Summary of Utilization Management (UM) Program Changes

April #2 2024

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Hemangeol	propranolol	For the treatment of proliferating infantile hemangioma requiring systemic therapy. For an initial approval duration of 6 months, criteria requires: 1) Diagnosis of proliferating infantile hemangioma; 2) Patient is less than or equal to 12 months of age	New	7/1/2024
Rezdiffra	resmetirom	Rezdiffra is indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Initial criteria requires: 1) Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH); 2) Patient does not have cirrhosis (e.g., decompensated cirrhosis); 3) Submission of medical records (e.g., chart notes) confirming diagnosis has been confirmed by one of the following: a) FibroScan-aspartate aminotransferase (FAST) b) MRI-aspartate aminotransferase (MAST) c) Liver biopsy 4) Submission of medical records (e.g., chart notes) confirming* disease is fibrosis stage F2 or F3 as confirmed by one of the following: a) FibroScan b) Fibrosis-4 index (FIB-4) c) Magnetic Resonance Elastography (MRE) 5) Presence of greater than or equal to 3 metabolic risk factors (e.g., Type 2 diabetes, hypertension, obesity); 6) Submission of medical records (e.g., chart notes) confirming drug is used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program); 7) Prescribed by or in consultation with one of the following: a) Gastroenterologist or b) Hepatologist	New	6/1/2024

Bimzelx	Bimekizumab-bkzx	Indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. Initial criteria requires: 1) Diagnosis of moderate to severe plaque psoriasis; 2) One of the following: a) At least 3% body surface area involvement b) Severe scalp psoriasis c) Palmoplantar (i.e., palms, soles), facial, or genital involvement; 3) Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: a) corticosteroids (e.g., betamethasone, clobetasol) b) vitamin D analogs (e.g., calcitriol, calcipotriene) c) tazarotene d) calcineurin inhibitors (e.g., tacrolimus, pimecrolimus) e) anthralin f) coal tar; 4) Prescribed by or in consultation with a dermatologist; 5) a) Both of the following: i) Trial and failure, contraindication, or intolerance to two of the following: • Cimzia (certolizumab pegol) • Enbrel (etanercept) • Humira (adalimumab), Cyltezo, Hadlima, or Brand Adalimumab-adbm • Skyrizi (risankizumab) • Stelara (ustekinumab) • Tremfya (guselkumab) AND ii) Trial and failure, contraindication, or intolerance to Taltz (ixekizumab)	New	7/1/2024
Opfolda	miglustat	Indicated, in combination with Pombiliti, a hydrolytic lysosomal glycogen-specific enzyme, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT). Initial criteria requires: 1) Diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency); 2) Disease is confirmed by one of the following:	New	7/1/2024

		a) Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay OR b) Molecular genetic testing confirms mutations in the GAA gene; 3) Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.); 4) Medication is used in combination with Pombiliti (cipaglucosidase alfa-atga); 5) Patient weight is greater than or equal to 40 kg; 6) Trial and inadequate response to one of the following: a) Lumizyme OR b) Nexviazyme; 7) Opfolda is not substituted with other miglustat products (i.e., Zavesca, Yargesa)		
Velsipity	entrasimod	Indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults. Initial criteria requires: 1) Diagnosis of moderately to severely active ulcerative colitis; 2) One of the following: a) Greater than 6 stools per day b) Frequent blood in the stools c) Frequent urgency d) Presence of ulcers e) Abnormal lab values (e.g., hemoglobin, ESR, CRP) f) Dependent on, or refractory to, corticosteroids 3) Trial and failure, contraindication, or intolerance to one of the following conventional therapies: a) 6-mercaptopurine b) Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine) c) Azathioprine d) Corticosteroids (e.g., prednisone) 4) One of the following: a) Trial and failure, contraindication, or intolerance to two of the following, or attestation demonstrating a trial may be inappropriate*: i) Humira (adalimumab), Cyltezo, Hadlima, or Brand Adalimumab-adbm ii) Simponi (golimumab) iii) Stelara (ustekinumab) iv) Rinvoq (upadacitinib) v) Xeljanz/XR (tofacitinib/ER) OR b) For continuation of prior therapy, defined as no more than a 45-day gap in therapy;	New	7/1/2024

		5) Prescribed by or in consultation with a gastroenterologist		
Braftovi	encorafenib	In combination with Mektovi (binimetinib) for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, as detected by an FDA-approved test. Initial criteria requires: 1) Diagnosis of metastatic non-small cell lung cancer (NSCLC); 2) Cancer is BRAF V600E mutant 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); 3) Used in combination with Mektovi (binimetinib)	Update	7/1/2024
Mektovi	binemetinib	In combination with Braftovi (encorafenib), for the treatment of adult patients with metastatic non-small cell lung cancer with a BRAF V600E mutation, as detected by an FDA-approved test. Initial criteria requires: 1) Diagnosis of metastatic non-small cell lung cancer (NSCLC); 2) Cancer is BRAF V600E mutant 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); 3) Used in combination with Braftovi (encorafenib)	Update	7/1/2024
*Ti*bsovo	ivosidenib	Indicated for the treatment of adult patients with relapsed or refractory myelodysplastic syndromes with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test. Initial criteria requires: 1) Diagnosis of Myelodysplastic Syndromes (MDS); 2) Disease is one of the following: a) Relapsed or b) Refractory; 3) Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)	Update	7/1/2024
Immune Globulins		Update to include drug-specific off-label criteria for Pediatric Acute-Onset Neuropsychiatric Syndrome/Pediatric Autoimmune Neuropsychiatric Disorders	Update	7/1/2024

		Associated with Streptococcal Infections (PANS/PANDAS). Initial criteria requires: 1) Diagnosis of one of the following: a) Pediatric Acute-onset Neuropsychiatric Syndrome (PANS) OR b) Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) 2) Disease is moderate to severe as defined by distressing symptoms that interfere with daily activities that occupy at least 50% of waking hours; 3) Trial and failure, contraindication, or intolerance to one of the following: a) Corticosteroids (e.g., prednisone, dexamethasone, methylprednisolone) or b) NSAIDs (e.g., Ibuprofen, naproxen, celecoxib); 4) [Applies to Asceniv and Panzyga only] Trial and failure, contraindication, or intolerance to two of the following: a) Gammagard, b) Gammaplex, c) Gamunex-C, d) Privigen		
Bosulif	bosutinib	Expanded indication: Treatment of adult and pediatric patients 1 year of age and older with chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), newly-diagnosed or resistant or intolerant to prior therapy. Previously, these indications were approved in adults only. Initial criteria requires: 1) Diagnosis of Philadelphia chromosome-positive chronic myelogenous/myeloid leukemia (Ph+ CML); 2) One of the following: a) Disease is in the accelerated or blast phase OR b) Both of the following: i) Disease is in the chronic phase; ii) Patient is 1 year of age or older; 3) One of the following: a) Trial and failure or intolerance to generic imatinib OR b) Continuation of prior therapy	Update	7/1/2024
Rozyltrek	entrectinib	Indicated for the treatment of adult and pediatric patients older than 1 month of age with solid tumors that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or	Update	7/1/2024

		have no satisfactory alternative therapy. Previously, this indication was approved in patients 12 years of age or older. Initial criteria will be updated without changing clinical intent. Initial criteria requires: 1) Diagnosis of solid tumors: 2) Patient has solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.) as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA); 3) Disease is without a known acquired resistance mutation (e.g., TRKA G595R, TRKA G667C or TRKC G623R substitutions); 4) Patient is 1 month of age or older; 5) Disease is one of the following: a) Metastatic or b) Unresectable (including cases where surgical resection is likely to result in severe morbidity); 6) One of the following: a) Disease has progressed following previous treatment (e.g., surgery, radiation therapy, or systemic therapy) b) Disease has no satisfactory alternative treatments		
Voxzogo	vosoritide	Expanded indication: To increase linear growth in pediatric patients with achondroplasia with open epiphyses. Previously, this indication was approved in patients age 5 years of age and older. Criteria will be updated to remove "patient is 5 years of age or older."	Update	7/1/2024
Zoryve	roflumilast	Expanded indication: For topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. Previously, this indication was approved in patients age 12 years and older. Criteria will be updated to require "patient is 6 years of age or older."	Update	7/1/2024
Olumiant *Litfulo*	baricitinib ritlecitinib	For both Olumiant and Litfulo, update for alopecia areata criteria to clarify examples for the criterion that requires "Other causes of hair loss have been ruled out" to be (e.g., androgenetic alopecia, trichotillomania, other scalp disease).	Update	7/1/2024
Exkivity	mobocertinib	Guideline is being retired due to discontinuation by the manufacturer.	Retirement	7/1/2024

Livmarli	maralixibat	Added gastroenterologist as an additional specialist option.	Update	7/1/2024
Bynfezia In Octreotide Products	octreotide	Product has been removed from guideline due to discontinuation by the manufacturer.	Update	7/1/2024