowel urgency or fecal incontinence, or disability or restriction of daily	1. Documentation of positive clinical response to therapy. 2. Authorization Duration: 12 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	activities due to IBS. 2. Prescribed for a female patient with a diagnosis of severe diarrhea-predominant IBS syndrome AND 3. Chronic IBS symptoms lasting at least 6 months. 4. Gastrointestinal tract abnormalities have been ruled out 5. There has been an inadequate response to conventional therapy (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.	

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	8. Approval Duration: 6 months.	
antihemophil FVIII, B-dom del (**Xyntha**), J7185	USE **MFC High-Cost Medication PA Criteria**	
Apremilast **(Otezla)** 10 mg, 20 mg, 30 mg XR tablets: 75 mg	<u>Active Psoriatic Arthritis (PsA)</u> 1. Age ≥ 18 years. 2. Prescriber or in consultation with rheumatologist **3. Step 1: Conventional Synthetic DMARD (Required)** Patient must have documented trial and failure, intolerance, or contraindication to ≥1 agent: • Methotrexate • Leflunomide • Sulfasalazine Minimum Duration Requirement: • ≥12 weeks of continuous therapy (unless intolerance or contraindication) Verification: • Pharmacy claims demonstrating ≥80% adherence (PDC ≥0.8) over 12 weeks	Documentation of clinical improvement: • PsA: reduction in joint symptoms • PsO: improvement in BSA/PASI • Behçet's: reduced ulcer frequency • Continued adherence (PDC ≥0.8 based on pharmacy claims) • No evidence of disease progression **Approval Duration: 6 months**

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	• OR documented intolerance/adverse event in medical record **4. Step 2: Biologic DMARD (Required)** Trial and failure, intolerance, or contraindication to ≥1 preferred biologic: • TNF inhibitor (adalimumab biosimilar) **Minimum Duration Requirement:** • ≥12 weeks (aligned with ACR response timelines) Verification: • Medical or pharmacy claims confirming administration/dispensing • Documentation of inadequate clinical response **5. Step 3: Otezla Eligibility** Authorization granted only if: • Failure/intolerance to ≥1 biologic • OR contraindication to biologics • OR documented inability to use injectable therapy	

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	Approval Duration: 6 months <u>Plaque Psoriasis (PsO):</u> 1. Age ≥18 years 2. Prescriber or in consultation with dermatologist 3. **Step 1: Topical Therapy + Phototherapy (Required)** • ≥2 topical agents (e.g., corticosteroids, vitamin D analogs) • Phototherapy (unless not feasible) Minimum Duration Requirement: • Topicals: ≥ 8 weeks • Phototherapy: ≥ 12 weeks Verification: • Pharmacy claims for topical agents • Medical records documenting phototherapy sessions or contraindication **Step 2: Systemic Oral Therapy (Required)**	

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	• Methotrexate • Cyclosporine • Acitretin Minimum Duration Requirement: • ≥12 weeks (unless intolerance/toxicity) Verification: • Pharmacy claims showing dispensing history • Lab monitoring consistent with therapy • Documentation of inadequate response or intolerance **Step 3: Biologic Therapy (Preferred Step)** • Trial and failure, intolerance, or contraindication to ≥1 preferred biologic: TNF inhibitor (adalimumab biosimilar) Verification: • Medical or pharmacy claims confirming use • Documentation of inadequate response 4. Prescriber or in consultation with a	

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	rheumatologist **PA approved for**: 6 months <u>Bechet's Disease (Oral Ulcers):</u> • Age ≥18 years • Prescriber or in consultation with rheumatologist **Step 1: First-Line Therapy** • Topical Corticosteroids • Colchicine Minimum Duration Requirement: ≥ 12weeks Verification: • Pharmacy claims or documented clinical use **Step 2: Systemic Therapy** • Azathioprine • Thalidomide (if appropriate)	

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	Minimum Duration Requirement: ≥12 weeks Verification: • Pharmacy claims or documented clinical use **Step 3: Otezla Eligibility** • Failure/intolerance to above therapies • Persistent oral ulcers impacting quality of life **PA approved for**: 6 months EXCLUSION CRITERIA Coverage will be denied for: • Use outside FDA-approved indications without compendia support • Lack of documented step therapy completion • Insufficient duration of prior therapies • Non-adherence (PDC < 0.8) without justification • Concurrent use with another targeted immunomodulator without clinical rationale	

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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. 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.	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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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 inhibitors (e.g. Tavalisse). <u>Chronic Immune Thrombocytopenia (ITP):</u> • 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),	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. 2. **<u>Thrombocytopenia in a patient with Chronic Liver Disease:</u>** • must meet initial use criteria for each request. • Approval Duration: 5 days, a maximum of 15 tablets per treatment

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	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 <u>Thrombocytopenia in a patient with Chronic Liver Disease:</u> • 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.	
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.

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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 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. <u>Rosacea:</u> *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.	1. Treatment for rosacea to be renewed for 12 months upon documentation of beneficial clinical effect.

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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. 3. Indication-specific quantity/dose limitations apply. <u>Alopecia Areata:</u> • 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: ○ A targeted immunomodulator e.g., adalimumab, Cimzia, Enbrel, Simponi, Orencia, Xeljanz, Rinvoq or Litfulo OR	**<u>Renewal Criteria applies to both Alopecia Areata and Rheumatoid Arthritis indications:</u>** 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.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	○ 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 <u>Rheumatoid Arthritis (RA):</u> • Diagnosis of moderately to severely active RA; AND • <u>One</u> 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	

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	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 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:	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	○ 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.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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)	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.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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., 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:	1. Prescriber attestation of continued clinical benefit.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• 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.	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	**Asthma:** 1. Documentation of positive clinical response to Fasenra therapy as

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	eosinophilic phenotype. • 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	demonstrated by at least one of the following: • Reduction in frequency of exacerbations • Decreased utilization of rescue medications • Increase in percent predicted FEV1 from pretreatment baseline. • Reduction in severity or frequency of asthma-related symptoms • Reduction in oral corticosteroid requirements. 2. Used in combination with inhaled corticosteroid (ICS)-containing controller medication. 3. Patient is not receiving treatment in combination with **ANY** of the following:

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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 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	• Anti-interleukin-5 therapy (e.g., Cinqair (resilizumab), Nucala (mepolizumab). • Anti-IgE therapy (e.g., Xolair (omalizumab). • Anti-interleukin-4 therapy (e.g., Dupixent (dupilumab). • Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., Tezpire (Tezepelumab)). 4. Approval Duration: 12 months. **<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.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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:	• A reduction or discontinuation of daily oral corticosteroid dose • No active vasculitis 2. Approval Duration: 12 months

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• 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	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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 J3490, J8499	USE **MFC High-Cost Medication PA Criteria**	
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	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 Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	coverage (Use CDC-approved PrEP formulary alternatives: generic Truvada or Descovy). 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), Epzicom (lamivudine-abacavir), Symfi or Symfi LO (efavirenz-lamivudine-tenofovir), Temixys (abacavir-dolutegravir-lamivudine), Trizivir (abacavir-lamivudine-zidovudine).	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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.

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
brigatinib (**Alunbrig**) tablets 30mg, 90mg, 180mg	1. Ordered for an approved indication for use: • The treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. • Ordered for treatment when the indication has been recognized by the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a category of Evidence and Consensus of 1, 2A, or 2B. <u>Non-Small Cell Lung Cancer (NSCLC):</u> • The tumor is anaplastic lymphoma kinase (ALK)-positive. • The cancer is either: metastatic, recurrent, or advanced. <u>Soft Tissue Sarcoma/Uterine Neoplasms:</u> • Diagnosis of inflammatory myofibroblastic tumor (IMT); and • Presence of ALK translocation. <u>Histiocytic Neoplasms:</u>	1. Patient does not show evidence of progressive disease while on Alunbrig therapy. 2. Approval Duration: 12 months.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• Diagnosis of symptomatic Erdheim-Chester Disease; and • Used as targeted therapy ALK-fusion; and • Disease is either relapsed or refractory. <u>Central Nervous System (CNS) Cancers:</u> • 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.	
buprenorphine products for chronic pain indication ONLY **Belbuca** (buccal films) 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, 900 mcg topical patches (generic of Butrans) 5 mcg/hr, 7.5 mcg/hr, 10 mcg/hr, 15 mcg/hr, 20 mcg/hr	1. Ordered for an approved indication for use: • Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 2. Patient aged ≥ 18 years. 3. NOT prescribed concurrently with ANY other long-acting opioid therapy. 4. NOT prescribed for the treatment of opioid dependence. 5. Requested dose is appropriate based on patient's opioid status:	1. All initial criteria are met. 2. Documentation that patient demonstrates meaningful improvement in pain relief as described by function or pain score improvement). **Limitations of Use:** Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and greater risk of

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<table>
<tr><th>Generic Medication (Brand Name)
Bolded medication specifies whether Brand or Generic is Formulary</th><th>Approval Criteria & Submission Requirements</th><th>Additional Considerations and Renewal Criteria</th></tr>
<tr><td>**All other dosage forms of buprenorphine have indications that are carved out to MDH for coverage.

OPIOID PRIOR AUTH FORM-MD</td><td>• Opioid-naïve or non-opioid tolerant patients:
○ Films: 75 mcg once daily, or if tolerated, every 12 hours for ≥ 4 then increase to 150 mcg every 12 hours;
○ Patches: 5 mcg/hr applied once every 7 days.
• Opioid experienced/tolerant patients:
○ MUST discontinue all other around-the-clock opioids once buprenorphine is initiated, AND
○ Current opioid dose should not exceed 30 MME per day, dose tapering before buprenorphine initiation required.
○ INITIAL buprenorphine dose based on opioid MME, before taper, as below:
<table><tr><td>Daily MME < 30</td><td>75 mcg every 12 to 24 hours</td></tr><tr><td>MME 30-89</td><td>150 mcg every 12 hours</td></tr><tr><td>MME 90-160</td><td>300 mcg every 12 hours</td></tr><tr><td>MME > 160</td><td>Not covered</td></tr></table></td><td>overdose and death with extended-release opioid formulations, reserve for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
Maximum Approval Duration: 6 months.</td></tr>
</table>

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	6. Dose does not exceed maximum dose recommended by product labeling and is within quantity limits. • Films: 900 mcg (1 film) every 12 hours. • Patches: 20 mcg per 7 days. 7. Quantity Limits: Films: 2 films per day. Patches: 4 patches per 28 days. 8. Maximum approval duration: 6 months; may be reduced based on any of the criteria as outlined in Pharmacy Policy 219: Opioid Prescription Prior Authorization.	
c1 Inhibitor [Human] cinryze sol; J0598 500 unit haegarda injection 2000unit, 3000unit; J0599	USE **MFC High-Cost Medication PA Criteria**	
cabotegravir and rilpivirine extended-release (**Cabenuva**) injectable suspension 600mg-900mg	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	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.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
**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.*	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. 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. 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). 5. Patient is antiretroviral treatment-experienced and has been virologically suppressed (HIV RNA < 50 copies/ml) for at least three months; AND 6. Patient has no history of treatment failure.	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.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	7. 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. 8. 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**	
Certolizumab pegol (**Cimzia**) 200 mg starter kit and maintenance dosing	1. Ordered for an approved indication for use: • Moderately to severely active Crohn's disease • Moderately to severely active rheumatoid arthritis (RA) • Active psoriatic arthritis • Active ankylosing spondylitis or non-radiographic axial spondylarthritis	1. Documentation of positive clinical response to Cimzia therapy. 2. Patient is not receiving Cimzia in combination with another targeted immunomodulator (e.g. adalimumab, Enbrel, Simponi, Orencia, Xeljanz, Olumiant, Rinvoq, Ustekinumab

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• Severe plaque psoriasis • Active polyarticular juvenile idiopathic arthritis 2. Patient has completed at least an 8-week trial of either adalimumab [Humira biosimilar] OR Ustekinumab [Stelara biosimilar] without achieving effective symptom control or has a contraindication to using. • Patients of reproductive age who are pregnant or planning to conceive are exempt from adalimumab/ustekinumab pre-cursor therapy. 3. Patient is not receiving Cimzia in combination with another targeted immunomodulator (e.g. adalimumab, Enbrel, Simponi, Orencia, Xeljanz, Olumiant, Rinvoq, Ustekinumab [Stelara or biosimilar], Skyrizi, Tremfya, Cosentyx, Taltz, Siliq, Ilumya, Otezla). 4. If ordered to treat moderate to severely active Crohn's Disease: • Patient has had an inadequate response to conventional therapies (such as anti-inflammatory drugs, corticosteroids, or oral immunosuppressive agents).	[Stelara or biosimilar], Skyrizi, Tremfya, Cosentyx, Taltz, Siliq, Ilumya, Otezla). 3. Approval Duration: 12 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	5. Approval Duration: 12 months.	
Ciltacabtagene autoleucel (**Carvykti**); Q2056	USE **MFC High-Cost Medication PA Criteria**	
Cipaglucosidase alfa (**Pombiliti**); J1203	USE **MFC High-Cost Medication PA Criteria**	
Coagulation factor IX (**Benefix**) recombinant; J7195	USE **MFC High-Cost Medication PA Criteria**	
crisaborole (**Eucrisa**) ointment 2% **STEP THERAPY**	1. Ordered for an approved indication for use: • Topical treatment of mild-to-moderate atopic dermatitis in adult and pediatric patients ≥ 3 months of age. 2. Step Therapy: • Unless patient age < 2 years of age. • Trial and failure to: ○ At least one medium- or high-potency topical steroid AND ○ 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	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. 3. Approval Duration: 12 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	affected area is greater than 5% of BSA. 5. 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 Consensus of 1, 2A, or 2B. <u>Non-Small Cell Lung Cancer (NSCLC):</u> • The cancer is either: metastatic, recurrent, or advanced. • The tumor is one of the following: ○ ALK-positive	1. Patient does not show evidence of progressive disease while on Xalkori therapy. 2. Approval Duration: 12 months.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	○ ROS1-positive ○ Positive for mesenchymal-epithelial transition (MET) amplification ○ Positive for MET exon 14 skipping mutation <u>Soft Tissue Sarcoma/Uterine Neoplasms:</u> • Diagnosis of inflammatory myofibroblastic tumor (IMT); and • Presence of ALK translocation. <u>Histiocytic Neoplasms:</u> • Diagnosis of one of the following: ○ Erdheim-Chester Disease ○ Langerhans Cell Histiocytosis ○ Rosai-Dorfman Disease • Used as targeted therapy ALK-fusion. <u>Central Nervous System (CNS) Cancers:</u> • Diagnosis of metastatic brain cancer from NSCLC; and • Tumor is ALK-positive OR ROS1-positive. <u>Anaplastic Large Cell Lymphoma:</u> • Tumor is ALK-positive; and • Disease is relapsed or refractory	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	<u>Melanoma:</u> • Diagnosis of metastatic or unresectable cutaneous melanoma; and • Disease is ROS1 gene fusion-positive; and • Used as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of 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.	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 Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options. • Treatment of adult and pediatric patients ≥ 6 years of age with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. • Treatment of pediatric patients ≥ 1 year of age with low-grade glioma (LGG) with BRAF V600E mutation who require systemic therapy. <u>Cutaneous Melanoma:</u> • 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.	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**

	<u>Central Nervous System Cancers (CNS):</u>
	• 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).
	<u>Non-Small Cell Lung Cancer (NSCLC):</u>
	• Diagnosis of metastatic, advanced or recurrent NSCLC; AND
	• Cancer is positive for BRAF V600E mutation.
	<u>Thyroid Cancer that is positive for BRAF V600E mutation:</u>
	• Diagnosis of Anaplastic Thyroid Cancer (ATC):
	  ○ disease is metastatic, locally advanced, or unresectable OR prescribed as adjuvant therapy following resection; and
	  ○ Will be used in combination with Mekinist (trametinib).
	• Diagnosis of one of the following carcinomas: follicular, oncocytic, or papillary; and
	• Disease if unresectable locoregional recurrent disease,	

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	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) <u>Histiocytic Neoplasms:</u> • Diagnosis of eith Langerhans Cell Histiocytosis or Erdheim-Chester Disease that is positive for BRAF V600E mutation <u>Solid Tumors:</u> • Presence of solid tumor positive for BRAF V600E mutation; and • Used as subsequent treatment after progression on or after systemic treatment; and	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• 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. 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	1. Improvement in walking speed as demonstrated by T25FW as compared with baseline. 2. Approval duration: 12 months.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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.	
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	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 Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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.	
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 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	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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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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.	

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	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	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 Formulary	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: 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.	
darolutamide (**Nubeqa**) tablets 300mg	1. Ordered for an approved indication for use: • Non-metastatic castration- resistant prostate cancer (nmCRPC) • Metastatic castration-sensitive prostate cancer (mCSPC), with or without docetaxel 2. Patient is ≥ 18 years of age, AND 3. For mCSPC, patient tried or has a contraindication to **Abiraterone (preferred product)**.	1. Patient has not shown disease progression. 2. Patient has not experienced unacceptable toxicity. 3. Patient should also receive a GnRH analog concurrently OR have had a bilateral orchiectomy. 4. Treatment may continue even if a cycle of docetaxel is delayed, interrupted, or discontinued. **Approval Duration:** 12 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	4. Concomitant Therapy: • May be used with or without docetaxel, depending on the clinical scenario 5. The patient meets ONE of the following: • The medication is used concurrently with a GnRH agonist or antagonist, or • Patient has bilateral orchiectomy 6. Medication ordered by an Oncologist or Urologist 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.	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.**

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture. • treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. • treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. 2. Patient age ≥ 18 years of age. 3. Tried and failed, had adverse reaction to, or contraindication to formulary preferred products (e.g., alendronate, calcitonin nasal spray). 4. Baseline calcium and vitamin D level results, with plan to correct any identified deficiencies before treatment 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.	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	8. For patients with advanced kidney disease (eGFR <30 mL/minute/1.73 m^2), including dialysis-dependent patients: evaluation for presence of chronic kidney disease-mineral disorder (CKD-MBD) must be completed prior to denosumab initiation. Treatment with denosumab in these patients should be supervised by a health care provider with expertise in the diagnosis and management of CKD-MBD. 9. Authorization duration: 12 months.	
deutetrabenzine (**Austedo**) tablets titration kit 6mg, 9mg, 12mg NOTE: *Austedo XR is covered ONLY for the titration pak. Maintenance doses must be converted to the IR tablets. Total daily dose is equivalent on a mg-to-mg basis, but the IR should be administered in 2 divided doses if the*	1. Ordered for an approved indication for use: • Chorea associated with Huntington's disease. (HD) • Tardive dyskinesia (TD) in adults. 2. Patient age ≥ 18 years. 3. Patient is not receiving other VMAT2 inhibitors (tetrabenazine or valbenazine), MAOI's or reserpine. 4. Patient does not have hepatic impairment. 5. Tardive dyskinesia: • AIMS score sheet along with the progress note must be provided for initial and renewal PA requests.	1. Prescriber attestation of continued clinical benefit and subsequent evaluation and monitoring performed. 2. TD: AIMS score must show improvement over initial score. 3. HD: TMC score must show improvement over the initial score and functional impairment must show improvement from baseline. 4. All initial criteria must be met.

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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<table>
<tr><th>Generic Medication (Brand Name)
Bolded medication specifies whether Brand or Generic is Formulary</th><th>Approval Criteria & Submission Requirements</th><th>Additional Considerations and Renewal Criteria</th></tr>
<tr><td>total dose is ≥ 12 mg per day. See table under renewal criteria.</td><td>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>5. Dose administered is optimized by tablet strength to achieve target dose as described in this table:<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</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 Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• Stroke • Traumatic brain injury 4. The baseline Center for Neurologic Study-Lability Scale (CNS-LS) score must be > 13. 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	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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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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 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.	3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

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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, Dovato,	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 Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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:	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 Formulary	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. 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, 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)	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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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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). 5. Approval Duration: continuous if no gaps in therapy > 90 days occur.	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
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	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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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	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: Atripla, Biktarvy, Cimduo, Combivir, Complera, Dovato, Epivir, Epzicom, Genvoya, Odefsey, Pifeltro, Stribild, Symfi or Symfi Lo, Symtuza, Temixys, Triumeq, Trizivir, Viread. 5. Approval Duration: continuous if no gaps in therapy > 90 days occur.	
Dolutegravir/ rilpivirine (**Juluca**) (DTG/RPV) 50 mg /25 mg tablets	1. Ordered for an approved indication for use: Treatment of HIV-1 infection as a complete regimen to replace the current antiretroviral (ARV) regimen in adults (age 18 years or older) 2. The use of Juluca for PrEP is off-label and not approved for coverage (Use CDC-approved PrEP formulary alternatives: generic Truvada or Descovy). 3. 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. **Approval Duration: 12 months**

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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), Epzicom (lamivudine-abacavir), Symfi or Symfi LO (efavirenz-lamivudine-tenofovir), Temixys (abacavir-dolutegravir-lamivudine), Trizivir (abacavir-lamivudine-zidovudine). Initial Approval Duration: 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	Renewal criteria are indication specific. Please review criteria for the patient-specific diagnosis. **Atopic Dermatitis:** • Documentation of a positive clinical response to therapy; At

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	3. The criteria for Dupixent are **indication specific**. Please review criteria for the patient-specific diagnosis. <u>Atopic Dermatitis:</u> Diagnosis of moderate-to-severe chronic atopic dermatitis with documentation of disease severity (e.g. EASI≥16, IGA≥3, or BSA ≥25%); AND • History of failure, contraindication, or intolerance after >**12 weeks** with at least **two** paid pharmacy claims or 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,	least one of the following: ○ **≥50% improvement in EASI score** ○ Reduction in **BSA involvement** ○ Improvement in **IGA score** ○ Decreased **pruritus severity** ○ Physician documentation of meaningful clinical benefit **AND** ○ Patient is not Dupixent concurrent with either of the following: Biologic immunomodulator (e.g., Adbry (tralokinumab-ldrm), Ebglyss

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	fluocinolone acetonide, fluocinonide) **AND** ○ A six-week trial of a topical calcineurin inhibitor (e.g., tacrolimus or pimecrolimus) OR ○ A four-week trial of a phosphodiesterase-4 enzyme inhibitor, e.g. Zoryve (roflumilast) or Eucrisa (crisaborole); **AND** • Patient must have failed at least one systemic therapy OR phototherapy after >12 weeks. Common systemic options are (Cyclosporine, Methotrexate, Azathioprine, Mycophenolate Mofetil) OR Photo therapy (Narroa-Band UVB) • Patient is not receiving Dupixent concurrent with either of the following: Biologic immunomodulator (e.g.,	(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:** 6 months. **Asthma:** ○ Documentation of positive

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	tralokinumab-ldrm); ○ Janus kinas inhibitor (e.g., Ebglyss (lebrikizumab), Rinvoq (Upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib) • Chronic Disease Impact documentation **Documentation** that the disease causes significant functional impairment, such as Severe Pruritus, Sleep disruption, recurrent infections, and impaired quality of life. • UNLESS Patient has ≥ 25% skin involvement and topical management is not feasible. • Prescribed by or a Dermatologist, Allergist or	clinical response as demonstrated by at least **ONE** of the following: ○ Reduction in frequency of 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

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	Immunologist. Notes on age limits: o Prefilled syringes may be used in ages ≥ 6 months. o Prefilled PENS are only for ages ≥ 2 years. o Loading doses are not necessary for ages < 6 years. **Approval Duration**: 16 weeks **<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.	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,

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	○ Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months o 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 ○ 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	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:** 6 months. **Chronic Obstructive Pulmonary Disease (COPD)** • Documentation of positive clinical response to therapy as defined by at least **one** of the following criteria:

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	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	○ 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

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	One additional asthma controller medication (e.g., LABA, montelukast or theophylline); AND • Patient is not receiving Dupixent in combination with ANY of the following: o Anti-interleukin-5 therapy (e.g. Nucala, Cinqair, Fasenra). o Anti-IgE therapy (e.g., Xolair). o Thymic stromal lymphopoietin (TSLP) inhibitor (e.g. Tezspire); AND • Patient age ≥ 6 years; AND • Prescribed by or a Dermatologist, Allergist, Immunologist or Pulmonologist. • **Approval Duration:** 6 months.	expiratory volume (FEV1). **Approval Duration:** 6 months. <u>Chronic Rhinosinusitis with Nasal Polyposis</u> • Documentation of positive clinical response to Dupixent therapy; **AND** Patient will continue to receiveDupixent as add-on maintenance therapy in combination with intranasal corticosteroids; **AND**

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	<u>Chronic Obstructive Pulmonary Disease (COPD)</u> • May be approved as an add-on therapy in patients with refractory disease who are inadequately controlled on standard therapies. Patient age ≥ 18 years. • Diagnosis of COPD confirmed by spirometry (FEV1/FVC < 0.7) and an esonophilc phenotype. • 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 failed initial therapy of **Daliresp** (Roflumilast)	• 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:** 6 months.

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	unless patient has contraindication or intolerance to use • 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:** 6 months. **Chronic Rhinosinusitis with Nasal Polyposis** • Diagnosis with chronic rhinosinusitis with nasal polyposis (CRSwNP) defined by ALL of the	**Eosinophilic Esophagitis:** • Documentation of positive clinical response to Dupixent therapy as evidenced by improvement in at least **ONE** of the following frombaseline: ○ Symptoms ○ Histologic measures ○ Endoscopic measures; • **AND**Patient is not receiving Dupixent in combination with **ANY** of the following: Anti-

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	following: ○ **TWO** or more of the following symptoms for longer than a 12-week duration: § 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	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

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	§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	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:** 6 months

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	agents at least 12 weeks: Ø Nasal saline irrigations Ø Intranasal corticosteroids Ø 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)	

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	inhibitor (e.g. Tezepelumab); AND • Patient is aged ≥ 12 years of age. • Prescribed by an Allergist, an Immunologist, an Otolaryngologist, or a Pulmonologist. **Approval Duration:** 6 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	

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	eosinophil-predominant inflammation on esophageal biopsy, consisting of a peak value of ≥15 intraepithelial eosinophils per high-power field (HPF) or 60 eosinophils per mm2; AND • 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	

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	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	

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	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 • 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	1. All initial criteria are met.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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.	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.	
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 is 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 devices (IUD) (e.g. Kyleena, Liletta, Mirena, Skyla), OR • Progestin-only oral contraceptive pills; OR	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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	• 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. Quantity Limits: 56 capsules for 28 days, lifetime limit of 24 fills. 6. Approval Duration is the lesser of 12 months OR 24 minus the number of months of cumulative therapy as listed above in criteria #4.	
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.	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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	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.	
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). **<u>Chronic Immune Thrombocytopenia (ITP):</u>** 1. Documentation of positive clinical response to Promacta. 2. Current platelet count.

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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. <u>Chronic Immune Thrombocytopenia (ITP):</u> 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.	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.

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	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. <u>Chronic Hepatitis C-associated Thrombocytopenia:</u> 1. Diagnosis of chronic hepatitis C-associated thrombocytopenia; AND 2. One of the following: • 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	**<u>Chronic Hepatitis C-associated Thrombocytopenia:</u>** 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 **<u>Aplastic Anemia:</u>** 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-

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	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.	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 the individual components of Genvoya.	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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	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	1. Ordered for an approved indication for use: • Combination with other antiretroviral agents for the	1. All initial criteria are met 2. Renewal or prior authorization is on

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200mg/25mg	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. • PrEP 2. Descovy prescribed for PrEP: Initial approval criteria: • Confirmation of negative HIV status with lab results within past 3 months, AND - Documentation is provided that patient has end stage renal disease (ESRD) and receiving chronic hemodialysis, OR - Documentation is provided that patient with or at risk of renal dysfunctions (i.e. CrCl 30 to <60 mL/min), osteopenia, or osteoporosis; - CrCl <30 mL/min: Use is not recommended - Approval Duration: 6 months 3. For patients with an HIV/AIDs diagnosis the following	required for gaps in therapy > 90 days. 3. Approval Duration is continuous if no gaps in therapy > 90 days occur.

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	criteria must be met:
	• Date(s) of opportunistic infection(s) OR CD4 laboratory 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:
	  ○ HIV RNA/DNA quantitative (if detectable)
	  ○ HIV RNA/DNA qualitative
	  ○ HIV P24 antigen
	  ○ HIV Western blot
	  ○ HIV genotype
	6. Request is for the 200/25 mg strength.
	7. Approval Duration: continuous if no gaps in therapy > 90 days.	

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	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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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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 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	3. Approval Duration: continuous if no gaps in therapy > 90 days occur.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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**	
Jardiance (**empagliflozin**) 10 mg, 25 mg	1. Ordered for an approved indication for use: • Type 2 diabetes mellitus • Hearts failure • Chronic Kidney disease Patient had a trial or intolerance or a documented reason not to use **dapagliflozin**. (for all indications) 2. **If ordered for Type 2 Diabetes Mellitus :** Coverage may be approved when all if the following criteria are met: • Patient is 10 years or older • Patient has a diagnosis of type 2 diabetes	1. Coverage may be renewed when all of the following criteria are met: • The patient demonstrates clinical benefit or disease stability • The patient continues to tolerate therapy **Approval duration**: 12 months

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	mellitus • Jardiance will be used in combination with diet and exercise • Renal function has been evaluated by estimated glomerular filtration rate(eGFR) • Jardiance is not recommended when eGFR is less than 30 mL/min/1.73m^2 3. **If ordered for Heart Failure:** Coverage may be approved when **all** of the following criteria are met: • Patient is 18 years or older • Patient has a diagnosis of heart failure • Patient has an eGFR of at least 20mL/min/1.73m^2 4. **If ordered for Chronic Kidney Disease:** Coverage may be approved when **all** of the following criteria are met: • Patient is 18 years or older • Patient has chronic kidney disease at risk of progression	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• patient has eGFR of at least 20 mL/min/1.73m^2 Approval duration: 12 months	
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 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. Approval Duration: 12 months.	Patients receiving Xtandi should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).
epocoritamab-bysp (**Epkinly**)	USE **MFC High-Cost Medication PA Criteria**	

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
J9321		
Aimovig (**erenumab-aooe**) 70 mg/mL (per mL), 140 mg/mL (per mL	Indicated for preventive treatment in adults: 1. Patient has a diagnosis of migraine consistent with the international classification of Headache disorders, 3rd edition (ICHD-3). 2. Patients is 18 years or older. 3. Patient meets **one** of the following migraine criteria: 4 to 7 migraine days per month with fewer than 15 headache days per month, OR 8 or more migraines days per month 4. Patient has experienced inadequate response, intolerance, or contraindication to at least **TWO** preventative migraine therapies after a minimum 2-month trial from the following: beta-blockers	1. Patient demonstrates clinical improvement, Including reduction in migraine frequency and/ or severity 2. Medication will not be used concurrently with another CGRP antagonist or inhibitor intended for migraine prevention **Approval duration:** 12 months

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	(atenolol, metoprolol, nadolol, propranolol, timolol), candesartan, divalproex sodium, Botox, SNRI therapy (duloxetine, venlafaxine), topiramate, or tricyclic antidepressants (amitriptyline, nortriptyline). 5. Requested medication will not be used concurrently with another CGRP antagonist or inhibitor intended for migraine prevention **Approval duration**: 12 months	
etanercept (**Enbrel**; **Enbrel Mini**; **Enbrel Sureclick**) injection 25mg/0.5mL, 50mg/mL syringes 50mg/mL autojector	<u>Rheumatoid Arthritis (RA):</u> 1. Diagnosis of moderately to severely active RA. **Patient meets the following:** • Has history of failure to a 3-month trial of one	Renewal Criteria applies to all approved indications described in the initial criteria column: 1. Documentation of detailed positive clinical response to therapy.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	nonbiologic 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). AND • History of 12 weeks of failure, contraindication, or intolerance to adalimumab with documentation of 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	2. Patient is not receiving Enbrel concurrently with another targeted immunomodulator (e.g. Cimzia, adalimumab, Simponi, Olumiant, Rinvoq, Xeljanz). **Approval Duration:** 6 months

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	and duration of therapy). (e.g. Cimzia, adalimumab, Simponi, Olumiant, Rinvoq, Xeljanz), Or 2. Patient is not receiving Enbrel in combination with another targeted immunomodulator. 3. Prescribed by or in consultation with a rheumatologist. **Approval Duration**: 6 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. **Approval Duration**: 6 months Psoriatic Arthritis (PsA): 1. Diagnosis of Psoriatic Arthritis.	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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), AND • History of 12 weeks failure, contraindication or intolerance to adalimumab with documentation of drug, date, and duration of trial. **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	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	include the name of the drug, dates, and duration of therapy. 3. Prescribed by or in consultation with a rheumatologist or dermatologist **Approval Duration**: 6 months. **Plaque Psoriasis:** 1. Diagnosis of moderate to severe plaque psoriasis. 2. Patient has greater than or equal to 3% body surface area 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:	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	○ Topical corticosteroids ○ Vitamin D analogs (calcitriol, calcipotriene) ○ Tazarotene ○ Calcineurin inhibitors ○ (tacrolimus/pimecrolimus) ○ Anthralin ○ Coal tar; AND • History of failure to a 3-month trial of methotrexate at maximally indicated dose unless contraindicated or clinically adverse effects occurred, AND • History of 12 weeks failure, contraindication or intolerance to adalimumab with documentation of drug, date, and duration of trial. 3. **Or** Patient has been previously treated with a	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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. **Approval Duration:** 6 months. **<u>Ankylosing Spondylitis:</u>** Diagnosis of active ankylosing spondylitis. **Patient meets the following:** • History of failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials) AND • History of 12 weeks failure, contraindication or intolerance to adalimumab with documentation of 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, Olumiant, Xeljanz). 2. Patient is not receiving Enbrel in combination with	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	another targeted immunomodulator (as listed in #2). 3. Prescribed by or in consultation with a rheumatologist. **Approval Duration:** 6 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 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	1. Patient exhibits a positive clinical response by at least one objective measure from baseline. (e.g., fecal calprotectin levels, C-reactive protein, endoscopic assessment, and/or decreased utilization of corticosteroids **OR** 2. Patient has a documented clinical improvement in at least one subjective measure from baseline (e.g., decreased pain, fatigue, stool frequency, and/or rectal bleeding). 3. Approval duration: 12 months.

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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.	
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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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
Fecal microbiota capsules, oral (**Vowst**)	1. Ordered for an approved indication for use: • To prevent recurrence of *Clostridioides difficile* infection (CDI) in individuals ≥ 18 years of age following antibacterial treatment for recurrent CDI. 2. Patient has had three or more episodes of CDI within previous 12 months (including most recent episode). 3. Patient has recent episode of recurrent CDI with all of the following: ○ At least 3 unformed stools per day for 2 consecutive days ○ Stool test confirming the presence of *C. difficile* toxin or toxigenic *C. difficile.* ○ An adequate clinical response (i.e., resolution of symptoms) following standard of care antibiotic therapy (e.g., vancomycin + metronidazole, fidaxomicin) 4. Patient does not have ANY of the following: ○ Known or suspected toxic megacolon and/or known small bowel ileus OR	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.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	○ Admitted to, or expected to be admitted to an ICU for medical reasons, OR ○ Absolute neutrophil count < 500 cells/mL^3 ○ History of major GI surgery within 3 months before treatment start (not including appendectomy or cholecystectomy) OR ○ History of total colectomy or bariatric surgery that disrupted the GI lumen OR ○ History of active inflammatory bowel disease (e.g. ulcerative colitis, Crohn's disease, microscopic colitis) with diarrhea believed to be cause by active inflammatory bowel disease in the past 3 months. ○ History of fecal microbiota transplantation (FMT) within 3 months 5. The patient will not be using the requested agent in combination with Rebyota or Zinplava for the requested indication. 6. Provider attests that patient will follow the bowel preparation protocol outlined in the package insert.	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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: 6 months; 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	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

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	starting therapy. 5. Patient must not have cirrhosis. 6. Patient does not have severe renal impairment (GFR < 30 ml/min) or end-stage renal disease. 7. The medication must not be used concomitantly with CYP1A2 inhibitors (e.g., acyclovir, allopurinol, amiodarone, cimetidine, clarithromycin, duloxetine, famotidine, fluoroquinolones, fluvoxamine, mexiletine, oral contraceptives, verapamil, zafirlukast, zileuton). 8. Patient must have treatment failure, intolerance, or contraindication to a 12-week trial of at least one menopausal hormone therapy. 9. Initial approval period: 1 month.	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.
finerenone (**Kerendia**) tablets 10mg, 20mg	1. Ordered for approved indication: • to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). 2. PA SUBMISSION REQUIREMENTS:	1. All initial criteria for approval; **AND** 2. Dosing appropriate based on 4-week potassium laboratory check. • 20 mg daily if Potassium ≤ 4.8 • 10 mg daily if K+ between 4.8-5.5 • Interrupt therapy if K+ > 5.5, may restart at 10 mg daily when potassium is ≥ 5.0

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• Serum potassium ≤ 5.0 mEq/L • eGFR ≥ 25 mL/min/1.73 m2 • Urine albumin-to-creatinine ratio ≥ 30 mg/g • Concomitant use with maximum tolerated doses of ACE-Inhibitor or ARB unless intolerant to or contraindicated. 3. Failed trial or contraindication to one formulary SGLT2i. 4. Approval duration: 3 months	3. Approval duration: 12 months
Fosdenopterin (**Nulibry**) injection 9.5mg; J3490	USE **MFC High-Cost Medication PA Criteria**	
Fostamatinib disodium hexahydrate (**Tavalisse**) tablets 100mg, 150mg	1. Ordered for an approved indication for use: • the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) when a prior treatment for ITP has not worked well enough. 2. Patient age ≥ 18 years. 3. Patient had an inadequate response to a previous treatment (e.g. corticosteroids, immunoglobulins, thrombopoietin receptor agonists or splenectomy). 4. Documentation of pre-treatment platelet count of ≤ $30*10^9$/L.	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, Doptelet, Nplate, Mulpleta, Promacta). 3. Approval duration: 12 months.

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	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.	
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	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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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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: ○ 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.	3. Approval Duration: continuous if no gaps in therapy > 90 days occur.
Ajovy (**Fremanezumab**); Auto-injector; prefilled syringe; 225 mg/1.5 mL (per mL)	**Indicated for preventive treatment in adults** 1. Patient has a diagnosis of migraine consistent with the International classification of headache disorders, 3ed edition(ICHD-3). 2. Patient 18 years or older.	1. Patient demonstrates clinical improvement, including reduction in migraine frequency and/or severity

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	3. Patient meets one of the following migraine frequency criteria: 4 to 7 migraine days per month with fewer than 15 headache days per month OR 8 or more migraine days per month 4. Patient has experienced inadequate response, intolerance, or contraindication to at least TWO preventative migraine therapies after a minimum 2-month trail from the following: beta-blockers (atenolol, metoprolol, nadolol, propranolol, timolol), candesartan, divalproex sodium, Botox, SNRI therapy (duloxetine, venlafaxine), topiramate, or tricyclic antidepressants (amitriptyline, nortriptyline). 5. Requested medication will not be used concurrently	2. Medication will not be used concurrently with another CGRP antagonist or inhibitor intended for migraine prevention **Approval duration**: 12 months

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	with another CGRO antagonist or inhibitor intended for migraine prevention. **Indicated for episodic migraine in pediatric patients who are 6 to 17 years of age and who weigh 45 kg or more.** 1. Patient has a diagnosis of migraine consistent with the intentional classification of headache disorders, 3rd edition (ICHD-3). 2. Patient age aligns with FDA-approved indication. 3. Patient meets one of the following migraine frequency criteria: 4 to 7 migraine days per month with fewer than 15 headache days per month OR 8 or more migraine days per month 4. Patient has experience inadequate response,	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	intolerance, or contraindication to at least one preventive migraine therapy after a minimum 2-month trail from the following: Topiramate, Amitriptyline, and propranolol 5. Requested medication will not be used concurrently with another CGRP antagonist or inhibitor intended for migraine prevention **Approval duration:** 12 months	
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	1. Patients must meet initial approval criteria for each request. 2. Dose has not exceeded 8 cartridges in the previous 30 days.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	○ 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. 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	

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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.
Emgality (**galcanezumab**) 100mg/mL syringe	Indicated for the treatment of **episodic cluster headache** **Initial Authorization Criteria** 1. Patient has a diagnosis of episodic cluster headache. 2. Patient is 18 years or older. 3. Patient has experience at least two cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least 3 months	1. Patient demonstrates clinical improvement, including reduction in cluster headache frequency and/ or severity 2. Medication will not be used concurrently with another CGRP antagonist

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	4. Requested medication will not be used concurrently with another CGRP antagonist or inhibitor. 5. Patient has experienced inadequate response, intolerance, or contraindication to at least **ONE** standard prophylactic therapy for cluster headache, such as verapamil, lithium, corticosteroids, or topiramate. **Approval duration**: 12 months	or inhibitor. Approval duration: 12 months
Emgality (**galcanezumab**) 120mg/mL	Indicated for preventive treatment in adults 1. Patient has a diagnosis of migraine consistent with the International Classification of Headache Disorders, 3rd edition (ICHD-3). 2. Patient is 18 years or older. 3. Patient meets one of the following migraine frequency	1. Patient demonstrate clinical improvement, including reduction in migraine frequency and/or severity 2. Medication will not be used

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	criteria: 4 to 7 migraine days per month with fewer than 15 headache days per month OR 8 or more migraine days per month. 4. Patient has experienced inadequate response, intolerance, or contraindication to at least **TWO** preventive migraine therapies after a minimum 2-month trial from the following: beta-blockers (atenolol, metoprolol, nadolol, propranolol, timolol), candesartan, divalproex sodium, Botox, SNRI therapy (duloxetine, venlafaxine), topiramate, or tricyclic antidepressants (amitriptyline, nortriptyline). 5. Requested medication will not be used concurrently with another CGRP antagonist or inhibitor intended for migraine prevention. **Approval duration:** 12 months	concurrently with another CGRP antagonist or inhibitor intended for migraine prevention **Approval duration:** 12 months
gilteritinib (**Xospata**) tablets 40mg	1. Ordered for an approved indication for use:	1. Patient does not show evidence of disease progression while on Xospata therapy. 2. Approval Duration: 12 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• 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	
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 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	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. 4. Approval Duration: 12 months. Hyperhidrosis Disease Severity Scale

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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.	
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:**

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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.	• Can not be administered for more than 6 months lifetime maximum. **Fertility Preservation:** • Patient currently receiving GnRH analog therapy for purpose of fertility preservation; and • Patient continues to receive a cytotoxic agent associated with primary ovarian insufficiency; and • Authorization duration: 12 months **Gender Affirming Care – Adolescents OR Gender Affirming Care – Transgender Adults:** • Approval Duration: 12 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	2. Approval Duration: Limited to 6 months. <u>Endometrial Thinning/Dysfunctional Uterine Bleeding:</u> • 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. <u>Fertility Preservation:</u> Clinical studies do not support use for this indication, and cryopreservation is clinically preferred. Please attempt to redirect to cryopreservation. Only clinically appropriate as a potential adjunct to cryopreservation. May be medically necessary for treatment of fertility preservation when both of the following criteria are met: • Patient is a pre-menopausal female. • Patient is receiving a cytotoxic agent associated with causing primary ovarian insufficiency, e.g., cyclophosphamide, procarbazine, vinblastine, cisplatin.	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• Approval Duration: 12 months. <u>Gender Affirming Care – Adolescents</u> • Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy. • Approval Duration: 12 months <u>Gender Affirming Care – Transgender Adults</u> • 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: <u>Treatment of children with central precocious puberty (CPP):</u> • Onset of secondary sexual characteristics in one of the following: ○ Females ≤ 8 years of age; or ○ Males ≤ 9 years of age. • Confirmation of diagnosis as defined by one of the following: • Pubertal basal level of luteinizing hormone (based	**<u>Central Precocious Puberty:</u>** • Patient is currently receiving therapy for central precocious puberty; and • Documented positive response to therapy. • Patient is currently younger than the appropriate age for the onset of puberty, i.e., Females < 11 years of age, Males < 12 years of

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	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. <u>Fertility Preservation:</u> 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. <u>Gender Affirming Care – Adolescents</u> • Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy.	age. • Approval Duration: 12 months. **<u>Fertility Preservation:</u>** • 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 **<u>Gender Affirming Care – Adolescents OR Gender Affirming Care – Transgender Adults:</u>** Approval Duration: 12 months.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• Approval Duration: 12 months <u>Gender Affirming Care – Transgender Adults</u> • Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy. • Approval Duration: 12 months	
human plasma-derived plasminogen (**Ryplazim**); J2998	USE **MFC High-Cost Medication PA Criteria**	
ibrutinib (**Imbruvica**) capsules 140mg	1. Ordered for an approved indication for use: • Chronic lymphocytic leukemia (CLL) in adult patients who have received at least one prior therapy. • CLL in Adult patients with 17p deletion. • Waldenström's macroglobulinemia in adult patients • Adult and pediatric patients ≥ 1 year of age with chronic graft versus host disease after failure of one or more lines of systemic therapy. 2. Medication ordered by an Oncologist. 3. Quantity limit: 4 tablets per day.	**<u>Limitations for use:</u>** • Indications for Mantle Cell Lymphoma and Marginal Zone Lymphoma were voluntarily withdrawn, April 2023 **<u>New dose modification guidelines adopted in December 2022:</u>** 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

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		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 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	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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	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	1. Used for cardiovascular risk reduction. 2. Documentation of positive clinical response to therapy 3. Patient is receiving maximally tolerated statin therapy.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	elevated triglyceride (TG) levels (≥ 150 mg/dL) AND ○ Established cardiovascular disease OR ○ Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease • As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. 2. Age ≥ 45 years 3. Diagnosis of hypertriglyceridemia (pre-treatment TG level ≥ 150 mg/dl) AND 4. Patient is considered high or very high risk for cardiovascular disease (CVD) as evidenced by <u>one</u> of the following: ○ Acute coronary syndrome ○ History of myocardial infarction ○ Stable or Unstable angina ○ Coronary or other arterial revascularization ○ Stroke ○ Transient ischemic attack ○ Peripheral arterial disease	4. Approval duration: 12 months

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	5. <u>OR, if not the criteria in #4:</u> ○ Type 2 Diabetes diagnosis AND TWO of the following: ○ Men ≥ 55 years and women ≥ 65 years ○ Cigarette smoker or stopped within past 3 months ○ Hypertension diagnosis ○ HDL-C ≤ 40 mg/dL for men or ≤ 50 mg/dL for women ○ High-sensitivity C-reactive protein > 3.0 mg/L ○ Creatinine clearance > 30 and < 60 ml/min ○ Retinopathy ○ Micro- or macro-albuminuria ○ Ankle-brachial index (ABI), 0.9 without symptoms of intermittent claudication 6. Patient has received at least 12 consecutive weeks of high-intensity statin therapy (Atorvastatin 40-80 mg; rosuvastatin 20-40 mg) OR <u>BOTH OF THE FOLLOWING:</u> • Intolerance to high-intensity statin as evidenced	

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	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**	
Inavolisib (**Itovebi**) tablets 3 mg, 9 mg	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	1. Provider attestation of continued benefit without adverse drug effects. 2. Provider attestation of continued monitoring as appropriate.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	and/or *in vitro* assay data. 2. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. 3. Patient is not homozygous in the CFTR gene. 4. Patient age ≥ 4 months. 5. Provider attestation of baseline and subsequent evaluation and monitoring as appropriate and as indicated in the FDA-approved labeling (provider must submit documentation). 6. Provider justification of necessity of medication change if currently stable on another CF regimen and asymptomatic. 7. Medication ordered by Pulmonologist. 8. Approval Duration: 12 months.	3. Approval Duration: 12 months.
ivermectin (**Stromectol**) tablets 3mg	1. Ordered for an approved indication for use:	**Limitations for use:**

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	• Strongyloidiasis of the intestinal tract (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis. • Onchocerciasis due to the nematode parasite Onchocerca volvulus. 2. Cannot be used for outpatient COVID-19 treatment. 3. Approval Duration and Quantity is indication specific and for most indications is limited to 2 doses.	• Ivermectin has no activity against adult *Onchocerca volvulus* parasites. Ivermectin is not active against *L. loa* (adult worms).
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	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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	3. The tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion; AND 4. The tumor is metastatic OR surgical resection of tumor will likely result in severe morbidity. 5. Medication ordered by an Oncologist. 6. Approval Duration: 6 months for first authorization.	
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).	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**

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	• 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). • 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.	3. Prescribed by or in consultation with a Dermatologist, Allergist, or Immunologist. 4. Approval Duration: 12 months.
Lenacapavir (**Sunlenca**)	1. Ordered for an approved indication for use; treatment of multidrug-resistant human immunodeficiency virus (HIV) in adult patients.	1. Patient has previously received treatment with Sunlenca.

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	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., 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	2. Patient has responded to a Sunlenca-containing regimen, as determined by the prescriber. Examples of a response are HIV RNA, 50 cells/mm^3, HIV-1 RNA ≥ 0.5 log_{10} reduction from baseline in viral load. 3. Provider confirms that patient has achieved a clinically significant viral response to therapy. 4. Provider confirms that patient will continue to take an optimized background antiretroviral regimen in combination with Sunlenca. 5. Maintenance dosing is in accordance with FDA-approved prescribing guidance. 6. Authorization Duration: 12 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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.	
Leniolisib (**Joenja**); J8499	USE **MFC High-Cost Medication PA Criteria**	
leuprolide injection **leuprolide acetate** kit 1mg/0.2ml **Eligard** SQ injection 45 mg **Lupron Depot** IM injection	1. Ordered for an approved indication for use: • palliative treatment of advanced carcinoma of the prostate. • in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. • management of endometriosis • palliative treatment of advanced breast cancer in pre- and peri-menopausal women.	**Central Precocious Puberty (CPP)** • 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 onset of puberty, for example: ○ Females ≤ 11 years of age

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1-month (3.75mg, 7.5mg) 3-month (11.25mg, 22.5mg) 4-month (30mg) **Lupron Depot-PED** IM injection kit 1-month (7.5mg, 11.25mg 15mg) 3-month (11.25mg, 30mg) 6-month (45mg) **Lupron Depot-PED Injection 7.5mg, 11.25mg 15mg, 30mg, 50mg**	• to cause endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. • management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. **Endometriosis:** 1. Contraindication, intolerance, or failure of initial treatment to BOTH of the following: • Oral contraceptives or depot medroxyprogesterone; **AND** • Non-steroidal anti-inflammatory drugs; **OR** • Patient has had surgical ablation to prevent recurrence. 2. 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	○ 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

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	with causing primary ovarian insufficiency, e.g., cyclophosphamide, procarbazine, vinblastine, cisplatin. • Approval Duration: 12 months. **Gender Affirming Care – Adolescents** 1. Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy. 2. Approval Duration: 12 months **Gender Affirming Care – Transgender Adults** 1. Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy. **Approval Duration**: 12 months **Oncology Indications:** 1. Prescribed by a hematologist/oncologist AND 2. The requested use is supported by the National Comprehensive Cancer Network (NCCN) clinical practice guidelines with a recommendation category level of 1 or 2A.	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 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

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	3. 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) –** 1. Lupron Depot formulation prescribed 2. Prescribed for use prior to surgery to reduce the size of fibroids to facilitate surgical procedure; OR 3. For the treatment of uterine leiomyomata-related anemia; AND 4. inadequate respond to iron therapy of one month duration; AND 5. For use prior to surgery **Approval Duration**: 6 months total. Central Precocious Puberty (CPP) 2. Diagnosis of CPP (idiopathic or neurogenic), AND 9. 3.75 mg every month for up to 6 months or 10. 11.25 mg every 3 months for up to 2 doses. 11. Approval Duration: Limited to 6 months. Fertility Preservation:	**Uterine Leiomyomata (Fibroids) –** • Can not be administered for greater than 3 months cumulative.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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, <u>Uterine Leiomyomata (Fibroids)</u> 1. Lupron Depot formulation prescribed 2. Prescribed for use prior to surgery to reduce the size of fibroids to facilitate surgical procedure; OR 3. For the treatment of uterine leiomyomata-related anemia; AND 4. inadequate respond to iron therapy of one month duration; AND 5. For use prior to surgery Approval Duration: 6 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).	1. Documented positive clinical response. 2. Approval Duration: 12 months.

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	2. Must have tried and failed artificial tears AND cyclosporine emulsion 0.05% (generic of Restasis). 3. Approval Duration: 12 months.	
Liraglutide (Victoza) injection 1.2 mg/day 2-pack pens (6 ml) 1.8 mg/day 3-pack pens (9 ml)	Ordered for the covered indication: • **Treatment of adult patients with Type 2 Diabetes mellitus (T2DM).** 1. Patient is 10 years or older 2. Documentation within the **past 3 months** of one of the following: • Hemoglobin A1c • Continuous Glucose Monitor (CGM) report with Time in Range (TIR%) 3. 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 the indication of weight management.** 1. Chart notes with A1c or CGM report with TIR% within previous 3 months. 2. Documented positive clinical response defined as one of the following: **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**

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	The patient has an A1c (hemoglobin A1c) of ≥ 7.5 (TIR ≤ 60%) **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 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** • 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. **Step Therapy Requirements** **Step 1 – Metformin**	**<u>but <</u>** **<u>7.5 and:</u>** • 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,Wegovy, 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:

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• Trial of **≥ 3 months** at maximum tolerated dose OR • Documented **contraindication or intolerance** **Step 2 –** Trial of **≥ 3 months** at maximum tolerated doses of **two (2)** of the following: • Insulin • Sulfonylurea (e.g., glipizide, glimepiride) • Pioglitazone • DPP-4 inhibitor (e.g., alogliptin) • SGLT2 inhibitor (e.g., empagliflozin/Jardiance®, dapagliflozin/Farxiga®) May not be concurrently using or taking **ANY** of the following: • ANY other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus, Wegovy, Saxenda, Soliqua, Trulicity, Victoza (liraglutide), Xultrophy, or Zepbound) • **ANY** DPP4i (e.g., alogliptin, Januvia (sitagliptin),	metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 5. PBM claims data shows consistent adherence as shown by no instance of a drug-free interval greater than 2 months at which time the patient would need to satisfy the initial criteria. 6. Approval Duration: 12 months

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	Onglyza (saxagliptin) or Tradjenta (linagliptin)). • Agents for *severe* constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all contraindications. 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. **Cannot be approved for indication of weight management.** 8. Dose escalation in accordance with manufacturer guidelines required. Initial dose is 0.6 mg once daily	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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 pens (6 ml) per 30 days. • 1.8 mg daily dose is limited to one pack containing 3 pens (9 ml) per 30 days. 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 1. Patient aged ≥ 18 years of age.	At this time, there is no clinical evidence to show benefit beyond 6 weeks of

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	2. Diagnosis of Demodex blepharitis, AND 3. Patient demonstrates one of the following signs of Demodex infestation: • Cylindrical cuff at the root of the eyelashes. • Lid margin erythema • Eyelash anomalies (eyelash misdirection); AND 4. Patient demonstrates two of the following symptoms of manifestation: • Itching/burning • Foreign body sensation • Crusting/matter lashers • Blurry vision • Discomfort/irritation; AND 5. Patient is practicing good eye-lid hygiene (e.g., non-prescription tree-tea oil). 6. Patient has not undergone more than one, 6-week treatment in the previous 12 months. 7. Written by or in consultation with an ophthalmologist or optometrist. 8. Approval limited to 1 bottle (10 ml) per 12 months.	treatment and shall not be approved for more than one treatment per 12 months.

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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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.	**Each treatment course requires a separate PA request. Initial criteria apply to all requests.**

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	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.	
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.

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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**	
Maribavir (**Livtencity**) tablets 200mg	1. Ordered for an approved indication for use: • treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet. 2. Medication is not prescribed in conjunction with ganciclovir or valganciclovir.	If a patient has a paid claim in the MFC system for ganciclovir, valganciclovir, cidofovir, or foscarnet, Livtencity will process at the pharmacy without PA. If there is no evidence of a paid claim for ganciclovir, valganciclovir, cidofovir, or foscarnet, a PA is required, and

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	3. Medication is prescribed by or in consultation with a hematologist, infectious disease specialist, oncologist or physician affiliated with a transplant center. 4. Approval Duration: not to exceed 8 weeks.	documentation of previous use of one of these medications should be submitted.
Mecasermin (**Increlex**) J2170	USE **MFC High-Cost Medication PA Criteria**	
Mepolizumab (**Nucala**) Injection 40mg/0.4ml, 100mg, 100mg/ml	1. Ordered for an approved indication for use: • Add-on maintenance treatment for severe asthma with eosinophilic phenotype in patients aged 6 years and older. • Add-on treatment of adult patients with chronic rhinosinusitis with nasal polyps. • Treatment of eosinophilic granulomatosis with polyangiitis (EGPA) in adults. • Treatment of adult and pediatric patients aged ≥ 12 years of age with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause. 2. Indications <u>excluded</u> from coverage include: • Atopic Dermatitis	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,

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	• COPD 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)). 4. Eosinophilic esophagitis, eosinophilic gastroenteritis, or eosinophilic colitis. Approval is indication specific: <u>Asthma, severe eosinophilic:</u> • 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	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, decreased sino-nasal symptoms, improved sense of smell. • Approval Duration: 12 months.

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	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: ○ Patient experienced 2 or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR ○ Patient experienced at least one asthma exacerbation requiring hospitalization, an emergency department visit, or urgent care visit in the previous year; OR ○ Patient has a forced expiratory volume in1 second (FEV_1) < 80% predicted; or	**<u>Eosinophilic granulomatosis with polyangiitis (EGPA) (previously known as Churg-Strauss syndrome):</u>** 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. **<u>Hypereosinophilic Syndrome (HES):</u>** • Patient shows positive clinical response to therapy. • Approval Duration: 12 months.

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	○ Patient has an FEV_1)/forced vital capacity (FVC) < 0.80; OR ○ Patient has asthma that worsens upon tapering of oral (systemic) corticosteroid therapy. • 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	

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	• 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.
	<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%.	

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	• 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).	

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	• 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. • Medication ordered by a Pulmonologist, Immunologist, or Allergist. • Approval Duration: 12 months. <u>Hypereosinophilic Syndrome (HES):</u> • 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	1.Ordered for an approved indication for use: • The management of chronic pain severe enough to require daily, around-the- clock, long-term opioid	All opioids require Prior Authorization (PA). The PA form can be accessed using the following link:

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Solution 5mg/5ml, 10mg/5ml, Tablets 5mg, 10mg	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: 6 months; may be reduced based on any of the criteria as outlined in Pharmacy Policy 219: Opioid Prescription Prior Authorization.	OPIOID PRIOR AUTH FORM-MD
mifepristone (**Korlym**) tablets Korlym-300mg ONLY; J8499	USE **MFC High-Cost Medication PA Criteria**	
mirikizumab (**Omvoh**) injection 100 mg/1 ml	1. Ordered for an approved indication for use: • The treatment of moderately to severely active ulcerative colitis (UC) in adults, or 1. Patient is ≥ 18 years of age, and 2. 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 3. Patient has both: • Pouchitis AND	1. Patient exhibits a positive clinical response by at least one objective measure from baseline. (e.g., fecal calprotectin levels, C-reactive protein, endoscopic assessment, and/or decreased utilization of corticosteroids **OR** 2. Patient has a documented clinical improvement in at least one subjective measure from baseline (e.g., decreased pain, fatigue, stool frequency, and/or rectal bleeding).

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	• Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND 4. Patient has failed or has contraindication to an 8-week trial of Ustekinumab. 5. Patient has failed or has contraindication to treatment with adalimumab after a trial of 8 weeks. 6. 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). 7. Medication is prescribed by or in consultation with a gastroenterologist. 8. Initial Approval Duration: 6 months; if patient has already received > 6 months of subcutaneous therapy, then approval duration is 12 months.	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	1. Documentation of positive clinical response to Pyrukynd therapy based on ONE of the following:

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	2. Confirmatory genetic testing of PKLR gene showing ≥ 2 variant alleles with at least one- missense mutation in the liver and red blood cell (PKLR) gene. 3. Patient is not homozygous for the c.1436G>A (p.R479H) variant. 4. Patient does not have two non-missense variants (without the presence of another missense variant) in the PKLR gene. 5. Baseline hemoglobin less than or equal to 10 g/dL. 6. Prescribed by or in consultation with a Hematologist. 7. Initial Approval Duration limited to 6 months.	• Patient has been on Pyrukynd for > 52 weeks and has maintained positive clinical response to therapy; OR • Reduction in transfusions of ≥ 33% in the number of red blood cell units transfused during the initial 24-week period compared with the patient's historical transfusion burden; OR • A ≥ 1.5 g/dL increase in hemoglobin from baseline sustained at 2 or more scheduled assessments 4 weeks apart during the initial 24-week period without any transfusions. 2. Authorization duration: 12 months 3. If documentation does not provide evidence of positive clinical response to Pyrukynd therapy, allow for dose

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
		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 MME per day, patients under age 18 are limited to a 3-day supply. 6. Maximum approval duration: 6 months; 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**
nanoparticle albumin bound sirolimus (**Fyarro**); J9331	USE **MFC High-Cost Medication PA Criteria**	

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal 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	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.	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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920 mg/23,000 units/23 ml	2. Age is ≥18 years of age. 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].	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	6. Medication ordered by a neurologist. 7. Approval duration: 12 months.	
odevixibat (**Bylvay**); J8499	USE **MFC High-Cost Medication PA Criteria**	
ofatumumab **(Kesimpta)** 20 mg/ 0.4 mL	1. Order for an approved indication for use: Treatment of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome (CIS), relapsing-remitting MS(RRMS), and active secondary progressive MS(SPMS) confirmed by clinical evaluation and/or MRI findings • Patient is 18 years or older. 2. **Step Therapy Requirements** Patient must have trail and failure, intolerance, or contraindication to two preferred disease- modifying therapies (DMTs), such as: - Interferon beta products (e.g., Avonex, Rebif, Extavia) - Dimethyl fumarate - Glatiramer acetate - Fingolimod **OR** patient has contraindication or intolerance to	1. **Reauthorization (Continuation of Therapy)** Patient must meet ONE of the following: a) Objective clinical response: • Stabilization or reduced worsening on MRI (fewer gadolinium-enhancing or T2 lesions) • Stable or improved EDSS score • Achievements of

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	all preferred agents. Interferon beta products(e.g., Avonex, Rebif, Extavia) 3. **Concomitant Therapy Restriction** Kesimpta must not be used in combination with another MS disease-modifying therapy 4. **Prescriber Requirement** Prescribed by or in consultation with a neurologist. 5. **Safety Requirements** Screening for the Hepatitis B virus (HBV) was completed prior to initiation. No active infection at the time of therapy. Approval duration: 12 months	NEDA-3 or NEDA-4 • Reduction in lapses • Improvement in MSFC, walking test, or fatigue scores • Attenuation of brain volume loss b) Symptom stabilization or improvement: • Improvement or stabilization in motor function, fatigue, vision, bowel/ bladder function, spasticity, gait, or sensory symptoms.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
		Approval duration: 12 months
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 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	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 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)), **AND indication specific criteria:**

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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)). <u>Asthma:</u> 1. Patient aged ≥ 6 years of age.	**<u>Asthma:</u>** 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. **<u>IgE-mediated Food Allergy:</u>** 1. Documentation of positive clinical response to Xolair therapy, e.g. reduction in type I allergic reactions, and

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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	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. **<u>Rhinosinusitis, chronic, with nasal polyps (CRSwNP):</u>** 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. **<u>Urticaria (chronic spontaneous):</u>** 1. Documentation of positive clinical response to Xolair therapy (e.g.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• 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. 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: ○ Food specific skin prick testing (SPT) ○ IgE antibody in vitro testing	reduction in exacerbations, itch severity, hives). 2. Approval Duration: 12 months.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	○ 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 5. ONE of the following findings using nasal endoscopy and/or sinus computed tomography (CT):	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• 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>	

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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 • 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.	
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	1. Documentation of positive clinical response. 2. Approval Duration: 12 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	adults who have an inadequate response to or are intolerant of an anticholinergic medication. • Urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury, multiple sclerosis] in adults who have an inadequate response to or are intolerant of an anticholinergic medication. • Neurogenic detrusor overactivity (NDO) in pediatric patients ≥ 5 years of age who have an inadequate response to or are intolerant of anticholinergic medication. • Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting ≥ 4 hours a day; AND ○ Patient has failed a minimum of a two-week trial of TWO different classes of compendial migraine prevention therapies including: ACEI or ARB therapy, beta blockers, antiepileptic drugs, or antidepressants. ○ NOTE: Coverage for prophylaxis of episodic	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**

	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:
	• Chronic anal fissure failing conventional non-surgical treatment.
	• Chronic sialorrhea	

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	• 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:	All opioids require Prior Authorization (PA). The PA form can be accessed using the following link:

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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 MME per day, patients under age 18 are limited to a 3-day supply. 5. Maximum approval duration: 6 months; may be reduced based on any of the criteria as outlined in Pharmacy Policy 219: Opioid Prescription Prior Authorization.	OPIOID PRIOR AUTH FORM-MD
oxycodone IR capsules, tablets, oral solution/ concentrate 5 mg capsules 100mg/5mL oral concentrate 5mg/5mL oral solution	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.	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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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
IR tablets 5, 10, 13, 20, 30 mg **Oxycontin ER** tablets 10, 15, 20, 30, 40 mg	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: 6 months; may be reduced based on any of the criteria as outlined in Pharmacy Policy 219: Opioid Prescription Prior Authorization.	
oxycodone/acetaminophen tablets, oral solution tablets 5-325, 7.5-325, 10-325 mg oral solution 5-325mg/5mL	1. Ordered for an approved indication for use: • The management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 2. Completion of the opioid prior authorization form. 3. Submission of supporting clinical documentation for last office visit, dated within previous 3 months. 4. 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.	All opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-MD

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	5. Maximum approval duration: 6 months; may be reduced 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: 6 months; 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
Ozanimod (**Zeposia**) capsules	1. Ordered for an approved indication for use:	1. Initial approval criteria continue to be met.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
7-day starting pack 0.92 mg capsules; Capsule starting kit which includes 0.23 mg, 0.46 mg, and 0.92 mg capsules.	• Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. • Treatment of moderately to severely active ulcerative colitis (UC) in adults. 2. Patient has not received a manufacturer supplied sample or any form of assistance from the manufacturer coupon or sample card as a means to establish as a current user of Zeposia. 3. 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), ustekinumab, biosimilars of Stelara) OR a Janus kinase	2. Patient is not receiving in combination a biologic DMARD or janus kinase inhibitor **<u>Multiple Sclerosis:</u>** • Patient experiencing disease stability or improvement while receiving Zeposia. • Maximum approval Duration: 12 months **<u>Ulcerative Colitis:</u>** • Patient has achieved or maintained remission. • Patient shows positive clinical response as evidenced by low disease activity or improvement in signs/symptoms of the condition when there is improvement in any ONE of the following from baseline: ○ Stool frequency

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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 • 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	○ 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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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	history or submission of medical records. (e.g., adalimumab, Entyvio (vedolizumab), (Ustekinumab biosimilars of Stelara), 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	1. Patient shows evidence of positive response to therapy. 2. Approval Duration: 12 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	4. Patient has hormone receptor positive (HR+) either estrogen receptor positive and/or progesterone receptor positive disease; and 5. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND 6. Patient meets one of the following: • Patient is post-menopausal; or • Patient is pre/peri-menopausal and has had either surgical bilateral oophorectomy or ovarian irradiation OR is receiving ovarian suppression/ablation with a GnRH. 7. Ibrance will be used in combination with one of the following: anastrozole, 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	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.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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.	
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**	

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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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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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• 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. <u>Chronic Myeloid Leukemia (CML):</u> 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: ○ Patient has accelerated-phase CML or blast-phase CML; AND ○ No other tyrosine kinase inhibitor is indicated. 4. Approval Duration: 12 months.	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	COVERED COMPENDIAL USES: <u>Gastrointestinal Stromal Tumor:</u> 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). 3. Approval Duration: 1 year. <u>Myeloid/Lymphoid Neoplasms with Eosinophilia:</u> 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	1. Ordered for an approved indication for use: • Treatment of invasive aspergillosis in adults and pediatric patients ≥ 13 years of age. (Injection and tablets).	

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***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.	• 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 3. The patient is being prescribed for the treatment for the prevention of invasive Aspergillus and Candida infections in a patient who is at high risk of developing these infections due to being severely immunocompromised; **OR** 4. The patient is being prescribed injection or delayed-release tablets for the treatment of invasive aspergillosis; **OR** 5. The patient is being prescribed oral suspension for the treatment of moderate to severe oropharyngeal candidiasis AND: • The patient has experienced an inadequate treatment response to fluconazole, OR	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• The patient has experienced an intolerance to fluconazole, OR • The patient has a contraindication that would prohibit a trial of fluconazole. Approval Duration: up to 12 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	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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	for non-blood contaminated exposures from secretions such as urine, saliva, sweat, tears, or nasal secretions. <u>When prescribed as part of an HIV-1 treatment regimen:</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. 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.	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
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: ○ Liver biopsy was performed within the 6 months preceding treatment with Rezdiffra; AND ○ Liver biopsy shows non-alcoholic fatty liver disease activity score ≥ 4 with a score > 1 in ALL of the following: steatosis, ballooning, and lobular inflammation OR • Patient has had ONE of the following imaging	1. Patient meets ONE of the following: • Completed ≥ 1 year and < 2 years of therapy with Rezdiffra AND the patient has derived benefit from treatment as demonstrated by at least ONE of the following: MASH/NASH resolution AND no worsening of fibrosis OR • No worsening of MASH/NASH AND improvement in fibrosis by ≥ 1 stage; **OR** • Patient has completed ≥ 2 years of treatment AND the patient has not had worsening of fibrosis or MASH/NASH AND according to the prescriber, the patient

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	exams performed within the 3 months preceding treatment with Rezdiffra: ○ Elastography (e.g. Fibroscan, transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, or shear wave elastography); OR ○ Computed tomography; OR ○ Magnetic resonance imaging. 4. Patient meets ONE of the following prior to treatment with Rezdiffra: • Patient has Stage F2 fibrosis; **OR** • Patient has Stage F3 fibrosis; **AND THREE** or more of the following metabolic risk factors that are managed according to Standards of Care: ○ Central obesity ○ Hypertriglyceridemia ○ Reduced high-density lipoprotein cholesterol, ○ Hypertension ○ Elevated fasting plasma glucose indicative	has not progressed to stage F4 (cirrhosis). 2. Metabolic risk factors are managed according to standard of care; **AND** 3. According to the prescriber, the patient meets ONE of the following: • 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.*

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	of diabetes or pre-diabetes; AND 5. According to the prescriber, the patient meets ONE of the following: • Female patients: Alcohol consumption < 20 grams per day; OR • Male patients: Alcohol consumption < 30 grams per day. *Note: One standard drink (or one alcoholic drink equivalent) contains ~14 grams of pure alcohol, which isfound 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	4. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. **Approval Duration**: 12 months.

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	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. **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). 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. 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 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:	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 Formulary	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. 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	5. Ordered for an approved indication for use: 6. Persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class. 7. Pulmonary Arterial Hypertension (PAH) (WHO Group 1) to improve exercise capacity, improve WHO functional class and to delay clinical worsening. **CTEPH**: 8. Patient is diagnosed with inoperable or	1. Clinical documentation supports that the patient is receiving clinical benefit from Adempas therapy. **Approval Duration**: 12 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH); AND 9. CTEPH is symptomatic; AND 10. Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist. 11. Approval Duration: 12 months. **PAH**: 1. Patient has symptomatic PAH. 2. Diagnosis of PAH is confirmed by right heart catheterization. 3. For patients with WHO functional class I PAH: patient has previous trials of at least one PDE5I medication (sildenafil, tadalafil) AND at least one endothelin receptor agonist medication (ambrisentan, macetentan, bosentan) 4. For patients with WHO functional class II-IV PAH: patient has previously tried and failed OR has a contraindication to using a PDE5I medication, as part of combination oral therapy with one or more PAH medications from other classes.	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	5. Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist. **Approval Duration:** 12 months.	
ripivirine, emtricitabine, tenofovir alafenamide **(Odefsey)**	1. Ordered for an approved indication for use: • Treatment of HIV-1 infection in adult and pediatric patients weighing at least 25 kg as initial therapy in those with no antiretroviral treatment history and an HIV-1 RNA ≤ 100,000 copies/ml; or • To replace a stable antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA < 50 copies/ml) for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to individual components of Odefsey. 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. Prior to or when initiating 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: abacavir, dolutegravir, doravirine, efavirenz, lamivudine, tenofovir, zidovudine, 6. 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	1. All initial criteria are met. 2. Approval Duration: 12 months

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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: 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.	**Limitations of Use:** • Avoid concomitant use with fluconazole doses greater than 200 mg. Reduce Jakafi dosage with fluconazole doses ≤ 200 mg.

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	• Polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea. • Steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older. • Chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older. 2. Medication ordered by Hematologist or Oncologist. **Approval Duration:** 12 months.	• Strong CYP3A4 Inhibitiors: Reduce, interrupt, or discontinue Jakafi doses as recommended except in patients with acute or chronic graft-versus-host-disease.
ruxolitinib (**Opzelura**) topical cream 1.5% For systemic Ruxolitinib (**Jakafi**) see above	1. Ordered for an approved indication for use: • The topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in Non-immunocompromised patients ≥ 12 years of age whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. • The topical treatment of nonsegmental vitiligo in patients ≥ 12 years of age.	1. Documented positive clinical response to therapy. 2. Patient is not receiving Opzelura in combination with another biologic medication (e.g. Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)) OR JAK inhibitor (e.g. Jakafi (ruxolitinib, Xeljanz

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	2. Patient is ≥ 12 years of age. **3. <u>Atopic Dermatitis:</u>** • Patient has inadequate treatment response, intolerance, or contraindication to at least two classes of formulary drugs (medium/high potency corticosteroid and a topical calcineurin inhibitor (e.g., tacrolimus or pimecrolimus) Adequate trial is considered 2 months AND • Treatment failure, intolerance, or contraindication to Eucrisa or Zoryve. • The drug will not be applied to affected areas greater than 20% of body surface area (BSA). **<u>Nonsegmental Vitiligo:</u>** The drug will not be applied to affected areas greater than 10% of body surface area (BSA). • Patient has inadequate treatment response, intolerance, or contraindication to at least two classes of formulary drugs (medium/high	(tolacitinib), Rinvoq (upadacitinib)). 3. Patient is not receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine). **Approval Duration**: 12 months

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	potency corticosteroid and a topical calcineurin inhibitor (e.g., tacrolimus or pimecrolimus). An adequate trial is considered 6 months. 4. Patient is not receiving Opzelura in combination with another biologic medication (e.g. Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)) OR JAK inhibitor (e.g. Jakafi (ruxolitinib, Xeljanz (tolacitinib), Rinvoq (upadacitinib)). 5. Patient is not receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine). 6. Prescribed by a Dermatologist 7. Patient has not received a sample or coupon trial supply to establish themselves as a current user for authorization under continuity-of-care. **8. <u>Initial authorization duration:</u>** • Atopic dermatitis: 2 months	

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	• Nonsegmental vitiligo: 6 months • Quantity limits: 60 gm per week or 180 gm per 28-days	
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	• 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. • 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. Step 1 – • Failure or intolerance to ≥2 NSAIDs for at least 12	**<u>Ankylosing Spondylitis</u>:** • Patient has been established on Cosentyx SQ or IV for at least 3 months; AND • Patient shows positive clinical response by way of at least one objective measure or improvement in at least one symptom. **Approval Duration:** 6 months. **<u>Enthesitis-Related Arthritis</u>:**

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	weeks. Examples include naproxen (up to 500 mg twice daily), celecoxib (up to 200 mg twice daily), or ibuprofen (up to 800 mg three times daily) unless patient has a contraindication or intolerance to use AND • Patient has failed a 12-week trial of a formulary adalimumab or has a contraindication to use. Step 2 – IL-17 Inhibitors (Second-Line Biologic Class) Approved when TNF inhibitors fail or are contraindicated. A patient is considered to have failed treatment with a TNF inhibitor for Ankylosing Spondylitis if, after at least 12 weeks of continuous therapy at FDA-approved dosing, there is inadequate clinical response, defined by: • persistent active disease (e.g., continued inflammatory back pain, BASDAI ≥4, elevated CRP/ESR, or physician documentation of insufficient improvement).	• Patient has been established on Cosentyx SQ for at least 3 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:** 6 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 objective measure from baseline

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	• TNF therapy may also be considered failed if treatment is discontinued due to intolerance, serious adverse events, or contraindications that prevent continued use. • Evidence of TNF inhibitor use, and failure may be supported by medical or pharmacy claims demonstrating at least two fills or administrations over a minimum 12-week period, followed by documentation of treatment discontinuation or switch to an alternative biologic therapy <u>Ankylosing Spondylitis:</u> • Patient age ≥ 18 years; AND • Meets all of the above criteria (step 1) AND • Prescribed by or in consultation with a rheumatologist **Approval Duration** 4 months <u>Enthesitis-Related Arthritis:</u> Patient age ≥ 4 years of age; AND • Meets all of the above criteria (step 1) AND • Prescribed by or in consultation with a	(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:** 6months. **<u>Non-Radiographic Axial Spondylarthritis</u>:** • Patient has been established on Cosentyx SQ or IV for at least 3 months; AND • Patient shows positive clinical response by way of at least one

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	rheumatologist **Approval Duration:** 4 months <u>Hidradenitis Suppurativa:</u> • Patient age ≥ 18 years; AND • Patient has tried at least one other therapies with duration ≥3 months (e.g. corticosteroids, systemic antibiotics, or isotretinoin) AND • Preferred Adalimumab failure or contraindication AND • Prescribed by or in consultation with a dermatologist. **Approval Duration:** 3 months <u>Non-Radiographic Axial Spondylarthritis:</u> 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	objective measure or improvement in at least one symptom. **Approval Duration:** 6 months. **<u>Plaque Psoriasis</u>:** • 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, induration/thickness and/or scale of areas affected by psoriasis.

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• TNF blocker failed and meets all above criteria (step 1) AND • Prescribed by or in consultation with a rheumatologist **Approval Duration:** 6 months <u>Plaque Psoriasis:</u> Patient age ≥ 6 years; AND • Patient has had an inadequate response, intolerance, or contraindication to at least one traditional systemic therapy (e.g., methotrexate, cyclosporine, acitretin) or phototherapy AND • Patient has failed an 8-week trial of adalimumab or has a contraindication for use AND • Patient has failed a 12-week trial of Ustekinumab biosimilar agent or has contraindication for use. • Prescribed by or in consultation with a dermatologist. **Approval Duration:** 3 months <u>Psoriatic Arthritis:</u>	• Patient has experienced a positive clinical response in at least one symptom such as decreased pain, itching, and/or burning. **Approval Duration:** 6 months. **<u>Psoriatic Arthritis:</u>** • Patient has been established on Cosentyx SQ or IV for at least 3 months; AND • Patient shows positive clinical response by way of at least one objective measure or improvement in at least one symptom. **Approval Duration:** 6 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• Patient has failed a 3-month trial of a formulary Adalimumab or has a contraindication to use; **AND** • Patient has failed 24-week trial of a ustekinumab biosimilars or has a contraindication to use **AND** • Prescribed by or in consultation with a rheumatologist or dermatologist. **Approval Duration:** 3 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):	1. Patient meets initial approval criteria. **Approval Duration: 12 months.**

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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 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.	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	10. Quantity Limits: 1 titration/starter pack per 365 days Max 2 tablets per day and total daily dose of 3200 mcg **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 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	1. Patient does not show evidence of progressive disease while on Retevmo therapy. **Approval Duration**: 12 months.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	or who have no satisfactory alternative treatment options. 2. Medication ordered by an Oncologist. **Approval Duration**: 12 months.	
Semaglutide (diabetes-labeled products only): • **Ozempic®**: 2 mg/3 mL (0.25/0.5 mg weekly), 4 mg/3 mL (1 mg weekly), 8 mg/3 mL (2 mg weekly) • **Rybelsus®**: 3 mg, 7 mg, 14 mg (daily) • **Ozempic®** tablet: 1.5 mg, 4 mg, 9 mg (daily)	Ordered for the covered indication: • **Treatment of adult patients with Type 2 Diabetes mellitus (T2DM).** 5. Patient is 18 years or older 6. Documentation within the **past 3 months** of one of the following: • Hemoglobin A1c • Continuous Glucose Monitor (CGM) report with Time in Range (TIR%) 3. A urine albumin-to-creatinine ratio (uACR) within the previous 12 months **Treatment of Type 2 Diabetes without regard to CVD risk**	**1) Product/Dose appropriateness** • **Ozempic 0.25-0.5 mg / Ozempic 1.5 mg/ Rybelsus® 3 mg** are a **starter dose only** and **may not be renewed**. unless there is **documented intolerance** that prevents escalation, in which case renewal is **not approved** and alternative therapy should be considered. Chart notes with A1c or CGM report with TIR% within previous 3 months.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	factors: The patient has an A1c (hemoglobin A1c) of ≥ 7.5 (TIR ≤ 60%) **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 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** • 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. **Step Therapy Requirements**	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. **Baseline (pre-GLP-1) 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. Patient has not had medical intervention for: Pancreatitis; or Severe

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	Step 1 – Metformin • Trial of **≥ 3 months** at maximum tolerated dose OR • Documented **contraindication or intolerance** **Step 2 –** Trial of **≥ 3 months** at maximum tolerated doses of **two (2)** of the following: • Insulin • Sulfonylurea (e.g., glipizide, glimepiride) • Pioglitazone • DPP-4 inhibitor (e.g., alogliptin) • SGLT2 inhibitor (e.g., empagliflozin/Jardiance®, dapagliflozin/Farxiga®) **Step 3 –** Trial of **≥ 3 months** at maximum tolerated dose of • **liraglutide (Victoza®)**	gastrointestinal events. (e.g., hospitalization or new start GI motility May not be concurrently using **ANY** of the following: • **ANY** other GLP1 or GLP1/GIP combination drug (e.g., Mounjaro, Rybelsus, Wegovy, 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). PBM claims data shows consistent

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	unless documented **contraindication or intolerance.** May not be concurrently using or taking **ANY** of the following: • ANY other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus, Wegovy, 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). Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all contraindications. May **not** be approved for patients with: • Any personal or family history of medullary thyroid	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. **Approval Duration**: 6 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN 2). • Current pregnancy • History of confirmed pancreatitis **Starter dose limits:** • **Ozempic 0.25-0.5 mg**: limit **2 fills (28 days each)**; then require escalation per titration unless intolerance documented. • **Rybelsus 3 mg**: limit **1 fill (30 days)**; then require escalation to 7 mg unless intolerance documented. • **Ozempic® 1.5 mg**: limit **1 fill (30 days)**; then require escalation per titration unless intolerance documented. **Quantity limits:** • **Ozempic:** max **1 pen per 28 days** • **Rybelsus / Ozempic :** max **30 tablets per 30 days**	

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	Cannot be approved for indication of weight management. **Initial Approval Duration:** 6 months	
Semaglutide (Wegovy) Available strengths: **0.25 mg, 0.5 mg, 1 mg, 1.7 mg, and 2.4 mg pens**	**1. Approved Indications** Wegovy may be prescribed **only for the following indications**: **A. Reduction of Major Adverse Cardiovascular Events (MACE)** To reduce the risk of major adverse cardiovascular events, **in combination with a reduced-calorie diet and increased physical activity**, in adults with **established cardiovascular disease** who are **obese or overweight**. **Criteria for MACE :** All of the following must be met: • **Prescribed by or in consultation with a cardiologist** • **Age ≥ 18 years** • **BMI ≥ 27 kg/m²** • **Current height and weight documented within the**	Renewal requests **will not be approved if BMI ≤ 24 kg/m²**. **1. MACE Indication** Renewal requires: • Documentation of **continued weight loss or weight maintenance** • Evidence that **treatment remains clinically appropriate** Renewal **will not be authorized** if: • Weight reduction or maintenance is not documented

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	last 90 days • **Established atherosclerotic cardiovascular disease (ASCVD)**, defined as history of one or more of the following: • Prior **myocardial infarction** • Prior **stroke** (ischemic or hemorrhagic) • **Symptomatic peripheral arterial disease (PAD)** PAD may be evidenced by one of the following: • Intermittent claudication with **ankle-brachial index (ABI) < 0.85 at rest** • **Peripheral arterial revascularization procedure** **Amputation due to atherosclerotic disease** **B. Non-cirrhotic Metabolic Dysfunction–Associated Steatohepatitis (MASH)** Treatment of **non-cirrhotic metabolic dysfunction–associated steatohepatitis (MASH)** (formerly nonalcoholic steatohepatitis, NASH) with **moderate to advanced liver fibrosis (F2–F3)** in adults.	• BMI ≤ 24 kg/m² **2. Non-cirrhotic MASH** By submitting a renewal request, the prescriber attests to continued clinical benefit, demonstrated by improvement or stabilization in liver enzymes and/or fibrosis measures, appropriate ongoing monitoring, adherence to therapy, and absence of disease progression to cirrhosis. **Renewal Approval Duration: 6 months**

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	Criteria for Non-cirrhotic MASH: All of the following must be met: • **Prescribed by or in consultation with a gastroenterologist or hepatologist** • **Diagnosis Requirements** • Confirmed diagnosis of **non-cirrhotic MASH with fibrosis stage F2 or F3** • Diagnosis confirmed by **liver biopsy or approved non-invasive testing method** (see Appendix) **within the past 180 days** Patients **must not have**: • Chronic liver disease other than non-cirrhotic MASH (e.g., alcoholic liver disease, autoimmune hepatitis, viral hepatitis, Wilson's disease) • **Cirrhosis** or history of **decompensated liver disease**	

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	• **History of liver transplantation**
	• **Current or prior hepatocellular carcinoma**
	• Patient **must not be receiving another medication indicated for non-cirrhotic MASH**
	• **Excessive alcohol consumption**
	  • 20 g/day (female)
	  • 30 g/day (male)
	2. For all indications:
	
	• Wegovy **must not be used concurrently with other semaglutide-containing products or any other GLP-1 receptor agonist**.
	• Prescriber must attest that the medication is prescribed **in accordance with FDA-approved prescribing information**, including screening for **black box warnings and contraindications**.	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	3. Concomitant Medication Restrictions Wegovy **may not be used concurrently with:** **GLP-1 or GLP-1/GIP medications**, including: • Mounjaro, Ozempic, Rybelsus, Saxenda, Soliqua • Trulicity, Victoza, Xultophy, Zepbound **DPP-4 inhibitors**, including: • Alogliptin, Sitagliptin (Januvia), Saxagliptin (Onglyza) • Linagliptin (Tradjenta **4.** Wegovy **will not be approved** for patients: • **Current pregnancy** • **Has a history of confirmed pancreatitis** 5. Medication must be administered **in accordance with current FDA-approved dosing and titration guidelines**.	

<table>
<tr><th>Generic Medication (Brand Name)
Bolded medication specifies whether Brand or Generic is Formulary</th><th>Approval Criteria & Submission Requirements</th><th>Additional Considerations and Renewal Criteria</th></tr>
<tr><td></td><td>
6. Dosing and Titration Requirements

• Patients should be titrated per FDA-recommended schedule to a maintenance dose of 1.7 mg or 2.4 mg weekly, as tolerated. Dose adjustments should be based on tolerability.
Expected Titration Schedule
Dose escalation should occur every 4 weeks:
<table>
<tr><td>Duration</td><td>Dose</td></tr>
<tr><td>Weeks 1-4</td><td>0.25 mg weekly</td></tr>
<tr><td>Weeks 5-8</td><td>0.5 mg weekly</td></tr>
<tr><td>Weeks 9-12</td><td>1.0 mg weekly</td></tr>
<tr><td>Weeks 13-16</td><td>1.7 mg weekly</td></tr>
<tr><td>Maintenance</td><td>2.4 mg weekly (if tolerated)</td></tr>
</table>
Recommended maintenance dose: 1.7mg or 2.4 mg weekly.

7. Quantity Limits
Four (4) pens per 28 days
</td><td></td></tr>
</table>

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	8. Initial Approval Duration: 6 months	
sildenafil (Revatio) 20 mg tablets 10 mg/ml solution ***NOTE: sildenafil 25 mg, 50 mg and 100 mg dosage forms are indicated for erectile dysfunction only and are not covered by the formulary.*	1. Ordered for an approved indication for use: • treatment of pulmonary arterial hypertension (PAH) (WHO Group I) in adults to improve exercise ability and delay clinical worsening. 2. 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.	1. All initial criteria continue to be met. 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.

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	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.	
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). • 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.	**Hepatitis C Medication Prior Authorization Form**

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	3. Patient treatment plan aligns with MDH Clinical Criteria recommendations. 4. Authorization is for a maximum of 24 weeks.	
solriamfetol (**Sunosi**) tablets 75 mg, 150 mg	1. Ordered for an approved indication for use: • narcolepsy • obstructive sleep apnea 2. If ordered for narcolepsy: • narcolepsy diagnosis must be confirmed by sleep study, OR provider justification is included confirming that a sleep study is not feasible, AND • must have failed at least one formulary stimulant treatment (e.g. modafinil, armodafinil) or have an intolerance or contraindication for use, AND • must be ordered to manage symptoms of excessive daytime sleepiness associated with narcolepsy, and is not being ordered to manage cataplexy symptoms 3. If ordered for obstructive sleep apnea: • OSA diagnosis must be confirmed by sleep	Renewal Criteria: 1. Initial approval criteria met. 2. Provider confirmation that patient experienced positive clinical benefit with the medication. • Narcolepsy – reduction in symptoms of excessive daytime sleepiness from baseline • OSA – reduction in symptoms of excessive daytime sleepiness from baseline, AND patient continues to be compliant with other treatments 3. Dose has been titrated

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	study, OR provider justification is included confirming that a sleep study is not feasible, AND • Standard treatments for the underlying airway obstruction have been used for ≥1 month (CPAP, BiPAP), AND • Patient is fully compliant with their ongoing treatment(s) for the underlying airway obstruction, as confirmed by provider attestation, AND • Must have failed at least one formulary stimulant treatment (e.g. modafinil, armodafinil) or have an intolerance or contraindication for use. 4. For patients with a known past medical history of chronic kidney disease, baseline labs with eGFR from within the last 2 months submitted with the request. • Requested dose is appropriate for treatment initiation based on the patient's level of kidney impairment. 5. Target maximum daily dose cannot exceed	appropriately, or patient has sufficient symptom control on requested dose. Approval Duration: 12 months

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	150 mg/day. Initial approval for six months.	
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. <u>Initial approval</u>: • Confirmation of open epiphysial growth plates • Patient meets at least one of the following: ○ Height is at least TWO standard deviations (SD) below the mean height for normal children of same age and gender; ○ 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 **<u>Limitations of Use:</u>** • Ngenla will not be approved for idiopathic short stature (ISS),

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
		athletic enhancement, central precocious puberty, congenital adrenal hyperplasia, constitutional delay of growth and puberty, or anti-aging purposes.
Somatropin [recombinant human growth hormone] (**Norditropin FlexPro**; **Serostim**) injection Norditropin 5/1.5ml, 10/1.5ml, 15/1.5ml, 30mg/3ml Serostim 4mg, 5mg, 6mg	1.Ordered for an approved indication: <u>Growth failure in pediatric patients:</u> ○ Due to inadequate endogenous growth hormone secretion; short stature associated with Turner Syndrome [Norditropin FlexPro] ○ Idiopathic Short Stature (ISS); short stature born small for gestational age (SGA) with no catch-up growth by age 2 to 4 years; Prader-Willi syndrome; short stature associated with Noonan syndrome [Norditropin ONLY] <u>Growth hormone deficiency in adults:</u> • replacement of endogenous growth hormone in adults with growth hormone deficiency [Norditropin FlexPro]	<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

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• 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.	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**) 10 mg/ml solution for SQ administration **Imcivree Prior Authorization Form**	1. Ordered for an approved indication for use: • 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.	**May not be renewed if BMI ≤ 24** 1. Patient meets initial authorization criteria. 2. Can not be renewed if BMI is ≤ 24. 3. Patient meets indication specific criteria listed below.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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.	**For patients treated for obesity attributed to *POMC*, *PCSK1*, or *LEPR* deficiency:** • 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. **For patients diagnosed with BBS:** • 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 Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	5. Body Mass Index (BMI) meets one of the following: • Adults: > 30 kg/m^2 • 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	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	syndrome and any other form of obesity not specifically described above. 11. 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. 3. Envarsus XR will be used in combination with other immunosuppressant medications to prevent kidney transplant rejection. 4. Patient has not been diagnosed with congenital long Qt-syndrome. 5. Prescribed by a Nephrologist and Transplant Specialist. 6. Approval Duration: 12 months	1. Patient has continued care with a nephrologist or transplant specialist. 2. Patient continues to meet the initial approval criteria. 3. No clinical evidence of organ failure. 4. Individual has not developed any significant adverse drug effects that may exclude continued use such as: • Pure red cell aplasia (PRCA) • Posterior reversible encephalopathy syndrome (PRES) • Torsades de points **Approval duration**: 12 months
tadalafil (Adcirca; Alyq)	1. Ordered for an approved indication for use:	1. All initial criteria continue to be met.

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
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.*	• 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: ○ Mean pulmonary artery pressure (mPAP) > 20 mmHg, and ○ Pulmonary arterial wedge pressure (PAWP) ≤ 15 mmHg, and ○ Pulmonary vascular resistance (PVR) ≥ 3 wood units.	2. IF patient is also prescribed macitentan (Opsumit), please **redirect** to Opsynvi (macitentan + tadalafil). 3. Patient has documented positive clinical response to tadalafil treatment. **Approval Duration**: 12 months.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	7. Medication ordered by a Pulmonologist, Cardiologist, or Rheumatologist. 8. Quantity Limits: 2 tablets per day. 9. Approval Duration: 12 months.	
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	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). **Approval duration**: 12 months.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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. • 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	1. All initial criteria are met. 2. Approval Duration for HIV, Hep B, or HIV with Hep B coinfection:

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	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. <u>HIV-1 infection treatment:</u> • 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: ○ HIV RNA/DNA quantitative (if detectable) ○ HIV RNA/DNA qualitative ○ HIV P24 antigen ○ HIV Western blot	Automated for continuous approval unless gaps in therapy > 90 days occur.

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	○ 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**	
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:	1. Documentation of positive clinical response (e.g., improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance).

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• 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.	2. Approval Duration: 12 months.
tirzepatide (**Mounjaro®**) injection **Note:** See separate policy for tirzepatide **(Zepbound®)**. **Available Strengths** • 2.5 mg/0.5 mL • 5 mg/0.5 mL • 7.5 mg/0.5 mL • 10 mg/0.5 mL	1. Ordered for the covered indication: • **Treatment of adult patients with Type 2 Diabetes mellitus (T2DM).** 2. Patient is 18 years or older 3. Documentation within the **past 3 months** of one of the following:	Chart notes with A1c or CGM report with TIR% within previous 3 months. 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

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
• 12.5 mg/0.5 mL • 15 mg/0.5 mL	• Hemoglobin A1c • Continuous Glucose Monitor (CGM) report with Time in Range (TIR%) 4. 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%) **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 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** • Prior stroke (ischemic or hemorrhagic); **or** • Symptomatic peripheral arterial disease (PAD) as evidenced	therapy **or** TIR% was ≤ 55% and has increased ≥ 10% **or** A1c is ≤ 7.0 at initiation dose. **Baseline (pre-GLP-1) 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. Patient has not had medical intervention for: Pancreatitis; or Severe gastrointestinal events. (e.g., hospitalization or new start GI motility May not be concurrently using **ANY** of the following: • **ANY** other GLP1 or GLP1/GIP combination drug (e.g., Ozempic,

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	by: ○ Intermittent claudication with ankle- brachial index (ABI) < 0.85 (at rest); **or** ○ Peripheral arterial revascularization procedure; **or** ○ Amputation due to atherosclerotic disease. **Step Therapy Requirements** **Step 1 – Metformin** • Trial of **≥ 3 months** at maximum tolerated dose OR • Documented **contraindication or intolerance** **Step 2 –** Trial of **≥ 3 months** at maximum tolerated doses of **two (2)** of the following: • Insulin • Sulfonylurea (e.g., glipizide, glimepiride) • Pioglitazone	Rybelsus, Wegovy, 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). 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. **Approval Duration**: 6 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• DPP-4 inhibitor (e.g., alogliptin) • SGLT2 inhibitor (e.g., empagliflozin/Jardiance®, dapagliflozin/Farxiga®) **Step 3 –** Trial of **≥ 3 months** at maximum tolerated dose of • **liraglutide (Victoza®)** unless documented **contraindication or intolerance.** May not be concurrently using or taking **ANY** of the following: • ANY other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus, Wegovy, 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).	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all contraindications. 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 • **2.5 mg weekly** is considered a **starter dose** • Limited to **one 28-day supply** Dose must escalate to **5 mg weekly** unless: • **A1c ≤ 7.0%** • **TIR ≥ 65%**	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	Cannot be approved for indication of weight management. **Initial Approval Duration:** 6 months	
tirzepatide (**Zepbound**) injection 2.5mg/0.5ml, 5mg/0.5ml, 7.5mg/0.5ml, 10mg/0.5ml, 12.5mg/0.5ml, 15mg/0.5ml *****NOTE: see separate listing with PA criteria for Mounjaro*****	1. Ordered for the **ONLY** covered indication for use: • To treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity. 2. Cannot be approved for indication of weight management. 3. Patient age ≥ 18 years. 4. Patient does **NOT** have Type 1 or Type 2 diabetes. • Persons with diabetes may be redirected to Mounjaro. 5. Moderate to severe OSA as diagnosed by polysomnography with an apnea-hypopnea index (AHI) ≥ 15 events per hour. Clinical documentation of sleep study results within previous 6 months. 6. BMI ≥ 30 kg/m^2 7. Provide current BMI, height, and weight measurements within the last 90 days.	1. **Cannot be approved for indication of weight management.** 2. Submission of BMI, height and weight within previous 90 days. NOT eligible for renewal if BMI < 30 kg/m2. 3. If Zepbound therapy has occurred for greater than 12 months, a repeat sleep study confirming moderate to severe OSA diagnosis is required and annually thereafter. **Approval Duration: 6 months.**

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	8. May not be concurrently using or taking ANY of the below: • **ANY** GLP-1 or GLP1/GIP combination drug (e.g. Mounjaro, Ozempic, Rybelsus, Saxenda, Soliqua, Trulicity, Victoza, Xultrophy, or Wegovy). • **ANY** DPP4i (alogliptin, Januvia [sitagliptin], Onglyza [saxagliptin], Tradjenta [linagliptin]). • Agents for severe constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 9. May NOT be approved in 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	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	10. Prescribed by or in consultation with a sleep specialist, pulmonologist, or other provider experienced in treating OSA. 11. Must be administered according to most current FDA guidelines for dosage and timing. • Dose titration is expected every 4 weeks until patient reaches a minimum weekly dose of 10 mg. • Expected titration schedule: ○ 2.5 mg/week for four weeks, then ○ 5.0 mg/week for four weeks, then ○ 7.5 mg/week for four weeks, then ○ 10.0 mg/week maintenance dose or higher ○ Recommended dose for treatment of OSA is 10 mg, 12.5 mg, or 15 mg per week. 12. Limited to 4 pens of any strength per 28 days. **Approval Duration:** 6 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.	1. Patient does not show evidence of disease progression while on Fotivda therapy. **Approval Duration**: 12 months.

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	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.	

tofacitinib
(Xeljanz) Tablets: 4 mg, 10 mg
XR extended-release tablets: 11mg, 22 mg
Oral Solution: 1 mg/ml
	Indication Coverage (FDA approved uses)
	Coverage may be authorized for adult patients (≥18 years) with:
	• Moderately to Severely Active Rheumatoid Arthritis (RA)
	• Active Psoriatic Arthritis (PsA)
	• Moderately to Severely Active Ulcerative Colitis (UC)
	PRESCRIBER REQUIREMENTS
	• Must be prescribed by or in consultation with:
	  • Rheumatologist (RA, PsA)
	  • Gastroenterologist (UC)
	GENERAL COVERAGE CRITERIA (ALL REQUIRED)
	• Documented diagnosis consistent with FDA labeling
		REAUTHORIZATION CRITERIA: Approval Duration: 6 MONTHS
		• Documented clinical improvement:
		  ○ RA: improvement in DAS28/CDAI
		  ○ PsA: reduction in joint/skin symptoms
		  ○ UC: improvement in Mayo score
		• Adherence confirmed (PDC ≥0.8 via pharmacy claims)

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	• Baseline disease severity documented (e.g., DAS28, CDAI, Mayo score) • Negative TB screening prior to initiation • No concurrent use with biologic DMARDs or other JAK inhibitors • Use consistent with FDA-approved dosing <u>Rheumatoid Arthritis (RA)</u>: Step 1: Conventional Synthetic DMARDs (Required) Trial and failure, intolerance, or contraindication to: • Methotrexate (preferred) • Leflunomide • Sulfasalazine Minimum Duration Requirement: • ≥12 weeks continuous therapy Verification: • Pharmacy claims demonstrating PDC ≥0.8 over 12 weeks OR documented intolerance/adverse effects	• No serious adverse events requiring discontinuation

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	Step 2: Biologic DMARD (Required) Trial and failure, intolerance, or contraindication to ≥1 preferred biologic: • TNF inhibitors (adalimumab biosimilar) **Minimum Duration Requirement:** • ≥12 weeks Verification: • Pharmacy or medical claims confirming administration Documentation of inadequate response **Step 3: Xeljanz Eligibility** Authorization only if: • contraindication to biologics • OR documented inability/refusal to use injectable therapy **Initial PA: 6 months** <u>Psoriatic Arthritis (PsA)</u>: **Step 1: Conventional DMARD (Required)** • Methotrexate	

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• Leflunomide • Sulfasalazine Minimum Duration Requirement: ≥12 weeks Verification: • Pharmacy claims (PDC ≥0.8) **Step 2: Biologic DMARD (Required)** • ≥1 TNF inhibitor Minimum Duration Requirement: ≥12 weeks Verification: • Claims + clinical documentation **Step 3: Xeljanz Eligibility** Same as RA: • Failure/intolerance to biologic • OR contraindication Initial PA: 6 months <u>Ulcerative Colitis (UC):</u> **Step 1: Conventional Therapy (Required)**	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• 5-ASA agents (mesalamine) or • Corticosteroids (induction) (moderate to severe) Minimum Duration Requirement: • 5-ASA: ≥8 weeks • Steroids: ≥2–8 weeks induction Verification: • Pharmacy claims or medical records Step 2: Biologic Therapy (Required) • ≥1 TNF blockers: ○ TNF inhibitor (adalimumab) And • Stelara biosimilar Minimum Duration Requirement: ≥ 12-16 weeks Verification: • Medical or pharmacy claims • Documentation of inadequate response Step 3: Xeljanz Eligiility Authorization only if:	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• Failure/intolerance to biologics • OR contraindication to biologics SAFETY RESTRICTIONS (STRICT) Due to boxed warnings: • Use requires careful risk-benefit assessment in patients with: o History of thrombosis (unless justified) o High cardiovascular risk (age ≥50 + CV risk factors) unless failure of alternatives • Dose restrictions per FDA label • Periodic monitoring required (CBC, lipids, LFTs) EXCLUSION CRITERIA Coverage will be denied if: • Use without prior biologic failure (unless exception justified) • Concurrent use with biologics or other JAK inhibitors • Insufficient duration of prior therapies • Non-adherence (PDC <0.8) without justification DOSING REQUIREMENTS	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**

	• Must follow FDA-approved dosing:
	  ○ RA/PsA: 5 mg BID or XR equivalent
	  ○ UC: induction (10 mg BID), then maintenance per label
	Initial PA: 6 months	

tramadol hydrochloride extended release (Ultram) capsules (biphasic release) 100mg, 150mg, 200mg, 300mg Tablets 100mg, 200mg, 300mg Tablets (biphasic release) 100mg, 200mg, 300m	1. Ordered for an approved indication for use: • in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. 2. Completion of the opioid prior authorization form. 3. Submission of supporting clinical documentation for last office visit, dated within the previous 3 months. 4. 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.	All opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-MD **Limitations of Use:** Not indicated as an as-needed (prn) analgesic.

MedStar Family Choice MD Prior Authorization and Step Therapy Table

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	5. Maximum approval duration: 6 months; may be reduced based on any of the criteria as outlined in Pharmacy Policy 219: Opioid Prescription Prior Authorization.	
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:	• Patient has a diagnosis of World Health Organization (WHO) Group I pulmonary arterial hypertension (PAH); **AND** • Patient has had a right heart catheterization; **AND** • The results of the right heart catheterization confirm the diagnosis of WHO Group I PAH; **AND** • 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. • Not prescribed concurrently with Uptravi (selexipag), inhaled prostacyclin products (e.g. Tyvaso

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	○ 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.	[Treprostinil], Tyvaso DPI, Ventavis [iloprost], epoprostenol). • Orenitram is prescribed by, or in consultation with a cardiologist or pulmonologist. • Approval Duration: 12 months.
Triptorelin (**Trelstar**) intramuscular injection	1. Ordered for an approved indication for use: • Palliative treatment of advanced prostate cancer	1. **<u>Prostate Cancer:</u>** • Patient is experiencing clinical

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3.75 mg; 11.25 mg; 22. 5 mg	• 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> • 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	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. • 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*

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• Gender affirming care: 12 months	*cumulative treatment course is < 5 years.* • Breast cancer: 12 months • Gender affirming care: 12 months
Trofinetide (Daybue); J8499	USE **MFC High-Cost Medication PA Criteria**	
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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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	dose. 6. Approval Duration: 12 months.	
Ustekinumab (**Stelara** biosimilars) 45 mg; 90 mg pre-filled syringes for injection • **Yesintek (** Ustekinumab-kfce) • **Steqeyma** (ustekinumab-stab)	• The criteria for ustekinumab are indication specific. Please review criteria for the patient-specific diagnosis. • Patient has been screened for Hepatitis B and Tuberculosis prior to initiation of therapy. • Patient is not receiving in combination with any other targeted immunomodulator (e.g., etanercept, certolizumab, golimumab, abatacept, adalimumab, Risankizumab, guselkumab, secukinumab, ixekizumab, brodalumab, tildrakizumab, rofacitinib, baricitinib, upadacitinib, apremilast, or similar). • Requested dose and frequency are aligned with FDA and manufacturer labeling. Hidradenitis suppurative: **excluded** from coverage; off-label indication. Note: **Adalimumab** (Humira biosimilars) is first line therapy. Remicade (infliximab) is the MedStar Family Choice recommended alternate. Crohn's disease:	**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). **Approval Duration**: 12 months.

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	○ Diagnosis of moderately to severely active Crohn's disease ○ Patient has had an inadequate response to conventional therapies (such as anti-inflammatory drugs, corticosteroids, and oral immunosuppressive agents). ○ **Tried and failed TNF blocker (Adalimumab) for ≥12 weeks** ○ Patient is currently on ustekinumab therapy for moderately to severely active Crohn's disease as documented by claims history or submission of medical records. **Approved dose:** Maintenance dosing (90 mg/ml every 8 weeks) following IV induction. **Approval Duration**: 12 months Plaque psoriasis: ○ Diagnosis of moderate to severe plaque psoriasis	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	○ ≥ 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, **AND** ○ **Tried and failed TNF blocker (Adalimumab) biosimilar for 12 weeks** ○ Must be prescribed by or in consultation with a dermatologist.	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	<u>Psoriatic arthritis:</u> • 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 • **Tried and failed TNF blocker (Adalimumab) biosimilar for 12 weeks** • Prescribed by or in consultation with a rheumatologist or dermatologist. • Approved dose: 45 mg/ml for patient weight ≤ 100 kg • Approved dose: 90 mg/ml for patient weight > 100 kg • Approval duration: 12 months <u>Ulcerative colitis, moderate to severe:</u> • Diagnosis of moderate to severe ulcerative colitis. • Prescribed by or in consultation with a gastroenterologist. • Approved dose: 90 mg/ml • Approval Duration: 12 months	

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
oteziaValoctocogene roxaparvovec (Roctavian); J1412	USE **MFC High-Cost Medication PA Criteria**	
Vamorolone (Agamree)	USE **MFC High-Cost Medication PA Criteria**	
Vedolizumab (Entyvio) Intravenous Infusion: For injection: 300 mg vedolizumab in a single-dose vial Subcutaneous injection Injection: single-dose prefilled syringe with needle safety device 108 mg/0.68 ml solution Injections: single-dose prefilled pen 108.068 ml solution**108 mg/0.68 ml solution** **Injections: single-dose prefilled pen 108.068 ml solution**	1. INDICATIONS (FDA-APPROVED USES) Coverage may be authorized for patients with: 1. Moderately to Severely Active Ulcerative Colitis (UC) (adult) 2. Moderately to Severely Active Crohn's Disease (CD) (adult) 2. PRESCRIBER REQUIREMENTS • Must be prescribed by or in consultation with a gastroenterologist 3. GENERAL COVERAGE CRITERIA (ALL REQUIRED) • Diagnosis consistent with FDA labeling • Documentation of moderate to severe disease activity (e.g., Mayo score for UC, CDAI for CD) • Negative TB screening prior to initiation • No concurrent biologic or JAK inhibitor therapy	We may renew coverage of Entyvio® if ALL the following criteria are met: 1. Individual continues to meet initial approval criteria; AND 2. Absence of unacceptable toxicity from the medication or serious allergic reactions, or severe infections; **AND** 3. Continued diagnosis and documentation of positive clinical response to Entyvio where a response to treatment as indicated by improvement

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	• Use consistent with FDA-approved dosing (IV induction → maintenance or SC maintenance where applicable) A. Ulcerative Colitis (UC) Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema for 8 weeks. **AND** Patient had a 12-week trial of one systemic agent for UC (e.g., 6-MP, azathioprine, cyclosporine, tacrolimus). **AND** • Patient has failed an 8-week trial of adalimumab or has a contraindication for use. **AND** • Patient has failed a 12-week trial of Ustekinumab biosimilar agent or has contraindication for use. **B. Crohn's Disease (CD)** Patient has had an inadequate response for at least 12 weeks	in signs and symptoms compared to baseline including but not limited to: a. Reduction in stool frequency/bloody stools; OR b. Improvement abdominal pain; **Or** c. Endoscopic and laboratory response (e.g., C-reactive Protein); **AND** 4. Documented Dose and Frequency must be submitted and must be within the FDA approved Dosing and Frequency **RE-AUTHORIZATION duration**: 6 months

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	to conventional therapies (such as anti- inflammatory drugs, corticosteroids, or oral immunosuppressive agents) • Patient has failed an 8-week trial of adalimumab or has a contraindication for use. **AND** • Patient has failed a 12-week trial of Ustekinumab biosimilar agent or has contraindication for use. Approval Duration: 6 months	
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).	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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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	**Additional Considerations and Renewal Criteria**
	2. Patient age ≥ 18 years. 3. Not taking concurrently with cyclophosphamide. 4. Prescriber specialty: immunologist, nephrologist, rheumatologist, or provider experienced in treatment of lupus nephritis. 5. Prescriber attestation that all baseline evaluations have been done, and not contraindications to use are present (strong 3A4 inhibitor contraindicated, live vaccines, pregnancy/breastfeeding negative, assessment of renal function). 6. Quantity Limit: 6 tablets per day (23.7 mg twice daily). 7. Approval Duration: 6 months	
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**	

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