Summary of Utilization Management (UM) Program Changes

September #2 2021

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Jadenu *Exjade*	deferasirox	Approval of branded Exjade, branded Jadenu, generic Exjade, and generic Jadenu sprinkles will require a trial and failure of generic deferasirox tablets (generic of Jadenu).	Update	11/15/2021
Fotivda	tivozanib	Treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. Initial criteria requires: 1) Diagnosis of renal cell carcinoma; 2) Disease is one of the following: relapsed or refractory; 3) Patient has received two or more prior systemic therapies (e.g., cabozantinib + nivolumab, lenvatinib + pembrolizumab, etc.); and 4) Prescribed by an oncologist or urologist.	New	11/15/2021
Roszet	rosuvastatin / ezetimibe	As adjunct therapy to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C); alone or as an adjunct to other LDL-C-lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C. Initial criteria requires: 1) Submission of medical records (e.g., chart notes) documenting one of the following diagnoses: a) Non-familial hyperlipidemia, or b) Homozygous familial hypercholesterolemia (HoFH); 2) Submission of medical records (e.g., chart notes) documenting history of a minimum 30-day trial and failure, contraindication, or intolerance to two of the following: rosuvastatin, atorvastatin, simvastatin; 3) Submission of medical records (e.g., chart notes) documenting history of a minimum 30-day trial and failure, or intolerance to ezetimibe; and 4) Physician has provided rationale for needing to use fixed-dose combination therapy with Roszet instead of taking individual products in combination.	New	11/15/2021
Praluent in PCSK9 Inhibitors	alirocumab	As an adjunct to other low density lipoprotein cholesterol (LDL-C)-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C. Criteria will be updated due to this new indication, and will mirror what is already in place for Repatha. Initial criteria requires: 1) Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following:	Update	11/15/2021

		a) Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH), OR b) BOTH of the following: i) Untreated/pre-treatment LDL-C greater than 500 mg/dL or treated LCL-C greater than 300 mg/dL, AND ii) Xanthoma before 10 years of age OR Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents; AND 2) One of the following: a) Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe), OR b) Patient has a documented inability to receive other lipid-lowering therapy (e.g., statin, ezetimibe); and 3) Prescribed by one of the following: Cardiologist, Endocrinologist, Lipid Specialist. Additionally, criteria for the existing indications will be updated as follows: - Prescriber attestation that the information provided is true and accurate will be removed. - Criteria prohibiting combination use with Juxtapid will be removed. For the diagnosis of homozygous familial hypercholesterolemia criteria will be updated to state: One of the following: a) Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe), OR b) Patient has a documented inability to take other lipid-lowering therapy (statin, ezetimibe).		
Repatha in PCSK9 Inhibitors	evolocumab	For all criteria sections, the following updates will be made: - Prescriber attestation that the information provided is true and accurate will be removed. - Criteria prohibiting combination use with Juxtapid will be removed. For the diagnosis of homozygous familial hypercholesterolemia criteria will be updated to state: One of the following: a) Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe), OR b) Patient has a documented inability to take other lipid-lowering therapy (statin, ezetimibe).	Update	11/15/2021
Tyvaso in Pulmonary Arterial Hypertens ion Agents	treprostinil	New indication for treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. Initial criteria requires: 1) Diagnosis of pulmonary hypertension associated with interstitial lung disease; 2) Diagnosis of pulmonary hypertension associated with interstitial lung disease was confirmed by diagnostic test(s) (e.g., right heart catheterization, doppler echocardiogram, computerized tomography imaging); and	Update	11/15/2021

		3) Prescribed a pulmonologist or cardiologist.		
Trodelvy	sacituzumab govetican-hziy	Two updates: 1) Expanded indication for the treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease. Previously only indicated for metastatic disease. 2) Treatment of locally advanced or metastatic urothelial cancer (UC) in adult patients who have previously received platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or a programmed death-ligand 1 (PD-L1) inhibitor. Criteria will be updated due to these new indications. <u>Breast Cancer</u>: Initial criteria requires: 1) Diagnosis of triple negative breast cancer (TNBC); 2) Disease is one of the following: unresectable, locally advanced, or metastatic; 3) Patient has received at least two prior therapies at least one of which is for metastatic disease (e.g., carboplatin, cisplatin, gemcitabine, paclitaxel, docetaxel, capecitabine, etc.); and 4) Prescribed by an oncologist. <u>Urothelial Cancer</u>: Initial criteria requires: 1) Diagnosis of urothelial cancer; 2) Disease is one of the following: locally advanced or metastatic; 3) Patient has previously received BOTH of the following: a) Platinum-containing chemotherapy (e.g., cisplatin, carboplatin) AND b) One of the following: programmed death receptor-1 (PD-1) inhibitor [e.g., Keytruda (pembrolizumab)] or programmed death-ligand 1 (PD-L1) inhibitor [e.g., Bavencio (avelumab)]; and 4) Prescribed by an oncologist.	Update	11/15/2021
Ragwitek in Sublingual Allergen Immunotherapy Products	short ragweed pollen allergy extract	Drug is now approved in pediatric patients 5 years and older. For approval, a patient must be between 5 and 65 years of age.	Update	11/15/2021
Eucrisa in Atopic Dermatitis Topical Agents Step Therapy	crisaborole	Approval of Elidel will require a trial for a minimum of 30 days and failure of a topical corticosteroid OR a generic topical calcineurin inhibitor (such as tacrolimus ointment).	Update	11/15/2021
Elidel	pimecrolimus	The branded drug is non-formulary. It will require a trial and failure of at least 3 formulary drugs.	Update	11/15/2021
Hetlioz, Hetlioz LQ	tasimelteon	The prescribing physician may be a specialist in sleep disorders OR a neurologist	Update	11/15/2021
Harvoni	ledipasvir / sofosbuvir	If a patient is post liver transplant, and does not have decompensated cirrhosis, the requirement for use with ribavirin has been removed. Approval for Harvoni in a patient with genotypes 1, 4,5, or 6, can be made for patients with prior failure (defined as viral relapse, breakthrough while on	Update	11/15/2021

		therapy, or non-responder to therapy) to Solvadi or NS5A-based therapy and used with ribavirin.		
Mavyret	glecaprenivir / pibrentasvir	For the genotypes 1, 2, 4, 5, 6 Sovaldi-experienced patients are allowed a longer treatment duration of 16 weeks. New sections were added: prior failure of Vosevi or a sofosbuvir-based regimen, and HCV-negative patients who received a liver transplant from an HCV-positive donor.	Update	11/15/2021
Farxiga in SGLT2 Inhibitors Step Therapy	dapagliflozin	For a non-diabetic patient, a diagnosis of chronic kidney disease is now approvable.	Update	11/15/2021
Sovaldi	sofosbuvir	A new section was added for prior failure of Vosevi based on updated national treatment guidelines, which recommends Mavyret plus sofosbuvir [Sovaldi] and ribavirin.	Update	11/15/2021
Synribo	omacetaxine mepesuccinate	Age criterion has been removed from guideline.	Update	11/15/2021
Tabrecta	capmatinib	Updated disease stage to be “metastatic” in line with FDA-approved indication.	Update	11/15/2021
Vosevi	sofosbuvir / velpatasvir / voxilaprevir	A new section was added for prior failure of Vosevi based on updated national guidelines which recommends retreatment with Vosevi plus ribavirin for 24 weeks.	Update	11/15/2021