Summary of Utilization Management (UM) Program Changes

December 2022

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Ztalmy	ganaxolone	Indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older. Initial criteria requires: 1) Diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD); 2) Patient has a mutation in the CDKL5 gene; 3) Patient is 2 years of age or older; 4) Patient is experiencing motor seizures (e.g., bilateral tonic, generalized tonic-clonic, bilateral clonic, atonic, focal, or bilateral tonic-clonic); 5) One of the following: a) Trial and failure, contraindication, or intolerance to two formulary anticonvulsants (e.g., valproic acid, levetiracetam, lamotrigine) OR b) For continuation of prior therapy; 6) Prescribed by a neurologist	New	2/15/2023
Skyrizi	risankizumab-rzaa	For treatment of moderately to severely active Crohn's disease in adults. Skyrizi SC 360 mg criteria requires: 1) Diagnosis of moderately to severely active Crohn's disease (CD); 2) Will be used as a maintenance dose following the intravenous induction doses; 3) Prescribed by a gastroenterologist	Update	2/15/2023
Imcivree	setmelanotide	For chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to Bardet-Biedl syndrome. Criteria for this new indication requires: 1) Patient is 6 years of age or older; 2) Patient has been diagnosed with obesity defined by one of the following: a) BMI greater than or equal to 30 kg/m2 for adults 18 years of age or older OR b) Weight greater than or equal to 95th percentile using growth chart assessments for pediatric patients 3) Diagnosis of Bardet-Biedl syndrome (BBS); 4) Other causes or types of obesity have been ruled out (e.g., obesity due to suspected POMC, PCSK1, or LEPR deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign; obesity associated with other genetic syndromes; polygenic obesity);	Update	2/15/2023
Mekinist	trametinib	In combination with Tafinlar (dabrafenib), for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid	Update	2/15/2023

		tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. Criteria for this new indication requires: 1) Diagnosis of solid tumors; 2) Patient is 6 years of age or older; 3) Disease is one of the following: a) unresectable, b) metastatic; 4) Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options; 5) Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA); 6) Medication is used in combination with Tafinlar (dabrafenib); 7) Prescribed by an oncologist		
Tafinlar	dabrafenib	In combination with Mekinist (trametinib), for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. Criteria for this new indication requires: 1) Diagnosis of solid tumors; 2) Patient is 6 years of age or older; 3) Disease is one of the following: a) unresectable, b) metastatic; 4) Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options; 5) Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA); 6) Medication is used in combination with Mekinist (trametinib); 7) Prescribed by an oncologist	Update	2/15/2023
Scemblix	asciminib	Criteria will be added to confirm FDA-approved dose is being prescribed based on the disease mutation status. The initial criteria will be updated to include the following requirement: 1) Both of the following: a) Patient has been previously treated with two or more alternative tyrosine kinase inhibitors (TKI) [e.g., Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib), Iclusig (ponatinib)], and b) Prescribed medication will be dosed at a maximum of 80 mg per day OR 2) Both of the following: a) Disease is T315I mutation positive, and 2) Prescribed medication will be dosed at a maximum of 400 mg per day.	Update	2/15/2023
Ibsrela	tenapanor	Non-formulary criteria will require submission of paid claims or medical records to confirm trial	Update	2/15/2023

		requirements or continuation of therapy allowances.		
Camzyos	mavacamten	New treatment indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms. Initial criteria requires: 1) Diagnosis of obstructive hypertrophic cardiomyopathy (HCM); 2) Patient has New York Heart Association (NYHA) Class II or III symptoms (e.g., shortness of breath, chest pain); 3) Patient has a left ventricular ejection fraction of greater than or equal to 55%; 4) Patient has valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation; 5) Trial and failure, contraindication, or intolerance to both of the following at a maximally tolerated dose: a) non-vasodilating beta blocker (e.g., bisoprolol, propranolol), b) calcium channel blocker (e.g., verapamil, diltiazem) 6) Prescribed by a cardiologist	New	2/15/2023
Verquvo	vericiguat	Due to updates from the 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure (HF), initial approval criteria will be updated to include additional first line agents indicated for HF. Initial criteria will require trial and failure, contraindication, or intolerance to ALL of the following at a maximally tolerated dose: 1) One of the following: a) Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), b) Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan), c) Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)]; 2) One of the following: a) bisoprolol, b) carvedilol, c) metoprolol succinate extended-release; 3) Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformin)]; 4) Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]	Update	2/15/2023
Corlanor	ivabradine	Due to updates from the 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure (HF), initial approval criteria will be updated to include additional first line agents indicated for HF. Initial criteria will require trial and failure, contraindication, or intolerance to ALL of the following at a maximally tolerated dose: 1) One of the following: a) Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), b) Angiotensin II receptor blocker (ARB) (e.g.,	Update	2/15/2023

		candesartan, valsartan), c) Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)]; 2) One of the following: i) bisoprolol, ii) carvedilol, iii) metoprolol succinate extended-release; 3) Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformin)]; 4) Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]		
Inlyta *Lenvima* *Votrient*	axitinib lenvatinib pazopanib	For Renal Cell Carcinoma, criteria will be differentiated between Non-Clear Cell RCC and Clear Cell RCC. Patients with Non-Clear Cell RCC will require a trial and failure, contraindication or intolerance to generic sunitinib. The criteria for Clear Cell Renal Cell Carcinoma will not be modified.	Update	2/15/2023
Eligard in Gonadotropin-Releasing Hormone Agonists	leuprolide	Eligard, will be added as a target drug to the existing Gender Dysphoria off-label criteria to allow approval pathway for gender affirming care.	Update	2/15/2023
Testosterone Products	various	The existing Gender Dysphoria/Gender Incongruence off-label criteria will be updated to confirm that patient is "using hormones to change characteristics to align with gender expression."	Update	2/15/2023
Fintepla	fenfluramine	Removed lamotrigine as a prerequisite for the diagnosis of Dravet Syndrome.	Update	2/15/2023