MedStar Family Choice Prior Authorization and Step Therapy Table

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

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	**Approval Criteria & Submission Requirements**	**Additional Considerations & Renewal Criteria**
abaloparatide (**Tymlos**) 3120mcg/1.56ml	1. Prescribed for an approved indication for use: • Treatment of postmenopausal women with osteoporosis at high risk for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. • Treatment to increase bone density in men with osteoporosis at high risk for fracture, or patients who have failed or intolerant to other available osteoporosis therapy. 2. Patient has diagnosis of post-menopausal osteoporosis 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:	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. Up to 12 months, not intended to last longer than the final infusion completing 24 months of therapy.

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	• BMD T-score between -1 and -2.5 based on BMD measurements from lumbar spine, hip, or radius; AND
	• ONE of the following FRAX 10-year fracture probabilities:
	  ○ 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. 3. Patient has had at least one prior systemic therapy. 4. Medication ordered by an Oncologist. 5. Approval Duration: 12 months.	1. Confirmation that medication still carries FDA-approval for intended indication. 2. Prescriber has submitted documentation showing periodic monitoring of AST, ALT, alkaline phosphatase, and total bilirubin. 3. No documentation of disease progression or unacceptable toxicity. 4. Approval Duration: 12 months
albuterol inhalers **levalbuterol inhalers**	1. If patient has exceeded 6 inhalers per 365 days: **Note: this applies to any combination of albuterol MDIs and levalbuterol MDIs.** • Provider must show that patient has been prescribed appropriate controller therapy for	

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	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. • Approval for asthma indication is for on 2. Approval for asthma indication is for one fill, one month only. 3. Approval for COPD may be longer depending upon documented COPD severity, concurrent therapy, compliance with COPD maintenance medication regimen, and oversight by a pulmonologist.	
alectinib (**Alecensa)** capsule 150mg	1. Ordered for an approved indication for use: • Treatment of patients with anaplastic lymphoma kinase (ALK)- positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. 2. Patient ≥ 18 years of age. 3. Patient has advanced or metastatic disease. 4. Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected by an approved test. 5. Medication ordered by an Oncologist. 6. Maximum Approval Duration: 12 months.	1. No documentation of disease progression or unacceptable toxicity. 2. Authorization Duration: 12 months.
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 criteria: • Frequent and severe abdominal pain/discomfort • Frequent bowel urgency or fecal incontinence • Disability or restriction of daily activities due to	1. Documentation of positive clinical response to therapy. 2. Authorization Duration: 12 months.

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	IBS 2. Chronic IBS symptoms lasting at least 6 months. 3. Gastrointestinal tract abnormalities have been ruled out 4. There has been an inadequate response to conventional therapy (e.g. loperamide, antispasmodics). 5. 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 6. Dose is limited to 2 tablets per day. 7. Initial authorization is for 6 months.	
armodafinil (**Nuvigil**) tablets 50mg, 150mg 200mg, 250mg	1. Ordered for an approved indication for use: • To improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea, narcolepsy, or shift work disorder. 2. Medication ordered by a Neurologist or certified sleep specialist.	
avatrombopag (**Doptelet**) tablets 20mg	1. Ordered for an approved indication for use: • thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.	When prescribed for thrombocytopenia in chronic liver disease with procedure scheduled:

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	• thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. 2. Patient age ≥ 18 years. 3. A recent (less than 1 month old) platelet count must be supplied with documentation submitted. 4. Medication ordered by a Hematologist. When prescribed for thrombocytopenia in patients with chronic liver disease-associated thrombocytopenia scheduled to undergo a procedure: • Approval limited to 15 tablets per treatment course. • Approval Duration: one month. When prescribed to patients with chronic immune thrombocytopenia with insufficient response to previous treatment: • Diagnosis of chronic immune thrombocytopenia (ITP). • Patient experienced insufficient response to a previous treatment (e.g., corticosteroids, immunoglobulins, thrombopoietin receptor agonists, splenectomy). • Approval duration: 12 months.	• must meet initial use criteria for each request. • Maximum approval duration: 1 month • Maximum of 15 tablets per treatment. When prescribed to patients with chronic immune thrombocytopenia with insufficient response to previous treatment: • Documented positive response to treatment. • Approval Duration: 12 months.
axicabtagene ciloleucel (**Yescarta**) Injection	1. Ordered for an approved indication for use: • treatment of adult patients with large B- cell lymphoma that is refractory to first-line chemotherapy. 2. The treatment facility that dispenses and administers Yescarta is enrolled and complies with the Risk Evaluation and Mitigation Strategy; AND 3. Patient age ≥ 18 years. 4. Patient has received prior treatment with first-line	**Not applicable. Maximum approval, one treatment course per lifetime.**

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	chemo-immunotherapy and has any of the following B-cell lymphoma sub-types: • Diffuse large B-cell lymphoma (DLBCL) • Primary mediastinal large B-cell lymphoma • High-grade B-cell lymphomas • HIV-related B-cell lymphomas • Monomorphic post-transplant lymphoproliferative B-cell type disorder 5. Patient does not have ANY of the following: • Primary CNS lymphoma • Previous treatment with Yescarta or other CD 19-directed chimeric antigen receptor (CAR) T-cell therapy. • ECOG performance status ≥ 3 (patient is not ambulatory, capable of self-care, or confined to bed or chair more than 50% of waking hours). • Inadequate or unstable kidney, liver, pulmonary, or cardiac function. • Active hepatitis B, active hepatitis C, or clinically active systemic infection. 6. Medication ordered by an Oncologist. 7. Approval duration: 3 months.	
azacitadine (**Onureg**) tablets 200mg, 300mg	1. Ordered for an approved indication for use: • Continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and are not able to complete intensive curative therapy. 2. Patient is not able to complete intensive curative	1. Patient does not show evidence of progressive disease while on Onureg therapy. 2. Approval duration: 12 months.

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	therapy (i.e. transplant-ineligible). 3. Medication ordered by an Oncologist.	
azelaic acid (**Finacea**) gel 15% **STEP THERAPY**	1. Ordered for Acne Vulgaris in adults. 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 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, the claim will adjudicate without manual review. 4. Approval Duration: 12 months.	
baricitinib (**Olumiant**) tablets 2 mg, 4 mg (1 mg non-formulary)	1. Ordered for an approved indication for use: • Treatment of patients with severe alopecia areata • Treatment of patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF blockers. 2. Patient age ≥ 18 years. **Alopecia Areata:** • Diagnosis of moderate to severe alopecia areata, with a current episode of alopecia areata with at least 50% scalp hair loss, **AND** • Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecias, secondary syphilis, tinea capitis, triangular alopecia, and trichotillomania); **AND** • Patient is not receiving Olumiant concurrent with **ANY** of the following:	**Renewal Criteria applies to both Alopecia Areata and Rheumatoid Arthritis indications:** 1. Documentation of positive clinical response to Olumiant therapy; **AND** 2. Patient is not receiving Olumiant concurrent with ANY of the following: • A targeted immunomodulator e.g. Adalimumab, Cimzia, Enbrel, Simponi, Orencia, Xeljanz, Rinvoq or Litfulo **OR** • A potent immunosuppressant (e.g. azathioprine or cyclosporine). 3. Approval Duration: 12 months.

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

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	○ 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: ○ 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.	

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	2. Medication ordered by an infectious disease specialist 3. Approval duration: 24 weeks	
belimumab (**Benlysta**) Inj 200mg/ml	1. Ordered for an approved indication for use: • patients ≥ 5 years of age with active systemic lupus erythematosus (SLE) who are receiving standard therapy. • Patients ≥ 18 years of age with active lupus nephritis who are receiving standard therapy. 2. Not prescribed for patients with severe active central nervous system lupus as use of Benlysta is not recommended for those patients. 3. Must be currently taking OR has tried and failed or had intolerance/contraindication to at least one standard therapy for SLE (e.g., corticosteroids, antimalarials, NSAIDS or immunosuppressives) or lupus nephritis (e.g., corticosteroids, mycophenolate, cyclophosphamide, azathioprine) 4. Prescriber attestation that all baseline evaluations have been done and no contraindications to use are present including counseling/assessment of recent live vaccine use and depression/suicide risk. 5. Prescriber attests that subsequent appropriate evaluation and monitoring will be done based on the package insert. 6. Patient is not receiving Benlysta in combination with **ANY** of the following: • Targeted Immunomodulator (e.g., Adalimumab, etanercept, certolizumab, anakinra)	1. All initial criteria continue to be met. 2. Documentation demonstrating clinical benefit and tolerance. 3. Patient is not receiving Benlysta in combination with **ANY** of the following: • Targeted Immunomodulator (e.g., Adalimumab, etanercept, certolizumab, anakinra) • Lupkynis (voclosporin) • Saphnelo (anifrolumab) 4. Approval Duration: 12 months.

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	• Lupkynis (voclosporin) • Saphnelo (anifrolumab) 7. Prescribed by an immunologist, nephrologist, rheumatologist, or provider experienced in the treatment of SLE or lupus nephritis. 8. Approval Duration: 12 months	
belumosudil (**Rezurock**) tablets 200mg	1. Ordered for an approved indication for use: • treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy. 2. Member must have tried and failed, have intolerance or medical contraindication to at least three of these medications: cyclosporine, methotrexate, mycophenolate, sirolimus, and glucocorticoids. 3. Patient age ≥ 12 years. 4. Provider attestation: Drug specific baseline evaluation and monitoring completed (CBC/CMP including total bilirubin, AST, ALT). Patient is not pregnant and is using effective contraception, concurrent use of CYP3A inducers and proton pump inhibitors is contraindicated. 5. Life expectancy is > 6 months. 6. Quantity limited to 30 tablets per 30 days. 7. Approval duration: 6 months	1. Prescriber attestation of continued clinical benefit. 2. Approval Duration: 6 months.
benralizumab (**Fasenra**) Pen 10mg/0.5ml, 30mg/ml	1. Ordered for an approved indication for use: • add-on maintenance treatment of patients ≥ 12 years of age with severe asthma and with an eosinophilic phenotype. 2. Diagnosis of severe, uncontrolled asthma as defined by at least ONE of the following: • Poor symptom control (e.g., Asthma Control	1. Documentation of positive clinical response to Fasenra therapy as demonstrated by at least one of the following: • Reduction in frequency of exacerbations • Decreased utilization of rescue

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	Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20). • Two or more bursts of systemic corticosteroids for at least 3 days each in previous 12 months. • Asthma-related emergency treatment (ER visit, hospital admission, or unscheduled OV for nebulizer or emergency treatment). • Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted. • Patient is currently dependent on oral corticosteroids for the treatment of asthma. 3. Submission of medical records documenting one of the following: • Asthma is eosinophilic phenotype as defined by baseline (pre-benralizumab treatment) peripheral blood eosinophil level ≥ 150 cells/uL within the past 6 weeks; OR • Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma. 4. Fasenra will be used in combination with ONE of the following: • One high-dose combination inhaled corticosteroid (ICS/LABA); OR • Combination therapy with BOTH one high dose inhaled corticosteroid and one additional asthma controller medication. 5. Patient is not receiving treatment in combination with ANY of the following: • Anti-interleukin-5 therapy (e.g., Cinqair	medications • Increase in percent predicted FEV1 from pretreatment baseline. • Reduction in severity or frequency of asthma-related symptoms • Reduction in oral corticosteroid requirements. 2. Used in combination with inhaled corticosteroid (ICS)-containing controller medication. 3. Patient is not receiving treatment in combination with ANY of the following: • Anti-interleukin-5 therapy (e.g., Cinqair (resilizumab), Nucala (mepolizumab). • Anti-IgE therapy (e.g., Xolair (omalizumab). • Anti-interleukin-4 therapy (e.g., Dupixent (dupilumab). • Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., Tezpire (Tezepelumab)). 4. Approval Duration: 12 months.

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	(resilizumab), Nucala (mepolizumab)). • Anti-IgE therapy (e.g., Xolair (omalizumab). • Anti-interleukin-4 therapy (e.g., Dupixent (dupilumab). • Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., Tezspire (Tezepelumab)). 6. Medication ordered by a Pulmonologist, Immunologist, or Allergist. 7. Approval Duration: 12 months.	
Beremagene geperpavec-svdt **(Vyjuvek)** topical gel 5×10^9 PFU/mL	1. Ordered for an approved indication for use: • Treatment of wounds in patients with diagnosis of dystrophic epidermolysis bullosa (DEB). 2. Patient age ≥ 6 months. 3. Submission of medical records (e.g., chart notes, laboratory values) confirming a mutation in the collagen type VII alpha 1 chain (COL7A1) gene. 4. Patient has at least one recurrent or chronic open wound that meets all of the following: adequate granulation tissue, excellent vascularization AND no evidence of active wound infection. 5. No evidence or history of squamous cell carcinoma. 6. Prescribed by, or in consultation with, a dermatologist with expertise in the treatment of DEB. 7. Dosing is in accordance with FDA approved labeling. Initial authorization limited to no more than 6 months and no more than 26 doses.	1. Patient has previously been treated with Vyjuvek therapy. 2. Patient had a positive clinical response to Vyjuvek therapy (e.g., decrease in wound size, increase in granulation tissue, complete wound closure). 1. Wound(s) being treated to meet all the following criteria: • Adequate granulation tissue • Excellent vascularization • No evidence of active wound infection • No evidence or history of squamous cell carcinoma • Dosing is in accordance with FDA approved labeling. Reauthorization limited to no more than 6 months and no more than 26 doses.
berotralstat (**Orladeyo**) capsules 110mg, 150mg	1. Ordered for an approved indication for use: • prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older.	1. Member meets the criteria for initial approval.

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	2. Patient age ≥ 12 years. 3. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test OR Normal X1-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. 4. Prescriber attestation that all baseline evaluations have been done, prophylactic therapy is medically necessary, and no contraindications to use. 5. Not used in combination with other approved products indicated for prophylaxis against HAE attacks (i.e., Cinryze, Haegarda, Takhzyro). 6. History of failure to BOTH of the following (document date of trial and list reason for therapeutic failure) Haegarda AND Takhzyro. Alternatively- could be failure of one of the following: Haegarda, Cinryze, Takhzyro. 7. Quantity limit of 1 capsule per day 8. Prescriber is a hematologist, immunologist, or allergist. Initial approval duration: 3 months	2. Member has experienced a significant reduction in frequency of attacks (≥ 50%) since starting treatment. 3. Member has reduced the use of medications to treat acute attacks since starting treatment. 4. Prescriber attests that patient has had an annual evaluation for the continued need for long-term prophylaxis therapy AND 5. Prescriber attests a recent review of patient's current medication has been completed and there is no concomitant use of P-gp inducers (e.g. rifampin, St John's wort), and dose adjustment has been made based on labeled recommendations for drug interactions if applicable. 6. Approval Duration: 3 months.
bosutinib (**Bosulif**) tablets 100mg, 500mg	1. Ordered for an approved indication for use: • Newly diagnosed chronic phase Ph+ chronic myelogenous leukemia (CML). • Chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy. 2. Medication ordered by an Oncologist. 3. Authorization Duration: 12 months.	1. Patient does not show evidence of disease progression while on Bosulif therapy. 2. Approval Duration: 12 months.

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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. **Non-Small Cell Lung Cancer (NSCLC):** • The tumor is anaplastic lymphoma kinase (ALK)-positive. • The cancer is either: metastatic, recurrent, or advanced. **Soft Tissue Sarcoma/Uterine Neoplasms:** • Diagnosis of inflammatory myofibroblastic tumor (IMT); and • Presence of ALK translocation. **Histiocytic Neoplasms:** • Diagnosis of symptomatic Erdheim-Chester Disease; and • Used as targeted therapy ALK-fusion; and • Disease is either relapsed or refractory. **Central Nervous System (CNS) Cancers:** • Diagnosis of metastatic brain cancer from NSCC; and • Tumor is ALK-positive. 2. Medication ordered by or in consultation with an Oncologist. 3. Approval Duration: 12 months.	1. Patient does not show evidence of progressive disease while on Alunbrig therapy. 2. Approval Duration: 12 months.

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buprenorphine products for chronic pain (**Belbuca**, Butrans) buccal film (**Belbuca**) 75mcg, 150mcg, 300mcg, 450mcg, 600mcg, 750mcg, 900mcg topical patches (Butrans **generic**) 5mcg/hr, 7.5mcg/hr, 10mcg/hr, 15mcg/hr, 20mcg/hr	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. 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: • Opioid-naïve or non-opioid tolerant patients ○ Buccal film – 75mcg once daily or Q12 for at least 4 days before titration ○ Topical patch – 5mcg/hr once every 7days, wait at least 72 hours before titration • Opioid-tolerant patients – convert based on patient's current opioid regimen ○ Buccal film – patients currently receiving >160 MME/day of other opioid may not receive adequate analgesic effect from buccal film at max doses; consider alternative opioid ○ Topical patch – patients currently receiving >80 MME/day of other opioid may not receive adequate analgesic effect from topical patch at max doses; consider alternative opioid ○ MUST discontinue all other around-the-clock opioids once buprenorphine is initiated	• All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: **OPIOID PRIOR AUTH FORM-DC** **Limitations of Use:** Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and greater risk of overdose and death with extended-release opioid formulations, reserve 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.

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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 12-24 hours</td></tr>
<tr><td>MME 30-89</td><td>150mcg 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>
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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 criteriat as outlined in Pharmacy policy 219.DC: Opioid Prescription Prior Authorization.
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<tr><td>c1 esterase Inhibitor [Human]
Cinryze solution
500 unit
Haegarda injection solution
2000unit, 3000unit</td><td>
1. Ordered for an approved indication for use:

Routine prophylaxis to prevent Hereditary Angioedema attacks in patients ≥ 6 years of age.

2. Cinryze will be considered for coverage when ALL of the criteria below are met and confirmed with medical documentation.

Diagnosis of hereditary angioedema (HAE) confirmed by one of the following:

Confirmed monoallelic mutation known to cause HAE in either the SERPING1 or F12 gene: OR
A C4 level below the lower limit of normal

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1. All of the criteria for initial therapy must be met; AND
2. Provider attests to a positive clinical response.
3. Continuing therapy will be authorized for 3 months.
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	and either C1 inhibitor (C1-INH) antigenic level below the lower limit of normal or C1-INH functional level below the lower limit of normal; AND • Used for prophylaxis of acute HAE attacks: AND • Patient is at least 6 years of age; AND • Patient has experienced the following: o History of recurrent laryngeal attacks; OR o ≥ 2 severe episodes/month (ex. debilitating GI or cutaneous effects); OR o ≥ 5 days/month of debilitating symptoms; AND • Prescribed by an allergist, immunologist, hematologist, or other appropriate specialist; AND • Medications known to cause angioedema (ex. ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate. 3. Length of Authorization: 3 months when criteria are met.	
cabotegravir (**Apretude**) extended-release intramuscular injection 600mg/3mL	1. Ordered for an approved indication for use: • At-risk adults and adolescents weighing at least 35 kg for PrEP to reduce the risk of sexually acquired HIV-1 infection. 2. Individuals must have a negative HIV-1 test prior to initiating APRETUDE and prior to each injection. 3. Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection; AND 4. Patient is not an appropriate candidate for oral PrEP (e.g., difficulty with adherence to prior oral PrEP, significant renal disease); AND	1. Patient has previously received treatment with Apretude 2. Patient has a negative HIV-1 test 3. Provider confirms that the patient will be tested for HIV-1 with each subsequent injection; and 4. Dosing is in accordance with FDA-approved labeling. 5. Approval Duration: 2 months

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	5. Provider attests that patient demonstrates treatment readiness by BOTH of the following: 6. Patient understands the risks of missed doses. 7. Patient has ability to adhere to the required every 2 months injection and testing appointments. 8. Dosing is in accordance with FDA-approved labeling. 9. Approval Duration: 2 months	
cabozantinib (**Cabometyx)** tablets 20mg, 40mg, 60mg	1. Ordered for an approved indication for use: • Patients with advanced renal cell carcinoma (RCC) • Patients with advanced renal cell carcinoma, as a first-line treatment in combination with nivolumab • Patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib • Adult and pediatric patients ≥ 12 years of age with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible 2. Medication ordered by an Oncologist.	
caplacizumab-yhdp (**Cablivi**) kit 11mg	1. Ordered for an approved indication for use: • Treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy. 2. Medication ordered by hematologist. 3. The patient received the requested medication with plasma exchange. 4. Cablivi will be given in combination with immunosuppressive therapy.	1. A request for continuation of therapy is for extension of therapy after the initial course of Cablivi. The initial course is treatment with Cablivi during and 30 days after plasma exchange. 2. The patient has either of the following documented signs of persistent, underlying aTTP: • ADAMTS13 activity level of < 10%, OR • All of the following:

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	5. The patient will not receive Cablivi beyond 30 days from the cessation of plasma exchange unless the patient has documented, persistent aTTP. 6. The patient has not experienced more than 2 recurrences of aTTP while on the requested medicaton. (A recurrence is when the patient needs to reinitiate plasma exchange, a 28-day extension of therapy is not considered a recurrence.) 7. Approval is for 30 days only.	○ Microangiopathic hemolytic anemia (MAHA) documented by the presence of schistocytes on peripheral smear ○ Thrombocytopenia and ○ Elevated lactate dehydrogenase (LDH) level 3. Cablivi will be given in combination with immunosuppressive therapy. 4. The patient has not received a prior 28-day extension of therapy after the initial course of Cablivi. 5. The patient has not experienced more than 2 recurrences of aTTP while on Cablivi. 6. Approval duration: 30 days.
capmatinib (**Tabrecta**) tablets 150mg, 200mg	1. Ordered for an approved indication for use: • treatment of adults with metastatic NSCLC whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an approved test. 2. Medication ordered by an oncologist.	
cariprazine (**Vraylar**) capsules 1.5mg, 3mg, 4.5mg, 6mg Therapy pack – 1.5mg & 3mg	1. Ordered for an approved indication for use: • Bipolar disorder • Major depressive disorder, as adjunctive therapy with an antidepressant medication • Schizophrenia 2. Patient is ≥18 years 3. Patient has completed adequate 12-week trials of at least 3 other antipsychotic medications, or has a contraindication to using other options.	

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	4. Medication ordered by a psychiatrist or behavioral health specialist. 5. Approval duration: 12 months	
casimersen (**Amondys 45**) injection 100mg/2ml	1. Ordered for an approved indication for use: • Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping. 2. Confirmed diagnosis of DMD with genetic confirmation of the DMD gene that is amenable to exon 45 skipping. 3. Provider attestation of baseline and subsequent evaluation and monitoring as appropriate such as hypersensitivity reactions and renal function. 4. Be on a stable dose of corticosteroid for ≥ 24 weeks. 5. Not ventilator dependent 6. Not receiving other RNA antisense therapy or gene therapy for DMD. 7. Maximum dose 30 mg/kg/dose once weekly 8. Prescribed by or in consultation with a pediatric neurologist with expertise in DMD.	• This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with AMONDYS 45. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials. • Duration of approval is limited to 6 months. **<u>Renewal Criteria:</u>** • Not receiving other antisense therapy or gene therapy. • Not ventilator dependent. • Provider attestation of continued benefit without ADE • Max dose 30 mg/kg/dose/week • Duration: 6 months
certolizumab pegol (**Cimzia**) kits 200mg/mL starter kit, maintenance kits	1. Ordered for an approved indication for use: • Moderate to severely active Crohn's disease • Moderate to severely active rheumatoid arthritis (RA) • Active psoriatic arthritis • Active ankylosing spondylitis or non-radiographic axial spondylarthritis • Severe plaque psoriasis • Active polyarticular juvenile idiopathic arthritis 2. Patient has completed at least an 8-week trial of	Renewal criteria: • Documentation of a positive clinical response to Cimzia therapy. • Patient is not receiving Cimzia in combination with another targeted immunomodulator (e.g. adalimumab [Humira or biosimilar], Enbrel, Simponi, Orencia, Xeljanz, Olumiant, Rinvoq, ustekinumab [Stelara or

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	adalimumab (Humira or biosimilar) or ustekinumab (Stelara or biosimilar) without achieving effective symptom control or has a contraindication to using this medication. • Patients of reproductive age who are pregnant or planning to conceive are exempt from the adalimumab trial requirement. 3. Patient is not receiving Cimzia in combination with another targeted immunomodulator (e.g. adalimumab [Humira or biosimilar], 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) 5. Approval Duration: 12 months	biosimilar], Skyrizi, Tremfya, Cosentyx, Taltz, Siliq, Ilumya, Otezla) • Duration: 12 months
chlordiazepoxide (Librium) capsules 5mg, 10mg, 25mg	1. Ordered for an approved indication for use: a) alcohol withdrawal syndrome treatment in adults b) management of anxiety disorders 2. No concurrent use of other benzodiazepines 3. If ordered for alcohol withdrawal syndrome: a) Current CIWA-AR score 10-15, indicating mild withdrawal symptoms. i) Scores >15 – contraindication to ambulatory management ii) Scores <10 – gabapentin is preferred as first-line therapy over benzodiazepines to manage very mild withdrawal symptoms	Renewal criteria: • Alcohol withdrawal syndrome requires a new authorization for each requested treatment course. ○ Consider referring to case management if a patient is requested for repeated treatments • Anxiety disorder ○ Confirmation of clinically significant improvement in symptoms

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	b) No prior history of withdrawal delirium (delirium tremens) or withdrawal seizures c) Confirmation of negative pregnancy status for female patients of reproductive age d) No presence of complex comorbidities or psychiatric comorbidities that can increase the risk of developing severe alcohol withdrawal syndrome: i) Heart failure class II or higher ii) Decompensated cirrhosis iii) COPD with oxygen dependence iv) CKD stage IV or higher v) Epilepsy or seizure history vi) Recent head injury with loss of consciousness or intracranial hemorrhage vii) Unstable or active psychiatric illness causing active psychosis, mania, depression , or suicidal ideation viii) Febrile illness ix) Benzodiazepine use disorder e) Evaluation confirming patient is an appropriate candidate for ambulatory management – able to self-monitor symptoms, take medications as directed, attend follow-up visits as instructed, etc. 4. If ordered for anxiety disorder management: a) No history of substance use disorder, misuse of medications, or depression b) Established contraindication/failure to using diazepam or clonazepam for this indication c) Adequate 8-12 week trial at a therapeutic dose of a serotonin reuptake inhibitor (SSRIs, SNRIs), or	○ Duration: 12 months once maintenance dose is established

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	contraindication to use 5. Initial approval Duration: a) Alcohol withdrawal syndrome treatment – only approve for the requested treatment regimen; max of #30 for a 4-day supply (25 mg capsules) b) Anxiety disorder management – 8 weeks	
crisaborole (**Eucrisa**) ointment 2% **STEP THERAPY**	1. Ordered for an approved indication for use: • Topical treatment of mild-to-moderate atopic dermatitis in adult and pediatric patients ≥ 3 months of age. 2. Step Therapy: **Unless patient age <2 years of age.** First must have completed a trial of, or have intolerance or contraindication to use **BOTH**: • 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 limited to 60 grams for a 30 day-supply or 180 grams for a 90 day supply. Additional quantity requests may be granted if the affected area is greater than 5% of body surface area (BSA). 4. Approval duration: 12 months	1. Patient has achieved or maintained a positive clinical response as evidenced by improvement or resolution of any of the following: • Erythema, edema, xerosis, erosions, excoriations, oozing and crusting, lichenification or pruritus. 2. Approval Duration: 12 months.
crizotinib (**Xalkori**) capsule 200mg, 250mg	1. Ordered for an approved indication for use: • the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test. • pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive.	1. Patient does not show evidence of progressive disease while on Xalkori therapy. 2. Approval Duration: 12 months.

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	• Ordered for treatment when the indication has been recognized by the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a category of Evidence and Consensus of 1, 2A, or 2B. **Non-Small Cell Lung Cancer (NSCLC):** • The cancer is either: metastatic, recurrent, or advanced. • The tumor is one of the following: o ALK-positive o ROS1-positive o Positive for mesenchymal-epithelial transition (MET) amplification o Positive for MET exon 14 skipping mutation **Soft Tissue Sarcoma/Uterine Neoplasms:** • Diagnosis of inflammatory myofibroblastic tumor (IMT); and • Presence of ALK translocation. **Histiocytic Neoplasms:** • Diagnosis of one of the following: o Erdheim-Chester Disease o Langerhans Cell Histiocytosis o Rosai-Dorfman Disesase • Used as targeted therapy ALK-fusion. **Central Nervous System (CNS) Cancers:** • Diagnosis of metastatic brain cancer from NSCLC; and • Tumor is ALK-positive OR ROS1-positive. **Anaplastic Large Cell Lymphoma:** • Tumor is ALK-positive; and	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	• Disease is relapsed or refractory **Melanoma:** • Diagnosis of metastatic or unresectable cutaneous melanoma; and • Disease is ROS1 gene fusion-positive; and • Used as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy. 2. Medication ordered by an Oncologist. 3. Approval Duration: 12 months.	
dabrafenib (**Tafinlar**) capsules 50mg, 75mg	1. Ordered for an approved indication for use: • treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test • adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection. • treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. • treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options. • Treatment of adult and pediatric patients ≥ 6 years of age with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.	**Limitations of use:** • Tafinlar is not indicated for treatments of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. • Tafinal is not indicated for treatment of patients with wild-type BRAF solid tumors • The indication for treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trials.

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	• Treatment of pediatric patients ≥ 1 year of age with low-grade glioma (LGG) with BRAF V600E mutation who require systemic therapy. 2. Medication ordered by an Oncologist 3. Approval duration: 12 months	
dalfampridine (Ampyra) ER tablets 10mg	1. Ordered for an approved indication for use: • To Improve walking in adult patients with multiple sclerosis (MS). 2. Patient age ≥ 18 years. 3. Patient is currently receiving therapy with an agent to reduce progression of multiple sclerosis. 4. Patient does not have history of seizure. 5. Patient has appropriate renal function; CrCl > 50 ml/min. 6. Must be able to walk 25 feet within 8 to 45 seconds at baseline. 7. Must have a baseline gait assessment by PT within 90 days of beginning Ampyra. 8. Limited to 2 tablets per day. 9. Medication ordered by a Neurologist. 10. **Initial approval for 3 months only** after 3 months, must show improvement in walking speed must be documented to obtain continued approval.	1. Improvement in walking speed as demonstrated by T25FW as compared with baseline. 2. Approval duration: 12 months.
daprodustat (**Jesduvroq**) tablets 1 mg, 2 mg, 4 mg, 6 mg, 8 mg	1. Ordered for an approved indication for use: • Treatment of anemia that is caused by chronic kidney disease (CKD) in adults who have been on dialysis for at least 4 months. 2. Patient age ≥ 18 years. 3. Patient on dialysis. 4. Pre-treatment hemglobin level is < 11 g/dL. 5. Serum transferrin saturation (TSAT) ≥ 20% within prior 3 months.	1. Can not increase dose more frequently than once every 4 weeks. 2. Serum transferrin saturation (TSAT) ≥ 20% within prior 3 months. 3. May not use concomitantly with other erythropoiesis stimulating agents. 4. After 24 weeks, if hemoglobin has not increased by ≥ 1 g/dL, then therapy should be discontinued and cannot be

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	6. Cannot use concomitantly with other erythropoiesis stimulating agents. 7. Maximum daily dose 24 mg per day. 8. Initial approval duration: 6 months.	approved. 5. Approval duration: 6 months.
darolutamide (**Nubeqa**) tablets 300mg	1. Ordered for an approved indication for use: • treatment of non-metastatic castration-resistant prostate cancer (mmCRPC). • Metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel. 2. Patient is ≥ 18 years of age, AND 3. The medication is concurrently used with docetaxel OR the patient has completed docetaxel therapy. 4. The patient meets ONE of the following: • The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) agonist, or • The medication is used concurrently with degarelix SQ injection; or • Patient has bilateral orchiectomy. 5. Medication ordered by an Oncologist or Urologist. 6. Approval Duration: 12 months.	1. Patient has not shown disease progression. 2. Patient has not experienced unacceptable toxicity. 3. Patient should also receive a GnRH analog concurrently OR have had a bilateral orchiectomy. 4. Treatment may continue even if a cycle of docetaxel is delayed, interrupted, or discontinued. 5. Approval Duration: 12 months.
denosumab (**Prolia**) injection 60mg/ml	1. Ordered for an approved indication for use: • treatment of postmenopausal women with osteoporosis at high risk for fracture. • treatment to increase bone mass in men with osteoporosis at high risk for fracture. • treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture. • treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. • treatment to increase bone mass in women at	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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	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. 7. Concomitant use of calcium and vitamin D supplement required. 8. For patients with advanced kidney disease (eGFR <30 mL/minute/1.73 m^2), including dialysis-dependent patients: evaluation for presence of chronic kidney disease-mineral disorder (CKD-MBD) must be completed prior to denosumab initiation. Treatment with denosumab in these patients should be supervised by a health care provider with expertise in the diagnosis and management of CKD-MBD. 9. Authorization duration: 12 months.	
dextromethorphan/quinidine (**Nuedexta**) tablets 10mg-20mg	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	1. Documentation of positive clinical response to therapy. 2. Authorization period is up to 12 months. **<u>Limitations of Use:</u>** The following indications are considered experimental and cannot be approved: • Heroin detoxification • Levodopa-induced Dyskinesia in

<table>
<tr><th>Generic Medication (Brand Name)
Bolded name indicates whether Brand or Generic is Formulary</th><th>Approval Criteria & Submission Requirements</th><th>Additional Considerations & Renewal Criteria</th></tr>
<tr><td></td><td>• Stroke
• Traumatic brain injury
4. The baseline Center for Neurologic Study-Lability Scale (CNS-LS) score must be > 13.
5. Dose must not exceed 2 capsules per day.
6. Prescribed by or in consultation with a neurologist.
7. Initial Authorization period is limited to 6 months.</td><td>Parkinson’s Disease
• Neuropathic pain
• Psychosis-Related Aggression
• Treatment Resistant Depression</td></tr>
<tr><td>diazepam nasal spray (Valtoco) doses:
5mg, 10mg, 15mg, 20mg doses</td><td>1. Ordered for an approved indication for use:
• Treatment of active seizures (non-status epilepticus) in patients diagnosed with a seizure disorder.
2. Patient age ≥6 and <12 years of age (if 12 years or older, Nayzilam [midazolam] is preferred for seizure treatment as it is provided as a flat dose).
3. Requested dose is appropriate based on current weight (dosing below is for children 6-11 years):
<table><tr><th>Weight (kg)</th><th>Dose (mg)</th></tr><tr><td>10 to <19</td><td>5 mg, as 1x 5mg device</td></tr><tr><td>19 to <38</td><td>10 mg, as 1x 10mg device</td></tr><tr><td>38 to <56</td><td>15 mg, as 2x 7.5mg devices</td></tr><tr><td>56 to 74</td><td>20 mg, as 2x10 mg devices</td></tr></table>Approval duration: 12 months</td><td>1. Initial approval criteria continue to be met.
2. Current patient weight is provided.
3. Requested dose is appropriate based on current weight.
Approval duration: 12 months</td></tr>
<tr><td>doxepin (Silenor) tablets

3 mg, 6 mg

STEP THERAPY</td><td>1. Ordered for an approved indication for use:
• To treat sleep-maintenance insomnia in adults ≥18 years old.
2. Patient has at least a 4-week trial of other formulary benzodiazepine receptor agonist (BZRA) medication (eszopiclone, zolpidem, temazepam) OR has a contraindication to using.</td><td>1. Patient has experienced clinical benefit of their insomnia symptoms based on recent clinical documentation.
2. Approval Duration: 12 months</td></tr>
</table>

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	• If the patient has a documented reason to avoid using a BZRA medication such as older age, cognitive dysfunction or concurrent opioid use, a precursor BZRA trial may be waived. 3. Quantity Limits: 1 tablet per day or prescribed strength 4. Approval Duration: 12 months	

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dupilumab (**Dupixent**) subcutaneous injection Pen-injector – 200 mg/1.14 ml Pen-injector – 300 mg/2 ml Prefilled syringe – 200mg/1.14 ml Prefilled syringe – 300 mg/2 ml	1. Prescribed for an FDA-approved indication for use. 2. The dosage and frequency requested are aligned with FDA and manufacturer guidelines for patient-specific parameters: • Patient age • Patient weight • Indication for use 3. The criteria for Dupixent are **indication specific**. Please review criteria for the patient-specific diagnosis. **<u>Atopic Dermatitis:</u>** • Diagnosis of moderate-to-severe chronic atopic dermatitis; **AND** • History of failure, contraindication, or intolerance to **TWO** of the following therapeutic **classes** of topical therapies (document drug, date of trial, and/or contraindication to medication). ○ Medium-high, or very-high potency topical corticosteroid (e.g. mometasone, fluocinolone acetonide, fluocinonide).	Renewal criteria are indication specific. Please review criteria for the patient-specific diagnosis. **<u>Atopic Dermatitis:</u>** • Documentation of a positive clinical response to therapy; **AND** • Patient is not Dupixent concurrent with either of the following: ○ Biologic immunomodulator (e.g., Adbry (tralokinumab-ldrm), Ebglyss (lebrikizumab), etc.) ○ Janus kinas inhibitor (e.g., Rinvoq (Upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib); **AND** • Prescribed by a Dermatologist, Allergist, or Immunologist.

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	○ Topical calcineurin inhibitor (e.g., tacrolimus or pimecrolimus). ○ Phosphodiesterase-4 Enzyme Inhibitor, e.g. Zoryve (roflumilast), Eucrisa (crisaborole); **AND** • Patient is not receiving Dupixent concurrent with either of the following: ○ Biologic immunomodulator (e.g., tralokinumab-ldrm); ○ Janus kinas inhibitor (e.g., Ebglyss (lebrikizumab), Rinvoq (Upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib) • **UNLESS** Patient has ≥ 25% skin involvement and topical management is not feasible. • Prescribed by or a Dermatologist, Allergist or Immunologist. • Approval Duration: 12 months. **Asthma, moderate to severe eosinophilic:** • Diagnosis of moderate-to-severe asthma; **AND** • Classification of asthma as uncontrolled or inadequately controlled as defined by at least **ONE** of the following: ○ Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently > 1.5 or Asthma Control Test [ACT] score consistently < 20. ○ Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months ○ Asthma-related emergency treatment (e.g., ER visit, hospital admission, or	• Approval Duration: 12 months. **Asthma:** • Documentation of positive 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 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,

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	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 defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level ≥ 150 cells/µL; **OR** ○ Patient is currently dependent on oral corticosteroids for the treatment of asthma; **AND** ○ Dupixent will be used in combination with **ONE** of the following: ▪ On maximally dosed combination inhaled ICS/LABA inhaler (e.g., Advair, AirDuo, Symbicort, Breo, etc); OR ○ Combination therapy including **BOTH** of the following: ▪ One maximally dosed ICS product (e.g. Alvesco, Asmanex, Qvar, etc); **AND** ▪ One additional asthma controller medication (e.g., LABA, montelukast or theophylline); **AND**	resilizumab, benralizumab); Anti-IgE therapy (e.g. omalizumab); and/or Thymic stromal lymphopoietin (TSLP) inhibitor (e.g. Tezepelumab); **AND** • Prescribed by an Allergist, Immunologist, or Pulmonologist. • Approval Duration: 12 months. **<u>Chronic Obstructive Pulmonary Disease (COPD)</u>** • Documentation of positive clinical response to therapy as defined by at least **<u>one</u>** of the following criteria: ○ A reduction in moderate exacerbations (i.e., those requiring systemic steroids and/or antibiotics). ○ A reduction of severe exacerbations (i.e. those requiring hospitalization and requiring more than one day of observation in an emergency department or urgent care facility). ○ An improvement in baseline lung function as assessed by pre-bronchodilator forced expiratory volume (FEV1).

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

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

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	▪ Patient has required systemic corticosteroids for CRSwNP in the previous 2 years ▪ Patient has been unable to obtain symptom relief after trial of **TWO** of the following classes of agents: ➢ Nasal saline irrigations ➢ Intranasal corticosteroids ➢ Antileukotriene agents; **AND** • Patient will receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids; **AND** • Patient is **NOT** receiving Dupixent in combination with **ANY** of the following: o Anti-interleukin-5 therapy (e.g. mepolizumab, resilizumab, benralizumab); o Anti-IgE therapy (e.g. omalizumab); and/or o Thymic stromal lymphopoietin (TSLP) inhibitor (e.g. Tezepelumab); **AND** • Prescribed by an Allergist, an Immunologist, an Otolaryngologist, or a Pulmonologist. • Approval Duration: 12 months. **<u>Eosinophilic Esophagitis:</u>** • Diagnosis of Eosinophilic Esophagitis; **AND** • Patient aged ≥ 2 years of age; **AND** • Patient is experiencing symptoms related to esophageal dysfunction (e.g., dysphagia, food impaction, chest pain that is centrally located and may not respond to antacids, gastroesophageal reflux disease-like symptoms/refractory heartburn, upper abdominal pain); **AND**	

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	• Submission of clinical documentation indicating eosinophil-predominant inflammation on esophageal biopsy, consisting of a peak value of ≥15 intraepithelial eosinophils per high-power field (HPF) or 60 eosinophils per mm^2; **AND**
	• Secondary causes of esophageal eosinophilia have been ruled out; **AND**
	• Mucosal eosinophilia is isolated to the esophagus and symptoms have persisted after an 8-week trial of at least **ONE** of the following:
	  ○ Proton pump inhibitor
	  ○ Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone); **AND**
	• Patient is **not** receiving Dupixent in combination with any of the following:
	  ○ Anti-interleukin-5 therapy (e.g. mepolizumab, resilizumab, benralizumab);
	  ○ Anti-IgE therapy (e.g. omalizumab); and/or
	  ○ Thymic stromal lymphopoietin (TSLP) inhibitor (e.g. Tezepelumab); **AND**
	• Prescribed by either a Gastroenterologist or Allergist.
	• Approval Duration: 6 months.
	<u>Prurigo Nodularis</u>
	• Diagnosis of prurigo nodularis; **AND**
	• Patient has ≥ 20 nodular lesions; **AND**
	• History of failure, contraindication, or intolerance to previous prurigo nodularis treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin); **AND**
	• Patient is not receiving Dupixent with **EITHER** of the following:	

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	○ Biologic immunomodulator (e.g. Adbry); **OR** ○ Janus kinase inhibitor (e.g., Rinvoq, Xeljanz/XR, Opzelura, Cibinqo); **AND** • Prescribed by a Dermatologist, Allergist, or Immunologist. 2. Approval Duration: 6 months.	
eculizumab (**Soliris**) injection – 300mg/30ml	1. Ordered for an approved indication for use: • treatment of adult and pediatric patients ≥ 1 month of age with paroxysmal nocturnal hemoglobinuria (PNH). • treatment of adult and pediatric patients ≥ 1 month of age with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA). • treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR+) antibody positive. • treatment of neuromyelitis optica spectrum disorder (NMOSD). 2. FDA approved patient age. 3. Documentation to support diagnosis: **PNH:** • Flow cytometric confirmation of PNH type III red cells; AND ○ Patient had at least one transfusion in the preceding 24 months; OR ○ Documented history of major adverse thrombotic vascular events from thromboembolism; OR ○ Patient has high disease activity defined as lactic dehydrogenase (LDH) level ≥ 1.5	1. Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit. 2. **PNH:** • Age ≥ 18 years • Decrease in serum LDH from pre-treatment baseline. • NO dual therapy with another PA medication for PNH (e.g., Empaveli or Ultomiris). **aHUS:** • Decrease in serum LDH from pre-treatment baseline. • Patient does not have Shiga toxin E.coli related hemolytic uremic syndrome (STEC-HUS). • NO dual therapy with another PA medication for aHUS (e.g., Ultomiris). **gMG**: • Age ≥ 18 years • Improvement and maintenance of at least a 2-point improvement

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	times the upper limit of normal with one of the following symptoms: weakness, fatigue, hemoglobinuria, abdominal pain, dyspnea, hemoglobin, 10 g/dL, a major vascular event, dysphagia, or erectile dysfunction. • History of failure to/contraindication or intolerance to Empaveli therapy; • Patient age < 18 years or currently pregnant. **aHUS:** • Common causes of aHUS have been ruled out, including infectious causes of HUS and thrombotic thrombocytopenic purpura (TTP). • Ultomiris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). • Must present with the following symptoms: ○ Hemoglobin < 10 g/dL ○ Platelets, 150,000/mm^3 ○ Documented evidence of hemolysis, such as elevated LDH levels, decreased haptoglobin level or schistocytosis. ○ Increased serum creatinine OR currently undergoing dialysis. **gMG:** • Patient has not failed previous course of Soliris or Ultomiris therapy; • Positive serologic test for anti-AChR antibodies; AND • One of the following: ○ History of abnormal neuromuscular transmission test demonstrated by single-	(reduction) in the MG-ADL score from pre-treatment baseline and reduction of signs and symptoms of MG required to show clinical benefit. • **NOTE:** dose escalation of immunosuppressive therapy, or additional rescue therapy from baseline to treat MG or exacerbation of symptoms during use is considered treatment failure. • Not receiving in combination with Empaveli or Ultomiris. **NMOSD:** • Documentation to demonstrate positive clinical response from baseline as demonstrated by both of the following: • Reduction in the number and/or severity of relapses or signs and symptoms of NMOSD; and • Maintenance, reduction or discontinuation of dose(s) of any baseline immunosuppressive therapy prior to starting Soliris. • **NOTE:** dose escalation of immunosuppressive therapy, or additional rescue therapy from baseline to treat MG or exacerbation of symptoms during

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	fiber electromyography (SFEMG) or repetitive nerve stimulation OR ○ History of positive anticholinesterase test (e.g. edrophonium chloride test) OR ○ Pt has demonstrated improvement in MG signs on oral cholinesterase inhibitors as assessed by the treating neurologist; AND • Patient has MGFA clinical classification of II, III, or IV at initiation of treatment; AND • Patient has Myasthenia gravis-specific activities of daily living scale (MG-ADL) total score ≥ 6 at initiation of treatment; AND • One of the following: ○ History of failure to at least two immunosuppressive agents over the previous 12-months (e.g., azathioprine, mtx, cyclosporing, mycophenolate); OR ○ History of failure to at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges, and/or intravenous immune globulin over the previous 12 months without symptom control **NMOSD:** • Documentation to support diagnosis of NMOSD by a neurologist confirming: ○ Optic neuritis; or ○ Acute myelitis; or ○ Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting; or	use is considered treatment failure. • Not receiving Soliris therapy in combination with any of the following: Disease modifying therapies for the treatment of MS (e.g., Gilenya, Tecfidera, Ocrevus, etc.); Anti-IL6 therapy (e.g., Actemra, Enspryng), B-cell depletion therapy (e.g., rituximab, Uplizna). 3. Approval Duration: 3 months.

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	○ Acute brainstem syndrome; or ○ Symptomatic cerebral syndrome with NMOSD-typical brain lesions; AND • Positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies; and • Diagnosis of multiple sclerosis or other diagnoses have been ruled out; and • Patient has not failed a previous course of Soliris therapy; and • History of failure of, contraindication, or intolerance to rituximab therapy; and • History of at least two relapses in the previous 12-months; or • History of at least three relapses during the previous 24-months, at least one relapse withing the previous 12-months; and • Not receiving Soliris therapy in combination with any of the following: Disease modifying therapies for the treatment of MS (e.g., Gilenya, Tecfidera, Ocrevus, etc.); Anti-IL6 therapy (e.g., Actemra, Enspryng), B-cell depletion therapy (e.g., rituximab, Uplizna). 4. Recommended vaccinations at least 2 weeks prior to administration of first dose Soliris. 5. Cannot be used in combination with other medications in the same class, such as Ultomiris. 6. Medication ordered by Hematologist, Nephrologist, or Oncologist. 7. Approval Duration: 3 months	

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elacestrant (**Orserdu**)	1. Ordered for an approved indication for use: • Treatment of postmenopausal women or adult men, with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy. 2. For patient aged < 19 years of age: • If criteria in #1 are met, approval shall be granted for 12 months. For patients ≥ 19 years of age: • Diagnosis of breast cancer that is either advanced or metastatic. • The cancer is ER+, HER2(-) and has a confirmed *ESR1* gene mutation. • Patient is either male or a postmenopausal female. • Disease has progressed following at least one line of endocrine therapy. 3. Authorization Duration: 12 months.	1. Patient does not show evidence of progressive disease while on Orserdu therapy. 2. Approval Duration: 12 months.
elagolix, estradiol, and norethindrone acetate (**Oriahnn**) capsules 300mg/1mg/0.5mg	1. Ordered for an approved indication for use: • the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. 2. The patient is biologically female and premenopausal. 3. Negative pregnancy test result. 4. Must have tried and failed or have a contraindication to using: • Combined estrogen/progestin-containing contraceptives (oral pills, transdermal patch, vaginal ring); OR	**Renewal Criteria:** 1. Patient continues to meet initial approval clinical criteria. 2. Approval Duration: up to 12 months, to allow the patient to reach the maximum lifetime duration of 24 months. **Limitations of use:** Due to risk of bone density loss that may not be reversible following discontinuation, limit duration of treatment to 24 months.

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	• Levonorgestrel-releasing intrauterine device (IUD; e.g. Kyleena, Liletta, Mirena, Skyla); OR • Progestin-only oral contraceptive pills; OR • Tranexamic acid capsules. 5. Confirmation the patient does not have any contraindication to use Oriahnn: history of thrombotic/thrombolic disorders and women at increased risk of these events, including women > 35 years who smoke and women with uncontrolled hypertension. 6. The patient has not exceeded 24 cumulative months of treatment with an elagolix-containing medicine (e.g. Oriahnn, Orilissa) or a relugolix-containing medicine (e.g. Myfembree). 7. The patient is not concurrently using another gonadotropin-releasing hormone (GnRH) antagonist medicine (Orilissa, Myfembree) 8. Approval Duration: • 12 months; OR • The remaining duration to equal 24 months of cumulative therapy as listed in criteria #6, if less than 12 months remain.	
elexacaftor, ivacaftor, and tezacaftor (**Trikafta**) tablets Therapy Pack	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.	
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. • 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	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. 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

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	condition increase the risk for bleeding and should not be used in an attempt to normalize platelet counts. **Chronic Immune Thrombocytopenia (ITP):** 1. Diagnosis of ITP; AND 2. Patient has had an insufficient response to a previous treatment (e.g. corticosteroids, immunoglobulins, thrombopoietin receptor agonists, splenectomy). 3. Pre-treatment platelet counts. 4. Untransfused platelet count at any point prior to the initiation of Promacta less than $30*10^9$/L or $30*10^9$/L to $50*10^9$/L with symptomatic bleeding (e.g. significant mucous membrane bleeding, GI bleeding or trauma) or risk factors for bleeding. 5. Ordered by or in consultation with a hematologist or oncologist. 6. Approval Duration: 6 months. **Chronic Hepatitis C-associated Thrombocytopenia:** 1. Diagnosis of chronic hepatitis C-associated thrombocytopenia; AND 2. One of the following: • 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. **Aplastic Anemia:** 1. Diagnosis of severe aplastic anemia; AND 2. Patient aged ≥ 2 years; AND 3. ONE of the following: • Used in combination with standard immunosuppressive therapy (e.g., Atgam	$50*10^9$/L to $200*10^9$/L, OR • patients with current platelet count > $200*10^9$/L to ≤ $400*10^9$/L for whom dosing Promacta will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding. **Chronic Hepatitis C-associated Thrombocytopenia:** 1. Documentation of positive clinical response to Promacta; AND 2. Patient is currently on antiviral interferon therapy for treatment of chronic hepatitis C. 3. Approval Duration: 6 months **Aplastic Anemia:** 1. Documentation of positive clinical response to Promacta. 2. Current platelet counts. 3. Approval Durations: • Up to 4 months total for patients with current platelet counts less than $50*10^9$/L who have not received appropriately titrated therapy with Promacta for at least 16 weeks. • Up to 4 months total for patients with current platelet counts < $50*10^9$/L who are transfusion-independent. • 12 months for patient with current platelet counts of $50*10^9$/L to $200*10^9$/L. • 12 months for patients with current

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	[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.	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.
enzalutamide (**Xtandi**) tablets 80mg	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).

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etrasimod (**Velsipity**) tablets 2 mg	1. Ordered for an approved indication for use: • Treatment of ulcerative colitis (UC), in adults with moderately to severely active disease. 2. Patient is ≥ 18 years of age. 3. Patient has had a trial of one systemic agent for ulcerative colitis. (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone). Note: a trial of one biologic is considered a trial of systemic agent for ulcerative colitis. 4. Patient is not being treated concurrently with a biologic or targeted synthetic disease-modifying antirheumatic drug (DMARD) for UC. (e.g., adalimumab, infliximab, sarilumab, abatacept, rituximab, mirkizumab, ustekinumab, apremilast, ozanimod, or similar). 5. Medication is prescribed by or in consultation with a gastroenterologist. 6. Initial Approval Duration: 12 months.	1. Patient exhibits a positive clinical response by at least one objective measure from baseline. (e.g., fecal calprotectin levels, C-reactive protein, endoscopic assessment, and/or decreased utilization of corticosteroids **OR** 2. Patient has a documented clinical improvement in at least one subjective measure from baseline (e.g., decreased pain, fatigue, stool frequency, and/or rectal bleeding). 3. Approval duration: 12 months.
evinacumab-dgnb (**Evkeeza**) injection 345mg/2.3ml, 1200mg/8ml	1. Ordered for an approved indication for use: • An adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, ≥ 12 years of age, with homozygous familial hypercholesterolemia (HoFH). 2. Documented genetic test confirming homozygous familial hypercholesterolemia (HoFH).	1. Meets all initial criteria 2. Must provide documentation of laboratory information to support continued use (full lipid panel) and continued use of concurrent therapies to lower cholesterol 3. Renewal Approval Duration: 3 months

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	3. Baseline laboratory information required (full lipid panel, genetic testing, negative pregnancy test and documentation of use/counseling regarding contraception to prevent pregnancy 4. Prior trial/failure and/or documented intolerance to one high potency statin (atorvastatin, rosuvastatin) and concurrent ezetimibe. • Must provide laboratory data to support failure/intolerance (full lipid panel, creatinine kinase). • If failure, but no intolerance, lipid lowering therapy should be continued with aa statin and/or ezetimibe. 5. Dosing 15 mg/kg IV every 4 weeks. 6. Initial Approval Duration: 6 months.	
factor VIIa, recombinant human (**NovoSeven RT**) injection 1mg, 2mg, 5mg, 8mg	1. Ordered for an approved indication for use: • treatment of bleeding episodes and perioperative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets. • treatment of bleeding episodes and perioperative management in adults with acquired hemophilia. 2. Diagnosis of congenital factor VIII deficiency confirmed by blood coagulation testing. 3. Confirmation that patient has acquired inhibitors to Factor VIII 4. Used as treatment in at least one of the following: • Control and prevention of acute bleeding episodes; or	1. Patient continues to meet indication-specific criteria 2. Absence of unacceptable toxicity from drug; and 3. Any dose increases must be supported by an acceptable clinical rationale (i.e., weight gain, half-life study results, increase in break-through bleeding when patient is fully adherent to therapy, etc). 4. The cumulative amount of medication that the patient has on-hand will be considered. The authorization will allow up to 5 doses on hand for the treatment of acute bleeding episodes as needed for the duration of the authorization.

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	• Perioperative management; or
	• Routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the following criteria are also met:
	  ○ Patient has at least two documented episodes of spontaneous bleeding into joints; or
	  ○ Patient has documented trial and failure of Immune Tolerance Induction (ITI).
	5. When ordered for Hemophilia B:
	• Diagnosis of congenital Factor IX deficiency has been confirmed by blood coagulation testing; and
	• Confirmation that patient has acquired inhibitors to Factor IX.
	6. When ordered for Congenital Factor VII Deficiency:
	• Diagnosis confirmed by blood coagulation testing.
	7. When ordered for Glanzmann's Thromboasthnia:
	• Diagnosis confirmed by blood coagulation testing; and
	• The use of platelet transfusions is known or suspected to be ineffective or contraindicated.
	8. Medication ordered by a Hematologist.
	9. Approval Duration:
	• For perioperative management of bleeding: 1 month.
	• All other indications: up to 3 months.
		5. Renewal duration: 3 months.

factor VIII, recombinant human pegylated (**Jivi**) injection 500 unit, 1000unit, 2000unit, 3000unit	1. Ordered for an approved indication for use: • On-demand treatment and control of bleeding episodes in adults and adolescents ≥ 12 years of age with hemophilia A. • Perioperative management of bleeding.	1. Documentation of positive clinical response to Jivi therapy. 2. Authorization Duration: 12 months.

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	• Routine prophylaxis to reduce the frequency of bleeding episodes. 2. Patient has previously received Factor VIII replacement therapy. 3. Not for the treatment of von Willebrand disease. 4. Medication ordered by a Hematologist. 5. Authorization Duration: 12 months.	
fecal microbiota capsules, oral (**Vowst**)	1. Ordered for an approved indication for use: • To prevent recurrence of *Clostridioides difficile* infection (CDI) in individuals ≥ 18 years of age following antibacterial treatment for recurrent CDI. 2. Patient has had three or more episodes of CDI within previous 12 months (including most recent episode). 3. Patient has recent episode of recurrent CDI with all of the following: o At least 3 unformed stools per day for 2 consecutive days o Stool test confirming the presence of *C. difficile* toxin or toxigenic *C. difficile.* o An adequate clinical response (i.e., resolution of symptoms) following standard of care antibiotic therapy (e.g., vancomycin + metronidazole, fidaxomicin) 4. Patient does not have ANY of the following: o Known or suspected toxic megacolon and/or known small bowel ileus OR o Admitted to, or expected to be admitted to an ICU for medical reasons, OR o Absolute neutrophil count < 500 cells/mL[3]	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 to treat CDI.

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	○ History of major GI surgery within 3 months before treatment start (not including appendectomy or cholecystectomy) OR ○ History of total colectomy or bariatric surgery that disrupted the GI lumen OR ○ History of active inflammatory bowel disease (e.g. ulcerative colitis, Crohn's disease, microscopic colitis) with diarrhea believed to be cause by active inflammatory bowel disease in the past 3 months. ○ History of fecal microbiota transplantation (FMT) within 3 months 5. The patient will not be using the requested agent in combination with Rebyota or Zinplava for the requested indication. 6. Provider attests that patient will follow the bowel preparation protocol outlined in the package insert. 7. Patient will not be taking a concurrent antibiotic. 8. Prescribed by or in consultation with an infectious disease specialist. 9. Approval is limited to 12 capsules per dispense; maximum of 24 capsules lifetime.	
fentanyl (Duragesic) transdermal patch 12mcg/hr, 25mcg/hr, 37.5mcg/hr, 50mcg/hr, 62.5mcg/hr, 75mcg/hr, 87.5mcg/hr, 100mcg/hr	1. Ordered for an approved indication for use: • 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	• All long-acting opioids require prior authorization (PA). The PA request form can be access using the following links: OPIOID PRIOR AUTH FORM-DC

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	per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid. 2. Fully completed opioid PA form submitted. 3. Submission of clinical documentation from last office visit, dated within 3 months of the request. 4. Maximum approval duration is 6 months but may be reduced based on any of the criteria as outlined in Pharmacy Policy 219.DC Opioid Prescription Prior Authorization.	
fezolinetant **(Veozah)** tablets 45mg	1. Ordered for an approved indication for use: • Treatment of moderate to severe vasomotor symptoms due to menopause. 2. Patient must be a perimenopausal or post-menopausal female 3. Documentation of baseline bloodwork to evaluate for hepatic function and injury including ALT, AST and serum bilirubin (total and direct) before initiation of treatment. 4. Provider attests to monitoring liver function tests at 3-months, 6-months, and 9-months after starting therapy. 5. Patient must not have cirrhosis. 6. Patient does not have severe renal impairment (GFR < 30 ml/min) or end-stage renal disease. 7. The medication must not be used concomitantly with CYP1A2 inhibitors (e.g., acyclovir, allopurinol, amiodarone, cimetidine, clarithromycin, duloxetine, famotidine, fluoroquinolones, fluvoxamine, mexiletine, oral contraceptives, verapamil, zafirlukast, zileuton). 8. Patient must have treatment failure, intolerance, or contraindication to at least one menopausal	**Renewal Criteria:** 1. All criteria listed for initial approval AND: 2. Documented improvement of symptoms 3. Documentation of liver function tests monitoring during first year of treatment with labs within previous 3 months. 4. Renewal duration: 12 months

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	hormone therapy. 9. Initial approval period: 9 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: • 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 at least one formulary SGLT2i. 4. Approval Duration: 3 months	1. All initial criteria for approval; AND 2. Dosing appropriate based on 4-week potassium laboratory check. • 20 mg daily if Potassium ≤ 4.8 • 10 mg daily if K+ between 4.8-5.5 • Interrupt therapy if K+ > 5.5, may restart at 10 mg daily when potassium is ≥ 5.0 3. Approval duration: 12 months
fosdenopterin (**Nulibry**) injection 9.5mg	1. Ordered for an approved indication for use: • To reduce mortality risk in patients with molybdenum cofactor deficiency (MoCD) Type A. • Diagnosis confirmed by genetic testing. 2. Will not be used in combination with other substrate replacement therapy (e.g., recombinant cyclic pyranopterin monophosphate, etc.); AND 3. Must be prescribed by, or in consultation with, a specialist in medical genetics or pediatric neurology. 4. Diagnosis of MoCD Type A is confirmed by molecular genetic testing, by a mutation in the *MOCS1* gene suggestive of disease. 5. Patient has biochemical features suggestive of MoCD	1. Patient continues to meet initial approval criteria as listed. 2. Absence of unacceptable toxicity from the drug (e.g., severe phototoxicity, clinically significant infection). 3. Disease response compared to pre-treatment baseline as evidenced by the following: • Reduction in urinary SSC normalized to creatinine; and • Stabilization or improvement in one or more signs and

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	Type A (i.e., elevated sulfites in urine, low serum uric acid, elevated urinary xanthine and hypoxanthine) and will be treated presumptively while awaiting genetic confirmation; and 6. Patient has baseline values for the following: • Elevated urinary s-sulfocysteine (SSC) normalized to creatinine; and • Clinical notes regarding signs and symptoms of disease which may include, but are not limited to, seizure frequency/duration, growth, and developmental milestones. 7. Approval Duration: 3 months	symptoms of disease including, but not limited to, seizure frequency/duration, growth, achievement of developmental milestones; OR 4. Patient initiated therapy as an inpatient based on presumptive diagnosis of MoCD Type A which was subsequently confirmed by genetic testing; AND patient is responding to therapy compared to one or more pre-treatment baseline parameters which prompted the workup for MoCD. 5. Approval Duration: 3 months
fostamatinib disodium hexahydrate (**Tavalisse**) tablets 100mg, 150mg	1. Ordered for an approved indication for use: • the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) when a prior treatment for ITP has not worked well enough. 2. Patient age ≥ 18 years. 3. Patient is not on hemodialysis. 4. Max dose: 150 mg 2 times daily with goal platelets ≥ 50 x 10^9/mmcp/L. 5. Medication ordered by a Hematologist. 6. Initial Approval Duration: 3 months.	1. Documentation of improved symptoms and attestation of lab parameters. 2. Renewal approval duration: 12 months
furosemide subcutaneous injection device (**Furoscix**) 80mg/10ml	1. Ordered for the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure. 2. Patient has CrCl > 30 ml/min OR eGFR > 20 ml/min 3. Patient has been stable and is refractory to at least one of the following loop diuretics, at up to maximally indicated doses:	**Limitations of Use:** • Furoscix is not indicated for emergency situations or in patients with acute pulmonary edema. • The On-Body Infusor will deliver only an 80-mg dose of Furoscix. • Patients must meet initial approval criteria for each request

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	○ Furosemide oral tablets; 40-160 mg/day ○ Torsemide oral tablets; 50-100 mg/day ○ Bumetanide oral tablets; 3-10 mg/day 4. Documentation that member is a candidate for parenteral diuresis outside of the hospital, as defined by all of the following: ○ Oxygen saturation ≥ 90% on exertion ○ Respiratory rate < 24 breaths per minute ○ Resting heart rate < 100 beats per minute ○ Systolic blood pressure > 100 mmHg 5. Patient does not have anuria 6. Patient does not allergy to medical adhesives or furosemide. 7. Patient does not have hepatic cirrhosis or ascites. 8. Dose does not exceed 80 mg (1 cartridge) per day. 9. Prescribed by cardiologist 10. Limited to 8 kits every 30 days 11. Approval requires that patient is referred for MFC Case Management 12. Authorization Duration: 3 months	
gabapentin extended-release (Gralise) tablets 300mg, 600mg **note, this is not the same as gabapentin enacarbil which is non-formulary.*	1. Ordered for an approved indication for use: • the management of Postherpetic Neuralgia (PHN). Not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect dosing frequency. 2. Patient age ≥ 18 years. 3. Patient CrCl > 30 ml/min; patient is not on hemodialysis. 4. Dose does not exceed 1800 mg per day. 5. Approval Duration: 12 months	1. Initial criteria continue to be met. 2. Approval duration: 12 months.
gilteritinib (**Xospata**) tablets	1. Ordered for an approved indication for use:	•

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40mg	• the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test. 2. Medication ordered by an Oncologist	
glycopyrronium (**Qbrexza**) pad 2.4%	1. Ordered for an approved indication for use: • topical treatment of primary axillary hyperhidrosis in adults and pediatric patients ≥ 9 years of age. 2. Patient age ≥ 9 years. 3. Must have tried and failed OTC Clinical Strength antiperspirants and at least one prescription strength antiperspirant (ex: Drysol or Xerac AC) for at least 4 weeks and experienced inadequate efficacy 3. Documentation that symptoms are persistent despite previous treatment attempts and that the degree of symptomatology impacts quality of life must be clearly indicated in a recent (within past 6 months) clinical encounter note. 4. Qbrexza will only be applied to the axillae, and is not being used on other areas of the body. 5. Patient does not have any of the following conditions: • Glaucoma • Paralytic ileus • Unstable cardiovascular status in acute hemorrhage • Severe ulcerative colitis • Toxic megacolon • Myasthenia gravis • Sjogren's syndrome 6. Limited to 30 cloths per 30 days. 7. Approval Duration: 12 months.	1. Patient has demonstrated benefit with Qbrexa. 2. Patient continues to meet initial approval criteria. 3. Approval Duration: 12 months
goserelin (**Zoladex**) implant	1. Ordered for an approved indication for use:	**<u>Endometriosis:</u>**

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3.6mg, 10.8mg	• palliative treatment of advanced carcinoma of the prostate. (3.6 mg and 10.8 mg) • in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. (3.6 mg and 10.8 mg) • management of endometriosis (3.6 mg) • palliative treatment of advanced breast cancer in pre- and peri-menopausal women. (3.6 mg) • to cause endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. (3.6 mg) • management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. **Endometriosis:** 1. Contraindication, intolerance, or failure of initial treatment to BOTH of the following: • Oral contraceptives or depot medroxyprogesterone; AND • Non-steroidal anti-inflammatory drugs; OR • Patient has had surgical ablation to prevent recurrence. 2. Approval Duration: Limited to 6 months. **Endometrial Thinning/Dysfunctional Uterine Bleeding:** 1. For use prior to endometrial ablation; AND 2. Other causes of symptoms of bleeding are ruled out; AND 3. Patient has been prescribed the 3.6 mg implant; AND 4. Approval duration is for a maximum of 2 depots. **Fertility Preservation:** Clinical studies do not support use for this indication,	• Can not be administered for more than 6 months lifetime maximum. **Endometrial thinning:** • Can not be administered for more than 6 months lifetime maximum. **Fertility Preservation:** • Patient currently receiving GnRH analog therapy for purpose of fertility preservation; and • Patient continues to receive a cytotoxic agent associated with primary ovarian insufficiency; and • Authorization duration: 12 months **Gender Affirming Care – Adolescents** **OR** **Gender Affirming Care – Transgender Adults:** • Approval Duration: 12 months.

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	and cryopreservation is clinically preferred. Please attempt to redirect to cryopreservation. Only clinically appropriate as a potential adjunct to cryopreservation. May be medically necessary for treatment of fertility preservation when both of the following criteria are met: • Patient is a pre-menopausal female. • Patient is receiving a cytotoxic agent associated with causing primary ovarian insufficiency, e.g., cyclophosphamide, procarbazine, vinblastine, cisplatin. • Approval Duration: 12 months. **Gender Affirming Care – Adolescents** 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. 2. Approval Duration: 12 months	
ibrutinib (**Imbruvica**) capsules 140mg	1. Ordered for an approved indication for use: • Chronic lymphocytic leukemia (CLL) in adult patients who have received at least one prior therapy. • CLL in Adult patients with 17p deletion. • Waldenström's macroglobulinemia in adult patients • Adult and pediatric patients ≥ 1 year of age with chronic graft versus host disease after failure of one or more lines of systemic therapy.	**Limitations for use:** • Indications for Mantle Cell Lymphoma and Marginal Zone Lymphoma were voluntarily withdrawn, April 2023 **New dose modification guidelines adopted in December 2022:** 1. Therapy should be withheld for any new onset or worsening Grade 2 cardiac failure or Grade 3 cardiac arrhythmia. Once symptoms have

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	2. Medication ordered by an Oncologist. 3. Quantity limit: 4 tablets per day.	resolved to Grade 1 cardiac failure or Grade 2 or lower cardiac arrhythmia, Imbruvica can be restarted at recommended adjusted doses.
icatibant acetate (Firazyr) injection 30mg/3ml	1. Ordered for an approved indication for use: • treatment of acute attacks of hereditary angioedema (HAE) in adults ≥ 18 years of age. 2. Patient age ≥ 18 years. 3. Prescribed for the treatment of acute HAE attacks. 4. Member has a C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets one of the following: 3. 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 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	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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	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) capsules (Vascepa) 0.5gm, 1gm	1. Ordered for an approved indication for use: • As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) AND ○ Established cardiovascular disease OR ○ Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease • As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. 2. Age ≥ 45 years 3. Diagnosis of hypertriglyceridemia (pre-treatment TG level ≥ 150 mg/dl) AND 4. Patient is considered high or very high risk for cardiovascular disease (CVD) as evidenced by **one** of the following: ○ Acute coronary syndrome ○ History of myocardial infarction ○ Stable or Unstable angina ○ Coronary or other arterial revascularization ○ Stroke ○ Transient ischemic attack ○ Peripheral arterial disease	**Renewal Criteria:** • Used for cardiovascular risk reduction • Documentation of positive clinical response to therapy • Patient is receiving maximally tolerated statin therapy. • Approval duration: 12 months

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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 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.	

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idecabtagene vicleucel (**Abecma**) injection	1. Ordered for an approved indication for use: • To treat relapsed or refractory multiple myeloma in adults after ≥4 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. 2. Lymphodepleting chemotherapy (with fludarabine and cyclophosphamide) is ordered for administration for 3 days followed by Abecma dose infusion 2 days after completion of lymphodepleting therapy. 3. Diagnosis of relapsed or refractory multiple myeloma (MM) 4. Age ≥ 18 years 5. Must have received at least 4 prior MM therapies (induction with or without hematopoietic stem cell transplant with or without maintenance therapy is considered a single regimen) 6. Must have received an immunomodulatory drug (iMiD), proteasome inhibitor (PI), and an anti-CD38 antibody 7. ECOG performance status of 0 or 1 8. HBV, HCV, and HIV screening within previous 30 days. 9. Provider attestation: Drug specific baseline evaluation and monitoring completed according to package insert (CBC/CMP, screening for HBV, hepatitis C, HIV), patient is not pregnant and is using effective contraception, counseling/assessment of recent live vaccine use. 10. Monitor immunoglobulin levels, blood counts, and for cytokine release syndrome during and after therapy.	**Limitations of use:** • Will be approved for ONE treatment dose. • Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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	11. Medication ordered by Hematologist or Oncologist enrolled in ABECMA REMS and compliance with REMS program criteria.	
immune globulin subcutaneous (human) (**Cutaquig**) solution 1gm/6ml, 1.65gm/10ml, 2gm/12ml, 3.3gm/20ml, 4gm/24ml, 8gm/48ml	1. Ordered for an approved indication for use: • Replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients ≥ 2 years of age. • Prevention of bacterial infection in patients with hypogammaglobulinemia and/or recurrent bacterial infections with malignancy (e.g., B-cell chronic lymphocytic leukemia) or primary humoral immunodeficiency disorders. 2. Medication ordered by an Immunologist.	
inavolisib (**Itovebi**) tablets	**USE MFC High-Cost Medication PA Criteria**	
interferon gamma-1b (**Actimmune)** injection 2 million IU/0.5ml	2. Ordered for an approved indication for use: • To reduce frequency and severity of serious infections associated with chronic granulomatous disease (CGD). • To delay time to disease progression in patients with severe, malignant osteopetrosis (SMO). 3. Patient age is less than 19 years. 4. When prescribed for: • Chronic Granulomatous Disease (CGD); • Osteopetrosis; or • Primary Cutaneous Lymphomas when the patient has a diagnosis of: o Mycosis fungoides (MF) or o Sezary Syndrome (SS) 5. Approval Duration: 3 months.	2. Patient does not show evidence of progressive disease while on Actimmune. 3. Reauthorization is for 3 months. 4. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
ivacaftor (**Kalydeco**) tablets 150mg	1. Ordered for an approved indication for use: • Treatment of cystic fibrosis (CF) in patients ≥ 4	1. Provider attestation of continued benefit without adverse drug effects.

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	months who have one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or *in vitro* assay data. 2. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. 3. Patient is not homozygous in the CFTR gene. 4. Patient age ≥ 4 months. 5. Provider attestation of baseline and subsequent evaluation and monitoring as appropriate and as indicated in the FDA-approved labeling (provider must submit documentation). 6. Provider justification of necessity of medication change if currently stable on another CF regimen and asymptomatic. 7. Medication ordered by Pulmonologist. 8. Approval Duration: 12 months.	2. Provider attestation of continued monitoring as appropriate. 3. Approval Duration: 12 months.
ivermectin (Stromectol) tablets 3mg	1. Ordered for an approved indication for use: • 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.**	**<u>Limitations for use:</u>** • At this time, **outpatient use for COVID-19 treatment is** prohibited. • Ivermectin has no activity against adult *Onchocerca volvulus* parasites. • Ivermectin is not active against *L. loa* (adult worms).
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	1. Patient continues to meet initial criteria. 2. Patient has documented positive response to therapy as defined by

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	metastatic or where surgical resection is likely to result in severe morbidity, and no satisfactory alternative treatments or that have progressed following treatment. 2. The patient is being treated for one of the following solid tumors: soft tissue sarcoma, salivary gland, infantile fibrosarcoma, thyroid, lung, or gastrointestinal stromal tumors; and 3. The tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion; AND 4. The tumor is metastatic OR surgical resection of tumor will likely result in severe morbidity. 5. Medication ordered by an Oncologist. 6. Approval Duration: 6 months for first authorization.	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
lebrikizumab (**Ebglyss**) injection 250mg/2mL syringe, autoinjector	1. Ordered for an approved indication: • Treatment of patients ≥ 12 years of age who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical therapies or when those therapies are not advisable. 2. Diagnosis of moderate-to-severe chronic atopic dermatitis; **AND** 3. Patient age is ≥ 12 years 4. Patient weight is ≥ 40 kg. 5. History of failure, contraindication, or intolerance to **TWO** of the following therapeutic **classes** of topical therapies (document drug, dates of trial, and/or contraindication to medication). • Medium-high, or very-high potency topical corticosteroid (e.g. mometasone, fluocinolone acetonide, fluocinonide).	1. Documentation of a positive clinical response to therapy; **AND** 2. Patient is not using Ebglyss concurrent with any of the following: • Biologic immunomodulator (e.g., Dupixent (dupilumab), Adbry (tralokinumab-ldrm); and/or • Janus kinase inhibitor (e.g., Rinvoq (Upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (ruxolitinib), Cibinqo (abrocitinib); **AND** 3. Prescribed by or in consultation with a Dermatologist, Allergist, or Immunologist. 4. Approval Duration: 12 months.

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	• 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.	
lecanemab-irmb (**Leqembi)** intraveneous solution 200 mg/2 ml, 500mg/5ml	1. Ordered for an approved indication: • Treatment of Alzheimer disease; to be initiated in patients with mild cognitive impairment or mild dementia stage of disease, with confirmed presence of amyloid beta pathology prior to initiation of treatment. 2. Patient has signed informed consent on file. 3. Patient meets criteria for mild cognitive impairment (MCI) or mild AD dementia. 4. Patient has had an MRI scan within last 12 months. 5. Amyloid PET imaging and/or CSF analysis consistent with AD. 6. Functional Assessment Staging Test Stage score of 2 to 4. 7. Mini-Mental State Examination score greater than 21, or St. Louis University Mental Status (SLUMS) score or Montreal Cognitive Assessment (MoCA) score of greater than 16.	**<u>Renewal Criteria:</u>** 1. Patient continues to meet criteria for initial approval. 2. Absence of unacceptable toxicity from drug AND 3. Patient has responded to therapy compared to pretreatment as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment in one or more of the following (not all-inclusive): ADAS-Cog 13; ADCS-ADL-MCI; MMSE: CDR-SB etc, AND 4. Patient has not progressed to moderate or severe AD; AND 5. Patient has received a pre-5th, 7th, AND 14th infusion MRI for monitoring of Amyloid Related Imaging

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	8. Patient does not have any of the following risk factors for intracerebral hemorrhage: • prior cerebral hemorrhage greater than 1 cm in greatest diameter, more than 4 microhemorrhages, superficial siderosis, • evidence of vasogenic edema, • evidence of cerebral contusion, • aneurysm, • vascular malformation, • infective lesions, • multiple lacunar infarcts or stroke involving a major vascular territory, • and severe small vessel or white matter disease. 9. Ordered by a Board-certified neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia.	Abnormalities-edema (ARIA-E) and Amyloid Related Imaging Abnormalities hemosiderin (ARIA-H) microhemorrhages.
leuprolide injection **leuprolide acetate** kit 1mg/0.2ml **Eligard** SQ injection 45 mg **Lupron Depot** IM injection 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)	1. Ordered for an approved indication for use: • palliative treatment of advanced carcinoma of the prostate. • in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. • management of endometriosis • palliative treatment of advanced breast cancer in pre- and peri-menopausal women. • to cause endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. • management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy.	**Endometriosis:** **1.** Can not be administered for more than 6 months lifetime maximum. **Fertility Preservation:** • Patient currently receiving GnRH analog therapy for purpose of fertility preservation; and • Patient continues to receive a cytotoxic agent associated with primary ovarian insufficiency; and • Authorization duration: 12 months **Gender Affirming Care – Adolescents OR** **Gender Affirming Care – Transgender Adults:** • Approval Duration: 12 months.

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	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 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. 2. Approval Duration: 12 months **Oncology Indications:** 1. Prescribed by a hematologist/oncologist AND	**Oncology Indications:** • Patient has positive clinical response and absence of unacceptable toxicity **Uterine Leiomyomata (Fibroids) –** • Treatment beyond 6 months requires combination with add-back therapy (progestin, estrogen + progestin, NSAID), and should only be considered if surgery is contraindicated, or in post-surgical patients with persistent pain inadequately controlled with empiric therapies (NSAIDs, OCPs)

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	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. 3. <u>Oncology Approval duration:</u> • 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. **<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 6. Approval Duration: 6 months total.	
lifitegrast ophthalmic (**Xiidra**) drops 5% **STEP THERAPY**	1. Ordered for an approved indication for use: • the treatment of the signs and symptoms of dry eye disease (DED). 2. Must have tried and failed artificial tears AND cyclosporine (ophth) emulsion 0.05% (generic of Restasis). 3. Approval Duration: 12 months.	
liraglutide (Victoza) injection 1.2 mg/day 2-pack pens (6 ml) 1.8 mg/day 3-pack pens (9 ml)	1. Ordered for an approved indication for use: • An adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes • To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.	**Cannot be approved for the indication of weight management.** 1. Chart notes with A1c or CGM report with TIR% within previous 3 months. 2. A urine albumin-to-creatinine ratio (uACR) within the previous 12 months.

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	2. Patient has Type 2 Diabetes Mellitus ******NOTE**: Type 1 DM does **NOT** qualify for coverage**** 3. A1c or CGM Time in Range% (TIR) report within past 3 months. 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%) **OR** Treatment of Type 2 Diabetes with CVD as defined below: • Pre-treatment A1c is ≥ 6.5 (TIR ≤ 70%) **AND** • BMI ≥ 27 kg/m2 (documentation within previous 90 days current height and weight); **AND** Documentation submitted to show that the patient has a least one of the following: • History of myocardial infarction; or • Prior stroke (ischemic or hemorrhagic); or • Symptomatic peripheral arterial disease (PAD) as evidenced by: o Intermittent claudication with ankle-brachia index (ABI) less than 0.85 (at rest); OR o Peripheral arterial revascularization procedure; OR o Amputation due to atherosclerotic disease. 6. May not be concurrently using: • **ANY** other GLP1 or GLP1/GIP combination drug (e.g., Mounjaro, Ozempic, Rybelsus, Wegovy, Saxenda, Soliqua, Trulicity, Xultrophy or Zepbound). • **ANY** DPP4i (e.g., alogliptin, Januvia (sitagliptin),	3. Documented positive clinical response defined as one of the following: **Baseline (pre-GLP1) A1c was ≥ 8.0 and:** • A1c has decreased by ≥ 1% since onset of therapy or TIR% was ≤ 55% and has increased ≥ 10% or • A1c is ≤ 7.0 at initiation dose. **Baseline (pre-GLP1) A1c was ≥ 6.5 but < 7.5 and:** • A1c or TIR% has improved. **NOT** eligible for renewal if A1c has increased or TIR% has decreased. 4. May not be concurrently using: • **ANY** other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus,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: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). **6.** PBM claims data shows consistent adherence as shown by no instance of a drug-free interval greater than 2 months at which time the patient would need to satisfy the initial

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	Tradjenta (Linagliptin), Onglyza (saxagliptin)). • Agents for severe constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 7. Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all contraindications. 8. May not be approved for patients with: • Personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). • Current pregnancy; and/or • A history of confirmed pancreatitis. 9. **Cannot be approved for indication of weight management.** 10. Dose escalation in accordance with manufacturer guidelines required. Initial dose is 0.6 mg once daily for 1 week, then must increase to 1.2 mg daily as the 0.6 mg dose does not provide effective glycemic control. 11. Quantity Limits: • 1.2 mg daily dose is limited to one-pack containing 2 pens (6 ml) per 30 days. • 1.8 mg daily dose is limited to one pack containing 3 pens (9 ml) per 30 days. 12. Maximum Approval Duration: 12 months.	criteria. 7. Approval Duration: 12 months
lisdexamfetamine (Vyvanse) capsules 10mg, 20mg, 30mg, 40mg, 50mg, 60mg, 70mg	1. Ordered for an approved indication for use: • Attention Deficit Hyperactivity Disorder (ADHD) in children ≥ 6 years of age.	

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chewables 10mg, 20mg, 30mg, 40mg, 50mg, 60mg **STEP THERAPY**	• Moderate to Severe Binge Eating Disorder (BED) in adults. 3. Step therapy: • ADHD: at least 4-week trial of an amphetamine salt combination AND a 4-week trial of methylphenidate. • BED: at least 12-week trial of a serotonin reuptake inhibitor (SSRI)	
lisocabtagene maraleucel (**Breyanzi**) injection 70,000,000 cells	1. Ordered for an approved indication for use: • Treatment of adult patients with large B-cell lymphoma (LBCL) including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have: a. refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or b. refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or c. relapsed or refractory disease after two or more lines of systemic therapy. 2. Age ≥ 18 years of age. 3. Prescriber attestation that all baseline evaluations have been done, and no contraindications to use are present.	**Not applicable. Maximum approval, one treatment course per lifetime.** **Limitations of Use:** • BREYANZI is not indicated for the treatment of patients with primary central nervous system lymphoma.

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	4. Prescriber attests that subsequent appropriate evaluation and monitoring will be done based on the package insert. 5. Dose: 50-110 x 10^6 CAR positive viable T cells, one time dose. 6. Medication ordered by an Oncologist or Hematologist. 7. Approval limited to once per lifetime.	
lomitapide (**Juxtapid**) capsules 5mg, 10mg, 20mg, 30mg	1. Ordered for an approved indication for use: • An adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce LDL-C, total cholesterol, apolipoprotein B, and non-HDL-C in patients with homozygous familial hypercholesterolemia. 2. Patient age ≥ 18 years. 3. Documentation of baseline LFTs (including ALT, AST, alkaline phosphatase and total bilirubin) prior to initiation of treatment. 4. Prescriber attestation that a low-fat diet (<20% of energy from fat) has been initiated. 5. Prior trial, failure, insufficient response, and/or documented intolerance to preferred lipid lowering treatments including statin + ezetimibe, or Praluent. 6. Medication ordered by a REMS registered cardiologist or endocrinologist. 7. Approval Duration: 12 months.	1. Meets all initial approval criteria. 2. Attestation of continued benefit without significant adverse drug effects. 3. Laboratory data (full lipid panel) submitted to support continued use. 4. Renewal Duration: 12 months
loncastuximab tesirine-lpyl (**Zynlonta**) solution 10mg	1. Ordered for an approved indication for use: • the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or	1. Patient continues to meet initial criteria for use.

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	more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma. 2. Patient is at least 18 years of age. 3. Used as a single-agent therapy. 4. Patient has not received prior anti-CD19 therapy (e.g., tafasitamab, CAR-T) or patient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; and 5. Patient does not have graft-versus-host disease; and 6. Patient has not had an autologous stem cell transplant (ASCT) within 30 days or allogeneic stem cell transplant within 60 days prior to start of therapy; and 7. Medication ordered by an Oncologist. 8. Approval Duration: 6 months	2. Positive disease response from treatment defined as stabilization of disease or decrease in size of tumor or tumor spread. 3. Absence of unacceptable drug toxicity. 4. Approval Duration: 6 months.
lotilaner 0.25% solution (**Xdemvy**) 2.5mg/ml	1. Ordered for an approved indication for use: • Treatment of Demodex blepharitis in adults 2. Patient aged ≥ 18 years of age. 3. Diagnosis of Demodex blepharitis, **AND** 4. Patient demonstrates at least one of the clinical signs of Demodex infestation: • Cylindrical cuff at the root of the eyelashes (collarettes), • lid margin erythema, • eyelash anomalies (misdirected lashes); **AND** 5. Patient demonstrates two of the following symptoms of Demodex blepharitis in at least one eye: • Itching/burning, • foreign body sensation, • crusting/matter lashers	• At this time, there is no clinical evidence to show benefit beyond 6 weeks of treatment.

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	• blurry vision • discomfort/irritation; **AND** 6. Clinical documentation indicates the patient has been educated about good eyelid hygiene practices. 7. Patient has not undergone more than 1 6-week treatment in the previous 12 months. 8. Written by or in consultation with an ophthalmologist or optometrist. 9. Approval limited to 1 bottle (10 ml) per 12 months.	
lumacaftor/ivacaftor (**Orkambi**) tablets 100mg-125mg, 200mg-125mg	1. Ordered for an approved indication for use: • 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	1. Ordered for an approved indication for use: • treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients. 2. Diagnosis of primary lyperoxaluria type 1 (PH1) confirmed by documentation of genetic test results showing a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene OR liver enzyme	1. All initial approval criteria is met, and 2. Submission of medical records documenting a positive clinical response to therapy from pre-treatment baseline. 3. Approval Duration: 3 months.

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	analysis demonstrating absent or significantly reduced alanine: glyoxylate aminotransferase (AGT) activity. 3. Metabolic testing demonstrating one of the following: • Increased urinary oxalate excretion (e.g., > 1 mm/1,73 m^2 per day [90 mg/1.73 m^2]), increased urinary oxalate: creatinine ratio relative to normative values for age OR • Increased plasma oxalate and glyoxylate concentrations. 4. Patient has not received a liver transplant. 5. Prescribed by or in consultation with a nephrologist or other provider (i.e., geneticist, urologist) with experience in treating PH1. 6. Approval Duration: 3 months.	
lumateperone (**Caplyta**) capsules 10.5mg, 21mg, 42mg	1. Ordered for an approved indication for use: • Treatment of depressive episodes associated with bipolar disorder I or II in adults as monotherapy or as an adjunct to lithium or valproate. • Treatment of schizophrenia in adults. 2. Documented trial and failure of at least two other antipsychotic medications indicated to treat the medical diagnosis. • Bipolar depression: lurasidone, olanzapine, quetiapine, or risperidone • Schizophrenia: aripiprazole, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, ziprasidone 3. Risk versus benefit evaluation if being ordered for adults older than 65 years. 4. Medication ordered by a psychiatrist or other behavioral health specialist.	**<u>Limitations of use:</u>** • Caplyta is not approved for the treatment of patients with dementia-related psychosis and will not be approved for this indication. • Use with caution in patients at risk of seizures or with conditions that lower the seizure threshold.

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lusutrombopag (**Mulpleta**) tablets 3mg	1. Ordered for an approved indication for use: • Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure. 2. Patient age ≥ 18 years. 3. Not being ordered for patient with chronic liver disease to normalize platelet counts. 4. Dose: 3 mg (1 tablet) daily for 7 days. 5. Approval Duration: one treatment course.	**Each treatment course requires a separate PA request. Initial criteria applies to all requests.**
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. Patient has WHO functional class II-IV PAH, or is class I and at high risk for disease progression. 4. Diagnosis is confirmed by right heart catheterization. 5. Patient has completed a previous at least 4-week trial of ambrisentan OR has a contraindication or intolerance to using it.	1. Documentation of positive clinical response. 2. Approval Duration: 12 months.

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	6. Patient is not concurrently prescribed another endothelin receptor agonist (ambrisentan, bosentan) 7. NOTE: if the patient is also prescribed for a PDE-5 inhibitor medication (tadalafil, sildenafil), please redirect to Opsynvi. 8. Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist. 9. Quantity Limits: 30 tablets per 30 days 10. Approval Duration: 12 months.	
macitentan and tadalafil (**Opsynvi**) 10-20 mg, 10-40 mg tablets	1. Ordered for an approved indication for use: • Treatment of chronic pulmonary arterial hypertension (PAH, WHO Group I) in adult patients of WHO functional class II-III. 2. Patient age ≥ 18 years. 3. Patient has WHO functional class II-IV PAH, or is class I and at high risk for disease progression. 4. Patient is not concurrently prescribed another endothelin receptor agonist (macitentan, ambrisentan, bosentan), PDE-5 inhibitor (sildenafil, tadalafil), or Adempas (riociguat). 5. Diagnosis is confirmed by right heart catheterization. 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 to therapy. 2. Approval Duration: 12 months.
maribavir (**Livtencity**) tablets 200mg **STEP THERAPY**	1. Ordered for an approved indication for use: • treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.	If a patient has a paid claim in the MFC system for ganciclovir, valganciclovir, cidofovir, or foscarnet, Livtencity will process at the pharmacy without PA. If there is no evidence of a paid claim for ganciclovir, valganciclovir, cidofovir, or foscarnet, a PA is required, and

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	2. Medication is not prescribed in conjunction with ganciclovir or valganciclovir. 3. Medication is prescribed by or in consultation with a hematologist, infectious disease specialist, oncologist or physician affiliated with a transplant center. 4. Approval Duration: not to exceed 8 weeks.	documentation of previous use of one of these medications should be submitted.
mepolizumab (**Nucala**) injection 40mg/0.4mL syringes 100mg pens, syringes	1. Ordered for an approved indication for use: • Add-on maintenance treatment for severe asthma with eosinophilic phenotype in patients aged 6 years and older. • Add-on treatment of adult patients with chronic rhinosinusitis with nasal polyps. • Treatment of eosinophilic granulomatosis with polyangiitis (EGPA) in adults. • Treatment of adult and pediatric patients aged ≥ 12 years of age with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause. 2. Approval is indication specific: **Asthma:** • Patient is ≥ 6 years or age; AND • Patient has blood eosinophil level ≥ 150 cells/µL within previous 6 weeks or within 6 weeks prior to treatment with Nucala or another monoclonal antibody therapy that reduces blood eosinophil levels, (e.g. Cinqair, Dupixent, Fasenra, Nucala, Tezspire or Xolair); AND • Patient has received at least three consecutive months of combination therapy with BOTH an inhaled corticosteroid AND at least one additional	**Asthma:** • Patient has already received 6 months of therapy with Nucala. • Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler. • Patient has responded to therapy (e.g. decreased asthma exacerbations, symptoms, hospitalizations, ER visits, urgent care visits, or decreased requirement for oral corticosteroid therapy. **Chronic Rhinosinusitis with Nasal Polyps:** • Patient has received at least 6 months of therapy with Nucala. • Patient continues to receive therapy with an intranasal corticosteroid; and • Patient has responded to therapy (e.g. reduced nasal polyp size, improved nasal congestion,

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

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

methadone (for pain) solution 5mg/5ml, 10mg/5ml tablets 5mg, 10mg	1. Ordered for an approved indication for use: • The management of chronic pain severe enough to require daily, around-the- clock, long-term opioid treatment and for which alternative treatment options are inadequate.	All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-DC

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	2. Completion of an opioid prior authorization form. 3. Submission of clinical documentation from last office visit, dated within 3 months of the request. 4. Maximum approval duration is 6 months but may be reduced based on any of the criteria as outlined in Pharmacy Policy 219.DC: Opioid Prescription Prior Authorization.	
methylphenidate (**Jornay PM**) extended-release capsules	1. Ordered for an approved indication for use: • To treat symptoms of attention deficit hyperactivity disorder (ADHD) in children ages 6 years and older and adults 2. Step therapy: at least 4-week trial of an amphetamine salt combination AND a 4-week trial of methylphenidate. 3. Patient has documented need for evening medication administration (e.g. frequent missed morning doses, autism diagnosis) 4. Will not be used concurrently with other stimulant medications. Jornay is designed with an extendable duration of effect and can be dose adjusted to increase the duration of symptom control time. 5. Prescribed by or in conjunction with a psychiatrist or other behavioral health specialist. 6. Approval Duration: 12 months	1. Initial criteria continue to be met. 2. Patient has documented positive clinical response with the medication since starting the medication. 3. Approval duration: 12 months
mifepristone (**Korlym**) tablets Korlym-300mg ONLY	7. Ordered for an approved indication for use: • Control of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. 8. Patient is ≥ 18 years of age.	4. Documentation of one of the following: • Patient has improved glucose tolerance while on Korlym therapy; or • Patient has stable glucose tolerance while on Korlym therapy.

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	9. Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). 10. Patient has type 2 diabetes mellitus OR the patient has glucose intolerance as defined by a 2-hour glucose tolerance test value of 140-199 mg/dL. 11. The patient has either failed surgery or is not a candidate for pituitary surgery. 12. Prescribed by or in consultation with an endocrinologist. 13. The dose does not exceed 20 mg/kg/day. 14. Approval Duration: 3 months.	5. Dose does not exceed 20 mg/kg/day. 6. Approval duration: 3 months per authorization. **No other indications approved, can redirect requests for Mifeprex brand to appropriate formulary alternatives.
mirikizumab (**Omvoh**) injection 100 mg/1 ml	1. Ordered for an approved indication for use: • Maintenance treatment of ulcerative colitis (UC) in adults with moderate to severe active disease. 2. Patient is ≥ 18 years of age, and 3. Patient has had a trial of one systemic agent for UC (e.g., 6-MP, azathioprine, cyclosporine, tacrolimus or a corticosteroid. Note that trial of a mesalamine product does not count as a systemic therapy for UC) **OR** 4. Patient has both: • Pouchitis AND • Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema 5. Patient has failed an 8-week trial of ustekinumab (Stelara or biosimilar) or has a contraindication to using this medicine. 6. Patient has failed an 8-week trial of adalimumab (Humira or biosimilar) or has a contraindication to using this medicine. 7. Patient is not being treated concurrently with a	1. Patient exhibits a positive clinical response by at least one objective measure from baseline. (e.g., fecal calprotectin levels, C-reactive protein, endoscopic assessment, and/or decreased utilization of corticosteroids **OR** 2. Patient has a documented clinical improvement in at least one subjective measure from baseline (e.g., decreased pain, fatigue, stool frequency, and/or rectal bleeding). 3. Approval duration: 12 months.

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	biologic or targeted synthetic disease-modifying antirheumatic drug (DMARD) for UC. (e.g., adalimumab, infliximab, sarilumab, abatacept, rituximab, ustekinumab, apremilast, ozanimod, or similar). 8. Medication is prescribed by or in consultation with a gastroenterologist. 9. Initial Approval Duration: 6 months; if patient has already received > 6 months of subcutaneous therapy, then approval duration is 12 months.	
mitapivat (**Pyrukynd**) tablets 5mg, 20mg, 50mg	1. Ordered for an approved indication for use: • The treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency 2. Confirmatory genetic testing of PKLR gene showing ≥ 2 variant alleles with at least one- missense mutation in the liver and red blood cell (PKLR) gene. 3. Patient is not homozygous for the c.1436G>A (p.R479H) variant. 4. Patient does not have two non-missense variants (without the presence of another missense variant) in the PKLR gene. 5. Baseline hemoglobin less than or equal to 10 g/dL. 6. Prescribed by or in consultation with a Hematologist. 7. Initial Approval Duration limited to 6 months.	1. Documentation of positive clinical response to Pyrukynd therapy based on ONE of the following: • Patient has been on Pyrukynd for > 52 weeks and has maintained positive clinical response to therapy; OR • Reduction in transfusions of ≥ 33% in the number of red blood cell units transfused during the initial 24-week period compared with the patient's historical transfusion burden; OR • A ≥ 1.5 g/dL increase in hemoglobin from baseline sustained at 2 or more scheduled assessments 4 weeks apart during the initial 24-week period without any transfusions. 2. Authorization duration: 12 months • If documentation does not provide evidence of positive clinical response to Pyrukynd therapy, allow for dose titration with discontinuation of therapy. In this

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		case, authorization duration is for 4 weeks.
modafinil (Provigil) tablets 100mg, 200mg	**1.** Ordered for an approved indication for use: • to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, or shift work disorder. 2. Will not be used concurrently with monoamine oxidase inhibitors (isocarboxazid, phenylzine, tranylcypromine) 3. No past medical history of left ventricular hypertrophy 4. If PMH of mitral valve prolapse, no previous occurrence of mitral valve prolapse syndrome with past use of CNS stimulants (including but not limited to ischemic ECG changes, chest pain, or arrhythmia) 5. No active symptoms of mania or psychosis 6. If the patient has a history of cardiovascular disease, psychosis, depression or mania, patient is on a treatment regimen with adequate disease state control, AND prescriber has conducted a risk vs. benefit assessment to ensure clinical appropriateness before modafinil initiation 7. Confirmation of negative pregnancy status within 1 week of treatment initiation for females of reproductive age. 8. Approval Duration: 12 months	• Maximum recommended daily dose is 200 mg (single dose or 2x100 mg doses); evidence is limited for daily doses >200 mg regardless of indication <u>Renewal criteria</u>: • Documentation of positive clinical response with modafinil treatment • Initial approval criteria continue to be met • Renewal duration: 12 months
morphine sulfate extended-release (MS Contin) tablets 15mg, 30mg, 60mg 100mg, 200mg	1. Ordered for an approved indication for use: • The management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 2. Completion of an opioid prior authorization form.	All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: **OPIOID PRIOR AUTH FORM-DC**

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	3. Submission of clinical documentation from last office visit, dated within 3 months of the request. 4. Maximum approval duration is 6 months but may be reduced or denied based on the criteria as outlined in Pharmacy Policy 219.DC: Opioid Prescription Prior Authorization.	
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	1. Ordered for an approved indication for use: • Treatment of Desmoid Tumors (aggressive fibromatosis) in adult patients. 2. Patient is aged 18 years or older. 3. Patient has been diagnosed with progressing desmoid tumors as defined as ≥ 20% progression within 12 months, AND 4. The desmoid tumors are not amenable to surgery or radiotherapy, AND 5. The patient requires systemic treatment. 6. Quantity Limits: 2 tablets daily, not to exceed 150 mg BID. 7. Approval Duration: 12 months.	1. Patient does not show evidence of progressive disease while on Ogsiveo therapy. 2. Approval Duration: 12 months
nitisinone (Orfadin) capsules	1. Ordered for an approved indication for use:	1. Meets all initial approval criteria.

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2mg, 5mg, 10mg, 20mg	• treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine. 2. Diagnosis of type 1 tyrosinemia by biochemical or DNA testing. 3. Patient adherent to dietary restrictions of tyrosine and phenylalanine. 4. Patient is under the care of a nutritionist. 5. Dose not to exceed 2 mg/kg/day. 6. Patient is not enrolled in any study involving the requested drug. 7. PA form completed completely. 8. Approval Duration: 3 months	2. MDH provided PA form completed with all required documentation. 3. Approval duration: 3 months.
nusinersen (**Spinraza**)	1. Ordered for an approved indication for use: • Diagnosis of SMA Type I, II, or III. • Diagnosis by a neurologist with expertise in the diagnosis of SMA; 2. Genetic testing confirming both: • 5q SMA homozygous gene deletion, homozygous gene mutation, or compound heterozygous mutation: AND • At least 2 copies of SMN2 3. AND • Patient is not dependent on invasive ventilation or tracheostomy. • Patient is not dependent on non-invasive ventilation beyond use for naps and nighttime sleep; • Patients with Type II and III SMA must have some functional upper extremity use. 4. **Initial therapy**	1. Cannot be used in combination with Zolgensma (onasemnogene abeparvovec). 2. Each Spinraza maintenance dose must be preauthorized; 3. Approval period is 3 months. 4. All the criteria for initial therapy must be met: • Medical records must be submitted that document repeat motor testing since the most recent Spinraza® dose using the same motor test done to establish baseline motor ability, unless it is determined that the original test is no longer appropriate;

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	• Medical records must be submitted documenting all of the above criteria; • Medical records must be submitted documenting a baseline motor examination utilizing at least one of the following exams (based on patient age and motor ability) to establish baseline motor ability. • Hammersmith infant neurological exam (HINE); • Hammersmith Functional Motor Scale Expanded (HFMSE); • Upper Limb Module Test (non-ambulatory; or • Childrens Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) 5. Prescribed by a neurologist with expertise in the treatment of SMA. 6. Spinraza must be given according to the current FDA labelling guidelines for dosage and timing; 7. Must be administered intrathecally by a physician or other healthcare professional experienced in performing lumbar punctures. 8. Initial and Renewal Approval Duration: 4 loading doses for initiation, 3 months each approval period thereafter.	• Repeat motor testing must document a response to treatment as defined by the following: **HINE:** 1. Improvement or maintenance of previous improvement of at least 2 points (or max score of 4) in ability to kick (improvement in at least 2 milestones); **OR** 2. Improvement or maintenance of previous improvement of at least 1 point increase in motor milestones of head control, rolling, sitting, crawling, standing, or walking (consistent with improvement by at least 1 milestone); **AND** 3. Improvement or maintenance of previous improvement in more HINE motor milestones. **HFMSE:** 1. Improvement or maintenance of improvement of at least a 3-point increase in score; **ULM:** 1. Improvement or maintenance of previous improvement of at least 2-point increase in score; **CHOP-INTEND:** 1. Improvement or maintenance of previous improvement of at least a 4-point increase in score.

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ocrelizumab (**Ocrevus**) IV injection 300mg/10ml ocrelizumab and hyaluronidase (**Ocrevus Zunovo**) SQ injection 920-23,000 mg-units/23mL	1. Ordered for an approved indication for use: • Primary progressive multiple sclerosis (MS); • Relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. 2. Age is ≥18 years and <55 years of age. 3. Patient has one of the following: • Ineffective treatment response due to continued clinical relapse, intolerance, or contraindication to two or more MS drugs; • Patient is not a candidate for any other preferred first-line treatments due to MS severity; • Patient is at higher risk of poor long-term outcome (spinal cord involvement, highly active disease, poor relapse recovery), as determined by their neurologist. 4. Not being used in combination with other immune-modulating or immunosuppressive therapies, including immunosuppressant doses of corticosteroids. 5. Not being used in combination with another MS disease modifying agent [Avonex, Betaseron, dimethyl fumarate, Extavia, fingolimod, glatiramer, glatopa, Kesimpta, Mayzent, Rebif, teriflunomide, Vumerity]. 6. Medication ordered by a neurologist. 7. Approval duration: 12 months.	1. All initial criteria continue to be met. 2. Documentation of positive clinical response to Ocrevus therapy. 3. Approval duration: 12 months.
olanzapine and samidorphan (**Lybalvi**) tablets 5mg/10mg, 10mg/10mg, 15mg/10mg, 20mg/10mg	1. Ordered for an approved indication for use: • Schizophrenia in adults • Bipolar I disorder in adults as acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate	1. All initial criteria continue to be met. 2. Documentation of positive clinical response to therapy. 3. Approval duration: 12 months.

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	• Bipolar I disorder in adults as maintenance monotherapy treatment 2. Clinical documentation the patient does not have active opioid use disorder, AND 3. Patient is not concurrently prescribed opioid medication(s), AND 4. Patient is not actively going through opioid withdrawal, AND 5. Negative baseline urine drug screen result from within the last 14 days. 6. Patient has a history of failure, contraindication, or intolerance to at least THREE (3) formulary atypical antipsychotic agents, such as: • aripiprazole • olanzapine • quetiapine IR or XR • risperidone • ziprasidone 7. Approval Duration: 12 months	
olipudase alfa-rpcp (**Xenpozyme**) 4mg, 20mg	1. Prescribed for an approved indication for use; treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients. 2. Acid sphingomyelinase enzyme assay (as measured in peripheral leukocytes, cultured fibroblasts, or lymphocytes) or genetic testing results documenting a mutation in the sphingomyelin phosphodiesterase-1 (SMPD1) gene. 3. Prior to initiation of Xenpozyme, baseline transaminase (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]) levels recorded within past 30 days.	1. Documented response to therapy improvement or stabilization in disease (e.g., improvement in lung function, reduction in spleen volume, reduction in liver volume, improvement in platelet count, improvement in linear growth progression). 2. Documentation of patient's current weight. 3. Dose does not exceed 3 mg/kg IV every 2 weeks. 4. Approval duration: 3 months

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	4. Documentation of patient's current weight. 5. Prescribed by or in consultation with a metabolic disease specialist or geneticist. 6. Dose does not exceed 3 mg/kg IV every 2 weeks. 7. Approval duration: 3 months	
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 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	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)). **<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

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	(dupilumab)). • Anti-interleukin-5 therapy (e.g., Cinqair (resilizumab), Fasenra, (benralizumab), Nucala (mepolizumab)). • Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., Tezspire (Tezepelumab)). **Asthma:** 1. Patient aged ≥ 6 years of age. 2. Positive skin test or in-vitro reactivity to a perennial aeroallergen, AND 3. Submission of clinical documentation showing the baseline (pre-treatment) serum total IgE level ≥ 30 IU/ml and ≤ 1300 IU/ml, AND 4. Diagnosed with moderate to severe asthma inadequately controlled with inhaled corticosteroids as defined by at least ONE of the following: • Poor symptom control (e.g., Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20); or • Two or more bursts of systemic corticosteroids for at least 3 days each in previous 12 months; or • Asthma-related emergency treatment (ER visit, hospital admission, or unscheduled OV for nebulizer or emergency treatment); **OR** • Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted; **OR** • Patient is currently dependent on oral corticosteroids for the treatment of asthma; **AND,** 5. Xolair will be used in combination with one maximally dosed combination ICS/LABA inhaler **OR** with an ICE	medication – **NOT** covered as monotherapy. 3. Approval Duration: 12 months. **IgE-mediated Food Allergy:** 1. Documentation of positive clinical response to Xolair therapy, e.g. reduction in type I allergic reactions, and 2. Used in conjunction with food allergen avoidance, and 3. Patient has access to epinephrine, and 4. Prescribed by an allergist or immunologist. 5. Approval Duration: 12 months. **Rhinosinusitis, chronic, with nasal polyps (CRSwNP):** 1. Documentation of positive clinical response to Xolair therapy. 2. Patient continues to use add-on maintenance therapy with intranasal corticosteroids – **NOT** covered as monotherapy. 3. Approval Duration: 12 months. **Urticaria (chronic spontaneous):** 1. Documentation of positive clinical response to Xolair therapy (e.g. reduction in exacerbations, itch severity, hives). 2. Approval Duration: 12 months.

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	inhaler and one additional asthma controller medication (e.g. montelukast, theophylline). 6. Prescribed by an allergist, immunologist or pulmonologist. 7. Approval Duration: 12 months. **IgE-mediated Food Allergy:** **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 ○ 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. **Rhinosinusitis, chronic, with nasal polyps (CRSwNP):** 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:	

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

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	• 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.	
omega-3-acid ethyl esters (Lovaza) capsules 1 Gram	1. Ordered for an approved indication for use: • as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia 2. Patient is ≥18 years old. 3. Member must have tried and failed a 30-day trial of OTC fish oil. 4. Approval Duration: 12 months.	1. The patient has achieved or maintained a reduction in triglyceride levels from baseline. 2. Approval Duration: 12 months.
onabotulinumtoxinA (**Botox**) injection 100 Unit, 200 Unit	1. Ordered for an approved indication for use: • Overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication. • Urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g.,	1. Documentation of positive clinical response. • Approval Duration: 12 months.

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	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 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	

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	age and older. 2. Ordered for a MedStar Family Choice approved compendial use: • Chronic anal fissure failing conventional non-surgical treatment. • Chronic sialorrhea • Focal dystonia • Hirschsprung Disease • Primary esophageal achalasia • Treatment of cholinergic-mediated secretions associated with a fistula refractory to pharmacotherapy. • Treatment of disabling essential tremor • Treatment of hemifacial spasms, seventh cranial nerve palsy (Bell's palsy) or Gaze palsies causing persistent pain or vision impairment. 3. Not prescribed for a cosmetic indication. 4. Requested volume of units and dosing frequency are aligned with FDA and manufacturer labeling for applicable indication. 5. Medication ordered by a Neurologist, Urologist, Ophthalmologist, or applicable specialist. 6. Approval Duration: 12 months.	
Opioids	FOR IMPORTANT INFORMATION ABOUT PRESCRIBING OPIOIDS FOR MEDSTAR FAMILY CHOICE MEMBERS, PLEASE VISIT THE OPIOID PRIOR AUTHORIZATION REQUIREMENTS PAGE OF THE MFC-DC WEBSITE. 1. Ordered for an approved indication for use: • The management of pain severe enough to require opioid treatment and for which alternative treatment options are inadequate. 2. Completion of the opioid prior authorization form.	The Opioid PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-DC

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	3. Submission of supporting clinical documentation for the last office visit, dated within the previous 3 months. 4. Maximum approval duration is 6 months but may be approved for a shorter duration based on any of the criteria as outlined in Pharmacy Policy 219.DC: Opioid Prescription Prior Authorization.	
oxcarbazepine extended release 24-hour (Oxtellar XR) tablets 150mg, 300mg, 600mg	1. Ordered for an approved indication for use: • Treatment of partial-onset seizures in adults and in children ≥ 6 years of age. 2. Treatment failure, adverse effects, or contraindication to formulary preferred agents. 3. Medication ordered by a Neurologist.	Immediate-release and extended-release preparations are not bioequivalent and not interchangeable on a mg per mg basis.
oxycodone IR capsules, tablets, oral solution/concentrate 5 mg capsules 100mg/5mL oral concentrate 5mg/5mL oral solution IR tablets 5, 10, 13, 20, 30 mg **Oxycontin ER** tablets 10, 15, 20, 30, 40 mg	1. Ordered for an approved indication for use: • The management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 2. Completion of the opioid prior authorization form. 3. Submission of supporting clinical documentation for last office visit dated within previous 3 months. 4. Maximum approval duration is 6 months but may be reduced or denied based on any of the criteria as outlined in Pharmacy Policy 219.DC: Opioid Prescription Prior Authorization.	All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-DC
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 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 the previous 3 months.	All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-DC

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	4. Maximum approval duration is 6 months but may be reduced or denied based on any of the criteria as outlined in Pharmacy Policy 219.DC: 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: • management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 2. Completion of the opioid prior authorization form. 3. Submission of supporting clinical documentation for last office visit, dated within previous 3 months. 4. Maximum approval duration is 6 months but may be reduced or denied based on any of the criteria as outlined in Pharmacy Policy 219.DC: Opioid Prescription Prior Authorization.	All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-DC
ozanimod (**Zeposia**) capsules 0.23mg, 0.46mg, and 0.92mg capsules 7-day starter pack Capsule Starter Kit	1. Ordered for an approved indication for use: • Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. • Treatment of moderately to severely active ulcerative colitis (UC) in adults. 2. Patient has not received a manufacturer supplied sample or any form of assistance from the manufacturer coupon or sample card as a means to establish as a current user of Zeposia. 3. Baseline evaluation of the following labs before starting treatment: CBC, ECG, LFT's	**Renewal Criteria:** 1. Initial approval criteria continue to be met. 2. Patient is not receiving in combination a biologic DMARD or janus kinase inhibitor **Multiple Sclerosis:** • Patient experiencing disease stability or improvement while receiving Zeposia. • Maximum approval Duration: 12 months **Ulcerative Colitis:**

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	4. No history (within previous 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure. 5. No severe untreated sleep apnea 6. Zeposia will not be used in combination with either a biologic DMARD (e.g. adalimumab, Simponi (golimumab), ustekinumab (biosimilars for Stelara) OR a Janus kinase inhibitor (e.g. Xeljanz (tofacitinib), Rinvoq (upadacitinib) (Note: Ampyra and Nuedexta are not disease modifying). **7. <u>Additional Criteria for Multiple Sclerosis</u>** • Prescribed by or within consultation with a neurologist. **8. <u>Additional Criteria for Ulcerative Colitis</u>** • Diagnosis of moderately to severely active UC • Patient has failed, contraindicated or intolerance to a course of oral corticosteroids and/or immunosuppressants (e.g. azathioprine, or 6-mercaptopurine) OR • Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of UC as documented by claims history or submission of medical records. (e.g., adalimumab, Simponi (golimumab), ustekinumab (Stelara or biosimilar), Xeljanz (tofacitinib), Rinvoq (upadacitinib)). • Prescribed by or in consultation with a gastroenterologist. 9. Approval duration: 12 months	• Patient has achieved or maintained remission. • Patient shows positive clinical response as evidenced by low disease activity or improvement in signs/symptoms of the condition when there is improvement in any ONE of the following from baseline: ○ Stool frequency ○ Rectal bleeding ○ Urgency of defecation ○ C-reactive protein (CRP) ○ Fecal calprotectin (FC) ○ Endoscopic appearance of the mucosa ○ Improvement on a disease activity scoring tool (e.g. Ulcerative Colitis Endoscopic Index of Severity (UCEIS, Mayo score) 3. Approval Duration: 12 months
palbociclib (**Ibrance**) capsules 75mg, 100mg, 125mg	1. Ordered for an approved indication for use:	1. Patient shows evidence of positive response to therapy.

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	• Treatment of adult patients with hormone receptor positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer in combination with: a. An aromatase inhibitor as initial endocrine based therapy. b. Fulvestrant in patients with disease progression following endocrine therapy. 2. Patient age ≥ 18 years. 3. Patient has recurrent or metastatic disease; and 4. Patient has hormone receptor positive (HR+) either estrogen receptor positive and/or progesterone receptor positive disease; and 5. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND 6. Patient meets one of the following: • Patient is post-menopausal; or • Patient is pre/peri-menopausal and has had either surgical bilateral oophorectomy or ovarian irradiation OR is receiving ovarian suppression/ablation with a GnRH. 7. Ibrance will be used in combination with one of the following: anastrozole, exemestance, letrozole, or fulvestrant. 8. Medication ordered by an Oncologist 9. Approval Duration: 12 months.	2. Approval Duration: 12 months.
palopegteriparatide (**Yorvipath**) 168 mcg/0.56 ml 294 mcg/0.98 ml 420 mcg/1.4 ml	1. Ordered for an approved indication for use: • Treatment of hypoparathyroidism in adults. 2. Patient has had hypoparathyroidism for ≥ 6 months. 3. Patient has documentation or claims history supporting treatment with a vitamin D metabolite/analog therapy with calcitriol ≥ 0.5 mcg per day or alfacalcidol ≥ 1.0 mcg per day.	1. Documentation of positive clinical benefit from therapy as evidenced by the maintenance or normalization of calcium levels compared to baseline. 2. Approval Duration: 12 months.

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	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.	
patisiran (**Onpattro**) Solution 10mg/5ml	1. Ordered for an approved indication for use: • Treatment of polyneuropathy in adults with hereditary transthyretin-mediated (hATTR) amyloidosis. 2. Patient age ≥ 18 years. 3. Medication ordered by a rheumatologist, neurologist, or a specialist in the treatment of amyloidosis. 4. Diagnosis of hATTR with polyneuropathy confirmed by the presence of a transthretin (TTR) gene mutation (e.g., V30M, A97S, T60A, E89Q, S50R). 5. Documentation of one of the following baseline tests: • Modified Neuropathy Impairment Scale +7 (mNIS+7) composite score. • Polyneuropathy disability (PND) score of ≤ IIIb • Familial amyloid polyneuropathy (FAP) Stage 1 or 2 6. Patient has clinical signs and symptoms of polyneuropathy (i.e., weakness, sensory loss, decreased motor strength, decreased gait speed)	1. Patient continues to meet the initial approval criteria. 2. Documentation of therapeutic response as evidenced by the stabilization or improvement from baseline in one of the following: • mNIS+7 score • polyneuropathy disability (PND) score ≤ IIIb • familial amyloid polyneuropathy (FAP) Stage 1 or 2. 3. Approval Duration: 12 months.

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	7. Other causes of peripheral neuropathy have been assessed and ruled out. 8. Patient will not be receiving Onpattro in combination with oligonucleotide agents (Onpattro, Tegsedi) 9. Prescribed by, or in consultation with, a neurologist, geneticist, or physician specializing in the treatment of amyloidosis. 10. Approval Duration: 12 months	
pegcetacoplan (**Empaveli**) injection 1080mg/20ml	1. Ordered for an approved indication for use: • Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). 2. Documentation supporting diagnosis of PNH as confirmed by both of the following: • Flow cytometry analysis confirming presence of PNH clones; and • Laboratory results, signs and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained or unusual thrombosis, hemolysis/hemogobinuria, kidney disease, pulmonary hypertension, etc.) 3. Patient age ≥ 18 years. 4. Patient is not receiving Empaveli in combination with another complement inhibitor used for the treatment of PNH (e.g., Soliris, Ultomiris); OR 5. Patient is currently receiving Soliris (eculizumab) which will be discontinued after an initial 4-week overlap period with Empaveli; OR 6. Patient is currently receiving Ultomiris (ravulizumab-cwvz) which will be discontinued and Empaveli will be initiated no more than 4 weeks after the last dose. 7. Prescribed by either a hematologist or oncologist.	1. Documentation of positive clinical response to Empaveli therapy (e.g, increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc.) 2. Patient is not receiving Empaveli in combination with another complement inhibitor used for the treatment of PNH (e.g., Soliris, Ultomiris). 3. Prescribed by or in consultation with an oncologist or hematologist. 4. Approval Duration: 12 months.

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	8. Approval Duration: 6 months.	
pegloticase (**Krystexxa**) injection solution 8mg/ml	1. Ordered for an approved indication for use: • Treatment of chronic gout in adults refractory to conventional therapy. 2. Verified there is no G6PD deficiency prior to therapy initiation. 3. Patient aged 18 years or older. 4. Not for the treatment of asymptomatic hyperuricemia. Patient as symptomatic gout. 5. Inadequate treatment response, intolerance, or contraindication to ONE of the following: allopurinol or probenecid. 6. Oral anti-hyperuricemic agents are discontinued. 7. Prescriber agrees to monitor serum uric acid levels prior to subsequent infusions and consider discontinuing treatment if levels rebound and exceed 6 mg/dl. 8. Medication ordered by Rheumatologist, Nephrologist or Podiatrist. 9. Approval duration: 3 months.	1. Patient must have chronic, symptomatic gout. 2. Documented improvement in serum uric acid level 3. NO glucose-6-phosphate dehydrogenase (G6PD) deficiency 4. Renewal request may be denied if patient has 2 or more consecutive uric acid levels above 6 mg/dl. 5. Renewal duration: 3 months.
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. 2. Medication ordered by an Oncologist.	1. Patient shows positive clinical response to therapy. 2. Patient has not experienced any severe adverse effects from therapy. 3. Approval Duration: 12 months.

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	Acute Lymphoblastic Leukemia: 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 • The acute lymphoblastic leukemia is T315I-positive; OR • The patient has tried at least one other tyrosine kinase inhibitor that is used for Ph+ ALL (e.g., Sprycel (dasatinib)). 4. Approval Duration: 12 months. **Chronic Myeloid Leukemia (CML):** 1. Patient is ≥ 18 years; AND 2. Patient has Philadelphia chromosome-positive chronic myeloid leukemia; AND 3. Patient meets ONE of the following: • The chronic myeloid leukemia is T315I-positive; OR • Patient has tried at least two other tyrosine kinase inhibitors indicated for use in Ph+ CML (e.g., imatinib, dasatinib, nilotinib); OR • Patient meets BOTH of the following: o Patient has accelerated-phase CML or blast-phase CML; AND o No other tyrosine kinase inhibitor is indicated. 4. Approval Duration: 12 months. COVERED COMPENDIAL USES: **Gastrointestinal Stromal Tumor:**	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	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. **Myeloid/Lymphoid Neoplasms with Eosinophilia:** 1. Patient age ≥ 18 years; and 2. Patient meets ONE of the following: • The tumor has an ABL1 rearrangement, OR • The tumor has an FGFR1 rearrangement. 3. Approval Duration: 12 months.	
posaconazole (Noxafil**)** 40mg/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). • 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**	• Patient at high infection risk: severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy. • Oral suspension is not substitutable with tablets or PowderMix oral suspension due to differences in dosing of each formulation. • Coadministration is Contraindicated with sirolimus, ergot alkaloids, HMG-CoA reductase inhibitors. • Significant risk for drug-drug interactions.

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	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 • The patient has experienced an intolerance to fluconazole, OR • The patient has a contraindication that would prohibit a trial of fluconazole. 6. Approval Duration: up to 12 months.	
ramelteon (Rozerem) tablets 8 mg **STEP THERAPY**	1. Ordered for an approved indication for use: • To treat insomnia in adults ≥18 years old. 2. Patient has predominately sleep-onset insomnia type. 3. Patient has at least a 4-week trial of other formulary benzodiazepine receptor agonist (BZRA) medication (eszopiclone, zolpidem, temazepam) OR has a contraindication to using. • If the patient has a documented reason to avoid using a BZRA medication such as older age, cognitive dysfunction, concurrent opioid use, or a need to prioritize avoiding next-morning residual sedation then a precursor BZRA trial may be waived. 4. Quantity Limits: 1 tablet per day or prescribed strength 5. Approval Duration: 12 months	1. Patient has a documented positive clinical improvement of insomnia symptoms while using this medication. 2. Approvel Duration: 12 months
ravulizumab-cwvz (**Ultomiris**) injection solution 300mg/ml, 1100mg/11ml	1. Ordered for an approved indication for use: • treatment of adult and pediatric patients ≥ 1 month of age with paroxysmal nocturnal hemoglobinuria (PNH). • treatment of adult and pediatric patients ≥ 1	1. Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit.

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	month of age with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA). • treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR+) antibody positive. 2. FDA approved patient age. 3. Documentation to support diagnosis: **PNH:** • Flow cytometric confirmation of PNH type III red cells; AND • Patient had at least one transfusion in the preceding 24 months; OR • Documented history of major adverse thrombotic vascular events from thromboembolism; OR • Patient has high disease activity defined as lactic dehydrogenase (LDH) level ≥ 1.5 times the upper limit of normal with one of the following symptoms: weakness, fatigue, hemoglobinuria, abdominal pain, dyspnea, hemoglobin, 10 g/dL, a major vascular event, dysphagia, or erectile dysfunction. • History of failure to/contraindication or intolerance to Empaveli therapy; • Patient age < 18 years or currently pregnant. **aHUS:** • Common causes of aHUS have been ruled out, including infectious causes of HUS and thrombotic thrombocytopenic purpura (TTP). • Ultomiris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).	2. **gMG**: Improvement and maintenance of at least a 2-point improvement (reduction) in the MG-ADL score from pre-treatment baseline and reduction of signs and symptoms of MG required to show clinical benefit. 3. **NOTE:** dose escalation of immunosuppressive therapy, or additional rescue therapy from baseline to treat MG or exacerbation of symptoms during use is considered treatment failure. 4. Not receiving in combination with Empaveli or Soliris. 5. Approval Duration: up to 12 months.

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	• Must present with the following symptoms:
	  ○ Hemoglobin < 10 g/dL
	  ○ Platlets, 150,000/mm^3
	  ○ Documented evidence of hemolysis, such as elevated LDH levels, decreased haptoglobin level or schistocytosis.
	• Increased serum creatinine OR currently undergoing dialysis.
	gMG:
	• Patient has not failed previous course of Soliris or Ultomiris therapy;
	• Positive serologic test for anti-AChR antibodies; AND
	• One of the following:
	○ History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation OR
	○ History of positive anticholinesterase test (e.g. edrophonium chloride test) OR
	○ Pt has demonstrated improvement in MG signs on oral cholinesterase inhibitors as assessed by the treating neurologist; AND
	• Patient has MGFA clinical classification of II, III, or IV at initiation of treatment; AND
	• Patient has Myasthenia gravis-specific activities of daily living scale (MG-ADL) total score ≥ 6 at initiation of treatment; AND
	• One of the following:
	○ History of failure to at least two immunosuppressive agents over the previous 12-months (e.g., azathioprine, mtx, cyclosporing,	

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	mycophenolate); OR ○ History of failure to at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges, and/or intravenous immune globulin over the previous 12 months without symptom control; AND 4. Recommended vaccinations at least 2 weeks prior to administration of first dose Ultomiris. 5. Cannot be used in combination with other medications in the same class, such as Soliris. 6. Medication ordered by Hematologist, Nephrologist, or Oncologist registered with Ultomiris REMS program. 7. Approval Duration: 12 months.	
resmetirom (**Rezdiffra**) tablets 80 mg, 100 mg **(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	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 has not progressed to stage F4 (cirrhosis).

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	• Patient has had ONE of the following imaging exams performed within the 3 months preceding treatment with Rezdiffra:
	  ○ Elastography (e.g. Fibroscan, transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, or shear wave elastography); OR
	  ○ Computed tomography; OR
	  ○ Magnetic resonance imaging.
	4. Patient meets ONE of the following prior to treatment with Rezdiffra:
	• Patient has Stage F2 fibrosis; **OR**
	• Patient has Stage F3 fibrosis; **AND THREE** or more of the following metabolic risk factors that are managed according to Standards of Care:
	  ○ Central obesity
	  ○ Hypertriglyceridemia
	  ○ Reduced high-density lipoprotein cholesterol,
	  ○ Hypertension
	  ○ Elevated fasting plasma glucose indicative of diabetes or pre-diabetes; AND
	5. According to the prescriber, the patient meets ONE of the following:
	• <u>Female patients</u>: Alcohol consumption < 20 grams per day; OR
	• <u>Male patients</u>: Alcohol consumption < 30 grams per day.
	Note: One standard drink (or one alcoholic drink equivalent) contains ~14 grams of pure alcohol, which is
		2. Metabolic risk factors are managed according to standard of care; **AND**
		3. According to the prescriber, the patient meets ONE of the following:
		• <u>Female patients</u>: Alcohol consumption < 20 grams per day; OR
		• <u>Male patients</u>: Alcohol consumption < 30 grams per day.
		Note: One standard drink (or one alcoholic drink equivalent) contains ~14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits.
		4. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
		5. Approval Duration: 12 months.

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	found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits. 6. Other causes of liver disease or hepatic steatosis have been ruled out (e.g., alcoholic steatohepatitis, acute fatty liver, autoimmune hepatitis, Hepatitis A, B, or C, hemochromatosis, drug-induced liver disease, etc.), AND 7. Provider attestation that member has adopted liver-protective lifestyle interventions such as optimizing weight loss, dietary changes, and exercise, AND 8. Member does not have evidence of cirrhosis, hepatic decompensation, or hepatocellular carcinoma (HCC). 9. All other indications are excluded from coverage as experimental. 10. Prescribed by, or in consultation with an endocrinologist, hepatologist or gastroenterologist. 11. Approval Duration: 12 months	
riociguat (**Adempas**) 0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg tablets	1. Ordered for an approved indication for use: • Persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class. • Pulmonary Arterial Hypertension (PAH) (WHO Group 1) to improve exercise capacity, improve WHO functional class and to delay clinical worsening. 2. Will not be used in combination with a phosphodiesterase 5 inhibitor (PDE5I; e.g. sildenafil, tadalafil) **CTEPH:**	1. Clinical documentation supports that the patient is receiving clinical benefit from Adempas therapy. 2. Approval Duration: 12 months.

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	1. Patient is diagnosed with inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH); AND 2. CTEPH is symptomatic; AND 3. Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist. 4. Approval Duration: 12 months. **PAH:** 1. Patient has symptomatic PAH. 2. Diagnosis of PAH is confirmed by right heart catheterization. 3. 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. 5. Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist. 6. Approval Duration: 12 months.	
ruxolitinib (**Jakafi**) tablets 5mg, 10mg, 15mg, 20mg, 25mg	1. Ordered for an approved indication for use: • Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults. • Polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea.	**Limitations of Use:** • Avoid concomitant use with fluconazole doses greater than 200 mg. Reduce Jakafi dosage with fluconazole doses ≤ 200 mg. • Strong CYP3A4 Inhibitiors: Reduce, interrupt, or discontinue Jakafi doses as recommended except in

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	• Steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older. • Chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older. 2. Medication ordered by Hematologist or Oncologist. 3. Approval Duration: 12 months.	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. 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	1. Documented positive clinical response to therapy. 2. Patient is not receiving Opzelura in combination with another biologic medication (e.g. Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)) OR JAK inhibitor (e.g. Jakafi (ruxolitinib, Xeljanz (tolacitinib), Rinvoq (upadacitinib)). 3. Patient is not receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine). 4. Approval Duration: 12 months

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	greater than 10% of body surface area (BSA). • Patient has inadequate treatment response, intolerance, or contraindication to at least two classes of formulary drugs (medium/high potency corticosteroid and a topical calcineurin inhibitor (e.g., tacrolimus or pimecrolimus). An adequate trial is considered 6 months. 4. Patient is not receiving Opzelura in combination with another biologic medication (e.g. Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)) OR JAK inhibitor (e.g. Jakafi (ruxolitinib, Xeljanz (tolacitinib), Rinvoq (upadacitinib)). 5. Patient is not receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine). 6. Prescribed by a Dermatologist 7. Patient has not received a sample or coupon trial supply to establish themselves as a current user for authorization under continuity-of-care. **8. <u>Initial authorization duration:</u>** • Atopic dermatitis: 2 months • Nonsegmental vitiligo: 6 months 9. Quantity limits: 60 gm per week or 180 gm per 28-days	
sastralizumab-mwge (**Enspryng**) injection solution 120mg/ml	1. Ordered for an approved indication for use: • Treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. 2. Must submit FDA-approved testing showing antibody positive.	1. Meets all initial criteria, AND 2. Provider attestation of continued benefit. 3. Use in caution if ALT/AST > 1.5 x ULN.

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	3. Age ≥ 18 years. 4. Prescriber attests that baseline evaluation has been done and there are no contraindications to use (e.g., Hep B, TB, LFT's, live or live-attenuated vaccines 4 weeks prior or 2 weeks for non-live vaccines). 5. Prescriber attests that subsequent appropriate evaluation and monitoring will be done based on the package insert (e.g., infections, LFT's, CBCs – neutrophils) 6. Medication ordered by neurologist, immunologist, or ophthalmologist experienced in treatment of this disease. 7. Approval Duration: 12 months.	4. Contraindicated in patients with active hepatitis B infection or active or untreated latent tuberculosis. 5. Approval duration: 12 months

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	○ Patient has failed a 3-month trial of psoralen plus ultraviolet light • Patient has failed an 8-week trial of an ustekinumab biosimilar or has a contraindication to use; AND • Patient has failed an 8-week trial of adalimumab or has a contraindication to use. • Prescribed by or in consultation with a dermatologist. • Approval Duration: 3 months. **Psoriatic Arthritis:** • Patient age ≥ 2 years; AND • Patient has failed a 3-month trial of a formulary TNF-agent (e.g. adalimumab or etanercepts) or has contraindication to use; AND • Patient has failed an 8-week trial of an ustekinumab biosimilar or has a contraindication to use; AND • Prescribed by or in consultation with a rheumatologist or dermatologist. • Approval Duration: 6 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. • Patient has experienced a positive clinical response in at least one symptom such as decreased pain, itching, and/or burning. • Approval Duration: 12 months. **Psoriatic Arthritis:** • Patient has been established on Cosentyx SQ or IV for at least 6 months; AND • Patient shows positive clinical response by way of at least one objective measure or improvement in at least one symptom. • Approval Duration: 12 months.
selexipag (**Uptravi**) tablets 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, 1600 mcg	1. Ordered for an approved indication for use: • Treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to delay disease progression and reduce the risk for hospitalization for PAH. 2. Patient aged ≥ 18 years. 3. Patient diagnosed with pulmonary hypertension WHO group 1. 4. Patient has had a right heart catheterization and the diagnosis of WHO Group 1 PAH is confirmed. 5. Patient meets one of the following criteria (a or b):	2. Patient meets initial approval criteria. 3. Approval Duration: 12 months.

	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. 10. Quantity Limits: 1 titration/starter pack per 365 days Max 2 tablets per day and total daily dose of 3200 mcg 11. Approval Duration: 12 months.	
selpercatinib (**Retevmo**) capsules 40mg, 80mg	1. Ordered for an approved indication for use: • Adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (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	4. Patient does not show evidence of progressive disease while on Retevmo therapy. 5. Approval Duration: 12 months.

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	(MTC) with a RET mutation, who require systemic therapy. • adult and pediatric patients ≥ 12 years of age with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). • Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. 2. Medication ordered by an Oncologist. 3. Approval Duration: 12 months.	

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semaglutide (**Wegovy**) 0.25 mg, 0.5 mg, 1 mg, 1.7 mg and 2.4 mg pens **Wegovy tablets 1.5 mg, 4 mg, 9 mg, 25 mg are only approved by FDA for weight loss therefore it's NOT a covered benefit.** *****NOTE: see separate listing with PA criteria for Ozempic/Rybelsus*****	1. Ordered **ONLY** for the indication: • To reduce the risk of Major Adverse Cardiovascular Events (MACE), in combination with a reduced calorie diet and increased physical activity, for adults with established cardiovascular disease and who are either obese or overweight. • Treatment of non-cirrhotic metabolic dysfunctionassociated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults 2. Criteria: • For both MACE and MASH indications: o Co-administration with other semaglutidecontaining products or with any other GLP-1 receptor agonist is not recommended. o Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all contraindications. • For MACE: o Prescribed by or in consultation with a cardiologist o Age: ≥ 18 o BMI ≥ 27 kg/m2 o Current accurate height and weight measurements (within the last 90 days) o Established ASCVD, defined as having a history of one or more of the following: o Prior myocardial infarction, and/or o Prior stroke, and/or o Symptomatic peripheral arterial disease, and/or o Prior myocardial infarction, prior stroke (ischemic or hemorrhagic stroke), or symptomatic peripheral arterial disease (PAD) as evidenced by;	**May not be renewed if BMI < or = 24 kg/m2** 1. MACE: i) Specific weight loss criteria have been achieved ii) Renewal requests will NOT be authorized unless continued weight reduction/maintenance is documented iii) Renewal requests will NOT be authorized if the member's BMI is < or = 24 kg/m2 2. Non-cirrhotic MASH: i) By requesting renewal, the prescriber attests to continued clinical benefit and subsequent evaluation and monitoring performed. 3. Approval Duration: 6 months. **Appendix: Acceptable tests for the determination of fibrosis in MASLD:** • **Transient elastography** • **Shear wave elastography (pSWE)** • **Magnetic resonance elastography (MRE)** • **ELF** • **Fibrotest** • **Fibrotic NASH Index (FNI)** • **MACK-3**

	• Intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), or • Peripheral arterial revascularization procedure, or • Amputation due to atherosclerotic disease • For noncirrhotic MASH: o Prescribed by or in consultation with a gastroenterologist or hepatologist o Exclusion: • Chronic liver disease other than noncirrhotic MASH (ie. alcoholic liver disease, autoimmune hepatitis, viral hepatitis, or Wilson's disease, etc.) • Presence of liver cirrhosis or a history of decompensated liver diseases • History of liver transplantation or current/ prior hepatocellular carcinoma • Excessive alcohol consumption (20 gm per day for female; 30 gm per day for male) o Diagnosis of noncirrhotic MASH with liver fibrosis stage F2 or F3, confirmed by liver biopsy or one of the non-invasive testing methods listed in the Appendix within the last 180 days o Absence of concurrent use of another medication(s) indicated for noncirrhotic MASH 3. May not be concurrently using or taking ANY of the below: • ANY GLP1 or GLP1/GIP combination drug (e.g., Mounjaro, Ozempic, Rybelsus, Saxenda, Soliqua, Trulicity, Victoza, Xultrophy, or Zepbound). • ANY DPP4i (alogliptin, Januvia [sitagliptin], Onglyza [saxagliptin], Tradjenta [linagliptin]). 4. . Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all contraindications.	

	5. May not be approved in patients with: • Current pregnancy • History of confirmed pancreatitis • Suicidal thoughts or new onset depression • Must be administered according to most current FDA guidelines for dosage and timing. • Per FDA-approved labeling, if patient cannot tolerate at least a 1.7 mg weekly dose, Wegovy should be discontinued. • Dose titration is expected every 4 weeks until patient reaches a minimum weekly dose of 1.7 mg. • Expected titration schedule: • 0.25 mg dose for 4 weeks, then • 0.5 mg dose for 4 weeks, then • 1.0 mg dose for 4 weeks, then • 1.7 mg dose for 4 weeks, then • 2.4 mg dose thereafter (if tolerated). • Dose titration is expected every 4 weeks until patient reaches a minimum weekly dose of 1.7 mg (2.4 mg per week is recommended weekly maintenance dose). 6. Quantity Limits: Four (4) pens/28 days 7. Approval Duration: Four (4) months initially	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	activity, for adults with established cardiovascular disease and who are either obese or overweight. • Treatment of non-cirrhotic metabolic dysfunctionassociated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults. 1. Criteria: • For both MACE and MASH indications: o Co-administration with other semaglutidecontaining products or with any other GLP-1 receptor agonist is not recommended. o Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all contraindications. 2. Patient age ≥ 18 years. 3. Patient does **NOT** have Type 1 or Type 2 diabetes. • Persons with T2DM may be redirected to Ozempic. • Persons with T1DM are **not** eligible for coverage. 4. Documentation submitted to show that patient is either obese or overweight. • Obesity/Overweight is defined as ≥ 27 kg/m^2. • Documentation of current BMI, height, **and** weight within last 90 days is **required;** **AND** 5. Documentation submitted to show that the patient has established atherosclerotic cardiovascular	• Renewal criteria is **not** met for weekly doses < 1.7 mg. 3. **Approval Duration: 6 months.**

	disease (ASCVD) as defined below: The patient has **<u>one</u>** or more of the following: ○ Prior myocardial infarction; **OR** ○ Prior stroke (ischemic or hemorrhagic); **OR** ○ Symptomatic peripheral arterial disease (PAD) as evidenced by **<u>one</u>** of the following: ▪ Intermittent claudication with ankle-brachial index (ABI) < 0.85 (at rest); **OR** ▪ Peripheral arterial revascularization procedure; **OR** ▪ Amputation due to atherosclerotic disease. 6. May not be concurrently using or taking **ANY** of the below: • ANY GLP1 or GLP1/GIP combination drug (e.g.,	

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	Mounjaro, Ozempic, Rybelsus, Saxenda, Soliqua, Trulicity, Victoza, Xultrophy, or Zepbound). • ANY DPP4i (alogliptin, Januvia [sitagliptin], Onglyza [saxagliptin], Tradjenta [linagliptin]). • Agents for severe constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 7. Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all contraindications. 8. May **not** be approved in patients with: • Current pregnancy • History of confirmed pancreatitis • Suicidal thoughts or new onset depression 9. Must be administered according to most current FDA guidelines for dosage and timing. • **Per FDA-approved labeling, if patient cannot tolerate at least a 1.7 mg weekly dose, Wegovy should be discontinued.** • Dose titration is expected every 4 weeks until patient reaches a minimum weekly dose of 1.7 mg. • Expected titration schedule: ○ 0.25 mg dose for 4 weeks, then ○ 0.5 mg dose for 4 weeks, then ○ 1.0 mg dose for 4 weeks, then ○ 1.7 mg dose for 4 weeks, then ○ 2.4 mg dose thereafter (if tolerated).	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	• Dose titration is expected every 4 weeks until patient reaches a minimum weekly dose of 1.7 mg (2.4 mg per week is recommended weekly maintenance dose). 10. Limited to 4 pens of any strength per 24 days. 11. **Approval Duration: 6 months.**	
sildenafil (Revatio) 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. **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.	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.

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	8. Approval duration: 12 months.	
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 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 treatement (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.	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 appropriately, or patient has sufficient symptom control on requested dose. 4. Approval Duration: 12 months

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	• Requested dose is appropriate for treatment initiation based on the patient's level of kidney impairment. 5. Target maximum daily dose cannot exceed 150 mg/day. 6. 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 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: o Height is at least TWO standard deviations (SD) below the mean height for normal children of same age and gender; o Height velocity less than 25th percentile for age. 5. Approval duration: 12 months	1. Confirmation of open epiphysial growth plates as above, OR the patient has not completed prepubertal growth 2. Patient meets at least one of the following: • Has an annual growth velocity of at least 2 cm during most recent approval year; • Is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm during the most recent approval year. 3. Approval duration: 12 months **<u>Limitations of Use:</u>** • Ngenla will not be approved for idiopathic short stature (ISS), athletic enhancement, central precocious puberty, congenital adrenal hyperplasia, constitutional delay of growth and puberty, or anti-aging purposes.
somatropin [recombinant human growth hormone] (**Norditropin FlexPro; Serostim**) injection	1. Ordered for an approved indication for use: • Growth failure in pediatric patients: o Due to inadequate endogenous growth hormone secretion; short stature	Growth failure in pediatric patients: 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

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
Norditropin 5/1.5ml, 10/1.5ml, 15/1.5ml, 30mg/3ml Serostim 4mg, 5mg, 6mg	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] ○ Growth failure associated with chronic kidney disease until time of renal transplant. • Growth hormone deficiency in adults: replacement of endogenous growth hormone in adults with growth hormone deficiency [Norditropin FlexPro] • Treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance [Serostim ONLY] 2. Medication ordered by an Endocrinologist or Infectious disease specialist (Serostim ONLY). 3. For pediatric patients with growth failure: Confirmation of open epiphysial growth plates. 4. Approval duration: 12 months	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. Adult indications for use: 1. Clinical documentation indicating positive clinical response during previous 12 months All ages: Approval duration: 12 months
tacrolimus extended-release (**Envarsus XR**) tablets 0.75mg, 1mg, 4mg	1. Ordered for an approved indication for use: • prophylaxis of organ rejection in kidney transplant in adult patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants. 2. Documented evidence that the patient is unable to achieve or maintain an appropriate therapeutic drug	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:

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	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	• Pure red cell aplasia (PRCA) • Posterior reversible encephalopathy syndrome (PRES) • Torsades de points 5. Approval duration: 12 months
tadalafil (Adcirca; Alyq) PAH: 20 mg tablets *Tadalafil for treatment of BPH is non-formulary. If medically necessary, must be requested under a non-formulary exception PA request.*	1. Ordered for an approved indication for use: • To treat signs and symptoms of benign prostatic hyperplasia (BPH). • To treat pulmonary arterial hypertension (World Health Organization group 1) to improve exercise ability. **2.** Patient is not concurrently on organic nitrates (i.e., isosorbide mononitrate, isosorbide dinitrate, nitroglycerin), OR sildenafil, OR Adempas (riociguat); AND **3.** IF patient is also prescribed macitentan (Opsumit), please **redirect** to Opsynvi (macitentan + tadalafil). **4. Erectile dysfunction is not a covered indication for use.** 5. Ordered for generic Adcirca (tadalafil PAH) 20 mg tablets. 6. The diagnosis of PAH is documented by right-heart catheterization with ALL of the following: ○ Mean pulmonary artery pressure (mPAP) > 20 mmHg, and ○ Pulmonary arterial wedge pressure (PAWP) ≤ 15 mmHg, and	1. All initial criteria continue to be met. 2. IF patient is also prescribed macitentan (Opsumit), please **redirect** to Opsynvi (macitentan + tadalafil). 3. Patient has documented positive clinical response to tadalafil treatment. 4. Approval Duration: 12 months.

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	○ Pulmonary vascular resistance (PVR) ≥ 3 wood units. 7. Medication ordered by a Pulmonologist, Cardiologist, or Rheumatologist. 8. Quantity Limits: 2 tablets per day. 9. Approval Duration: 12 months.	
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. • Hepatitis Be antigen (HBeAg) status. • Liver function tests. Not recommended for Child-Pugh class B or C hepatic impairment. 3. Patient has a history of adverse event, intolerance to or contraindication to treatment with entecavir OR meets one of the following criteria: • Patient age < 20 years. • Documentation of osteopenia or osteoporosis as defined by a T-score ≤ 1 and supported by clinical documentation of DEXA scan results. • Submission of medical records documenting a prior low-trauma or non-traumatic fracture. 4. 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.	1. Documentation of a positive clinical response to Vemlidy therapy. 2. Patient is not a suitable candidate for entecavir. 3. Approval duration: 12 months.

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	6. Initial authorization period: 12 months.	
teriparatide (Forteo) 620mcg/2.48ml Pen-injector	1. Ordered for an approved indication for use: • Treatment of postmenopausal women with osteoporosis at high risk for fracture. • To increase bone mass in men with primary or hypogonadal osteoporosis at high risk of fracture. • Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dose equivalent to ≥ 5 mg of prednisone) at high risk for fracture. 2. Age ≥ 18 years or documentation of closed epiphyses on X-ray. 3. Patient is at very high fracture risk as evidenced by one of the following: • Recent osteoporotic fracture within the past 12 months. • Bone mineral density (BMD) T-score at hip or spine ≤ -3.0 • BMD T-score at hip or spine ≤ -2.5 AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus). 4. Patient has completed a 3-year trial of bisphosphonate therapy at up to maximally indicated doses, UNLESS one of the following: • All bisphosphonates are contraindicated. • Clinically adverse effects are experienced to both IV and PO formulations. • Patient has experienced a loss of- or a lack of increase in- BMD while receiving bisphosphonate therapy.	**<u>Osteoporosis</u>** 1. Patient previously met initial approval criteria. 2. Documentation supports positive response to therapy. 3. If request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture) and that the risk versus benefit of continued therapy has been reviewed with the member. 4. If request is for a dose increase, the new dose does not exceed 20 mcg per day (1 per per 28 days). 5. Approval duration: 12 months **<u>Glucocorticoid-induced osteoporosis:</u>** 1. Documentation supports positive response to therapy. 2. If request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture) and that the risk versus benefit of continued therapy has been reviewed with the member.

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	• Patient experienced an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy. 5. If request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture) and that the risk versus benefit of continued therapy has been reviewed with the member. 6. Dose does not exceed 20 mcg per day (1 pen every 28 days) 7. Approval Duration: 6 months.	3. Approval duration: not to exceed 6 months.
tesamorelin (**Egrifta SV**) injection 2mg	1. Ordered for an approved indication for use: • Reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy. 2. Diagnosis of HIV-associated lipodystrophy. 3. Patient age ≥ 18 years and ≤ 65 years. 4. Patient meets ONE of the following: • If male, waist circumference is ≥ 95 cm (37.4 inches) and waist-to-hip ratio is ≥ 0.94; OR • If female, waist circumference is ≥ 94 cm (37 inches) and waist-to-hip ratio is ≥ 0.88; AND 5. Patient has been stable on antiretroviral regimen for at least 8 weeks; AND 6. Medication is prescribed by or in consultation with an endocrinologist or physician specializing in the treatment of HIV-infection. 7. Approval Duration: 6 months.	1. Documentation of positive clinical response (e.g., improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance). 2. Approval Duration: 12 months.
tirzepatide (**Mounjaro**) injection *****NOTE: see separate listing with PA criteria for Zepbound*****	1. Ordered for the covered indication: • Treatment of adult patients with Type 2 Diabetes mellitus (T2DM). 2. Patient age ≥ 18 years. *3.* Patient has diagnosis of T2DM.	**Cannot be approved for indication of weight management.** 1. Chart notes with A1c or CGM report with TIR% within previous 3 months. 2. A urine albumin-to-creatinine ratio

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2.5mg/0.5ml, 5mg/0.5ml, 7.5mg/0.5ml, 10mg/0.5ml, 12.5mg/0.5ml, 15mg/0.5ml	***NOTE:*** *this product is not indicated for use in T1DM.* 4. A1c **or** Time in Range% (TIR%) CGM-report within past 3 months. 5. A urine albumin-to-creatinine ratio (uACR) within the previous 12 months. **Treatment of Type 2 Diabetes without regard to CVD risk factors:** The patient has an A1c (hemoglobin A1c) of ≥ 7.5 (TIR ≤ 60%)**.** **OR** **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.	(uACR) within the previous 12 months. 3. Documented positive clinical response defined as one of the following: **Baseline (pre-GLP-1) A1c was ≥ 8.0 and:** • A1c has decreased by ≥ 1% since onset of therapy **or** TIR% was ≤ 55% and has increased ≥ 10% **or** 5. A1c is ≤ 7.0 at initiation dose. **Baseline (pre-GLP-1) A1c was ≥ 6.5 but < 8.0 and:** 6. A1c or TIR% has improved. Not eligible for renewal if A1c has increased **or** TIR% has decreased. 4. Patient has not had medical intervention for: 7. Pancreatitis; or 8. Severe gastrointestinal events. (e.g., hospitalization or new start GI motility agent). 5. May not be concurrently using **ANY** of the following: • **ANY** other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus, 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

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	6. 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). 7. Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all contraindications. 8. May **not** be approved for patients with: • Any personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN 2). • Current pregnancy • History of confirmed pancreatitis 9. Starter doses are limited and require dose escalation. Mounjaro 2.5 mg is a starter dose and is limited to one, 28-day supply and then must be dose escalated to 5 mg per week dose **UNLESS** A1c ≤ 7.0 or TIR ≥ 65% on 2.5 mg dose. 10. **Cannot be approved for indication of weight management.** 11. Maximum Approval Duration: up to 12 months	(lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 5. PBM claims data shows consistent adherence as shown by no instance of a drug-free interval greater than 2 months at which time the patient would need to satisfy the initial criteria. 6. Approval Duration: up to 12 months.

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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. 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. 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).	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. 4. Approval Duration: 6 months.

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	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 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. 13. **Approval Duration: 6 Months.**	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
tivozanib (**Fotivda**) capsules 0.89mg, 1.34mg	1. Ordered for an approved indication for use: • the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. 2. Patient has relapsed or Stage IV disease; AND 3. Patient has tried at least two other systemic regiments (i.e. Inlyta + Keytruda; Cabometyx + Opdivo; Lenvima + Keytruda; Yervoy + Opdivo, sunitinib, pazopaniv, or Lenvima + everolimus. 4. Medication order by Hematology/oncology. 5. Approval Duration: 12 months.	1. Patient does not show evidence of disease progression while on Fotivda therapy. 2. Approval Duration: 12 months.
tramadol hydrochloride extended release (Ultram) capsules (biphasic release) 100mg, 150mg, 200mg, 300mg Tablets 100mg, 200mg, 300mg Tablets (biphasic release) 100mg, 200mg, 300m	1. Ordered for an approved indication for use: • in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. 2. Completion of the opioid prior authorization form. 3. Submission of supporting clinical documentation for last office visit, dated within the previous 3 months. 4. Opioid naïve adult patients (no opioid use within the previous 30-days) are limited to a 7-day supply with an MME ≤ 50 MME per day, patients under age 18 are limited to a 3-day supply. 5. Maximum approval duration is 6 months but may be reduced or denied based on any of the criteria as outlined in Pharmacy Policy 219.DC: Opioid Prescription Prior Authorization.	All long-acting opioids require Prior Authorization (PA). The PA form can be accessed using the following link: OPIOID PRIOR AUTHORIZATION FORM-DC **Limitations of Use:** Not indicated as an as-needed (prn) analgesic.

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
triptorelin (**Trelstar**) intramuscular injection 3.75 mg; 11.25 mg; 22. 5 mg	1. Ordered for an approved indication for use: • Palliative treatment of advanced prostate cancer • Preservation of ovarian function • Breast cancer (ovarian suppression) • Gender affirming care. 2. **Prostate Cancer:** • Prescribed by an oncologist. **Preservation of ovarian function:** • Patient is premenopausal and undergoing chemotherapy. **Breast cancer:** • Patient is premenopausal with hormone-receptor positive breast cancer at high-risk for recurrence using in combination with endocrine therapy. **Gender affirming care:** • Patient has diagnosis of gender dysphoria and meets MDH regulatory requirements for care. • Patient has reached Tanner stage ≥ 2 of puberty. 3. **Approval Durations:** • Prostate Cancer: 12 months • Preservation of ovarian function: 3 months • Breast cancer (ovarian suppression): 12 months • Gender affirming care: 12 months	1. **Prostate Cancer:** • Patient is experiencing clinical benefit (e.g., serum testosterone < 50 ng/dl) • Patient has not experienced unacceptable toxicity. **Preservation of ovarian function:** • Patient meets all initial criteria. **Breast cancer:** • Patient was premenopausal at diagnosis and is still undergoing treatment with endocrine therapy. • Total treatment with triptorelin does not exceed 5 years. **Gender affirming care:** • Patient has reached Tanner stage ≥ 2 of puberty. 2. Approval Durations: • Prostate Cancer: 12 months • Preservation of ovarian function: up to 12 months ***providing that cumulative treatment course is < 5 years.* • Breast cancer: 12 months • Gender affirming care: 12 months
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 NSAIDs **and** at least two formulary triptans or have a	1. Meets all initial clinical criteria. 2. Documentation of positive clinical response to treatment. 3. Quantity limited to 16 doses per 30 days, 200 mg max daily dose. 4. Approval Duration: 12 months.

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	contraindication to taking both classes of medications. *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. 4. Quantity limited to 16 doses per 30 days, 200 mg max daily dose. 5. Approval Duration: 12 months.	
Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	**Approval Criteria & Submission Requirements**	**Additional Considerations & Renewal Criteria**

valbenazine (**Ingrezza**) capsules 40 mg, 60 mg, 80 mg	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 deutetrabenazine), MAOIs or reserpine. 4. Patient does not have hepatic impairment. 5. Tardive dyskinesia: • AIMS score sheet along with the progress note must be provided for initial and renewal PA requests. 6. Huntington's disease: • Description of functional impairment, including Total Maximal Chorea (TMC) score sheet along with progress notes must be provided for both initial and renewal PA requests. 7. Patient must not be suicidal or have	1. Prescriber attestation of continued clinical benefit and subsequent evaluation and monitoring performed. 2. TD: AIMS score must show improvement over initial score. 3. HD: TMC score must show improvement over the initial score and functional impairment must show improvement from baseline. 4. All initial criteria must be met. 5. Approval Duration: 12 months
Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	**Approval Criteria & Submission Requirements**	**Additional Considerations & Renewal Criteria**
	untreated/inadequately treated depression. 8. Patient is not prescribed to concurrently use multiple strengths of Ingrezza. 9. Quantity Limit: 1 capsule per day. 10. Approval Duration: 12 months	

vigabatrin (Sabril; **Vigadrone**) 500 mg powder pack	1. Ordered for an approved indication for use: • treatment of Refractory Complex Partial Seizures as adjunctive therapy in patients ≥ 2 years of age who have responded inadequately to several alternative treatments. • Infantile Spasms - monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss. 2. Medication prescribed by a provider registered in the vigabatrin REMS program. 3. Medication prescribed by a Neurologist.	**Limitations of Use:** Vigabatrin is not indicated as a first line agent.
viloxazine extended release (**Qelbree**) capsules 100mg, 150mg, 200mg **STEP THERAPY**	1. Ordered for an approved indication for use: • treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients ≥ 6 years of age. 2. History of a ≥4-week trial of, contraindication to, or intolerance of both of the following stimulant medications: • a methylphenidate class stimulant (e.g. generic Concerta) • an amphetamine class stimulant (e.g. generic Adderall XR) • OR history of a substance use disorder or concern for potential misuse or diversion of stimulant medication AND 3. History of a ≥4-week trial of, contraindication to, or intolerance of both of the following non-stimulant	
Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	**Approval Criteria & Submission Requirements**	**Additional Considerations & Renewal Criteria**

	medications: • guanfacine ER (generic Intuniv) • atomoxetine (generic Straterra) 4. Daily dose does not exceed 400 mg per day for patients 11 years of age or younger; 600 mg per day max for ages ≥12 years.	
viltolarsen (**Viltepso**) 250 mg/5ml solution	1. Ordered for an approved indication for use: • treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. 2. Genetic testing must confirm patient's DMD gene is amenable to exon 53 skipping. 3. Current patient weight, including date weight was obtained and within 30 days of requested date. 4. Baseline renal function test (GFR) and Urine protein-to-creatinine ratio prior to starting treatment. 5. Documented baseline function testing using a tool to demonstrate physical functions, including, but not limited to: Brooke Upper Extremity Scale, Baseline 6-minute walk test, Pediatric Evaluation of Disability Inventory. 6. Stable dose of glucocorticoid for at least 3 months. 7. Confirmation that drug continues to carry FDA-approval for indication. 8. Prescribed by a neurologist with expertise in treatment of DMD. 9. Approval duration: 3 months	1. Documentation and provider attestation of continued benefit, including respiratory status assessment, without adverse effects. 2. Not receiving another antisense therapy or gene therapy. 3. Verification that drug continues to carry FDA-approval for indication. • Approval duration: 3 months
voclosporin (**Lupkynis**) capsule 7.9mg	1. Ordered for an approved indication for use: • in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus	1. All initial criteria continue to be met. 2. Documentation provided or attestation of therapeutic benefit. 3. Approval Duration: 6 months.

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

	nephritis. (mycophenolate mofetil and corticosteroids). 2. Patient age ≥ 18 years. 3. Not taking concurrently with cyclophosphamide. 4. Prescriber specialty: immunologist, nephrologist, rheumatologist, or provider experienced in treatment of lupus nephritis. 5. Prescriber attestation that all baseline evaluations have been done, and not contraindications to use are present (strong 3A4 inhibitor contraindicated, live vaccines, pregnancy/breastfeeding negative, assessment of renal function). 6. Quantity Limit: 6 tablets per day (23.7 mg twice daily). 7. Approval Duration: 6 months	

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

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	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) (adult and pediatric ≥5 years) **Ophthalmology** Non-infectious Uveitis (intermediate, posterior, or panuveitis) PRESCRIBER REQUIREMENTS • Must be prescribed by or in consultation with: o Rheumatologist (RA, PsA, AS, nr-axSpA, pJIA) o Dermatologist (PsO, HS) o Gastroenterologist (CD, UC) o 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 • Use consistent with FDA-approved dosing	REAUTHORIZATION CRITERIA • Documented clinical improvement • Continued adherence (PDC ≥0.8) • No serious adverse events • Approval Duration: 12 Months

	STEP THERAPY REQUIREMENTS A. **Rheumatoid Arthritis (RA)** Step 1: Conventional DMARDs (Required) • Methotrexate (preferred) • Leflunomide • Sulfasalazine Minimum Duration: • ≥12 weeks Verification: • Pharmacy claims with PDC ≥0.8 • OR documented intolerance Authorization granted if: • Inadequate response to ≥1 DMARD OR contraindication to DMARD B. **Psoriatic Arthritis (PsA)** Step 1: Conventional DMARD • ≥12 weeks methotrexate or equivalent Verification: Pharmacy claims with PDC ≥0.8 OR documented intolerance Authorization granted if: o Inadequate response to ≥1 DMARD OR contraindication to DMARD C. **Ankylosing Spondylitis / nr-axSpA** Step 1: NSAIDs • ≥2 NSAIDs • ≥4 weeks each Step 2: Hadlima • First-line biologic after NSAID failure D. **Plaque Psoriasis (PsO)** Step 1: Topicals + Phototherapy	

	• ≥12 weeks Step 2: Systemic therapy • Methotrexate, cyclosporine, or acitretin (≥12 weeks) Step 3: Hadlima • Preferred biologic option E. **Hidradenitis Suppurativa (HS)** Step 1: Antibiotics • ≥90 days (e.g., doxycycline, clindamycin/rifampin) Step 2: Hadlima F. **Crohn's Disease (CD) / Ulcerative Colitis (UC)** Step 1: Conventional therapy • Corticosteroids • Immunomodulators (azathioprine, 6-MP) Duration: • ≥12 weeks Step 2: Hadlima • Preferred TNF inhibitor G. **Uveitis** Step 1: Corticosteroids ± immunosuppressants • ≥12 weeks Step 2: Hadlima 5. EXCLUSION CRITERIA Coverage denied if: • Use outside FDA-approved indication without compendia support • No prior therapy or insufficient duration • Non-adherence (PDC <0.8) • Concurrent biologic/JAK use 6. DOSING REQUIREMENTS • Must follow FDA-approved dosing by indication • Weight-based dosing for pediatric patients where applicable Initial PA: 12 Months	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal 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 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**	**Ankylosing Spondylitis:** • 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. **Enthesitis-Related Arthritis:** • 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. **Hidradenitis Suppurativa:** • Patient has been established on Cosentyx SQ for at least 3 months; and • Patient has experienced positive

	disease (e.g., continued inflammatory back pain, BASDAI ≥4, elevated CRP/ESR, or physician documentation of insufficient improvement). 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 **Ankylosing Spondylitis:** • 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. **Enthesitis-Related Arthritis:** • Patient age ≥ 4 years of age; AND • Meets all of the above criteria (step 1) AND • Prescribed by or in consultation with a rheumatologist **Approval Duration:** 4 months. **Hidradenitis Suppurativa:** • Patient age ≥ 18 years; AND • Patient has tried at least two other therapies for 3 month duration (e.g. corticosteroids, systemic antibiotics, or isotretinoin). AND • Preferred Adalimumab failure or Contraindication AND	clinical response to at least one objective measure from baseline (e.g. Hurley staging, Sartorius score, Physician Global Assessment, and Hidradenitis Suppurativa Severity index); AND • Patient has experienced positive clinical response in at least one symptom (e.g. decreased pain ordrainage of lesions, nodules, or cysts). **Approval Duration:** 6months. **Non-Radiographic Axial Spondylarthritis:** • 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. **Plaque Psoriasis:** • Patient has been established on Cosentyx SQ for at least 3 months. • Patient has experienced a positive clinical response defined as improvement from baseline in at least

	• Prescribed by or in consultation with a dermatologist. **Approval Duration:** 3 months. **Non-Radiographic Axial Spondylarthritis:** • Patient age ≥ 18 years; AND • Patient has objective signs of inflammation, defined as at least ONE of the following: • C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory, OR • Sacroiliitis reported on magnetic resonance imaging; AND • TNF blocker failed and meets all above criteria (step 1) AND • Prescribed by or in consultation with a rheumatologist **Approval Duration:** 6 months **Plaque Psoriasis:** • 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.	one of the following: estimated affected BSA, erythema, induration/thickness and/or scale of areas affected by psoriasis. • Patient has experienced a positive clinical response in at least one symptom such as decreased pain, itching, and/or burning. **Approval Duration:** 6 months. **Psoriatic Arthritis:** • 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.

	Psoriatic Arthritis: • 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	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
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 • 12.5 mg/0.5 mL • 15 mg/0.5 mL	All of the following criteria must be met. **1. Covered Indication** Medication is prescribed for **treatment of Type 2 Diabetes Mellitus (T2DM)** in adults. • Not indicated for **Type 1 diabetes mellitus** • Requests for **weight management** will not be approved. Medication is prescribed for the **treatment of Type 2 Diabetes with CVD.** **2. Age Requirement** • Patient is **≥ 18 years of age** **3. Diagnosis** • Confirmed diagnosis of **Type 2 Diabetes Mellitus** **4. Baseline Glycemic Assessment** Documentation within the **past 3 months** of one of the following: • **Hemoglobin A1c** • **Continuous Glucose Monitor (CGM) report with Time in Range (TIR%)** **Clinical Eligibility:** Patient meets: • **A1c ≥ 7.5%** OR • **TIR ≤ 60%** **Step Therapy Requirements**	All of the following must be met. **1. Updated Clinical Documentation** Within the **previous 3 months**: • A1c **OR** • CGM report with **TIR%** **2. Clinical Response** Evidence of **positive clinical response**. **If baseline A1c ≥ 8.0:** • A1c reduced **≥ 1%** OR • TIR improved **≥ 10%** **If baseline A1c 6.5–7.9:** • A1c or TIR **improved or maintained** • Requests **not eligible** if A1c increased or TIR worsened **3. Safety Monitoring** No medical intervention for: • **Pancreatitis** • **Severe gastrointestinal events** (e.g., hospitalization or initiation of GI motility agents) **4. Concomitant Therapy Restrictions** Patient **may not be using**: • Any **GLP-1 or GLP-1/GIP combination therapy** • Any **DPP-4 inhibitor** • **Severe constipation agents** listed above

	Step 1 – Metformin • Trial of **≥ 3 months** at maximum tolerated dose OR • Documented **contraindication or intolerance** **Step 2 – Two Additional Agents** 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 – GLP-1 Requirement** Trial of **≥ 3 months** at maximum tolerated dose of: • **liraglutide (Victoza®)** OR documented **contraindication/intolerance** **Definition of Treatment Failure** Failure is defined as: • Lack of improvement in **A1c from baseline** despite adherence OR • **Discontinuation due to intolerance or adverse effects** **Concomitant Therapy Restrictions** Patient **may not be using** any of the following: **Other GLP-1 or GLP-1/GIP agents** • Ozempic®, Rybelsus®, Wegovy®, Saxenda® • Trulicity®, Victoza®,Soliqua®,Xultophy® • Zepbound®	**5. Adherence Requirement** PBM claims data must demonstrate **consistent adherence**, defined as: • No **drug-free interval > 2 months** Patients exceeding this interval must **re-qualify under initial criteria**. **Renewal Approval Duration**:6 months

	DPP-4 inhibitors • Alogliptin, sitagliptin (Januvia®), saxagliptin (Onglyza®), linagliptin (Tradjenta®) **Agents for Severe Constipation** • Metoclopramide, lubiprostone (Amitiza®) • linaclotide (Linzess®), prucalopride (Motegrity®) • plecanatide (Trulance®) **Safety Criteria** Requests will **not be approved** for patients with: • Personal or family history of **medullary thyroid carcinoma (MTC)** • **Multiple endocrine neoplasia syndrome type 2 (MEN2)** • **Current pregnancy** • **History of pancreatitis** Prescriber must attest the medication is prescribed in accordance with **FDA labeling**, including screening for all contraindications and boxed warnings. **Dosing Requirements** • **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%** **Initial Approval Duration:** 6 months	

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

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**. **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. **2. General Criteria (Applies to Both 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**. **3. Criteria for MACE Indication** 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 last 90 days** • **Established atherosclerotic cardiovascular disease (ASCVD)**, defined as history of one or more of the following: • Prior **myocardial infarction**	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 • 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**

	• 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**
	4. 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**
	• **History of liver transplantation**
	• **Current or prior hepatocellular carcinoma**
	• **Excessive alcohol consumption**
	  • 20 g/day (female)
	  • 30 g/day (male)	

Additional Requirements

- Patient **must not be receiving another medication indicated for non-cirrhotic MASH**

5. 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

6. Patient Safety Restrictions

Wegovy **will not be approved** for patients with:

- **Current pregnancy**
- **History of confirmed pancreatitis**

Medication must be administered **in accordance with current FDA-approved dosing and titration guidelines**.

7. 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**:

Duration	Dose
Weeks 1-4	0.25 mg weekly
Weeks 5-8	0.5 mg weekly

	Weeks 9-12	1.0 mg weekly	
	Weeks 13-16	1.7 mg weekly	
	Maintenance	2.4 mg weekly(if tolerated)	
	Recommended maintenance dose: 1.7mg or 2.4 mg weekly. **8. Quantity Limits** **Four (4) pens per 28 days** **9. Initial Approval Duration** **4 months**		

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

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:
	1. **Moderately to Severely Active Rheumatoid Arthritis (RA)**
	2. **Active Psoriatic Arthritis (PsA)**
	3. **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
	• Baseline disease severity documented (e.g., DAS28, CDAI, Mayo score)
	• Negative TB screening prior to initiation
	• Trail and failure, or Inadequate response or intolerance to one or more TNF inhibitors.
	• No concurrent use with biologic DMARDs or other JAK inhibitors
	• Use consistent with FDA-approved dosing
	
	Rheumatoid Arthritis (RA)
	
	1. Step 1: Conventional Synthetic DMARDs (Required)
	Trial and failure, intolerance, or contraindication to:
	• Methotrexate (preferred)
	• Leflunomide
		REAUTHORIZATION CRITERIA (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)
		
		No serious adverse events requiring discontinuation

	• Sulfasalazine Minimum Duration Requirement: • ≥12 weeks continuous therapy Verification: • Pharmacy claims demonstrating PDC ≥0.8 over 12 weeks OR documented intolerance/adverse effects **2. 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 **3.Step 3: Xeljanz Eligibility** Authorization only if: • contraindication to biologics • OR documented inability/refusal to use injectable therapy Initial PA: 6 months **Psoriatic Arthritis (PsA)** 1. Step 1: Conventional DMARD (Required) • Methotrexate • Leflunomide • Sulfasalazine Minimum Duration Requirement: ≥12 weeks Verification: • Pharmacy claims (PDC ≥0.8) 2. Step 2: Biologic DMARD (Required)	

	• ≥1 TNF inhibitor Minimum Duration Requirement: ≥12 weeks Verification: • Claims + clinical documentation 3. Step 3: Xeljanz Eligibility Same as RA: • Failure/intolerance to biologic • OR contraindication Initial PA: 6 months **Ulcerative Colitis (UC)** Step 1: Conventional Therapy (Required) • 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 Eligibility	

	Authorization only if:
	• Failure/intolerance to biologics
	• OR contraindication to biologics
	
	SAFETY RESTRICTIONS (STRICT)
	Due to boxed warnings:
	• Use requires careful risk-benefit assessment in patients with:
	  ○ History of thrombosis (unless justified)
	  ○ 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
	• 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	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
Ustekinumab (Stelara biosimilars) 45 mg; 90 mg pre-filled syringes for injection • **Yesintek (** Ustekinumab-kfce) • **Steqeyma** (ustekinumab-stab)	1. The criteria for ustekinumab are **indication specific**. Please review criteria for the patient-specific diagnosis. 2. Patient has been screened for Hepatitis B and Tuberculosis prior to initiation of therapy. 3. 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). 4. 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**: • 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.	**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.

	Approved dose: Maintenance dosing (90 mg/ml every 8 weeks) following IV induction. **Approval Duration**: 12 months **<u>Plaque psoriasis</u>**: Diagnosis of moderate to severe plaque psoriasis ≥ 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis; **AND** History of 8 weeks failure to **TWO** 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. **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>Psoriatic arthritis</u>**:	

	Diagnosis of active psoriatic arthritis; AND History of failure to a 3-month trial of methotrexate at aximally 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 **Ulcerative colitis, moderate to severe:** Diagnosis of moderate to severe ulcerative colitis. Prescribed by or in consultation with a gastroenterologist. **Tried and failed TNF blocker (Adalimumab) biosimilar for 12 weeks** **Approved dose:** 90 mg/ml **Approval Duration:** 12 months	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
Apremilast **(Otezla)** 10 mg, 20 mg, 30 mg XR tablets: 75 mg	**Active Psoriatic Arthritis (PsA)** 1. Patient is 18+ years old. 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 • 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:	REAUTHORIZATION CRITERIA (6 MONTHS) Authorization may be renewed if: • Documented clinical improvement: o PsA: reduction in joint symptoms o PsO: improvement in BSA/PASI o Behçet's: reduced ulcer frequency • Continued adherence (PDC ≥0.8 based on pharmacy claims) No evidence of disease progression

	• Failure/intolerance to ≥1 biologic • OR contraindication to biologics • OR documented inability to use injectable therapy PA Approval: 6 months **<u>Plaque Psoriasis (PsO)</u>** 1. Patient is 18+ years old. 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 4. Step 2: Systemic Oral Therapy (Required) • 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 5. 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 6. Prescriber or in consultation with a rheumatologist PA approved for 6 months. **Bechet's Disease (Oral Ulcers)** Patient is 18+ years old. Prescriber or in consultation with rheumatologist **Step 1: First-Line Therapy** • Topical corticosteroids • Colchicine Minimum Duration Requirement: • ≥ 12 weeks Verification: • Pharmacy claims or documented clinical use **Step 2: Systemic Therapy** • Azathioprine • Thalidomide (if appropriate) Minimum Duration Requirement: • ≥12 weeks o Verification: • Pharmacy claims and/or clinical documentation	

	Step 3: Otezla Eligibility • Failure/intolerance to above therapies • Persistent oral ulcers impacting quality of life **PA Approval**: 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	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
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®**: 1.5 mg, 4 mg, 9 mg (daily) • **Non-covered:** semaglutide products indicated for **weight management** (e.g., **Wegovy®**) regardless of diagnosis.	**Covered Indications (must meet A or B)** **A. Glycemic control in adults with Type 2 diabetes mellitus(T2DM)** As adjunct to diet and exercise to improve glycemic control in adults with T2DM. **B. CV risk reduction in adults with T2DM and established CVD** Risk reduction of major adverse cardiovascular events (**CV death, nonfatal MI, nonfatal stroke**) in adults with T2DM who have **established cardiovascular disease (CVD)**. **Not covered (all cases):** use for **weightloss/weightmanagement** (obesity/overweight, metabolic syndrome, insulin resistance, prediabetes/diabetes prevention). **Eligibility (hard stops)** 1. **Age ≥ 18 years** 2. **Documented T2DM is required** • **Type 1 diabetes mellitus does not qualify** • Not eligible: **gestational diabetes**, **prediabetes** without T2DM **Required Submission Documentation** Must submit:	**Non-covered use:** Renewal **will not be approved** when the indication is **weight management/weight loss**, including obesity/overweight, metabolic syndrome, insulin resistance, or prediabetes. **1) Product/Dose appropriateness (hard stop)** • **Rybelsus® 3 mg** is a **starter dose only** and **may not be renewed**. Member must be escalated to **7 mg or 14 mg daily** unless there is **documented intolerance** that prevents escalation, in which case renewal is **not approved** and alternative therapy should be considered. **2) Required renewal documentation (must submit)** 1. **Chart notes** documenting ongoing **Type 2 diabetes mellitus** diagnosis and continued medical necessity. 2. **A1c** *or* **CGM report with TIR%** within the **previous 90 days**. 3. **Baseline (pre-GLP-1) value** and **current value** must be provided for A1c and/or

	1. **A1c** *or* **CGM Time-in-Range (TIR%)** report **within the past 90 days**
	2. **Medication history** documenting step therapy trials (drug, dose, dates, outcome, intolerance/contraindication if applicable)
	3. If requesting under CV indication: documentation of **established CVD**
	
	Clinical Thresholds (must meet one pathway)
	
	Pathway 1 — T2DM (glycemic control)
	• **A1c ≥ 7.5%** *or* **TIR ≤ 60%**, **and**
	• Meets **all step therapy** in Section 7
	
	Pathway 2 — T2DM + established CVD (CV risk reduction)
	• Meets **established CVD** definition in **and**
	• **Pre-treatment A1c ≥ 6.5%** *or* **TIR ≤ 70%**, **and**
	• Meets **all step therapy** in Section 7 (**including liraglutide failure**)
	Go through 7.3 for pathway 2
	
	Definition: Established CVD (required for CV indication)
	Documentation must show **≥ 1** of:
	• Prior **myocardial infarction**, or
	• Prior **stroke** (ischemic or hemorrhagic), or
	• **Symptomatic PAD** evidenced by:
	  • Claudication with **ABI < 0.85 at rest**, or
	  • **Peripheral arterial revascularization**, or
	  • **Amputation due to atherosclerotic disease**
	Step Therapy
	Must follow all for the following pathways
	
	Pathway 1 — T2DM (glycemic control)
		TIR to allow objective assessment of response.
		
		3) Objective clinical response requirement (must meet one)
		
		Renewal requires **documented positive clinical response** as defined below:
		
		A) If baseline (pre-GLP-1) A1c ≥ 8.0%
		Member must meet **at least one**:
		• **A1c decrease ≥ 1.0%** from baseline, **or**
		• If baseline **TIR ≤ 55%**, **TIR increase ≥ 10 percentage points**
		
		B) If baseline (pre-GLP-1) A1c ≥ 6.5% and < 8.0%
		Member must demonstrate **objective improvement**, defined as **at least one**:
		• **A1c decrease ≥ 0.5%**, **or**
		• **TIR increase ≥ 5 percentage points**
		
		Not eligible for renewal if:
		• **A1c is unchanged or increased**, **or**
		• **TIR is unchanged or decreased**, **or**
		• Required baseline/current values are not provided.
		
		This replaces “A1c or TIR has improved” with numeric thresholds to reduce subjectivity and appeals.
		
		4) Safety events / medical interventions (hard stops)

	7.1 Metformin Failed **≥ 3 months** at **maximum tolerated dose** of **metformin**, **or** documented contraindication/intolerance. **7.2 Two additional agents** Failed **≥ 3 months** at **maximum tolerated doses** of **two (2)** of: • Insulin • Sulfonylurea (e.g., glipizide, glimepiride) • Pioglitazone • DPP-4 inhibitor (e.g., alogliptin) • **SGLT2 inhibitor** (e.g., empagliflozin/Jardiance®, dapagliflozin/Farxiga®) (great heart failure **Failure definition (recommended to include):** "Failure" means **lack of A1c improvement** from baseline after adequate adherence, or discontinuation due to intolerance/adverse effects. **7.3 Liraglutide (required for ALL requests)** Failed **≥ 3 months** at **maximum tolerated dose** of **liraglutide** (Victoza®) for diabetes management, **or** documented contraindication/intolerance. **Pathway 2 — T2DM + established CVD (CV risk reduction)** **7.3 Liraglutide (required for ALL requests)** Failed **≥ 3 months** at **maximum tolerated dose** of **liraglutide** (Victoza®) for diabetes management, **or** documented contraindication/intolerance. **8) Concomitant Therapy Exclusions** Not approved if concurrently using: • **Any other GLP-1 RA or GLP-1/GIP** agent (other than	Renewal is **not approved** if, during the approval period, the member had medical intervention for: • **Pancreatitis**, **or** • **Severe gastrointestinal event** defined as **ED visit or hospitalization** for GI symptoms (e.g., severe nausea/vomiting, dehydration, ileus/obstruction, suspected gastroparesis), **or** • **New start** of a GI motility/"severe constipation" agent (see Section 6C) **unless** documentation shows the agent was started for a **non-motility indication** and the prescriber attests semaglutide can be continued safely. **5) Concomitant therapy exclusions (hard stops)** Renewal is **not approved** if the member is concurrently using: **A) Other incretin-based injectables/orals** • **Any other GLP-1 receptor agonist** or **GLP-1/GIP** combination therapy (other than the requested product) **B) DPP-4 inhibitors** • **Any DPP-4 inhibitor** (e.g., alogliptin, sitagliptin, saxagliptin, linagliptin) **C) Severe constipation / GI motility agents (policy exclusion)**

	the requested semaglutide product) • **Any DPP-4 inhibitor** • **Concomitant Gastrointestinal Motility Medication Exclusion** Semaglutide **will not be approved** for members who are currently receiving pharmacologic therapy for **severe constipation, chronic gastrointestinal dysmotility, or gastroparesis**, due to the potential for **worsening gastrointestinal motility and increased risk of adverse gastrointestinal events** associated with GLP-1 receptor agonist therapy. Requests for semaglutide will be **denied** if the member is actively using any medication primarily indicated for the treatment of **severe or chronic constipation or gastrointestinal motility disorders**, including but not limited to: • **Metoclopramide (Reglan®)** • **Lubiprostone (Amitiza®)** • **Linaclotide (Linzess®)** • **Plecanatide (Trulance®)** • **Prucalopride (Motegrity®)** **Required Condition for Approval** Members must **not have an active prescription for the above agents within the previous 90 days**, unless documentation is submitted demonstrating: • The medication has been **discontinued**, and • The member **does not have an underlying gastrointestinal motility disorder** that would increase the risk of adverse effects from GLP-1 receptor agonist therapy. **Clinical Rationale**	• **Metoclopramide**, **lubiprostone (Amitiza®)**, **linaclotide (Linzess®)**, **plecanatide (Trulance®)**, **prucalopride (Motegrity®)** **Lookback window:** active use or fill within the **previous 90 days** constitutes concurrent use unless documentation confirms discontinuation. **6) Adherence requirement (claims-based; hard stop)** PBM claims data must demonstrate **consistent adherence**, defined as: • **No drug-free interval > 60 days** during the prior authorization period. If a drug-free interval **> 60 days** is identified, the member must **re-qualify under initial approval criteria**. **7) Approval duration** **Renewal approval duration:** 6 months

	GLP-1 receptor agonists, including semaglutide, **delay gastric emptying and reduce gastrointestinal motility**. Concurrent use with medications used to treat **severe constipation or gastrointestinal dysmotility** may indicate underlying motility disorders and may increase the risk of **severe gastrointestinal adverse effects**, including worsening constipation, ileus, or gastroparesis. **9) Safety Exclusions / Contraindications** Not approved if: • Personal/family history of **MTC** or **MEN2** • **Current pregnancy** • History of **confirmed pancreatitis** • **Active suicidal ideation** or documented new-onset depression temporally associated with GLP-1 therapy (if used as a denial criterion, define documentation trigger) Prescriber attests medication is prescribed per labeling, including screening for boxed warnings/contraindications. **10) Dose Escalation and Quantity Limits** **Starter dose limits:** • **Ozempic 0.25 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**	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
Dupilumab (Dupixent) SQ inj Pen-injector – 200 mg/1.14 ml Pen-injector – 300 mg/2 ml Prefilled syringe – 200mg/1.14 ml Prefilled syringe – 300 mg/2 ml	1. Prescribed for an FDA-approved indication for use. 2. The dosage and frequency requested are aligned with FDA and manufacturer guidelines for patient-specific parameters: • Patient age • Patient weight • Indication for use 3. The criteria for Dupixent are **indication specific**. Please review criteria for the patient-specific diagnosis. **Atopic Dermatitis:** • Diagnosis of moderate-to-severe chronic atopic dermatitis 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, fluocinolone	Renewal criteria are indication specific. Please review criteria for the patient-specific diagnosis. **Atopic Dermatitis:** • Documentation of a positive clinical response to therapy; At 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 (lebrikizumab), etc.) • Janus kinas inhibitor (e.g., Rinvoq

	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., 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.	(Upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib); **AND** • Prescribed by a Dermatologist, Allergist, or Immunologist. **Approval Duration:** 6 months. **<u>Asthma:</u>** • Documentation of positive 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 corticosteroid requirements; **AND** ○ Dupixent is being used in combination with an ICS-containing

	• UNLESS Patient has ≥ 25% skin involvement and topical management is not feasible. • Prescribed by or a Dermatologist, Allergist or 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 **Asthma, moderate to severe eosinophilic:** • Diagnosis of moderate-to-severe asthma; AND • Classification of asthma as uncontrolled or inadequately controlled as defined by at least **ONE** of the following o Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently > 1.5 or Asthma Control Test [ACT] score consistently < 20. o 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	maintenance medication (e.g.fluticasone/salmeterol, Breo Ellipta, budesonide/formoterol, Trelegy); **AND** o 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. **Chronic Obstructive Pulmonary Disease (COPD)** • Documentation of positive clinical response to therapy as defined by at least **one** of the following criteria: o A reduction in moderate exacerbations (i.e., those requiring systemic steroids and/or antibiotics). o A reduction of severe exacerbations

	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 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.	(i.e. those requiring hospitalization and requiring more than one day of observation in an emergency department or urgent care facility). ○ An improvement in baseline lung function as assessed by pre-bronchodilator forced expiratory volume (FEV1). **Approval Duration:** 6 months. <u>Chronic Rhinosinusitis with Nasal Polyposis</u> • Documentation of positive clinical response to Dupixent therapy; **AND** • Patient will continue to receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids; **AND** • Patient is not receiving Dupixent in combination with **ANY** of the following: Anti-interleukin-5 therapy (e.g. mepolizumab, resilizumab, benralizumab); Anti-IgE therapy (e.g. omalizumab); and/or Thymic stromal

	Alvesco, Asmanex, Qvar, etc); AND § One additional asthma controller medication (e.g., LABA, montelukast or theophylline); AND • Patient is not receiving Dupixent in combination with ANY of the following: 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. **Chronic Obstructive Pulmonary Disease (COPD)** • 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.	lymphopoietin (TSLP) inhibitor (e.g. Tezepelumab); **AND** • Prescribed by an Allergist, Immunologist, or Pulmonologist. **Approval Duration:** 6 months. **Eosinophilic Esophagitis:** • Documentation of positive clinical response to Dupixent therapy as evidenced by improvement in at least **ONE** of the following frombaseline: o Symptoms o Histologic measures o Endoscopic measures; **AND** • Patient is not receiving Dupixent in combination with **ANY** of the following: Anti-interleukin-5 therapy (e.g. mepolizumab, resilizumab, benralizumab); Anti-IgE therapy (e.g. omalizumab); and/or Thymic stromal lymphopoietin (TSLP) inhibitor (e.g. Tezepelumab); **AND** • Prescribed by a Gastroenterologist or

	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) 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. **<u>Chronic Rhinosinusitis with Nasal Polyposis</u>** • Diagnosis with chronic rhinosinusitis with nasal polyposis (CRSwNP) defined by ALL of the following: o **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 o **ONE** of the following findings using nasal	Allergist. **Approval Duration:** 6 months. **<u>Prurigo Nodularis</u>** • Documentation of positive clinical response to Dupixent therapy; **AND** • Patient is not receiving Dupixent in combination with **EITHER** of the following: o Biologic immunomodulator (e.g., Adbry) **OR** o Janus kinase inhibitor (e.g., Rinvoq, Xeljanz/XR, Opzelura, Cinginqo); **AND** • Prescribed by a Dermatologist, an Allergist, or an Immunologist. **Approval Duration:** 6 months.

	endoscopy and/or sinus computed tomography: § Purulent mucus or edema in the middle meatus or ethmoid regions § Polyps in the nasal cavity or the middle meatus §Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses; AND ○ **ONE** of the following: § Prescence of bilateral nasal polyposis § Patient has previously required surgical removal of bilateral nasal polyps; AND ○ **ONE** of the following: § Patient has required prior sinus surgery § Patient has required systemic corticosteroids for CRSwNP in the previous 2 years § Patient has been unable to obtain symptom relief after trial of TWO of the following classes of agents 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:
	  ○ 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
	• 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 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 with any of the following: ○ Anti-interleukin-5 therapy (e.g. mepolizumab,resilizumab, benralizumab); ○ Anti-IgE therapy (e.g. omalizumab); and/or ○ Thymic stromal lymphopoietin (TSLP) inhibitor (e.g. Tezepelumab); AND • Prescribed by either a Gastroenterologist or Allergist. **Approval Duration:** 6 months. **<u>Prurigo Nodularis</u>** • Diagnosis of prurigo nodularis; AND • Patient has ≥ 20 nodular lesions; AND • History of failure, contraindication, or intolerance to	

	previous prurigo nodularis treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin); AND • Patient is not receiving Dupixent with EITHER of the following: ○ Biologic immunomodulator (e.g. Adbry); OR ○ Janus kinase inhibitor (e.g., Rinvoq, Xeljanz/XR, Opzelura, Cibinqo); AND • Prescribed by a Dermatologist, Allergist, or Immunologist. **Approval Duration:** 6 months.	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
etanercept (**Enbrel; Enbrel Mini; Enbrel Sureclick**) injection 25mg/0.5mL, 50mg/mL syringes 50mg/mL autojector	**Rheumatoid Arthritis (RA):** 1. Diagnosis of moderately to severely active RA. **Patient meets the following:** • Has history of failure to a 3-month trial of one 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 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.	Renewal Criteria applies to all approved indications described in the initial criteria column: 1. Documentation of detailed positive clinical response to therapy. 2. Patient is not receiving Enbrel concurrently with another targeted immunomodulator (e.g. Cimzia, adalimumab, Simponi, Olumiant, Rinvoq, Xeljanz). **Approval Duration:** 6 months

	3. Prescribed by or in consultation with a rheumatologist. **Approval Duration**: 6 months **<u>Polyarticular Juvenile Idiopathic Arthritis (PJIA)</u>** 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 **<u>Psoriatic Arthritis (PsA)</u>** 1. Diagnosis of Psoriatic Arthritis. 2. The patient meets ONE of the following: • Patient has history of failure to a 3-month trial of methotrexate a maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (with documentation of trial dates and details), AND • History of 12 weeks failure, contraindication or intolerance to adalimumab with documentation of drug, date, and duration of trial. • **<u>Or</u>** Patient has been previously treated with a targeted immunomodulator that is FDA-approved for the treatment of PsA as documented in claims	

	history or submission of medical records that include the name of the drug, dates, and duration of therapy. 3. Prescribed by or in consultation with a rheumatologist or dermatologist. **Approval Duration:** 6 months. **<u>Plaque Psoriasis:</u>** 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: ○ 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 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. **Ankylosing Spondylitis:** 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 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 another targeted immunomodulator (as listed in #2). 3.Prescribed by or in consultation with a rheumatologist. **Approval Duration:** 6 months.	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal 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	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 • Use consistent with FDA-approved dosing (IV induction → maintenance or SC maintenance where applicable) **A. Ulcerative Colitis (UC)** **Step 1: Conventional Therapy (Required**) • 5-ASA agents (e.g., mesalamine) • Corticosteroids (for induction) (moderate to severe) Minimum Duration Requirement: • 5-ASA: ≥8 weeks • Corticosteroids: ≥2–8 weeks induction Verification: • Pharmacy claims for 5-ASA • Medical/pharmacy claims for corticosteroids	REAUTHORIZATION CRITERIA (6MONTHS) Authorization may be renewed if: • Documented clinical improvement: ○ UC: improvement in Mayo score or symptom reduction ○ CD: improvement in CDAI or clinical remission markers • Continued adherence: ○ PDC ≥0.8 (for SC) or consistent infusion claims (for IV) • No serious adverse events require discontinuation • Positions Entyvio as second-line or later biologic • Uses claims-based adherence and duration enforcement Aligns with cost-containment while allowing clinical exceptions

	Step 2: Immunomodulator Therapy (Required) • Azathioprine • 6-mercaptopurine Minimum Duration Requirement: • ≥12–16 weeks Verification: • Pharmacy claims with adherence (PDC ≥0.8) • Lab monitoring consistent with use **Step 3: Preferred Biologic Therapy (Required)** • ≥1 TNF inhibitor (adalimumab biosimilar) ≥12 weeks And • Stelara Biosimilar ≥24 weeks Verification: • Medical or pharmacy claims confirming administration • Documentation of inadequate response **Step 4: Entyvio Eligibility** Authorization granted only if: • Failure/intolerance to Adalimumab and Stelara Biosimilars **B. Crohn's Disease (CD)** **Step 1: Conventional Therapy (Required)** • Corticosteroids • Immunomodulators (azathioprine, 6-MP, or methotrexate) Minimum Duration Requirement: • Steroids: ≥2–8 weeks • Immunomodulators: ≥12–16 weeks Verification: • Pharmacy/medical claims • Lab monitoring	

	Step 3: Preferred Biologic Therapy (Required) • ≥1 TNF inhibitor (adalimumab biosimilar) ≥12 weeks And • Formulary Stelara Biosimilar (Yesintek (Ustekinumab-kfce) , Steqeyma (Ustekinumab-stba) ≥24 weeks Verification: • Medical or pharmacy claims confirming administration • Documentation of inadequate response **Step 3: Entyvio Eligibility** Authorization granted only if: • Failure/intolerance/Contraindications to TNF inhibitor and Stelara biosimilar 4. EXCLUSION CRITERIA Coverage will be denied if: • Use outside FDA-approved indications without compendia support • No documented failure of required step therapies • Insufficient duration of prior therapies • Non-adherence (PDC <0.8) without justification • Concurrent use with other biologics or JAK inhibitors **Approval Duration:** 6 Months	