+ Summary of Utilization Management (UM) Program Changes

January #2 2023

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Zoryve	roflumilast	For topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older. Initial criteria requires: 1) Diagnosis of plaque psoriasis; 2) Patient is 12 years of age or older; 3) Minimum duration of a 4 week trial and failure, contraindication, or intolerance to TWO of the following topical therapies: i) Corticosteroids (e.g., betamethasone, clobetasol), ii) Vitamin D analogs (e.g., calcitriol, calcipotriene), iii) Tazarotene, iv) Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), v) Anthralin, vi) Coal tar 4) Prescribed by or in consultation with a dermatologist	New	4/1/2023
Enhertu	fam-trastuzumab deruxtecan-nxki	Two new indications were approved: 1) Treatment of adult patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-low (immunohistochemistry [IHC] 1+ or IHC 2+/ in situ hybridization [ISH]-) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy; 2) Treatment of adult patients with unresectable or metastatic non-small cell lung cancer whose tumors have activating HER2 mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy. Criteria for Breast Cancer will be updated. Initial criteria requires: 1) Diagnosis of breast cancer; 2) One of the following: a) Both of the following: i) Disease is human epidermal growth factor receptor 2 (HER2)-positive, ii) Patient has received prior anti-HER2-based regimens (e.g. trastuzumab + pertuzumab + docetaxel, ado-trastuzumab emtansine) OR b) Both of the following: i) Disease is HER2-low, ii) Patient has received a prior chemotherapy 3) Disease is ONE of the following: a) Unresectable or b) Metastatic; 4) Prescribed by or in consultation with an oncologist	Update	4/1/2023

		Criteria for Non-Small Cell Lung Cancer will be created. Initial criteria requires: 1) Diagnosis of Non-Small Cell Lung Cancer (NSCLC); 2) Disease is ONE of the following: a) Unresectable or b) Metastatic; 3) Patient has known active human epidermal growth factor receptor 2 (HER2) ERBB2 mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA); 4) Patient has received a prior systemic therapy (e.g., chemotherapy); 5) Prescribed by or in consultation with an oncologist		
Imbruvica	ibrutinib	Newly indicated for patients aged 1 year and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy. Previously approved in adults only. Criteria for chronic graft versus host disease (cGVHD) will be updated to include age criterion that confirms patient is 1 year of age or older.	Update	4/1/2023
Myfembree in Oriahnn, Myfembree	relugolix / estradiol / norethindrone acetate	For the management of moderate to severe pain associated with endometriosis in premenopausal women. Limitations of Use: Use should be limited to 24 months due to the risk of continued bone loss, which may not be reversible. Initial criteria for new indication requires: 1) Diagnosis of moderate to severe pain associated with endometriosis; 2) Patient is premenopausal; 3) ONE of the following: a) History of inadequate pain control response following a trial of 30 days, or history of intolerance or contraindication to one of the following: i) Danazol, ii) Combination (estrogen/progestin) contraceptive, iii) Progestins OR b) Patient has had surgical ablation to prevent recurrence; 4) Treatment duration of Myfembree has not exceeded a total of 24 months	Update	4/1/2023
Orkambi	lumacaftor-ivacaftor	Treatment of Cystic Fibrosis (CF) in patients aged 1 year and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. Previously approved in patients aged 2 years or older.	Update	4/1/2023

		Criteria for granule packet formulations will be modified to reduce the minimum patient age requirement from 2 to 1 year of age or older to reflect the updated indication.		
Pemazyre	pemigatinib	Treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms with fibroblast growth factor receptor 1 rearrangement. PA Criteria will be created for new indication. For an initial approval duration of 12 months, criteria requires: 1) Diagnosis of Myeloid/Lymphoid Neoplasms (MLNs); 2) Disease is relapsed or refractory; 3) Disease has presence of fibroblast growth factor receptor 1 (FGFR1) rearrangement; 4) Prescribed by or in consultation with a hematologist/oncologist;	Update	4/1/2023
Olumiant	baricitinib	Initial criteria for alopecia areata will remove trial and failure, contraindication, or intolerance to one previous treatment (e.g., topical, intralesional, or systemic corticosteroids, topical immunotherapy). Initial criteria for rheumatoid arthritis will be updated to add criterion "Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Humira, Simponi)" to align with the prescribing information.	Update	4/1/2023
Strensiq	asfotase alfa	The specialist requirement will be updated to require Strensiq be prescribed by a specialist experienced in the treatment of inborn errors of metabolism. Examples of acceptable specialists include but are not limited to endocrinologist, rheumatologist, geneticist, orthopedist. Submission of medical records (e.g., chart notes) will be required to confirm diagnosis.	Update	4/1/2023
Camzyos	mavacamten	Submission of medical records and/or paid claims to confirm trial requirements of a non-vasodilating beta blocker and a calcium channel blocker	Update	4/1/2023
Lynparza	olaparib	Indication withdrawal: Treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Criteria for this indication will be removed from the guideline.	Update	4/1/2023
Zejula	niraparib	Indication withdrawal: Treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 3 or more prior	Update	4/1/2023

		chemotherapy regimens and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA mutation, or genomic instability and who have progressed more than 6 months after response to the last platinum-based chemotherapy. Criteria for this indication will be removed from the guideline.		
Evrysdi	risdiplam	Updated criteria to add additional exam options to confirm baseline motor ability. Name of exam was clarified. The allowed tests are: • Hammersmith Infant Neurological Exam Part 2 (HINE-2) (infant to early childhood) • Hammersmith Functional Motor Scale Expanded (HFMSE) • Revised Upper Limb Module (RULM) Test (Non ambulatory) • Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) • Motor Function Measure 32 (MFM-32) Scale • Item 22 of the Bayley Scales of Infant and Toddler Development Third Edition (BSID-III)	Update	4/1/2023
Galafold	migalastat	For initial criteria, objective measures will be added to confirm diagnosis. These are: • Detection of pathogenic mutations in the GLA gene by molecular genetic testing • Deficiency in α-galactosidase A (α-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS) • Significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata)	Update	4/1/2023
Juxtapid	lomitapide	For initial criteria: 1) Specialist requirement updated to allow for specialist to be consulted with instead of requiring the specialist to prescribe the drug, 2) Criteria that requires trial of lipid lowering therapy updated to allow a bypass to trial if patients have inability to take other lipid lowering therapies, 3) Initial "untreated" LDL requirement updated to also allow "pre-treatment" LDL for clarification, 4) Removed	Update	4/1/2023

		requirement of low fat diet and exercise regimen.		