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	

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	prescribed appropriate controller therapy for indication (asthma, COPD). • Provider must provide documentation of treatment plan and patient follow-up that will occur. • Patient must be referred for follow up with MFC Case Management. • 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	1. Documentation of positive clinical response to therapy. 2. Authorization Duration: 12 months.

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	• Disability or restriction of daily activities due to 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.	
alpelisib (**Piqray**; **Vijoice**) tablets Piqray: 200 mg, 250 mg, 300 mg dose Vijoice: 50mg, 125mg, 250 mg dose	1. Ordered for an approved indication for use: **Vijoice**: Treatment of adult and pediatric patients ≥ 2 years of age with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy. **Piqray:** treatment of men or postmenopausal women in combination with fulvestrant and men, with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-	• Confirmation that medication still carries FDA-approval for intended indication • No documented disease progression or unacceptable toxicity. **Vijoice:**

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	mutated, advanced, or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen. 2. Confirmation that product continues to carry FDA-approved indication for requested treatment. **3. <u>Vijoice:</u>** • Patient ≥ 2 years of age. • Patient has at least one severe clinical manifestation of PROS (e.g., excessive tissue growth, blood vessel malformations, scoliosis, vascular tumors, cardiac or renal manifestations, and those requiring systemic treatment. • PIK3CA mutation confirmed by genetic testing. • Ordered by or in consultation with a physician specializing in the treatment of genetic disorders. • Maximum Initial Approval Duration: 6 months **4. <u>Piqray:</u>** • Patient has diagnosis of breast cancer that is either advanced or metastatic. • The disease is hormone-receptor positive. • The disease is growth factor receptor 2 (HER-2) negative. • There is confirmation of one or more PIK3CA mutations. • Patient is one of the following: o Postmenopausal o Premenopausal with ovarian ablation/suppression o Male • Will be used in combination with fulvestrant • Disease has progressed on or after an endocrine-	• Patient has been established on Vijoice for at least 6 months; AND • There is documentation of a reduction in volume from baseline for at least one lesion, as confirmed by measurement; AND • Patient has documented improvement in at least one sign or symptom or PROS from baseline. • Approval duration: 12 months **Piqray:** • Patient does not show evidence of progressive disease while on Piqray therapy. 1. Approval duration: 12 months

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	based regimen. 5. Approval duration: 12 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.	**Limitations of Use:** • In OSA, Nuvigil is indicated to treat excessive sleepiness and not as a treatment for the underlying obstruction.
asciminib (**Scemblix**) tablets 20mg, 40mg	1. Ordered for an approved indication for use: • Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs). • Ph+ CML in CP with the T315I mutation. 2. Medication ordered by Oncologist or Hematologist	
avacopan (**Tavneos**) capsule 10mg	1. Ordered for an approved indication for use: • adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. 2. Documentation of baseline Birmingham vasculitis activity score (BVAS), with either one of the following: • At least one major item • At least 3 minor items • At least 2 renal items, proteinuria and hematuria are present 3. Documentation that patient will continue standard therapy including glucocorticoids 4. Medication ordered by a Rheumatologist.	

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avapritinib (**Ayvakit**) tablets 100mg, 200mg, 300mg	1. Ordered for an approved indication for use: • Gastrointestinal Stromal Tumor (GIST) ○ Treatment of adults with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. • Advanced Systemic Mastocytosis (AdvSM) ○ Treatment of adult patients with AdvSM. AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), and mast cell leukemia (MCL). • Indolent Systemic Mastocytosis (ISM) Treatment of adult patients with ISM. 2. Patient age ≥ 18 years. 3. Patient has experienced treatment failure to first-line therapy. 4. Patient's platelet count is ≥ 50 x 10^9/L; AND 5. Patient meets one of the following criteria: • Diagnosis of indolent systemic mastocytosis OR • Patient has one of the following subtypes of advanced systemic mastocytosis: ○ Aggressive systemic mastocytosis; or ○ Systemic mastocytosis with an associated hematological neoplasm; or ○ Mast cell leukemia. 6. Approval Duration: 1 year	1. No evidence of disease progression. 2. Approval Duration: 12 months.
avatrombopag (**Doptelet**) tablets 20mg	1. Ordered for an approved indication for use: • thrombocytopenia in adult patients with chronic liver disease who are scheduled to	When prescribed for thrombocytopenia in chronic liver disease with procedure scheduled:

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	undergo a procedure. • thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. 2. Patient age ≥ 18 years. 3. A recent (less than 1 month old) platelet count must be supplied with documentation submitted. 4. Medication ordered by a Hematologist. When prescribed for thrombocytopenia in patients with chronic liver disease-associated thrombocytopenia scheduled to undergo a procedure: • Approval limited to 15 tablets per treatment course. • Approval Duration: one month. When prescribed to patients with chronic immune thrombocytopenia with insufficient response to previous treatment: • Diagnosis of chronic immune thrombocytopenia (ITP). • Patient experienced insufficient response to a previous treatment (e.g., corticosteroids, immunoglobulins, thrombopoietin receptor agonists, splenectomy). • Approval duration: 12 months.	• 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.	**Not applicable. Maximum approval, one treatment course per lifetime.**

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	4. Patient has received prior treatment with first-line 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.	
bedaquiline (**Sirturo**) tablets 20mg, 100mg	1. Ordered for an approved indication for use: • as part of combination therapy in adult and pediatric patients ≥ 5 years of age and weighing at least 15 kg with pulmonary multi-drug resistant tuberculosis (MDR-TB). [Reserved for use when an effective treatment regimen cannot otherwise be provided. 2. Medication ordered by 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 ≥ 5 years of age with active lupus nephritis who are receiving standard therapy.	**Limitations of Use:** • The efficacy of BENLYSTA has not been evaluated in patients with severe active central nervous system lupus. Use of BENLYSTA is not recommended in this situation.

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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 30mg/ml	1. Ordered for an approved indication for use: • add-on maintenance treatment of patients ≥ 12 years of age with severe asthma and with an eosinophilic phenotype. 2. Diagnosis of severe, uncontrolled asthma as defined by at least ONE of the following: • Poor symptom control (e.g., Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20). • Two or more bursts of systemic corticosteroids for at least 3 days each in previous 12 months. • Asthma-related emergency treatment (ER visit,	1.Documentation of positive clinical response to Fasenra therapy as demonstrated by at least one of the following: • Reduction in frequency of exacerbations • Decreased utilization of rescue medications • Increase in percent predicted FEV1 from pretreatment baseline. • Reduction in severity or frequency of asthma-related

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	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 (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)).	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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	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. 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	1. Member meets the criteria for initial approval. 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.

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	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	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.
brigatinib (**Alunbrig**) tablets 30mg, 90mg,180mg	1. Ordered for an approved indication for use: • The treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. 2. Medication ordered by an Oncologist.	
budesonide delayed-release (**Tarpeyo**) capsules 4mg	1. Ordered for an approved indication for use: • to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of	**<u>Limitations of Use:</u>** • This indication is approved under accelerated approval based on a

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	rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g. 2. History of failure, contraindication or intolerance to a glucocorticoid. 3. Patient is on a stable and maximally tolerated dose of a renin-angiotensin system (RAS) inhibitor (ACEI or ARB), for at least 3 months, unless contraindicated. 4. Medication ordered by a nephrologist.	reduction in proteinuria. It has not been established whether TARPEYO slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.
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. 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	• 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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	topical patch at max doses; consider alternative opioid	
c1 esterase Inhibitor [Human] **Cinryze** solution 500 unit **Haegarda** injection solution 2000unit, 3000unit	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 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: ○ History of recurrent laryngeal attacks; OR ○ ≥ 2 severe episodes/month (ex. debilitating GI or cutaneous effects); OR ○ ≥ 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	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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	when appropriate. 3. Length of Authorization: 3 months when criteria are met.	
cabotegravir (**Apretude**) extended-release intramuscular injection 600mg/3mL (**Vocabria**) tablets 30 mg	1. Ordered for an approved indication for use: • At-risk adults and adolescents weighing at least 35 kg for PrEP to reduce the risk of sexually acquired HIV-1 infection. 2. Individuals must have a negative HIV-1 test prior to initiating APRETUDE and prior to each injection. 3. Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection; AND 4. Patient is not an appropriate candidate for oral PrEP (e.g., difficulty with adherence to prior oral PrEP, significant renal disease); AND 5. Provider attests that patient demonstrates treatment readiness by BOTH of the following: 6. Patient understands the risks of missed doses. 7. Patient has ability to adhere to the required every 2 months injection and testing appointments. 8. Dosing is in accordance with FDA-approved labeling. • Approval Duration: 2 months	**1.** Patient has previously received treatment with Apretude **2.** Patient has a negative HIV-1 test **3.** Provider confirms that the patient will be tested for HIV-1 with each subsequent injection; and **4.** Dosing is in accordance with FDA-approved labeling. **5.** Approval Duration: 2 months
cabozantinib (**Cabometyx)** tablets 20mg, 40mg, 60mg (**Cometriq**) kit 20mg, 60mg, 100mg, 140mg	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	

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	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. 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.	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: ○ 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	1. Ordered for an approved indication for use:	

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150mg, 200mg	• 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. 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	• 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.

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	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.	• Not ventilator dependent. • Provider attestation of continued benefit without ADE • Max dose 30 mg/kg/dose/week • Duration: 6 months
ceritinib (**Zykadia**) 150mg tablets	1. Ordered for an approved indication for use: • treatment of adults with metastatic non-small cell lung cancer whose tumors are anaplastic lymphoma kinase-positive as detected by an FDA-approved test. 2. Medication ordered by an Oncologist	
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 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	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 ○ Duration: 12 months once maintenance dose is established

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	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 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.**	

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	First must have tried and failed: • At least one topical steroid AND • Topical tacrolimus OR pimecrolimus.	
crizotinib (**Xalkori**) capsule 200mg, 250mg	1. Ordered for an approved indication for use: • the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test. 2. 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. 3. Medication ordered by an Oncologist	**Limitations of Use:** • The safety and efficacy of XALKORI have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL.
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.

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

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	stimulating agents. 7. Maximum daily dose 24 mg per day. 8. Initial approval duration: 6 months.	cannot be approved. 5. Approval duration: 6 months.
darolutamide (**Nubeqa**) tablets 300mg	1. Ordered for an approved indication for use: • treatment of non-metastatic castration-resistant prostate cancer (mmCRPC). • Metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel. 2. Patient is ≥ 18 years of age, AND 3. The medication is concurrently used with docetaxel OR the patient has completed docetaxel therapy. 4. The patient meets ONE of the following: • The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) agonist, or • The medication is used concurrently with degarelix SQ injection; or • Patient has bilateral orchiectomy. 5. Medication ordered by an Oncologist or Urologist. 6. Approval Duration: 12 months.	1. Patient has not shown disease progression. 2. Patient has not experienced unacceptable toxicity. 3. Patient should also receive a GnRH analog concurrently OR have had a bilateral orchiectomy. 4. Treatment may continue even if a cycle of docetaxel is delayed, interrupted, or discontinued. 5. Approval Duration: 12 months.
delandistrogene moxeparvovec-rokl (**Elevidys**) Kit	1. Prescribed for treatment of Duchenne muscular dystrophy (DMD). 2. Prescribed by, or in consultation with, a pediatric neuromuscular specialist with expertise in the diagnosis of DMD. 3. Submission of medical records confirming both of the following: • A mutation in the DMD gene AND • The mutation is not a deletion in exon 8 or exon 9 4. Patient is aged 4 or 5 years of age. 5. Submission of documentation confirming that the patient is ambulatory without needing an assistive	**Not applicable. Maximum approval, one treatment course per lifetime.**

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	device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.). 6. Patient does not have an elevated anti-AAVrh74 total binding antibody titer ≥ 1:400. 7. Patient will not receive exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)] concomitantly or following Elevidys treatment. 8. Patient has never received Elevidys treatment in their lifetime. 9. Dosing in accordance with FDA guidelines: 1.33×10^{14} vector genomes (vg)/kg. 10. Authorization will be issued for no more than one treatment per lifetime and for no longer than 30 days from approval or until 6 years of age, whichever is first.	
denosumab (**Prolia**; **Xgeva**) injection 60mg/ml	1. Ordered for an approved indication for use: • treatment of postmenopausal women with osteoporosis at high risk for fracture. • treatment to increase bone mass in men with osteoporosis at high risk for fracture. • treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture. • treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. • treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. 2. Patient age ≥ 18 years of age. 3. Tried and failed, had adverse reaction to, or contraindication to formulary preferred products (e.g.,	1. All initial criteria met. 2. Approval Duration: 12 months. **3. NOTE: drug discontinuation conveys an increased risk of fractures and would require transition to alternative agent based on clinical guidance.**

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	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.	
deutetrabenzine (**Austedo, Austedo XR**) tablets titration kit (XR formulation) 6mg, 9mg, 12mg (immediate release [IR] formulation) **NOTE:** **Austedo XR is covered ONLY for the titration pak. Maintenance doses must be converted to the IR tablets. Total daily dose is equivalent on a mg-to-mg basis, but the IR should be administered in 2 divided doses if the total dose is ≥ 12 mg per**	1. Ordered for an approved indication for use: • Chorea associated with Huntington's disease. (HD) • Tardive dyskinesia (TD) in adults. 2. Patient age ≥ 18 years. 3. Patient is not receiving other VMAT2 inhibitors (tetrabenazine or valbenazine), 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	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. Maintenance dose is optimized by tablet strength to achieve target dose as described in the table below:

<table>
<tr><th>Generic Medication (Brand Name)
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<tr><td>day. See table under renewal criteria.</td><td>sheet along with progress notes must be provided for both initial and renewal PA requests.
7. Patient must not be suicidal or have untreated/inadequately treated depression.
8. Approval Duration: 1 fill of starder dose (XR formulation).</td><td><table><tr><th>Total Daily Dose</th><th>Regimen to Approve AFTER starter kit completed</th></tr><tr><td>12 mg</td><td>IR 6 mg BID</td></tr><tr><td>18 mg</td><td>IR 9 mg BID</td></tr><tr><td>24 mg</td><td>IR 12 mg BID</td></tr><tr><td>30 mg</td><td>IR 12 mg x 2 tabs + IR 6 mg QD</td></tr><tr><td>36 mg</td><td>IR 12 mg x 3 tabs QD</td></tr><tr><td>42 mg</td><td>IR 12 mg x 3 tabs + 6 mg IR QD</td></tr><tr><td>48 mg</td><td>12 mg IR x 2 BID</td></tr></table>6. Approval duration: 12 months.</td></tr>
<tr><td>dextromethorphan/quinidine (Nuedexta) tablets
10mg-20mg</td><td>1. Ordered for an approved indication for use:
• Treatment of pseudobulbar affect (PBA)
2. Patient age ≥ 18 years.
3. Patient has been diagnosed with ONE of the following:
• Amyotrophic lateral sclerosis (ALS)
• Alzheimer’s disease
• Multiple sclerosis (MS)
• Parkinson’s disease
• Stroke
• Traumatic brain injury
4. The baseline Center for Neurologic Study-Lability Scale (CNS-LS) score must be > 13.
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>1. Documentation of positive clinical response to therapy.
2. Authorization period is up to 12 months.

<u>Limitations of Use:</u>
The following indications are considered experimental and cannot be approved:
• Heroin detoxification
• Levodopa-induced Dyskinesia in Parkinson’s Disease
• Neuropathic pain
• Psychosis-Related Aggression
• Treatment Resistant Depression</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).</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>
</table>

<table>
<tr><th>Generic Medication (Brand Name)
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<tr><td></td><td>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></td></tr>
<tr><td>dulaglutide (Trulicity)
0.75 mg, 1.5 mg, 3 mg, 4.5 mg</td><td>1. Ordered for an approved indication for use:
• As an adjunct to diet and exercise to improve glycemic control in adults or pediatric patients ≥ 10 years of age with type 2 diabetes mellitus.
• In adult patients with T2DM for risk reduction of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.
• Use in patients aged ≥10 years to < 18 years of age with type 2 DM is limited to those who are ≥3 months post-diagnosis with an HbA1c of ≥6.5% while on metformin therapy (maximized).
2. A1c or TIR% report within past 3 months.
3. Baseline A1c is ≥ 8.0, for patients WITHOUT CVD OR Baseline A1c is ≥ 7.0, for patients WITH CVD defined as:
Patient is considered high or very high risk for ASCVD-risk as evidenced by one of the following:
• Acute coronary syndrome</td><td>Cannot be approved for indication of weight management.
1. Chart notes with A1c or CGM report with TIR% within previous 3 months.
2. Documented positive clinical response defined as one of the following:
• Dose titration is occurring at expected monthly intervals which applies only to the first 6 months of treatment or until A1c labs are available, or
• A1c goal has been reached on requested dose; or
• A1c has decreased by ≥ 1% since onset of therapy; or
• Patient is at maximum tolerated dose and used as part of a comprehensive diabetes regimen in combination with other anti-hyperglycemic medications.
3. Patient has not had medical</td></tr>
</table>

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

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Syringe: 100 mg/0.67 mL, 200 mg/1.14 mL, 300 mg/2 mL Pen: 200 mg/1.14 mL, 300 mg/2 mL	months and older with moderate-to- severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids. • add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent asthma. • add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis. • treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis 2. Medication ordered by an Allergist or Dermatologist	
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:	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.

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	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).
	• 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.
		• 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 (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

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	○ 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, 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	• 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 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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	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
	  ○ 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,	

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	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	
efgartigimod alfa-fcab (**Vyvgart**) injection 400mg/20ml	1. Ordered for an approved indication for use: • Treatment of adult patients with anti-acetylcholine receptor antibody positive (AChR+) generalized myasthenia gravis (gMG) as monotherapy or in combination with glucocorticoids in patients with glucocorticoid-resistant or glucocorticoid-dependent disease. 2. Patient age ≥ 18 years. 3. Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II, III, or IV at initiation of therapy. 4. MG activities of daily living (MG-ADL) total score of ≥ 5. 5. Documentation of positive serologic test for anti-AChR antibodies. 6. Greater than 50% of baseline MG-ADL score is due to non-ocular symptoms. 7. Patient is currently receiving a stable dose of at least one gMG treatment (including cholinesterase inhibitors, corticosteroids, or non-steroidal immunosuppressants). 8. Documentation of patient's current weight for appropriate dosing.	1. Patient continues to meet initial approval criteria. 2. Patient has absence of toxicity to drug. 3. Patient has had an improvement (reduction) of at least 2-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score sustained for at least 4-weeks; and 4. Improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline; and 5. Patient requires continuous treatment, after an initial beneficial response, due to new or worsening disease activity (Note: a minimum of 50 days must have elapsed from the start of the previous treatment cycle). 6. Approval Duration: 3 months

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	9. Trial and failure, contraindication or documentation of intolerance to at least two of the following: • Rituximab or biosimilar (e.g., truxima) • Cyclophosphamide • Azathioprine • Mycophenolate mofetil 10. Not currently prescribed with other immunomodulatory therapies (e.g., eculizumab (Soliris)) 11. Medication ordered by or in consultation with a neurologist. 12. Approval Duration: 3 months	
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.

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elagolix (**Orilissa**) tablets 150mg, 200mg	1. Ordered for an approved indication for use: • the management of moderate to severe pain associated with endometriosis. 2. Must have tried and failed at least two of the following: NSAIDs, hormonal options (OCP, progesterone, hormonal IUD), or have a contraindication to using these therapies.	**Contraindications:** • Pregnancy • Osteoporosis • Severe hepatic impairment (Child-Pugh class C) • Concomitant use of Organic Anion Transporting Polypeptide (OATP) 1B1 e.g. pazopanib, vandetanib, nilotinib, canertinib, or erlotinib. **Limitations of use:** • Limit the duration of use based on the dose and coexisting condition per prescribing guidelines. Max duration 6 to 24 months depending on patient specific variables.
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. Must have tried and failed at least two of the following: NSAIDs, hormonal options (OCP, progesterone, hormonal IUD), or have a contraindication to using these therapies.	• Contraindicated in women with current or history of thrombotic/thrombolic disorders and women at increased risk of these events, including women > 35 years who smoke and women with uncontrolled hypertension. **Limitations of use:** Due to risk of bone density loss that may not be reversible following discontinuation, limit duration of treatment to 24 months.
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	1. Provider attestation of continued benefit without adverse drug effects. 2. Provider attestation of continued monitoring as appropriate.

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	CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data. 2. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation or a mutation that is responsive based on in vitro data. 3. Patient age ≥ 2 years. 4. Provider attestation of baseline and subsequent evaluation and monitoring as appropriate and indicated by the FDA-approved product labeling (provider must submit documentation). 5. Provider justification of necessity of medication change if currently stable on another CF regiment and asymptomatic. 6. Medication ordered by a Pulmonologist. 7. Approval duration: 12 months.	3. Approval Duration: 12 months.
esketamine (**Spravato**) solution 56mg DOS, 84mg DOS	1. Ordered for an approved indication for use: • Treatment-resistant depression in adults, in conjunction with an oral antidepressant. • Treatment of adults with major depressive disorder with suicidal ideation or behavior. • Major depressive disorder with acute suicidal ideation or behavior (MDD w/ SI) 2. Intolerance to or treatment failure following an adequate trial of at least 2 preferred oral antidepressants within the past 12 months (adequate trial = at least 8 weeks at therapeutic dose of the medication) 1. Age: ≥ 18 years 2. MUST be given concurrently with oral antidepressant medication.	• Reauthorization for continued treatment is contingent on evidence of therapeutic benefit. • Patient must be observed in office for at least 2 hours following each administration. • Renewal Criteria ○ TRD: Prescriber attests need of continued use based on clinical benefit. • Quantity Limit: 4 dose kits per 28 days (maintenance) • Approval Duration: 6 months

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	3. No history of aneurysmal vascular disease, history of intracerebral hemorrhage, or hypersensitivity to any components of drug. 4. Quantity Limit: • Induction: 8 dose kits per 28 days • Maintenance: 4 dose kits per 28 days 5. Approval Duration: 6 months (TRD); 4 weeks (MDD w/ SI) • If ordered for treatment-resistant depression, the patient must also be prescribed an oral antidepressant medicine. 6. Ordered by REMS registered psychiatrist.	○ MDD with SI – no PA renewal – one-time approval ○ Any subsequent request would need a new PA and review to support repeat use, including any recent hospitalization data.
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.

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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). 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.	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
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.	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-

Generic Medication (Brand Name) **Bolded** name indicates whether Brand or Generic is Formulary	Approval Criteria & Submission Requirements	Additional Considerations & Renewal Criteria
	• 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 • 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:	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. 5. Renewal duration: 3 months.

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	• For perioperative management of bleeding: 1 month. • All other indications: up to 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. • 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.	1. Documentation of positive clinical response to Jivi therapy. 2. 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:	**Limitations of Use:** • VOWST is not indicated for treatment of CDI.

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	○ Known or suspected toxic megacolon and/or known small bowel ileus OR ○ Admitted to, or expected to be admitted to an ICU for medical reasons, OR ○ Absolute neutrophil count < 500 cells/mL^3 ○ History of major GI surgery within 3 months before treatment start (not including appendectomy or cholecystectomy) OR ○ History of total colectomy or bariatric surgery that disrupted the GI lumen OR ○ History of active inflammatory bowel disease (e.g. ulcerative colitis, Crohn's disease, microscopic colitis) with diarrhea believed to be cause by active inflammatory bowel disease in the past 3 months. ○ History of fecal microbiota transplantation (FMT) within 3 months 5. The patient will not be using the requested agent in combination with Rebyota or Zinplava for the requested indication. 6. Provider attests that patient will follow the bowel preparation protocol outlined in the package insert. 7. Patient will not be taking a concurrent antibiotic. 8. Prescribed by or in consultation with an infectious disease specialist. 9. Approval is limited to 12 capsules per dispense; maximum of 24 capsules lifetime.	
fentanyl (Duragesic) transdermal patch 12mcg/hr, 25mcg/hr, 37.5mcg/hr, 50mcg/hr, 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.	• 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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	Patients considered opioid- tolerant are those taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid. 2. Fully completed opioid PA form submitted. 3. Submission of clinical documentation from last office visit, dated within 3 months of the request. 4. Maximum approval duration is 6 months but may be reduced based on any of the criteria as outlined in Pharmacy Policy 219.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,	**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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	famotidine, fluoroquinolones, fluvoxamine, mexiletine, oral contraceptives, verapamil, zafirlukast, zileuton). 8. Patient must have treatment failure, intolerance, or contraindication to at least one menopausal hormone therapy. 9. Initial approval period: 9 months	
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.	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).

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	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 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	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 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.	1. Documentation of improved symptoms and attestation of lab parameters. 2. Renewal approval duration: 12 months

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	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.	
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: o Furosemide oral tablets; 40-160 mg/day o Torsemide oral tablets; 50-100 mg/day o 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: o Oxygen saturation ≥ 90% on exertion o Respiratory rate < 24 breaths per minute o Resting heart rate < 100 beats per minute o 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	**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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gabapentin extended-release (**Gralise**) tablets 300mg, 450mg, 600mg, 750mg, 900mg **note, this is not the same as gabapentin enacarbil which is non-formulary.*	1. Ordered for an approved indication for use: • the management of Postherpetic Neuralgia (PHN). Not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect dosing frequency. 2. Patient age ≥ 18 years. 3. Patient CrCl > 30 ml/min; patient is not on hemodialysis. 4. Dose does not exceed 1800 mg per day. 5. Approval Duration: 12 months	1. Initial criteria continue to be met. 2. Approval duration: 12 months.
gilteritinib (**Xospata**) tablets 40mg	1. Ordered for an approved indication for use: • the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test. 2. Medication ordered by an Oncologist	•
glycopyrronium (**Qbrexza**) pad 2.4%	1. Ordered for an approved indication for use: • topical treatment of primary axillary hyperhidrosis in adults and pediatric patients ≥ 9 years of age. 2. Patient age ≥ 9 years. 3. Must have tried and failed OTC Clinical Strength antiperspirants and at least one prescription strength antiperspirant (ex: Drysol or Xerac AC) for at least 4 weeks and experienced inadequate efficacy 3. Documentation that symptoms are persistent despite previous treatment attempts and that the degree of symptomatology impacts quality of life must be clearly indicated in a recent (within past 6 months) clinical encounter note. 4. Qbrexza is not intended for application to areas other than the axillae.	1. Patient has demonstrated benefit with Qbrexa. 2. Patient continues to meet initial approval criteria. 3. Approval Duration: 12 months

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	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.	
goserelin (**Zoladex**) implant 3.6mg, 10.8mg	1. Ordered for an approved indication for use: • palliative treatment of advanced carcinoma of the prostate. (3.6 mg and 10.8 mg) • in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. (3.6 mg and 10.8 mg) • management of endometriosis (3.6 mg) • palliative treatment of advanced breast cancer in pre- and peri-menopausal women. (3.6 mg) • to cause endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. (3.6 mg) • management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. **Endometriosis:** 1. Contraindication, intolerance, or failure of initial treatment to BOTH of the following: • Oral contraceptives or depot medroxyprogesterone; AND	**Endometriosis:** • Can not be administered for more than 6 months lifetime maximum. **Endometrial thinning:** • Can not be administered for more than 6 months lifetime maximum. **Fertility Preservation:** • Patient currently receiving GnRH analog therapy for purpose of fertility preservation; and • Patient continues to receive a cytotoxic agent associated with primary ovarian insufficiency; and • Authorization duration: 12 months **Gender Affirming Care – Adolescents OR** **Gender Affirming Care – Transgender Adults:** • Approval Duration: 12 months.

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	• Non-steroidal anti-inflammatory drugs; OR • Patient has had surgical ablation to prevent recurrence. 2. Approval Duration: Limited to 6 months. **Endometrial Thinning/Dysfunctional Uterine Bleeding:** • For use prior to endometrial ablation; AND • Other causes of symptoms of bleeding are ruled out; AND • Patient has been prescribed the 3.6 mg implant; and • Approval duration is for a maximum of 2 depots. **Fertility Preservation:** Clinical studies do not support use for this indication, and cryopreservation is clinically preferred. Please attempt to redirect to cryopreservation. Only clinically appropriate as a potential adjunct to cryopreservation. May be medically necessary for treatment of fertility preservation when both of the following criteria are met: • Patient is a pre-menopausal female. • Patient is receiving a cytotoxic agent associated with causing primary ovarian insufficiency, e.g., cyclophosphamide, procarbazine, vinblastine, cisplatin. • Approval Duration: 12 months. **Gender Affirming Care – Adolescents** • Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy. • Approval Duration: 12 months **Gender Affirming Care – Transgender Adults**	

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	• Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy. • 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. 2. Medication ordered by an Oncologist. 3. Quantity limit: 4 tablets per day.	**<u>Limitations for use:</u>** • Indications for Mantle Cell Lymphoma and Marginal Zone Lymphoma were voluntarily withdrawn, April 2023 **<u>New dose modification guidelines adopted in December 2022:</u>** 1. Therapy should be withheld for any new onset or worsening Grade 2 cardiac failure or Grade 3 cardiac arrhythmia. Once symptoms have resolved to Grade 1 cardiac failure or Grade 2 or lower cardiac arrhythmia, Imbruvica can be restarted at recommended adjusted doses.
icatibant acetate (Firazyr) injection 30mg/3ml	1. Ordered for an approved indication for use: • treatment of acute attacks of hereditary angioedema (HAE) in adults ≥ 18 years of age. 2. Patient age ≥ 18 years. 3. Prescribed for the treatment of acute HAE attacks. 4. Member has a C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets one of the following: • C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test; OR • Normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of	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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	normal as defined by the laboratory performing the test). 5. If not the criteria in #4 above, the patient has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria: • Patient has an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation as confirmed by genetic testing; or • Patient has a documented family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy (i.e. cetirizine at 40 mg per day or the equivalent) for at least 30 days. 6. Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g. Berinert, Kalbitor, or Ruconest). 7. Medication ordered by an Allergist or ENT. 8. Approval Duration: 6 months.	
icatibant acetate (Firazyr; Sajazir) injection 30mg/3ml	9. Ordered for an approved indication for use: • treatment of acute attacks of hereditary angioedema (HAE) in adults ≥ 18 years of age. 10. Medication ordered by an Allergist or ENT	• Self-administered by the patient upon recognition of symptoms of an HAE attack after training under the guidance of a healthcare professional.
icosapent ethyl (E-EPA) 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	**<u>Renewal Criteria:</u>** • 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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	○ Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease • As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. 2. Age ≥ 45 years 3. Diagnosis of hypertriglyceridemia (pre-treatment TG level ≥ 150 mg/dl) AND 4. Patient is considered high or very high risk for cardiovascular disease (CVD) as evidenced by **<u>one</u>** of the following: ○ Acute coronary syndrome ○ History of myocardial infarction ○ Stable or Unstable angina ○ Coronary or other arterial revascularization ○ Stroke ○ Transient ischemic attack ○ Peripheral arterial disease 5. **<u>OR, if not the criteria in #4:</u>** ○ Type 2 Diabetes diagnosis **AND TWO of the following:** ○ Men ≥ 55 years and women ≥ 65 years ○ Cigarette smoker or stopped within past 3 months ○ Hypertension diagnosis ○ HDL-C ≥ 40 mg/dL for men or ≥ 50 mg/dL for women ○ High-sensitivity C-reactive protein > 3.0 mg/L ○ Creatinine clearance > 30 and < 60 ml/min ○ Retinopathy ○ Micro- or macro-albuminuria	

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	○ 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.	
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	**<u>Limitations of use:</u>** • 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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	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. 11. Medication ordered by Hematologist or Oncologist enrolled in ABECMA REMS and compliance with REMS program criteria.	
imiglucerase (**Cerezyme**) injection solution 400 units	1. Ordered for an approved indication for use: • Treatment of adults and pediatric patients 2 years of age and older with Type 1 Gaucher disease that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly. • Administration under the supervision of a health care provider experienced in the treatment of Gaucher disease. 2. Diagnosis of Type 1 Gaucher disease confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing. 3. Symptoms of one of the following complications	1. Patient meets criteria for initial approval. 2. Patient has documentation of beneficial response (e.g., reduced severity or resolution of anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly. 3. Patient is not experiencing an inadequate response or any intolerable adverse events from therapy. 4. Approval Duration: 12 months.

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	associated with Type 1 Gaucher disease: • Anemia • Thromobocytopenia • Bone disease • Hepatomegaly • Splenomegaly 4. Patient ≥ 2 years of age. 5. Quantity limited to no more than three times weekly administration. 6. Approval Duration: 12 months.	
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.	
inebilizumab-cdon (**Uplizna**) solution 100mg/10ml	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. Medication ordered by neurologist or ophthalmologist.	**<u>Limitations for use:</u>** • It is not known if Uplizna is safe or effective in children. • Contraindicated in patients with an active hepatitis B infection. • Contraindicated in patients with an active or untreated inactive (latent) tuberculosis.
interferon gamma-1b (**Actimmune)** injection 2 million IU/0.5ml	1. Ordered for an approved indication for use:	1. Patient does not show evidence of progressive disease while on Actimmune.

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	• 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). 2. Patient age is less than 19 years. 3. When prescribed for: • Chronic Granulomatous Disease (CGD); • Osteopetrosis; or • Primary Cutaneous Lymphomas when the patient has a diagnosis of: ○ Mycosis fungoides (MF) or ○ Sezary Syndrome (SS) 4. Approval Duration: 3 months.	2. Reauthorization is for 3 months. 3. 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 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	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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	asymptomatic. 7. Medication ordered by Pulmonologist. 8. Approval Duration: 12 months.	
ivermectin (Stromectol) tablets 3mg	1. Ordered for an approved indication for use: • Strongyloidiasis of the intestinal tract (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis. • Onchocerciasis due to the nematode parasite Onchocerca volvulus. **2. Cannot be used for outpatient COVID-19 treatment.**	**<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).
lanadelumab-flyo (**Takhzyro**) subcutaneous injection 300mg/2ml, 150mg/ml	1. Ordered for an approved indication for use: • hereditary angioedema (HAE) prophylaxis in adult and pediatric patients ≥ 12 years of age. 2. Prescribed by or in consultation with a specialist in allergy, immunology, hematology, pulmonology, or medical genetics. 3. Patient aged 12 years or older. 4. History of one of the following criteria for long-term HAE prophylaxis: • History of two or more severe HAE attacks per months (i.e., airway swelling, debilitating cutaneous or GI episodes. • Patient is disabled by HAE more than 5 days per month. • History of at least one laryngeal attack caused by HAE AND 5. Treatment with “on-demand” therapy (e.g., Kalbitor, Firazyr, Ruconest or Berinert) did not provide satisfactory control or access to “on-demand therapy is limited” AND 6. Not used in combination with C1 inhibitor prophylaxis	1. Documentation of positive clinical response from Takhzyro therapy. 2. Not used in combination with other products indicated for prophylaxis against HAE attacks (Cinryze, Haegarda, Orladeyo). 3. Approval Duration: 3 months.

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	(e.g., Cinryze, Haegarda, or Orladeyo) AND 7. Confirmation that patient is avoiding the following triggers for HAE attacks: • Estrogen-containing oral contraceptive agents AND hormone replacement therapy • Antihypertensive agents containing ACE inhibitors. 8. Approval Duration: 3 months.	
larotrectinib (**Vitrakvi**) capsules 25mg, 100mg	1. Ordered for an approved indication for use: • Treatment of adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and no satisfactory alternative treatments or that have progressed following treatment. 2. Medication ordered by an Oncologist	
lecanemab-irmb (**Leqembi)** 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.	**<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

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	7. Mini-Mental State Examination score greater than 21, or St. Louis University Mental Status (SLUMS) score or Montreal Cognitive Assessment (MoCA) score of greater than 16. 8. Patient does not have any of the following risk factors for intracerebral hemorrhage: • prior cerebral hemorrhage greater than 1 cm in greatest diameter, more than 4 microhemorrhages, superficial siderosis, • evidence of vasogenic edema, • evidence of cerebral contusion, • aneurysm, • vascular malformation, • infective lesions, • multiple lacunar infarcts or stroke involving a major vascular territory, • and severe small vessel or white matter disease. 9. Ordered by a Board-certified neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia.	4. Patient has not progressed to moderate or severe AD; AND 5. Patient has received a pre-5th, 7th, AND 14th infusion MRI for monitoring of Amyloid Related Imaging Abnormalities-edema (ARIA-E) and Amyloid Related Imaging Abnormalities hemosiderin (ARIA-H) microhemorrhages.
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. 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.	**Endometriosis:** • Can not be administered for more than 6 months lifetime maximum. **Fertility Preservation:** • Patient currently receiving GnRH analog therapy for purpose of fertility preservation; and • Patient continues to receive a cytotoxic agent associated with primary ovarian insufficiency; and • Authorization duration: 12

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1-month (7.5mg, 11.25mg 15mg) 3-month (11.25mg, 30mg) 6-month (45mg) **Fensolvi** SQ injection, 6-month (45mg)	• to cause endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. • management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. **Endometriosis:** 1. Contraindication, intolerance, or failure of initial treatment to BOTH of the following: • Oral contraceptives or depot medroxyprogesterone; **AND** • Non-steroidal anti-inflammatory drugs; **OR** • Patient has had surgical ablation to prevent recurrence. • Approval Duration: Limited to 6 months. **Fertility Preservation:** May be medically necessary for treatment of fertility preservation when both of the following criteria are met: • Patient is a pre-menopausal female. • Patient is receiving a cytotoxic agent associated with causing primary ovarian insufficiency, e.g., cyclophosphamide, procarbazine, vinblastine, cisplatin. • Approval Duration: 12 months. **Gender Affirming Care – Adolescents** • Prescribed by or in consultation with a medical provider experienced in transgender hormone therapy. • Approval Duration: 12 months **Gender Affirming Care – Transgender Adults** • Prescribed by or in consultation with a medical	months **Gender Affirming Care – Adolescents OR Gender Affirming Care – Transgender Adults:** • Approval Duration: 12 months. **Oncology Indications:** • Patient has positive clinical response and absence of unacceptable toxicity **Uterine Leiomyomata (Fibroids) –** • 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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	provider experienced in transgender hormone therapy. • Approval Duration: 12 months **<u>Oncology Indications:</u>** • Prescribed by a hematologist/oncologist AND • The requested use is supported by the National Comprehensive Cancer Network (NCCN) clinical practice guidelines with a recommendation category level of 1 or 2A. <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>** • Lupron Depot formulation prescribed • Prescribed for use prior to surgery to reduce the size of fibroids to facilitate surgical procedure; OR • For the treatment of uterine leiomyomata-related anemia; AND • inadequate respond to iron therapy of one month duration; AND • For use prior to surgery • Approval Duration: 6 months total.	
lifitegrast ophthalmic (**Xiidra**) Drop 5%	1. Ordered for an approved indication for use: • the treatment of the signs and symptoms of dry eye disease (DED). 2. Must have tried and failed artificial tears AND cyclosporine (ophth) emulsion 0.05% (generic of Restasis). 3. Approval Duration: 12 months.	•

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lisdexamfetamine (Vyvanse) capsules 10mg, 20mg, 30mg, 40mg, 50mg, 60mg, 70mg chewables 10mg, 20mg, 30mg, 40mg, 50mg, 60mg **STEP THERAPY**	1. Ordered for an approved indication for use: • Attention Deficit Hyperactivity Disorder (ADHD) in children ≥ 6 years of age. • 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)	**Limitations to use:** • Not for use in pediatric patients younger than 6 years of age. • Not indicated nor recommended for weight loss.
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.	**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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	3. Prescriber attestation that all baseline evaluations have been done, and no contraindications to use are present. 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 more lines of systemic therapy, including diffuse large B-	1. Patient continues to meet initial criteria for use. 2. Positive disease response from treatment defined as stabilization of

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	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	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 based on presence of clinical signs such as collarettes, lid erythema, madarosis and/or misdirected lashes. 4. Documentation indicating that the patient has symptoms attributable to Demodex blepharitis in at least one eye (e.g., itching, foreign body sensation, burning, etc.); and 5. Patient has not undergone more than 1 6-week treatment in the previous 12 months. 6. Written by or in consultation with an ophthalmologist or optometrist. 7. Approval limited to 1 bottle (10 ml) per 12 months.	• At this time, there is no clinical evidence to show benefit beyond 6 weeks of treatment.
lubiprostone (Amitiza) capsules 8mcg, 24 mcg	1. Ordered for an approved indication for use: • chronic idiopathic constipation (CIC) in adults.	**<u>Limitations of use:</u>**

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	• opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Limitations of Use: • irritable bowel syndrome with constipation (IBS-C) in females ≥ 18 years old. 2. Failure of at least 2 of the following: docusate, mineral oil, sennosides, psyllium, psyllium/aspartame, calcium polycarbophil, polyethylene glycol 3350, lactulose, methylcellulose	Effectiveness of Lupiprostone in the treatment of OIC in patients taking diphenylheptane opioids (e.g., methadone) has not been established.
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.	1. All initial approval criteria is met, and 2. Submission of medical records documenting a positive clinical

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	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 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.	response to therapy from pre-treatment baseline. 3. 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	**<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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	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.	
lurasidone (Latuda) tablets 20mg, 40mg, 60mg, 80mg, 120mg	1. Ordered for an approved indication for use: • Schizophrenia in adults and adolescents (13 to 17 years). • Depressive episode associated with Bipolar I Disorder (bipolar depression) in adults and pediatric patients (10 to 17 years) as monotherapy. • Depressive episode associated with Bipolar I Disorder (bipolar depression) in adults as adjunctive therapy with lithium or valproate. 2. Medication ordered by psychiatrist or other behavioral health specialist.	**<u>Limitations of use:</u>** • Lurasidone is not approved for the treatment of patients with dementia-related psychosis and will not be approved for this indication.
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.**
maribavir (**Livtencity**) tablets 200mg	1. Ordered for an approved indication for use: • treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.	If a patient has a paid claim in the MFC system for ganciclovir, valganciclovir, cidofovir, or foscarnet, Livtencity will process at the pharmacy without PA. If there is no evidence of a paid claim for ganciclovir, valganciclovir, cidofovir, or foscarnet, a PA is required, and documentation of previous use of one of

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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.	these medications should be submitted.
mepolizumab (**Nucala**) injection 40mg/0.4mL syringes 100mg pens, syringes, vials	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. Medication ordered by an Allergist or Pulmonologist.	
methadone (for pain) concentrate 10mg/ml solution 5mg/5ml, 10mg/5ml tablets 5mg, 10mg	1. Ordered for an approved indication for use: • The management of chronic pain severe enough to require daily, around-the- clock, long-term opioid treatment and for which alternative treatment options are inadequate. 2. Completion of an opioid prior authorization form. 3. Submission of clinical documentation from last office visit, dated within 3 months of the request. 4. Maximum approval duration is 6 months but may be reduced based on any of the criteria as outlined in Pharmacy Policy 219.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

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mifepristone (**Korlym**) tablets Korlym-300mg ONLY	1. 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. 2. Patient is ≥ 18 years of age. 3. Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). 4. 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. 5. The patient has either failed surgery or is not a candidate for pituitary surgery. 6. Prescribed by or in consultation with an endocrinologist. 7. The dose does not exceed 20 mg/kg/day. 8. Approval Duration: 3 months.	1. 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. 2. Dose does not exceed 20 mg/kg/day. 3. Approval duration: 3 months per authorization. **No other indications approved, can redirect requests for Mifeprex brand to appropriate formulary alternatives.
mirabegron (Myrbetriq) tablets 25mg, 50mg **STEP THERAPY**	1. Ordered for an approved indication for use: • Overactive bladder (OAB) in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency, either alone or in combination with the muscarinic antagonist solifenacin succinate. • Pediatric neurogenic detrusor overactivity (NDO) in patients weighing ≥ 35 kg. 2. OAB: adequate trial (30 days), or intolerance to at least 2 preferred bladder agents. 3. NDO: Adequate trial (30 days), or intolerance to oxybutynin IR or ER OR the patient is ≥ 5 years of age	**Limitations for use:** Extended-release tablets and granules are not bioequivalent and cannot be substituted on a mg:mg basis. Do not combine dosage forms to achieve a specific dose.

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	4. No concurrent diagnosis of severe hepatic impairment (Child-Pugh Class C) 5. No step therapy or prior authorization is required for patients aged ≥ 65 years. 6. If computer claims data supports the Step Therapy requirement, the claim will adjudicate without manual review. • An adequate trial of two formulary preferred ingredients that include: oxybutynin, solifenacin, tolterodine, and/or trospium. An adequate trial is 30 days. 7. Approval Duration: 12 months.	
mirikizumab (**Omvoh**) injection 100 mg/1 ml	1. Ordered for an approved indication for use: • Maintenance treatment of ulcerative colitis (UC) in adults with moderate to severe active disease. 2. Patient is ≥ 18 years of age, and 3. Patient has had a trial of one systemic agent for UC (e.g., 6-MP, azathioprine, cyclosporine, tacrolimus or a corticosteroid. Note that trial of a mesalamine product does not count as a systemic therapy for UC) **OR** 4. Patient has both: • Pouchitis AND • Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema 5. Patient is not being treated concurrently with a biologic or targeted synthetic disease-modifying antirheumatic drug (DMARD) for UC. (e.g., adalimumab, infliximab, sarilumab, abatacept, rituximab, ustekinumab, apremilast, ozanimod, or similar). 6. Medication is prescribed by or in consultation with a gastroenterologist. 7. Initial Approval Duration: 6 months; if patient has	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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	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 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.	• Maximum recommended daily dose is 200 mg (single dose or 2x100 mg doses); evidence is limited for daily doses >200 mg regardless of indication

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	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	Renewal criteria: • 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. 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.	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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mosunetuzumab-axgb (**Lunsumio**) solution 1mg/ml, 30mg/30ml	1. Ordered for an approved indication for use: • Treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. 2. Documentation of at least two lines of systemic therapy including an anti-CD20 monoclonal antibody (e.g. rituximab) and an alkylating agent (e.g. bendamustine). 3. Patient age ≥ 18 years. 4. Patient does not have central nervous system (CNS) lymphoma; AND 5. Used for histologically confirmed grades 1-3a disease; AND 6. Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1. 7. Confirmation that drug continues to carry FDA-approval for indication. 8. Coverage for eight, 21-day cycles.	1. Patient continues to meet the requirements for initial approval. 2. Patient has absence of unacceptable toxicity from the drug. 3. Patient achieved a partial response or has stable disease as evidenced by metabolic and radiologic response criteria. 4. Confirmation that drug continues to carry FDA-approval for indication. 5. Patient has not exceeded a maximum total of 17 cycles. 6. Approval for up to eight, 21-day cycles.
naloxegol (**Movantik**) tablets 12.5mg, 25mg	1. Ordered for an approved indication for use: • treatment of opioid-induced constipation in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. 2. Failure of at least 2 of the following: docusate, sennosides, polyethylene glycol 3350, lactulose, methylcellulose.	**Limitations of use:** • Contraindicated with known or suspected GI obstruction • Contraindicated with concomitant use with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, etc.)
nintedanib (**Ofev**) capsule 100mg, 150mg	1. Ordered for an approved indication for use: • Treatment of adults for idiopathic pulmonary fibrosis. • Treatment of adults for chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.	1. All initial criteria are met. 2. Documentation of positive clinical response to Ofev therapy. 3. Approval Duration: 12 months

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	• To slow the rate of decline in pulmonary function in patients with systemic sclerosis associated interstitial lung disease (SSc-ILD). 2. Documentation that patient does not smoke. 3. Medication ordered by a pulmonologist. 4. Authorization Duration: 12 months.	
niraparib (**Zejula**) capsules 100mg, 200mg, 300mg	1. Ordered for an approved indication for use: • maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy. • maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy. 2. Medication ordered by an Oncologist. 3. Approval duration: 6 months	Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA.
nirogacestat (**Ogsiveo**) tablets 50 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.	1. Patient does not show evidence of progressive disease while on Ogsiveo therapy. 2. Approval Duration: 12 months

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	7. Approval Duration: 12 months.	
nitisinone (Orfadin) capsules 2mg, 5mg, 10mg, 20mg	1. Ordered for an approved indication for use: • 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	1. Meets all initial approval criteria. 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;	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

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	• Patients with Type II and III SMA must have some functional upper extremity use. 4. **Initial therapy** • 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.	original test is no longer appropriate; • 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:**

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		1. Improvement or maintenance of previous improvement of at least a 4-point increase in score.
ocrelizumab (**Ocrevus**) injection 300mg/10ml	1. Ordered for an approved indication for use: • Primary progressive multiple sclerosis (MS); • Relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. 2. Age is ≥18 years and <55 years of age. 3. Patient has one of the following: • Ineffective treatment response due to continued clinical relapse, intolerance, or contraindication to two or more MS drugs; • Patient is not a candidate for any other preferred first-line treatments due to MS severity; • Patient is at higher risk of poor long-term outcome (spinal cord involvement, highly active disease, poor relapse recovery), as determined by their neurologist. 4. Not being used in combination with other immune-modulating or immunosuppressive therapies, including immunosuppressant doses of corticosteroids. 5. Not being used in combination with another MS disease modifying agent [Avonex, Betaseron, dalfampridine, dimethyl fumarate, Extavia, fingolimod, glatiramer, glatopa, Kesimpta, Mayzent, Rebif, teriflunomide, Vumerity]. 6. Medication ordered by a neurologist. 7. Approval duration: 12 months.	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	1. Ordered for an approved indication for use: • Schizophrenia in adults	**Limitations to Use:**

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5mg/10mg, 10mg/10mg, 15mg/10mg, 20mg/10mg	• Bipolar I disorder in adults as acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate • Bipolar I disorder in adults as maintenance monotherapy treatment 2. Urine drug screen 3. 4-week trial and failure of at least two formulary atypical antipsychotic agents.	• Contraindicated in patients using opioids; do not initiate within 14 days of opioid medication use. • Contraindicated in patients undergoing acute opioid withdrawal.
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. 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	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
omacetaxine (**Synribo**) Injection 3.5mg	1. Ordered for an approved indication for use: • treat adults with chronic phase (CP) or accelerated phase (AP) CML with resistance and/or intolerance to two or more TKIs 2. Medication ordered by an oncologist	

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omega-3-acid ethyl esters (Lovaza) capsules 1 Gram	1. Ordered for an approved indication for use: • as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia 2. Member must have tried and failed OTC fish oil.	
Omnipod insulin pump management system	1. Ordered for an approved indication for use: • Diabetes mellitus in persons requiring insulin. 2. Medication ordered by an Endocrinologist or practitioner who specializes in diabetes. 3. Office visit notes from last two encounters with prescribing provider to support Medical Necessity. 4. Evidence of face-to-face visit within past 3 months. 5. Documentation of uncontrolled diabetes on multiple daily injections. 6. Documentation that patient has been educated on device. 7. Documentation of self-blood-glucose monitoring (30-day blood glucose log or CGM report). 8. May not be used if patient needs to make insulin adjustments of less than 2-unit increments due to risk of hypoglycemia. 9. Approval Duration: 12 months.	1. Office visit notes from last two encounters with prescribing provider support of Medical Necessity. 2. Prescribed by Endocrinologist or practitioner who specializes in diabetes with evidence of face-to-face visit within the past 3 months. 3. Documentation of self-blood glucose monitoring (30-day blood glucose log or CGM report). 4. Approval duration: 12 months.
onabotulinumtoxinA (**Botox**) injection 100 Unit, 200 Unit	1. Ordered for an approved indication for use: • Overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication. • Urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury, multiple sclerosis] in adults who have an inadequate response to or are intolerant of an anticholinergic medication.	**Limitations for Use:** • **Botox will NOT be approved for cosmetic purposes** • Safety and effectiveness have not been established for: • Prophylaxis of episodic migraine (≤ 14 headache days/month).

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	• Neurogenic detrusor overactivity (NDO) in pediatric patients ≥ 5 years of age who have an inadequate response to or are intolerant of anticholinergic medication. • Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting ≥ 4 hours a day. • Spasticity in adult patients. • Cervical dystonia in adult patients to reduce the severity of abnormal head position and neck pain. • Severe axillary hyperhidrosis of adults inadequately managed by topical agents. • Treatment of blepharospasm associated with dystonia in patients 12 years of age and older. • Treatment of strabismus in patients 12 years of age and older. 2. Medication ordered by a Neurologist, Urologist, Ophthalmologist, or applicable specialist.	• treatment of upper or lower limb spasticity in pediatric patients.
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. 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	The Opioid PA form can be accessed using the following link: OPIOID PRIOR AUTH FORM-DC

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	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 ER and IR capsules, tablets, oral solution/concentrate 5 mg capsules 100mg/5mL oral concentrate 5mg/5mL oral solution IR tablets 5, 10, 13, 20, 30 mg ER tablets 10, 20, 40 mg	1. Ordered for an approved indication for use: • The management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 2. Completion of the opioid prior authorization form. 3. Submission of supporting clinical documentation for last office visit dated within previous 3 months. 4. Maximum approval duration is 6 months but may be reduced or denied based on any of the criteria as outlined in Pharmacy Policy 219.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. 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

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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 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	**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:** • Patient has achieved or maintained remission. • Patient shows positive clinical response as evidenced by low disease activity or improvement

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	(golimumab), Stelara (ustekinumab) 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), Stelara (ustekinumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)). • Prescribed by or in consultation with a gastroenterologist. 9. Approval duration: 12 months	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
pacritinib (**Vonjo**) capsules 100mg	1. Ordered for an approved indication for use: • treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 109 /L. 2. Prescribed by Oncologist or Hematologist.	**<u>Limitations of Use:</u>** • Contraindicated with strong CYP3A4 inhibitors or inducers. • Avoid use in patients with baseline QTc interval > 480. • Avoid use in patients with eGFR < 30 ml/min.

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		• Avoid use in moderate to severe hepatic impairment (Child-Pugh B or C)
palbociclib (**Ibrance**) capsules 75mg, 100mg, 125mg	1. Ordered for an approved indication for use: • Treatment of adult patients with hormone receptor positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer in combination with: a. An aromatase inhibitor as initial endocrine based therapy. b. Fulvestrant in patients with disease progression following endocrine therapy. 2. Medication ordered by an Oncologist	
palivizumab (**Synagis**) injection 50mg, 50mg/0.5ml, 100mg/ml	1. Ordered for an approved indication for use: • with a history of premature birth (≤35 weeks gestational age) and who are ≤ 6 months of age at the beginning of RSV season • with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and ≤ 24 months of age or younger at the beginning of RSV season 2. with hemodynamically significant congenital heart disease (CHD) and ≤ 24 months of age at the beginning of RSV season.	To view the most up to date AAP Synagis Guidelines, follow the link below: AAP SYNAGIS GUIDELINES **Limitations of Use:** Safety and efficacy of Synagis have not been established for treatment of RSV.
pasireotide (**Signifor LAR**) Injection 10mg, 20mg, 30mg, 40mg, 60mg	1. Ordered for an approved indication for use: • treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option. • Patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. 3. Medication ordered by an Endocrinologist	•

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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) 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	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.
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:	1. Documentation of positive clinical response to Empaveli therapy (e.g, increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in

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	• 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. 8. Approval Duration: 6 months.	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.
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.	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.

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	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.	
pemigatinib (**Pemazyre**) tablets 4.5mg, 9mg, 13.5mg	1. Ordered for an approved indication for use: • treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 fusion (FGFR2) or other rearrangement as detected by an FDA-approved test. • Treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement. 2. Medication ordered by an Oncologist.	This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit.
ponatinib (**Iclusig**) tablets 15mg, 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	**<u>Limitations of Use:</u>** • Iclusig is not indicated and is not recommended for the treatment of patients with newly diagnosed CP-CML. Risk for significant drug-drug interactions.
posaconazole (Noxafil**)** 40mg/ml suspension	1. Ordered for an approved indication for use:	• Patient at high infection risk: severely immunocompromised, such as HSCT recipients with GVHD

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	• Treatment of invasive aspergillosis in adults and pediatric patients ≥ 13 years of age. (Injection and tablets). • Prophylaxis of invasive Aspergillus and Candida infections in patients at high risk of infection development (ages vary by dose formulation). • Treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adults or pediatric patients ≥ 13 years of age. 2. Medication ordered by Infectious Disease specialist. 3. Confirmation of need for oral liquid formulation.	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.
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 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	1. Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit. 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.

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	• 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). • Must present with the following symptoms: o Hemoglobin < 10 g/dL o Platlets, 150,000/mm^3 o 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: o History of abnormal neuromuscular transmission test demonstrated by single-fiber	5. Approval Duration: up to 12 months.

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	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; 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.	
regorafenib (**Stivarga**) tablet 40mg	1. Ordered for an approved indication for use:	**Limitations of Use:**

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	• treatment of metastatic colorectal cancer previously treated with: fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) therapy, and, if RAS wild-type, an anti-EGFR therapy. • Treatment of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST), previously treated with imatinib mesylate and sunitinib malate. • hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. 2. Medication ordered by Oncologist.	• According to guidelines from the American Society of Clinical Oncology for systemic therapy for advanced HCC, regorafenib is a potential second-line therapy option in patients who received atezolizumab and bevacizumab as first-line therapy, although sorafenib or lenvatinib are preferred in this setting. Regorafenib is also a second-line therapy option in patients who received first-line therapy with sorafenib or lenvatinib. • Interrupt therapy in patients who develop new or acute onset ischemia or infarction; resume only if the benefit of therapy outweighs the cardiovascular risk.
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	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**

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	○ Liver biopsy shows non-alcoholic fatty liver disease activity score ≥ 4 with a score > 1 in ALL of the following: steatosis, ballooning, and lobular inflammation OR • Patient has had ONE of the following imaging exams performed within the 3 months preceding treatment with Rezdiffra: ○ Elastography (e.g. Fibroscan, transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, or shear wave elastography); OR ○ Computed tomography; OR ○ Magnetic resonance imaging. 4. Patient meets ONE of the following prior to treatment with Rezdiffra: • Patient has Stage F2 fibrosis; **OR** • Patient has Stage F3 fibrosis; **AND THREE** or more of the following metabolic risk factors that are managed according to Standards of Care: ○ Central obesity ○ 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	• Patient has completed ≥ 2 years of treatment AND the patient has not had worsening of fibrosis or MASH/NASH AND according to the prescriber, the patient has not progressed to stage F4 (cirrhosis). 2. Metabolic risk factors are managed according to standard of care; **AND** 3. According to the prescriber, the patient meets ONE of the following: • <u>Female patients</u>: Alcohol consumption < 20 grams per day; OR • <u>Male patients</u>: Alcohol consumption < 30 grams per day. *Note: One standard drink (or one alcoholic drink equivalent) contains ~14 grams of pure alcohol, which is found in 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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	• Male patients: Alcohol consumption < 30 grams per day. *Note: One standard drink (or one alcoholic drink equivalent) contains ~14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits.* 6. Other causes of liver disease or hepatic steatosis have been ruled out (e.g., alcoholic steatohepatitis, acute fatty liver, autoimmune hepatitis, Hepatitis A, B, or C, hemochromatosis, drug-induced liver disease, etc.), AND 7. Provider attestation that member has adopted liver-protective lifestyle interventions such as optimizing weight loss, dietary changes, and exercise, AND 8. Member does not have evidence of cirrhosis, hepatic decompensation, or hepatocellular carcinoma (HCC). 9. All other indications are excluded from coverage as experimental. 10. Prescribed by, or in consultation with an endocrinologist, hepatologist or gastroenterologist. 11. Approval Duration: 12 months	
rituximab (**Rituxan**) injection 100mg/10mL, 500mg/50mL	1. Ordered for an approved indication for use: • Pediatric patients aged 6 months and older with mature B-cell NHL and mature B-cell acute leukemia (B-AL) 2. Previously untreated, advanced stage, CD20-positive, diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy. • Moderate to severe Pemphigus Vulgaris (PV) in adult patients	Note: Prior authorization requirements apply for patients new to starting therapy. Documentation showing history of prior use of Rituxan within the past 90 days will be considered and PA Criteria will not apply.

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	• Demonstrated failure or intolerance to Truxima for the following indications: • Adult patients with Non-Hodgkin's Lymphoma (NHL) 3. Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent. 4. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy. 5. Non-progressing (including stable disease), low-grade, CD20-positive, Bcell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. 6. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens. • Adult patients with Chronic Lymphocytic Leukemia (CLL) 7. Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC). • Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely active RA who have inadequate response to one or more TNF antagonist therapies • Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients ≥ 2 years of age in combination with glucocorticoids	

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	8. Prescribed by oncologist or rheumatologist.	
ruxolitinib (**Jakafi**) tablets 5mg, 10mg, 15mg, 20mg, 25mg	1. Ordered for an approved indication for use: • Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults. • Polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea. • Steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older. • Chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older. 2. Medication ordered by Hematologist or Oncologist.	**Limitations of Use:** • Avoid concomitant use with fluconazole doses greater than 200 mg. Reduce Jakafi dosage with fluconazole doses ≤ 200 mg. • Strong CYP3A4 Inhibitiors: Reduce, interrupt, or discontinue Jakafi doses as recommended except in patients with acute or chronic graft-versus-host-disease.
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. Atopic Dermatitis:** • 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)	**1.** Documented positive clinical response to therapy. 2. Patient is not receiving Opzelura in combination with another biologic medication (e.g. Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)) OR JAK inhibitor (e.g. Jakafi (ruxolitinib, Xeljanz (tolacitinib), Rinvoq (upadacitinib)). 3. Patient is not receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine). 4. Approval Duration: 12 months

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	Adequate trial is considered 2 months AND • Treatment failure, intolerance, or contraindication to Eucrisa. • The drug will not be applied to affected areas greater than 20% of body surface area (BSA). **Nonsegmental Vitiligo:** • The drug will not be applied to affected areas greater than 10% of body surface area (BSA). • Patient has inadequate treatment response, intolerance, or contraindication to at least two classes of formulary drugs (medium/high potency corticosteroid and a topical calcineurin inhibitor (e.g., tacrolimus or pimecrolimus). An adequate trial is considered 6 months. 4. Patient is not receiving Opzelura in combination with another biologic medication (e.g. Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)) OR JAK inhibitor (e.g. Jakafi (ruxolitinib, Xeljanz (tolacitinib), Rinvoq (upadacitinib)). 5. Patient is not receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine). 6. Prescribed by a Dermatologist 7. Patient has not received a sample or coupon trial supply to establish themselves as a current user for authorization under continuity-of-care. **8. Initial authorization duration:** • Atopic dermatitis: 2 months • Nonsegmental vitiligo: 6 months 9. Quantity limits: 60 gm per week or 180 gm per 28-days	

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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. 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.	1. Meets all initial criteria, AND 2. Provider attestation of continued benefit. 3. Use in caution if ALT/AST > 1.5 x ULN. 4. Contraindicated in patients with active hepatitis B infection or active or untreated latent tuberculosis. 5. 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 (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	1. Patient does not show evidence of progressive disease while on Retevmo therapy. 2. Approval Duration: 12 months.

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	appropriate). • Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. 2. Medication ordered by an Oncologist. 3. Approval Duration: 12 months.	
semaglutide (**Ozempic, Rybelsus**) **Ozempic** 2mg/3 ml (0.25 mg or 0.5 mg/week; 4mg/3ml (1 mg per week) 8mg/3ml (2 mg per week) **Rybelsus** 3mg, 7mg, 14mg	1. Ordered for an approved indication for use: • As adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. 2. Patient age ≥ 18 years. **NOTE: Semaglutide is only approved in adolescents for weight loss and is not a covered benefit.** 3. A1c or TIR% report within previous 3 months. 4. **Baseline A1c is ≥ 8.0**, for patients WITHOUT CVD **OR** **Baseline A1c is ≥ 7.0**, for patients WITH CVD defined as: Patient is considered high or very high risk for ASCVD-risk as evidenced by at least **one** of the following: • Acute coronary syndrome • History of myocardial infarction • Stable or Unstable angina • Coronary or other arterial revascularization • Stroke • Transient ischemic attack • Peripheral arterial disease • ≥ 20% 10-year CVD risk according to the AHA Prevent Calculator: https://professional.heart.org/en/guidelines-and-statements/prevent-calculator 5. May not be concurrently using:	**Cannot be approved for indication of weight management.** 1. Chart notes with A1c or CGM report with TIR% within previous 3 months. 2. Documented positive clinical response defined as one of the following: • Dose titration is occurring at expected monthly intervals which applies only to the first 6 months of treatment or until A1c labs are available, or • A1c goal has been reached on the requested dose, or • A1c has decreased by ≥ 1% since onset of therapy; or • Patient is at maximum tolerated dose and used as part of a comprehensive diabetes regimen in combination with other anti-hyperglycemic medications. 3. Patient has not had medical intervention for pancreatitis OR severe gastrointestinal events. (e.g.,

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	• Any other GLP1 or GLP1/GIP combination drug (e.g., Mounjaro, Trulicity, Victoza, Xultrophy or Soliqua). • Any DPP4i (e.g., alogliptin, Januvia (sitagliptin), Tradjenta (Linagliptin), Onglyza (saxagliptin). • Agents for severe constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 6. No history of pancreatitis. 7. Not approved for use in Type 1 Diabetes mellitus. 8. Starter doses are limited and require dose escalation. Starter doses are defined as: • Ozempic: the 0.25/0.5 mg strength combines the starter-dose and titration-dose and is limited to two, 28-day dispenses before requiring clinical review. • Rybelsus 3 mg is a starter dose and limited to one, 30-day dispense. 9. Maximum approval duration: 12 months.	hospitalization or new start GI motility agent). These patients will be directed to other anti-hyperglycemic agents. 4. May not be concurrently using: • any other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus, Trulicity, Victoza, Xultrophy or Soliqua) AND/OR • a DPP4i (e.g., alogliptin, Januvia (sitagliptin), Onglyza, or Tradjenta (linagliptin)). • Agents for severe constipation: metoclopramide, Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride) or Trulance (plecanatide). 5. PBM claims data shows consistent adherence as shown by no instance of a drug-free interval greater than 2 months at which time the patient would need to satisfy the initial criteria. 6. Approval Duration: 12 months
sildenafil (Revatio) tablet 20mg	1. Ordered for an approved indication for use: • treatment of pulmonary arterial hypertension (PAH) (WHO Group I) in adults to improve exercise ability and delay clinical worsening. 2. Medication ordered by a cardiologist or pulmonologist. 3. Approval duration: 12 months	**<u>Limitations of Use:</u>** • Medication will not be covered for use to treat erectile dysfunction (ED). • Viagra and generic product strengths (25 mg, 50 mg, 100 mg) are not covered.

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sodium oxybate (**Xyrem**) solution 500mg/ml	1. Ordered for an approved indication for use: • treatment of cataplexy or excessive daytime sleepiness (EDS) in patients ≥ 7 years of age with narcolepsy. • alternative diagnoses must have been excluded 2. for cataplexy, must have failed tricyclic or SSRIs 3. for excessive daytime sleepiness, must have failed at least one formulary stimulant treatment (ex: methylphenidate or dextroamphetamine) 4. initial approval for maximum of 1-month supply with subsequent renewals for maximum approval period of 3 months at a time (Patients are to be re-evaluated by physician no less frequently than every 3 months) 5. Medication ordered by a Neurologist	**<u>Limitations of Use:</u>** • Xyrem is available only through a restricted program called the Xyrem REMS or Xyway REMS. • Contraindicated in combination with sedative hypnotics or alcohol • Contraindicated in patients with succinic semialdehyde dehydrogenase deficiency.
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

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		idiopathic short stature (ISS), athletic enhancement, central precocious puberty, congenital adrenal hyperplasia, constitutional delay of growth and puberty, or anti-aging purposes.
somatropin [recombinant human growth hormone] (**Norditropin FlexPro; Serostim**) injection Norditropin 5/1.5ml, 10/1.5ml, 15/1.5ml, 30mg/3ml Serostim 4mg, 5mg, 6mg	1. Ordered for an approved indication for use: • Growth failure in pediatric patients: ○ Due to inadequate endogenous growth hormone secretion; short stature associated with Turner Syndrome [Norditropin FlexPro] ○ Idiopathic Short Stature (ISS); short stature born small for gestational age (SGA) with no catch-up growth by age 2 to 4 years; Prader-Willi syndrome; short stature associated with Noonan syndrome[Norditropin ONLY] ○ 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	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 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: • Clinical documentation indicating positive clinical response during previous 12 months All indications: Approval duration: 12 months
sotorasib (**Lumakras**) tablet 120mg, 320mg	1. Ordered for an approved indication for use: • treatment of adult patients with KRAS G12C-	• This indication is approved under accelerated approval based on

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	mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy 2. Medication ordered by Oncologist	overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
tacrolimus extended-release (**Envarsus XR**) tablets 0.75mg, 1mg, 4mg	1. Ordered for an approved indication for use: • prophylaxis of organ rejection in kidney transplant in adult patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants. 2. Documented evidence that the patient is unable to achieve or maintain an appropriate therapeutic drug level with immediate-release tacrolimus---Lab values must be submitted. 3. Envarsus XR will be used in combination with other immunosuppressant medications to prevent kidney transplant rejection. 4. Patient has not been diagnosed with congenital long Qt-syndrome. 5. Prescribed by a Nephrologist and Transplant Specialist. 6. Approval Duration: 12 months	1. Patient has continued care with a nephrologist or transplant specialist. 2. Patient continues to meet the initial approval criteria. 3. No clinical evidence of organ failure. 4. Individual has not developed any significant adverse drug effects that may exclude continued use such as: • Pure red cell aplasia (PRCA) • Posterior reversible encephalopathy syndrome (PRES) • Torsades de points 5. Approval duration: 12 months
tadalafil (Adcirca; Alyq) tablets 20mg	1. Ordered for an approved indication for use: • To treat signs and symptoms of benign prostatic hyperplasia (BPH). • To treat pulmonary arterial hypertension (World Health Organization group 1) to improve exercise ability. 2. Confirmation the patient is not currently taking any forms of nitrate-containing medication (e.g. Nitrodur, NitroStat). 3. BPH-specific requirements:	BPH: • Tadalafil should not be used concurrently with an alpha-1 blocker (e.g. tamsulosin) due to minimal added benefit and higher adverse effect likelihood. • If using tadalafil and finasteride, max recommended duration of tadalafil is ≤26 weeks (manufacturer's labeling).

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	• Ordered for generic Cialis (tadalafil) 5 mg tablets • Ordered by a urologist. 4. PAH-specific requirements: • Ordered for generic Adcirca (tadalafil PAH) 20 mg tablets. 5. Medication ordered by a Pulmonologist, Cardiologist, or Rheumatologist. 6. **Erectile dysfunction is not a covered indication for use.** 7. Approval Duration: 12 months.	PAH: • Tadalafil is contraindicated in patients taking guanylate cyclase stimulators (e.g. riociguat) due to potentially severe hypotension.
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 ≥ 12 years of age with compensated liver disease. 2. Baseline test results prior to treatment start. • Confirmed negative HIV test result prior to starting medication. • Hepatitis Be antigen (HBeAg) status. • Liver function tests. Not recommended for Child-Pugh class B or C hepatic impairment. 3. Patient has a history of adverse event, intolerance to or contraindication to treatment with entecavir OR meets one of the following criteria: • Patient age < 20 years. • Documentation of osteopenia or osteoporosis as defined by a T-score ≤ 1 and supported by clinical documentation of DEXA scan results. • Submission of medical records documenting a prior low-trauma or non-traumatic fracture. 4. In patients with renal impairment, patients who are not receiving chronic hemodialysis must have an estimated creatinine clearance > 15 ml/minute	1. Documentation of a positive clinical response to Vemlidy therapy. 2. Patient is not a suitable candidate for entecavir. 3. Approval duration: 12 months.

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	5. Medication ordered or in consultation with an Infectious Disease specialist, Gastroenterologist, or Hepatologist. 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.	**<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

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	• Patient has experienced a loss of- or a lack of increase in- BMD while receiving bisphosphonate therapy. • Patient experienced an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy. 5. If request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture) and that the risk versus benefit of continued therapy has been reviewed with the member. 6. Dose does not exceed 20 mcg per day (1 pen every 28 days) 7. Approval Duration: 6 months.	that the risk versus benefit of continued therapy has been reviewed with the member. 3. Approval duration: not to exceed 6 months.
tesamorelin (**Egrifta SV**) injection 2mg	1. Ordered for an approved indication for use: • Reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy. 2. Approval Duration: 6 months.	1. Documentation of positive clinical response (e.g., improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance). 2. Approval Duration: 12 months.
tetrabenazine (Xenazine) tablets 12.5mg, 25mg	1. Ordered for an established indication for use: • the treatment of chorea associated with Huntington's disease. • Tardive dyskinesia in adults 2. Medication ordered by a Neurologist.	**<u>Contraindications:</u>** • In patients with untreated or inadequately treated depression or who are actively suicidal. • Patients with hepatic impairment • Patients taking monoamine oxidase inhibitors (MAOIs) or within a minimum of 14-days of discontinuing therapy with MAOIs.

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		• Patients taking reserpine, deutetrabenazine or valbenazine.
tirzepatide (**Mounjaro**) injection 2.5mg/0.5ml, 5mg/0.5ml, 7.5mg/0.5ml, 10mg/0.5ml, 12.5mg/0.5ml, 15mg/0.5ml	1. Ordered for an approved indication for use: • Treatment of adult patients with Type 2 Diabetes mellitus. 2. Patient age ≥ 18 years. 3. A1c or TIR% report within past 3 months. 4. **Baseline A1c is ≥ 8.0,** for patients WITHOUT CVD **OR** **Baseline A1c is ≥ 7.0,** for patients WITH CVD defined as: Patient is considered high or very high risk for ASCVD-risk as evidenced by **one** of the following: • Acute coronary syndrome • History of myocardial infarction • Stable or Unstable angina • Coronary or other arterial revascularization • Stroke • Transient ischemic attack • Peripheral arterial disease • ≥ 20% 10-year CVD risk according to the AHA Prevent Calculator: https://professional.heart.org/en/guidelines-and-statements/prevent-calculator 4. May not be concurrently using or taking: • Any other GLP1 or GLP1/GIP combination drug (e.g., Ozempic, Rybelsus, Trulicity, Victoza, Xultrophy or Soliqua) AND/OR • a DPP4i (e.g., alogliptin, Januvia (sitagliptin), Onglyza, or Tradjenta (linagliptin)). • Agents for *severe* constipation: metoclopramide,	**Cannot be approved for indication of weight management.** 1. Chart notes with A1c or CGM report with TIR% within previous 3 months. 2. Documented positive clinical response defined as one of the following: • Dose titration is occurring at expected monthly intervals which applies only to the first 6 months of treatment or until A1c labs are available, **or** • A1c goal has been reached on requested dose, **or** • A1c has decreased by ≥ 1% since onset of therapy, **or** • Patient is at maximum tolerated dose and used as part of a comprehensive diabetes regimen in combination with other anti-hyperglycemic medications. 3. Patient has not had medical intervention for pancreatitis **OR** severe gastrointestinal events. (e.g., hospitalization or new start GI motility agent). These patients will be directed to other anti-hyperglycemic agents. 4. May not be concurrently using:

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

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tramadol hydrochloride extended release (Ultram) capsules (biphasic release) 100mg, 150mg, 200mg, 300mg Tablets 100mg, 200mg, 300mg Tablets (biphasic release) 100mg, 200mg, 300m	1. Ordered for an approved indication for use: • in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. 2. Completion of the opioid prior authorization form. 3. Submission of supporting clinical documentation for last office visit, dated within the previous 3 months. 4. Maximum approval duration is 6 months but may be reduced or denied based on any of the criteria as outlined in Pharmacy Policy 219.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.
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:**	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

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	• Prostate Cancer: 12 months • Preservation of ovarian function: 3 months • Breast cancer (ovarian suppression): 12 months • Gender affirming care: 12 months	• Preservation of ovarian function: 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 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.	1. Meets all initial clinical criteria. 2. Documentation of positive clinical response to treatment. 3. Quantity limited to 16 doses per 30 days, 200 mg max daily dose. 4. Approval Duration: 12 months.
ustekinumab (**Stelara**) Injection, 45 mg; 90 mg	1. The criteria for Stelara are **indication specific**. Please review criteria for the patient-specific diagnosis. 2. **Stelara induction therapy requires Prior Authorization and must meet the prior authorization criteria below.** 3. Patient has been screened for Hepatitis B and Tuberculosis prior to initiation of therapy. 4. Patient is not receiving in combination with any other targeted immunomodulator (e.g., etanercept,	**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,

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	certolizumab, golimumab, abatacept, adalimumab, Risankizumab, gueslkumab, secukinumab, ixekizumab, brodalumab, tildrakizumab, rofacitinib, baricitinib, upadacitinib, apremilast, or similar). **Hidradenitis suppurative**: excluded from coverage; off-label indication. Note: Humira (or biosimilars) is first line therapy. Remicade (infliximab) is the MFC recommended alternate. **Crohn's disease**: • Diagnosis of moderately to severely active Crohn's disease • Patient is currently on Stelara therapy for moderately to severely active Crohn's disease as documented by claims history or submission of medical records. • Must have trialed and failed therapy with adalimumab, this includes patients who have failed infliximab. (1A recommendation from AGA Practice Guidelines 2021). • Approved dose: 90 mg/ml • Approval Duration: 12 months **Plaque psoriasis**: • Diagnosis of moderate to severe plaque psoriasis • ≥ 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis; AND • History of failure to one of the following topical therapies: o Corticosteroids o Vitamin D analogs (calcitriol, calcipotriene) o Tacrolimus or pimecrolimus.	brodalumab, tildrakizumab, rofacitinib, baricitinib, upadacitinib, apremilast, or similar). 3. Approval Duration: 12 months.

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	• History of failure to a 3-month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced. The trial must be documented in chart notes with date and duration of trial, **OR** • Patient has been previously treated with a targeted immunomodulator indicated for the treatment of plaque psoriasis as documented by claims history or submission of medical records that include drug name, date, and duration of therapy. (e.g., adalimumab, certolizumab, apremilast, Risankizumab, gueslkumab or similar). • Must be prescribed by or in consultation with a dermatologist. • Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Janssen sponsored CarePath Savings program shall be required to meet initial authorization criteria as if the patient were new to therapy. • Approved dose: 45 mg/ml for weight ≤ 100 kg • Approved dose: 90 mg/ml for weight > 100 kg • Approval duration: 12 months. **Psoriatic arthritis**: • Diagnosis of active psoriatic arthritis; AND • History of failure to a 3-month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced. The trial must be	

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	documented in chart notes with date and duration of trial, OR • Patient has been previously treated with a targeted immunomodulator indicated for the treatment of plaque psoriasis as documented by claims history or submission of medical records that include drug name, date, and duration of therapy. (e.g., adalimumab, certolizumab, apremilast, golimumab, gueslkumab, tofacitinib, upadacitinib, or similar). • Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Janssen sponsored CarePath Savings program shall be required to meet initial authorization criteria as if the patient were new to therapy. • Prescribed by or in consultation with a rheumatologist or dermatologist. • Approved dose: 45 mg/ml for weight ≤ 100 kg • Approved dose: 90 mg/ml for weight > 100 kg • Approval duration: 12 months **<u>Ulcerative colitis, moderate to severe:</u>** • Must show treatment failure or contraindication to first-line therapies: Remicade (infliximab) or Entyvio (vedolizumab). • Prescribed by or in consultation with a gastroenterologist. • Approved dose: 90 mg/ml • Approval Duration: 12 months	

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V-go wearable insulin delivery system kit 20, 30, 40	1. Ordered for an approved indication for use: • Diabetes mellitus type 1 or 2 with insulin requirement. 2. Medication ordered by an Endocrinologist or practitioner who specializes in diabetes. 3. Office visit notes from last two encounters with prescribing provider to support Medical Necessity. 4. Evidence of face-to-face visit within past 3 months. 5. Documentation of uncontrolled diabetes on multiple daily injections. 6. Documentation that patient has been educated on device. 7. Documentation of self blood-glucose monitoring (30-day blood glucose log or CGM report). 8. May not be used if patient needs to make insulin adjustments of less than 2-unit increments due to risk of hypoglycemia. 9. Approval Duration: 12 months.	1. Office visit notes from last two encounters with prescribing provider support of Medical Necessity. 2. Prescribed by Endocrinologist or practitioner who specializes in diabetes with evidence of face-to-face visit within the past 3 months. 3. Documentation of self-blood glucose monitoring (30-day blood glucose log or CGM report). 4. May not be used if patient needs to make insulin adjustments of less than 2-unit increments should not use V-GO as it may result in hypoglycemia. 5. Approval duration: 12 months.
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	1. Ordered for an approved indication for use: • treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients ≥ 6 years of age.	**Contraindications:** • Concomitant administration of a monoamine oxidase inhibitor

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	2. No diagnosis of biopolar disorder within prior 365 days. 3. No diagnosis of suicidal ideation or suicide attempt within previous 180 days. 4. Treatment failure or contraindication to formulary preferred agents (e.g., guanfacine ER, atomoxetine, clonidine ER, amphetamine salts or methylphenidate product). 5. Single dose does not exceed 400 mg per day for patients 17 years of age or younger; 600 mg per day max for ages ≥ 18 years. 6. Ordered by a psychiatrist	(MAOI) or within 14 days of discontinuing an MAOI • Concomitant administration of sensitive CYP1A2 or CYP1A2 substrates with a narrow therapeutic range.
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

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voclosporin (**Lupkynis**) capsule 7.9mg	1. Ordered for an approved indication for use: • in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis. (mycophenolate mofetil and corticosteroids). 2. Patient age ≥ 18 years. 3. Not taking concurrently with cyclophosphamide. 4. Prescriber specialty: immunologist, nephrologist, rheumatologist, or provider experienced in treatment of lupus nephritis. 5. Prescriber attestation that all baseline evaluations have been done, and not contraindications to use are present (strong 3A4 inhibitor contraindicated, live vaccines, pregnancy/breastfeeding negative, assessment of renal function). 6. Quantity Limit: 6 tablets per day (23.7 mg twice daily). 7. Approval Duration: 6 months	1. All initial criteria continue to be met. 2. Documentation provided or attestation of therapeutic benefit. 3. Approval Duration: 6 months.
vosoritide (**Voxzogo**) injection 0.4mg, 0.56mg, 1.2mg	1. Ordered for an approved indication for use: 1. to increase linear growth in pediatric patients with achondroplasia who are ≥ 5 years of age with open epiphyses. 2. Genetic test confirming a mutation in the fibroblast growth factor receptor 3 (FGFR3) gene. 3. Patient age ≥ 5 years but < 18 years of age. 4. Documentation of radiographic evidence indicating open epiphyses (growth plates) 5. Documentation of baseline annualized growth velocity, calculated based on standing height measured over the course of 6 months prior to request 6. Voxzogo is not prescribed concurrently with any human growth hormone products (e.g., Genotropin®,	This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

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	Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Saizen®, Zomacton®) 7. Medication ordered by or in consultation with a pediatric endocrinologist	
zuranolone **(Zurzuvae)** 20mg, 25mg tablets	1. Ordered for an approved indication: • indicated to treat postpartum depression in adults 2. Confirmed diagnosis of post-partum depression in 3rd trimester of pregnancy or within 4 weeks of delivery. 3. Not prescribed concurrently with Zulresso. 4. Confirmation patient is not breastfeeding or has plan to pump and discard breast milk during therapy and for 1 week after last dose. 5. Approval Duration: One 14-day treatment course • 50 mg (25mg tabs x2) once daily for 14 days; or • Reduce to 40 mg (20mg tabs x2) once daily for 14 days, based on tolerability	30 mg tablets are non-formulary; requests will only be approved for patients with eGFR 15 to 59 mL/minute/1.73 m2 OR Child-Turcotte-Pugh class C hepatic dysfunction who meet all other PA criteria. Renewal Criteria: None. A new initial request is required for any subsequent treatment courses associated with a different pregnancy/post-partum period.