Summary of Utilization Management (UM) Program Changes

September 2020

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Jardiance *Farxiga* *Xigduo XR* *Synjardy* *Synjardy XR* *Invokana* *Invokomet* *Invokomet XR*	emplagliflozin dapagliflozin dapagliflozin/metformin empagliflozin/metformin empagliflozin/metformin canagliflozin canagliflozin/metformin canagliflozin/metformin	New Step Therapy for the Sodium-glucose Cotransport 2 Inhibitors alone, and in combination with metformin, will require a trial or current use of metformin (for diabetic patients). Jardiance may also be used as initial diabetes therapy if the patient has heart failure with a low ejection fraction, heart disease, or risk factors for heart disease. Invokana may also be used as initial diabetes therapy if the patient has diabetes-related kidney disease, heart disease, or risk factors for heart disease. For patients without diabetes, Farxiga will require the patient to have heart failure with a decreased ejection fraction and a trial of ONE of the following: an angiotensin-converting enzyme inhibitor (such as enalapril, lisinopril, or others), a beta blocker used in heart failure (such as metoprolol), or spironolactone or eplerenone. If a patient is currently on one of these medications, step therapy is not a requirement to continue.	New	12/1/2020
Ajovy *Aimovig* *Emgality* *Vyepti* *Nurtec ODT* *Ubrelvy (in CGRP Inhibitors)*	Fremanezumag erenumab Galcanezumab Eptinezumab Rimegepant ubrogepant	Multiple updates: Nurtec ODT criteria align with Ubrelvy criteria: • Diagnosis of migraine with or without aura • Not to be used as preventive treatment • Having less than 15 headache days per month • Age of 18 years or older • Trial of 2 triptans (example: sumatriptan)	Update	12/01/2020

		• If having 4 or more headache days per month, being treated with amitriptyline or venlafaxine OR divalproex sodium or topiramate OR a beta blocker OR unable to take any of these medications • Being treated by a specialist: neurologist or pain specialist • Cannot be used with another oral CGRP inhibitor Vyepti will have the same requirements that Aimovig and Emgality have for migraine headaches For the injectable CGRP inhibitors, the medication cannot be used with another injectable CGRP inhibitor.		
Nexlitol *Nexlizet*	Bempedoic acid Bempodoic acid/ezetimibe	Two new products with the same criteria for an addition to diet and maximally tolerated statin medication for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of low-density cholesterol (LDL-C). Criteria for authorization requires: A. ONE of the following diagnoses: 1. <u>Heterozygous familial hypercholesterolemia (HeFH)</u> as confirmed by ONE of the following: a. Both of the following: • Untreated/pre-treatment LDL-cholesterol (LDL-C) >190 mg/dL AND • A family history of heart attack, LDL-C > 190 mg/dL, familial hypercholesterolemia, or signs associated with the disease (tendinous xanthomata and/or arcus cornealis) OR b. Both of the following:	New	12/01/2020

		• Untreated/pre-treatment LDL-C >190 mg/dL AND • One of the following: Functional mutation in the LDL receptor, ApoB, or PCSK9 gene; tendinous xanthomata; or arcus cornealis before age 45 OR 2. Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: Acute coronary syndrome, history of heart attack, stable or unstable angina, coronary or other arterial revascularization by surgery, stroke, transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin, clinically significant coronary heart disease diagnosed by invasive or noninvasive testing AND B. One of the following: 1. Patient has been receiving at least 12 consecutive weeks of the highest tolerated statin dose. If the regimen is not a HIGH-INTENSITY statin dose, the reason is documented based on symptoms or elevated lab values OR the patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times normal AND C. One of the following LDL values while on maximally tolerated statin therapy within the last 120 days is > 70 mg/dL or 100 mg/dL depending on the diagnosis. AND D. One of the following: 1. Patient has been receiving at least 12 consecutive weeks of generic ezetimibe therapy as adjunct to maximally tolerated statin therapy, OR 2. Patient has a history of contraindication or intolerance to ezetimibe. Initial Duration is for 6 months.		
Sarclissa	isatuximab	New medication indicated for use in combination with Pomalyst	New	12/01/2020

		(pomalidomide) and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor. Criteria for authorization requires: 1) Diagnosis of multiple myeloma; 2) Patient has received at least two prior treatment regimens which included both of the following: a) Lenalidomide, b) A proteasome inhibitor (such as, bortezomib, carfilzomib); 3) Used in combination with both of the following: a) Pomalidomide b) Dexamethasone; 4) Prescribed by an oncologist/hematologist.		
Epclusa	Sofosbuvir-valpatasvir	Expanded indication for the treatment of adult and pediatric patients 6 years of age and older or weighing at least 17 kg with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection: - Without cirrhosis or with compensated cirrhosis - With decompensated cirrhosis for use in combination with ribavirin. This indication was previously approved in adults only. To define decompensated liver disease, Child-Pugh classes were added.	Update	12/01/2020
Ofev (in Interstitial Lung Disease Agents)	nintedanib	New indication for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype. Initial authorization requires: 1) Diagnosis of chronic fibrosing interstitial lung disease; 2) Patient has a high-resolution computed tomography (HRCT) showing at least 10% of lung volume with fibrotic features; 3) Disease has a progressive phenotype as observed by one of the following: decline of forced	Update	12/01/2020

		vital capacity (FVC), worsening of respiratory symptoms or increased extent of fibrosis seen on imaging; 4) Prescribed by a pulmonologist.		
Aemcolo	rifamycin	Approval is given as a one-time approval. Coverage duration is revised to 14 days coverage duration. [The length of therapy is 3 days].	Update	12/01/2020
Antiemetic Quantity Limit Override	modafinil armodafinil	For the chemotherapy and radiotherapy sections the provider will have to attest "that a higher quantity is needed due to the number of chemotherapy (or radiation) sessions."	Update	12/01/2020
Harvoni	Ledipasvir-sofosbuvir	Update criteria's required medication trials due to Epclusa's expanded indication, which allows for use in pediatric patients age 6 years of age and older or weighing at least 17 kg with chronic hepatitis C virus genotypes 1, 2, 3, 4, 5, or 6 infection. For the Harvoni authorized brand alternative, the required medication trial will be modified to allow for pediatric use due to the age expansion for Epclusa. Epclusa is added as a step option for liver transplant patients to align with clinical guidelines.	Update	12/01/2020
Sovaldi	sofosbuvir	Update criteria's required medication trials due to Epclusa's expanded indication, which allows for use in pediatric patients age 6 years of age and older or weighing at least 17 kg with chronic hepatitis C virus genotypes 1, 2, 3, 4, 5, or 6 infection. Adjusted required steps for genotypes 2 and 3 to account for the approval of Epclusa for select pediatric patients.	Update	12/01/2020
Xeljanz/Xeljanz XR	tofacitinib	For psoriatic arthritis (PsA) criteria, **removal** of the requirement for a trial and failure to one nonbiologic disease modifying anti-rheumatic drug (DMARD) (such as methotrexate	Update	12/01/2020

		[Rheumatrex/Trexall], Arava [leflunomide], Azulfidine [sulfasalazine]).		
Daklinza	daclatasvir	Minor verbiage updates for clarification to ensure patients with decompensated cirrhosis do not step through a regimen with a protease inhibitor (e.g., Mavyret).	Update	12/01/2020
Nexavar	sorafenib	For Thyroid Carcinoma, unresectable disease has been added as an option of disease status.	Update	12/01/2020
Viekera	ombitasvir, paritaprevir, ritonavir, and dasabuvir	Epclusa is added as a step option for liver transplant patients to align with clinical guidelines.	Update	12/01/2020