Summary of Utilization Management (UM) Program Changes

May 2023

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Krazati	adagrasib	For treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer, as determined by an FDA-approved test, who have received at least one prior systemic therapy. Initial criteria requires: 1) Diagnosis Non-Small Cell Lung Cancer (NSCLC); 2) Disease is one of the following: a) Locally advanced b) Metastatic 3) Disease is KRAS G12C-mutated 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 at least one prior systemic therapy (e.g., chemotherapy, immunotherapy); 5) Prescribed by or in consultation with an oncologist	New	8/1/2023
Rebyota	fecal microbiota, live-jslm	Prevention of recurrence of Clostridioides difficile (C. difficile) infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI. Criteria requires: 1) Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following: a) Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days b) A positive stool test for C.difficile toxin or toxigenic C.difficile 2) Patient is 18 years of age or older 3) One of the following: a) Patient has a history of one or more recurrent episodes of CDI OR b) Patient has had at least two episodes of severe CDI resulting in hospitalization within the past year 4) Both of the following: a) Patient has completed at least 10 consecutive days of antibiotic therapy between 24 to 72 hours prior to initiating Rebyota	New	8/1/2023

		b) Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days) 5) Prescribed by or in consultation with a gastroenterologist or infectious disease specialist.		
Rezlidhia	olutasidenib	For the treatment of adult patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test. Initial criteria requires: 1) Diagnosis of acute myeloid leukemia (AML) 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) Prescribed by or in consultation with an oncologist or hematologist	New	8/1/2023
Lunsumio	mosunetuzumab	For the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. Initial criteria requires: 1) Diagnosis of follicular lymphoma; 2) Disease is one of the following: Relapsed or Refractory; 3) Patient has had two or more lines of systemic therapy (e.g., chemotherapy); 4) Prescribed by or in consultation with an oncologist	New	8/1/2023
Sunlenca	lencapavir	In combination with other antiretroviral(s), for the treatment of human immunodeficiency virus (HIV)-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations. Initial criteria requires: 1) All of the following: a) Diagnosis of HIV-1 infection b) Both of the following: i) Patient is heavily treatment-experienced with multidrug resistance as confirmed by a resistance assay;	New	8/1/2023

		ii) Patient is failing their current antiretroviral regimen due to one of the following: Resistance, Intolerance, or Safety considerations; c) Patient is currently taking, or will be prescribed, an active and optimized background antiretroviral therapy regimen; d) Prescribed by or in consultation with a clinician with HIV expertise OR 2) For continuation of prior therapy Alternate approval criteria require the presence of atherosclerotic cardiovascular disease, severe chronic kidney disease or high risk for atherosclerotic cardiovascular disease.		
Colony-Stimulating Factors	filgrastim pegfilgrastim	Preferred products are Xarxio for filgrastim/biosimilars and Neulasta and Udenyca for pegfilgrastim/biosimilars. Approval of other products will require a trial of the preferred product(s). Stimufend was added to the guideline.	Update	8/1/2023
Tymlos	abaloparatide	New indication to increase bone density in men with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy. Initial criteria requires: 1) Diagnosis of primary or hypogonadal osteoporosis or osteopenia; 2) One of the following: a) For diagnosis of osteoporosis, both of the following: i) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); ii) One of the following: - History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm OR - Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) b) For diagnosis of osteopenia, both of the following: i) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) ii) One of the following: - History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm OR	Update	8/1/2023

		- Both of the following: • Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) • One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions OR Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; 3) Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime.		
Wegovy phentermine in Anorexiants	semaglutide phentermine	Applicable to FEHB members only For Wegovy, new indication for chronic weight management in pediatric patients aged 12 years and older with an initial body mass index (BMI) at the 95th percentile or greater for age and sex (obesity). For this group of patients: Initial criteria requires patient is between 12 and 17 years of age and initial BMI is in the 95 percentile or greater standardized for age and sex Phentermine was removed from requiring prior authorization.	Update	8/1/2023
Hyftor	sirolimus	Additional specialists were added for prescriber requirement options: neurologist and geneticist	Update	8/1/2023
Palynziq	pegvalise-pqpz	Approval requires a trial and failure of generic sapropterin. Medical record documentation of drug trial must be submitted.	Update	8/1/2023
Sotyktu	deucravacitinib	Update to require paid claims or submission of medical records (e.g., chart notes) to confirm existing trial requirements of 1) one topical therapy, 2) two biologics from the following: a) Cimzia, b) Enbrel, c) Skyrizi, d) Stelara, e) Tremfya, f) Humira or Amjevita, and 3) Taltz.	Update	8/1/2023
Ubrelvy in CGRP Inhibitors	ubrogepant	Removed criterion "will not be used for preventative therapy of migraine" from Ubrelvy initial criteria for clarity.	Update	8/1/2023
Onfi, Sympazan	clobazam	Age requirement updated for diagnosis of Dravet syndrome to align with updated label indication of Diacomit. Diacomit is approved for use in combination with clobazam for patients age 6 months or older weighing 7kg or more.	Update	8/1/2023

Rituximab Products	rituximab and biosimilars	Preferred products are Ruxience and Truxima. Approval of Rituxan or Riabni require a trial of the preferred products.	Update	8/1/2023