Summary of Utilization Management (UM) Program Changes

October #2 2020

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Isturisa	osilodrostat	Indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. Initial authorization requires: 1) Diagnosis of Cushing's disease; 2) One of the following: a) Patient is not a candidate for pituitary surgery, or b) Pituitary surgery did not cure the patient; and 3) Prescribed by an endocrinologist	New	1/15/2021
Koselugo	selumetinib	New product indicated for treatment of pediatric patients, 2 years of age and older, with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN). Criteria for initial authorization requires: 1) Diagnosis of neurofibromatosis type 1; 2) Patient has plexiform neurofibromas that are both of the following: a) can't be treated with surgery, and b) causing significant problems (such as disfigurement, movement problems, pain, breathing problems, or vision problems); 3) One of the following: a) Patient is less than 18 years of age, or b) Patient is 18 years of age or older and is continuing therapy; 4) Patient is able to swallow a capsule whole; and 5) Prescribed by an oncologist or neurologist	New	1/15/2021
Pemazyre	pemigatinib	New product indicated for treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a	New	1/15/2021

		fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. Criteria for initial authorization requires: 1) Diagnosis of cholangiocarcinoma; 2) Disease is one of the following: a) unable to be treated with surgery, locally advanced, or b) metastatic; 3) Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement; 4) Patient has been previously treated; and 5) Prescribed by a hepatologist, gastroenterologist, or oncologist		
Trodelvy	sacituzumab govitecan-hziy	New product indicated for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease. Criteria for initial authorization requires: 1) Diagnosis of triple negative breast cancer (TNBC); 2) Disease is metastatic; 3) Patient has received at least two prior therapies for metastatic disease (such as carboplatin, cisplatin, gemcitabine, paclitaxel, docetaxel, capecitabine); 4) Prescribed by an oncologist	New	1/15/2021
Tukysa	tucatinib	New product indicated for the treatment of adult patients with advanced forms of HER2-positive breast cancer that can't be removed with surgery, or has spread to other parts of the body, including the brain, and who have received one or more prior treatments. Criteria for initial authorization requires: 1) Diagnosis of breast cancer;	New	1/15/2021

		2) Disease is one of the following: Advanced unresectable (can't be treated with surgery) or metastatic; 3) Disease is human epidermal growth factor receptor 2 (HER2)-positive; 4) Used in combination with trastuzumab and capecitabine; 5) Patient has received one or more prior anti-HER2 based regimens (such as, trastuzumab, pertuzumab, ado-trastuzumab emtansine); and 6) Prescribed by an oncologist		
Vyndaqel *Vyndamax*	tafamidis meglumine tafamidis	Vyndaqel and Vyndamax are transthyretin stabilizers indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. Criteria is the same for Vyndaqel and Vyndamax. Criteria for initial approval requires: 1) Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM); 2) One of the following: a) patient has a transthyretin (TTR) mutation (e.g., V122I), b) cardiac or noncardiac tissue biopsy demonstrating tissue confirmation of TTR amyloid deposits, or c) all of the following: echocardiogram or cardiac magnetic resonance imagine suggestive of amyloidosis, scintigraphy scan suggestive of cardiac TTR amyloidosis, and absence of light-chain amyloidosis; 3) One of the following: a) History of heart failure (HF), with at least one prior hospitalization for HF, or b) presence of clinical signs and symptoms of HF (e.g., dyspnea, edema); 4) Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart	New	1/15/2021

		failure; 5) Prescribed by a cardiologist		
Braftovi	encorafenib	New indication to be used in combination with Erbitux (cetuximab), for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAFV600E mutation, as detected by an FDA-approved test, after prior therapy. Criteria for initial authorization requires: 1) One of the following diagnoses: colon cancer or rectal cancer; 2) One of the following: a) Unable to be treated with surgery or advanced disease, or b) Metastatic disease; 3) Patient has received prior therapy; 4) Cancer is BRAFV600E mutant type as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA); 5) Used in combination with Erbitux (cetuximab); and 6) Prescribed by an oncologist	Update	1/15/2021
Reblozyl	luspatercept-aamt	New indication for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell (RBC) units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T). Initial authorization criteria requires: 1) One of the following diagnoses: a) Very low-to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS), or b) Myelodysplastic or myeloproliferative neoplasm with	Update	1/15/2021

		ring sideroblasts and thrombocytosis (MDS/MPN-RS-T); 2) Patient has failed an erythropoiesis stimulating agent [e.g., Epogen (epoetin alfa), Aranesp (darbepoetin)]; 3) Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks; and 4) Prescribed by one of the following: hematologist or oncologist.		
Alunbrig	brigatinib	Updated lab test criterion to "…as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)".	Update	1/15/2021
Balversa	erdafitinib	Indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) that has susceptible fibroblast growth factor receptor (FGFR)3 or FGFR2 genetic alterations and progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy Criteria for initial authorization requires: 1) Diagnosis of urothelial cancer 2) One of the following: a) Locally advanced disease, or b) Metastatic disease; 3) 4) Cancer has a FGFR2 or FGFR3 genetic alteration as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA); 5) Patient has progressed during or after at least one line of chemotherapy or immunotherapy OR patient has progressed within 12 months of platinum-containing chemotherapy and 6) Prescribed by an oncologist	New	1/15/2021