Summary of Utilization Management (UM) Program Changes

August #2 2023

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Daybue	trofetinide	For the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older. Initial criteria requires: 1) Diagnosis of Rett syndrome; 2) One of the following: a) Presence of all of the following clinical signs and symptoms: i) A pattern of development, regression, then recovery or stabilization ii) Partial or complete loss of purposeful hand skills such as grasping with fingers, reaching for things, or touching things on purpose iii) Partial or complete loss of spoken language iv) Repetitive hand movements, such as wringing the hands, washing, squeezing, clapping, or rubbing v) Gait abnormalities, including walking on toes or with an unsteady, wide-based, stiff-legged gait OR b) Molecular genetic testing confirms mutations in the MECP2 gene; 3) Patient is 2 years of age or older; 4) Prescribed by or in consultation with one of the following: a) Geneticist, b) Neurologist	New	11/1/2023
Skyclarys	omaveloxolone	For the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older. Initial criteria requires: 1) Diagnosis of Friedreich's ataxia confirmed via genetic testing demonstrating mutation in the FXN gene; 2) Patient is 16 years of age or older; 3) Patient has a Modified Friedreich's Ataxia Rating Scale (mFARS) score of greater than or equal to 20 and less than or equal to 80; 4) Patient has B-type natriuretic peptide value less than or equal to 200 pg/mL; 5) Prescribed by or in consultation with one of the following: a) Neurologist, b) Neurogeneticist, or c) Physiatrist (Physical Medicine and Rehabilitation Specialist)	New	11/1/2023
Rezlidhia	olutasidenib	Initial criteria requires: 1) Diagnosis of acute myeloid leukemia (AML);	Update	11/1/2023

		2) Disease is one of the following: Relapsed or Refractory; 3) Presence of a susceptible isocitrate dehydrogenase-1(IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA); 4) One of the following: a) Trial and failure, contraindication, or intolerance to Tibsovo (ivosidenib) OR b) For continuation of prior therapy; 5) Prescribed by or in consultation with an oncologist/hematologist		
Onfi *Sympazan*	clobazam clobazam	For review of an off-label use for refractory seizures. Initial criteria requires: 1) Diagnosis of refractory seizures (inadequate response to at least two antiepileptic drugs); 2) Used as adjunctive therapy; 3) For brand Onfi and Sympazan only: trial and failure or intolerance to generic clobazam tablets or oral suspension OR 4) Prescribed by or in consultation with a neurologist	Update	11/1/2023
Filspari	sparsentan	The trial and failure of a glucocorticoid has been removed.	Update	11/1/2023
Cabometyx	cabozantinib	The criteria for the hepatocellular carcinoma will not have a bypass option for the required trial of Nexavar (such a request would be reviewed through the off-label process). For the indication for thyroid cancer, the age requirement of 12 years and older will be removed.	Update	11/1/2023
Hyqvia	immune globulin/recombinant hyaluronidase	For the treatment of primary immunodeficiency in adults and pediatric patients two years of age and older. Previously, Hyqvia was only approved for this indication in adults. Age criterion that requires "patient is 2 years of age or older" will be added.	Update	11/1/2023
Rebyota	fecal microbiota, live-jslm	Initial criteria will require the submission of medical records and/or paid claims to confirm trial requirement of oral vancomycin or Dificid (fidaxomicin).	Update	11/1/2023
Afinitoe *Afinitor Disperz*	everolimus	Removed requirements that patient is not a candidate for curative surgical resection, patient does not require immediate surgery, patient is post menopausal, used as adjunctive therapy, and used in	Update	11/1/2023

		combination with Aromasin (exemestane) for their respective indications.		
Emflaza	deflazacort	Non-Formulary criteria to require “Submission of medical records (e.g., chart notes, laboratory values)" to confirm diagnostic/gene mutation criteria.	Update	11/1/2023
Imbruvica	ibrutinib	Criteria will be removed for marginal zone lymphoma and mantle cell lymphoma as the FDA indications are being withdrawn.	Update	11/1/2023
Lenvima	lenvatinib	The section of the thyroid cancer indication criteria stating "disease is refractory to radioactive iodine treatment” will be removed.	Update	11/1/2023
Nexletol *Nexlizet*	bempodoic acid bempodoic acid/ezetimibe	Removed "clinically significant coronary heart disease" as an option for confirming diagnosis of atherosclerotic cardiovascular disease.	Update	11/1/2023
Verzenio	abemaciclib	Updated criteria based on full FDA labeling for expanded indications. Removed criteria referencing Ki-67 score and criteria for "patient is a male or postmenopausal female" as that is no longer a requirement with updated labeling.	Update	11/1/2023
Xtandi	enzalutamide	Criteria update to remove "metastatic" or "recurrent" from cancer stage.	Update	11/1/2023
Yonsa	abiraterone acetate	Criteria update to remove "metastatic" or "recurrent" from cancer stage and remove "used in combination with methylprednisolone."	Update	11/1/2023
Zytiga	abiraterone acetate	Criteria update to remove requirement that drug must be used in combination with prednisone.	Update	11/1/2023
Vumerity in Multiple Sclerosis Agents	diroxemel fumarate	Criteria will be updated to require a trial of dimethyl fumarate instead of three formulary agents.	Update	10/1/2023