Summary of Utilization Management (UM) Program Changes

June 2022

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Tezspire	Tezepelumab-ekko	A new drug approved for add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma (administered as a subcutaneous injection). Initial criteria requires: 1) Diagnosis of severe asthma; 2) Patient is 12 years of age or older; 3) One of the following: a) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months, OR b) Prior asthma-related hospitalization within the past 12 months; 4) Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: High-dose inhaled corticosteroid (ICS) (i.e., greater than 500 mcg fluticasone propionate equivalent/day) and Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium), OR b) One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol]); 5) Prescribed by one of the following: Pulmonologist or Allergist/Immunologist;	New	8/15/2022
Leqvio	inclisiran	Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C). Initial criteria requires: 1) One of the following diagnoses: A) Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: i) Both of the following: a) Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL, AND b) One of the following: Family history of myocardial infarction in first-degree relative less than 60 years of age, Family history of myocardial infarction in second-degree relative less than 50 years of age, Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative, Family history of familial hypercholesterolemia in first- or second-degree relative, Family history of tendinous	New	8/15/2022

		xanthomata and/or arcus cornealis in first- or second-degree relative; ii) Both of the following: a) Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL, AND b) Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following: Functional mutation in the LDL receptor, ApoB, or PCSK9 gene, Tendinous xanthomata, Arcus cornealis before age 45; B) Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: Acute coronary syndromes, History of myocardial infarction, Stable or unstable angina, Coronary or other arterial revascularization, Stroke, Transient ischemic attack, Peripheral arterial disease presumed to be of atherosclerotic origin; 2) One of the following: A) Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY statin therapy and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose; or B) Both of the following: i) Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: Myalgia (muscle symptoms without CK elevations) or Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]); AND ii) One of the following: Patient has been receiving at least 12 consecutive weeks of MODERATE-INTENSITY statin therapy and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose, OR Patient has been receiving at least 12 consecutive weeks of LOW-INTENSITY statin therapy and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose; C) Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins: Myalgia (muscle symptoms without CK elevations) or Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]); D) Patient has a labeled contraindication to all statins; E) Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN; 3) One of the following: Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy OR Patient has a history of contraindication or intolerance to ezetimibe; 4) Patient is unable to maintain adherence to PCSK 9 inhibitor therapy; 5) Submission of medical records (e.g., laboratory values) documenting one of the following LDL-C		

		values while on maximally tolerated lipid lowering therapy within the last 120 days: a) LDL-C greater than or equal to 70 mg/dL for diagnosis of ASCVD, OR b) LDL-C greater than or equal to 100 mg/dL for diagnosis of HeFH; 6) Prescribed by one of the following: Cardiologist, Endocrinologist, Lipid Specialist; 7) Medication will not be used in combination with PCSK9 inhibitor therapy.		
Kimmtrak	tebentafusp-tdbn	Treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma (first in class T cell receptor bispecific immunotherapy). Initial criteria requires: 1) Diagnosis of uveal melanoma; 2) Disease is unresectable or metastatic; 3) Patient is HLA-A*02:01 genotype positive as determined by a high-resolution genotyping test; and 4) Prescribed by an oncologist.	New	8/15/2022
Cupvosa	glycopyrrolate	Cuvposa is an oral solution formulation indicated to reduce chronic severe drooling in patients aged 3 to 16 years with neurologic conditions associated with problem drooling (e.g., cerebral palsy). Initial criteria requires: 1) Diagnosis of chronic severe drooling (sialorrhea); 2) Diagnosis of a neurologic condition (e.g., cerebral palsy) associated with chronic severe drooling (sialorrhea); 3) Patient is between 3 and 16 years of age; 4) One of the following: a) Trial and failure, or intolerance to generic glycopyrrolate tablets, or b) Patient requires liquid formulation due to dosing or inability to take tablet formulation.	New	8/15/2022
Dartisla ODT	glycopyrrolate	New oral disintegrating tablet formulation approved in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer. Initial criteria requires: 1) Diagnosis of peptic ulcer as confirmed by endoscopy; 2) One of the following: a) Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (such as lansoprazole, omeprazole), or b) Patient has a contraindication or intolerance to PPIs and is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine); 3) One of the following: a) Trial and failure to generic glycopyrrolate tablets, or b) Patient is unable to swallow tablets; and 4) Prescribed by a gastroenterologist.	New	8/15/2022
Tarpeyo	budesonide	A new drug to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.	New	8/15/2022

		Initial criteria requires: 1) Diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy; 2) Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]; 3) Used to reduce proteinuria; 4) Estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m2; 5) One of the following: a) Patient has been on a minimum 90-day trial of a maximally tolerated dose and will continue to receive therapy with one of the following: An angiotensin-converting enzyme (ACE) inhibitor (such as benazepril, lisinopril), An angiotensin II receptor blocker (ARB) (such as losartan, valsartan); OR b) Patient has a contraindication or intolerance to both ACE inhibitors and ARBs; 6) Trial and failure of another glucocorticoid (such as methylprednisolone, prednisone); and 7) Prescribed by a nephrologist.		
Recorlev	levoketoconazole	For the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative. Initial criteria requires: 1) Diagnosis of Cushing's syndrome demonstrated by urinary free cortisol (UFC) increase of 50% from baseline; 2) Patient is being treated for endogenous hypercortisolemia (such as pituitary adenoma, ectopic tumor, adrenal adenoma); 3) One of the following: Patient is not a candidate for surgery OR Surgery has not been curative; 4) Trial and failure for a minimum of 120 days (supported by paid claims or submission of medical records), or intolerance to oral ketoconazole; and 5) Prescribed by an endocrinologist.	New	8/15/2022
Evusheld	tixagevimab and cilgavimab	FDA has granted emergency use authorization (EUA) to be used for pre-exposure prophylaxis of coronavirus disease 2019 (COVD-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg): 1) Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARSCoV-2, and 2) Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination, or 3) For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID19 vaccine component(s).	New	8/15/2022

		Initial criteria requires: 1) Used for pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19); 2) Patient is 12 years of age or older; 3) Patient weighs at least 40 kg; 4) Both of the following: a) Patient is not currently infected with SARS-COV-2, and b) Patient has not had a known recent exposure to an individual infected with SARS-COV-2; 5) One of the following: a) Both of the following: i) Patient is moderately to severe immune compromised due to a medical condition or receipt of immunosuppressive medications or treatments, and ii) Patient may not mount to an adequate immune response to COVID-19 vaccination; or b) Patient is unable to complete the COVID-19 vaccine series due to a severe adverse reaction (e.g., difficulty breathing or wheezing, swelling of the tongue or throat) to the COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).		
Apretude (in Cabotegravir-containing Agents)	cabotegravir	Approved for at-risk adults and adolescents weighing at least 35 kg for short-term pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating Vocabria for HIV-1 PrEP. Vocabria may be used as: oral lead-in to assess the tolerability of cabotegravir prior to administration of Apretude (cabotegravir extended-release injectable suspension) or oral PrEP for patients who will miss planned injection dosing with Apretude. Apretude was added into the existing Cabenuva, Vocabria guideline and the guideline will be renamed to Cabotegravir-Containing Agents. Apretude criteria requires: 1) Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection; 2) Patient weight is greater than or equal to 35 kg; 3) Documentation both of the following U.S. Food and Drug (FDA)-approved test prior to use of Vocabria or Apretude: Negative HIV-1 antigen/antibody test, AND Negative HIV-1 RNA assay; 4) One of the following: a) Contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg, OR b) Provider attests to both of the following: Patient would benefit from long-acting injectable therapy over standard oral regimens, AND Patient would be adherent to testing and dosing schedule.	Update	8/15/2022
Vocabria (in Cabotegravir-containing Agents)	cabotegravir	Approved for at-risk adults and adolescents weighing at least 35 kg for short-term pre-exposure prophylaxis (PrEP) to reduce the risk of sexually	Update	8/15/2022

		acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating Vocabria for HIV-1 PrEP. Vocabria may be used as: oral lead-in to assess the tolerability of cabotegravir prior to administration of Apretude (cabotegravir extended-release injectable suspension) or oral PrEP for patients who will miss planned injection dosing with Apretude. Criteria was updated and will mirror Apretude for this indication. Initial criteria requires: 1) Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection; 2) Patient weight is greater than or equal to 35 kg; 3) Documentation both of the following U.S. Food and Drug (FDA)-approved test prior to use of Vocabria or Apretude: Negative HIV-1 antigen/antibody test, AND Negative HIV-1 RNA assay; 4) One of the following: a) Contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg, OR b) Provider attests to both of the following: Patient would benefit from long-acting injectable therapy over standard oral regimens, AND Patient would be adherent to testing and dosing schedule.		
Firdapse *Ruzurgi (in* Lambert-Eaton Myasthenic Syndrome (LEMS) Agents	amifampridine	Full FDA approval for Ruzurgi was recently converted to a tentative approval based on litigation with the Firdapse manufacturer, which is based on Firdapse having a 7-year orphan-drug exclusivity that expires on 11/28/2025. Per the FDA letter, Ruzurgi may not be marketed until receiving full approval again from the FDA. Criteria will be updated to remove the trial of Ruzurgi, and Ruzurgi criteria will be removed from the guideline.	Update	8/15/2022
Chenodal	chenodiol	Updated diagnosis criteria to clarify that it's for gallstones: "Patient has diagnosis of radiolucent gallstones." Added specialist requirement for a gastroenterologist or a provider who has specialized expertise in the management of gallstones.	Update	8/15/2022
Reyvow	lasmiditan	Added candesartan as alternative concomitant therapy: "Currently being treated with Atacand (candesartan) unless there is a contraindication or intolerance to this medication." This aligns with other migraine treatment medications that require prior authorization.	Update	8/15/2022
Sutent	sunitinib	Brand Sutent criteria updated to include step through its generic.	Update	8/15/2022
Testosterone Agents	testosterone	Added age criteria to align with package inserts for the diagnosis of male hypogonadism. Updated male hypogonadism initial auth criteria to allow bypass for pretreatment testosterone measurement in patients continuing testosterone therapy started before current insurance. For Gender Dysphoria criteria,	Update	8/15/2022

		added "Gender Incongruence" as an additional diagnosis option to align with ICD-11 (lists diagnoses) diagnostic revision.		
Ultomiris	ravulizumab-cwvz	Add age requirement (1 year and older) to align with package insert and specialist requirement within the initial criteria for paroxysmal nocturnal hemoglobinuria (specialist is hematologist/oncologist) and atypical hemolytic uremic syndrome (specialist is a hematologist or urologist)	Update	8/15/2022