Summary of Utilization Management (UM) Program Changes

August 2021

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Bronchitol	mannitol	New mannitol formulation--capsules for use by oral inhalation. Indicated as add-on maintenance therapy to improve pulmonary function in adult patients 18 years and older with cystic fibrosis (CF). Initial criteria requires: 1. Patient is 18 years of age or older; 2. Diagnosis of cystic fibrosis (CF); 3. Patient has passed the Bronchitol Tolerance Test (BTT); 4. **One** of the following: a) Patient is currently receiving Pulmozyme (dornase alfa), **or** a contraindication, intolerance, **or** is not a candidate for continued Pulmozyme therapy; 5. Trial and failure to inhaled hypertonic saline; **and** 6. Prescribed by: pulmonologist, or a specialist affiliated with a CF care center.	New	10/15/2021
Cosela	trilaciclab	To decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC). Initial criteria requires 1. Diagnosis of extensive-stage small cell lung cancer (ES-SCLC); 2. Prescribed by a hematologist/oncologist; 3. Patient is receiving **one** of the following anti-cancer chemotherapeutic regimens: platinum/etoposide-containing regimen or topotecan-containing regimen; 4. Infusion is completed within 4 hours prior to the start of chemotherapy; **and** 5. The interval between doses on sequential days will not be greater than 28 hours.	New	10/15/2021
Elmiron	pentosan polysulfate sodium	Initial criteria requires: 1. Diagnosis of interstitial cystitis; 2. Patient has bladder pain or discomfort; **and** 3. Trial and failure (of a minimum 30 days supply), to **two** of the following: amitriptyline, cimetidine, hydroxyzine **or** for continuation of therapy	New	10/15/2021
Evkeeza	evinacumab-dgnb	Initial criteria requires: 1. Patient is 12 years of age or older; 2. Submission of medical records (for example, chart notes, laboratory values) documenting diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by **one** of the following: a) Genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, **or**	New	10/15/2021

		b) **Both** of the following: **i)** One of the following: Untreated/pre-treatment LDL-C greater than 500 mg/dL OR Treated LDL-C greater than 300 mg/dL; **AND ii)** One of the following: Xanthoma before 10 years of age OR Evidence of heterozygous familial hypercholesterolemia in both parents; 3. Patient has failed to achieve a low-density lipoprotein-cholesterol (LDL-C) goal of less than 100 mg/dL despite use of both of the following: a) One of the following: **i)** Patient is currently treated with maximally tolerated statin therapy plus ezetimibe, **ii)** Patient is unable to tolerate statin therapy as evidenced by one of the following intolerable and persistent symptoms: muscle symptoms with or without CK elevations, **iii)** Patient has a labeled contraindication to **all** statins as documented in medical records, **or iv)** Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN, AND b) **One** of the following: **i)** Patient has been treated with PCSK9 therapy or did not respond to PCSK9 therapy, **ii)** Physician attests that the patient is known to have two LDL-receptor negative alleles (little to no residual function) and therefore would not respond to PCSK9 therapy, **iii)** Patient has a history of intolerance or contraindication to PCSK9 therapy, **iv)** Patient has previously been treated with Juxtapid (lomitapide), or **v)** Patient has previously been treated with lipoprotein apheresis; 4. Patient will continue other traditional lipid-lowering therapies (for example., maximally tolerated statins, ezetimibe) in combination with Evkeeza; 5. Dose will not exceed 15 milligrams per kilogram of bodyweight infused once every 4 weeks; 6. Prescribed by: cardiologist, endocrinologist, or lipid specialist.		
Tepmetko	tepotinib	Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations. Initial criteria requires: 1. Diagnosis of non-small cell lung cancer (NSCLC); 2. Disease is metastatic; 3. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations; and 4. Prescribed by an oncologist	New	10/15/2021
Ukoniq	umbralisib	Indicated for the treatment of: 1.Adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20 based regimen and 2. Adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least	New	10/15/2021

		three prior lines of systemic therapy. Initial criteria for MZL requires: 1. Diagnosis of marginal zone lymphoma (MZL); 2. Disease is **one** of the following: relapsed or refractory; 3. Patent has received at least **one** prior anti-CD20-based regimen (for example, bendamustine + rituximab, bendamustine + obinutuzumab, etc.); and 4. Prescribed by a hematologist/oncologist. Initial criteria for FL requires: 1. Diagnosis of follicular lymphoma (FL); 2. Disease is **one** of the following: relapsed or refractory; 3. Patient has received at least **three** prior lines of systemic therapy (for example, bendamustine + rituximab, bendamustine + obinutuzumab, etc.); and 4. Prescribed by a hematologist/oncologist.		
Botox	onabutulinimtoxinA	New approval for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication. Initial criteria requires: 1. Diagnosis of neurogenic detrusor overactivity 2. Prescribed by an urologist 3. Trial and failure to at least **one** anticholinergic medication 4) Patient is performing or willing/able to perform a clean intermittent self-catherization if he/she has a post void residual greater than 200 ml	Update	10/15/2021
Gocovri in Anti-Parkinson's Agents	amantadine ER	Adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes. Previously approved to treat dyskinesia in PD patients treated with levodopa-based therapy, with or without other dopaminergic medications. Initial criteria requires: 1. Diagnosis of Parkinson's disease; 2. Patient is experiencing "off" episodes; 3. Used in combination with levodopa/carbidopa therapy; 4. **Both** of the following: a) Trial and failure, or intolerance to amantadine immediate release, and b) Trial and failure to **one** of the following: • MAO-B inhibitor (for example. rasagiline, selegiline) • Dopamine Agonist (for example, pramipexole, ropinirole), • COMT inhibitor (for example, entacapone) 5. Prescribed by a neurologist.	Update	10/15/2021
Humira	adalimumab	Indication expanded for use in pediatric patient ages 5 and up for the treatment of moderately to severely	Update	10/15/2021

		active ulcerative colitis. Based on FDA label changes, the indications for Crohn's disease (CD) and Ulcerative colitis (UC) have been simplified. CD: Indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older. UC: Indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older. Limitations of use: The effectiveness of Humira has not been established in patients who have lost response to or were intolerant to TNF blockers. Since the CD indication no longer has any reference to previous trial of infliximab, criteria for CD will be no longer require a trial of infliximab.		
Lorbrena	lorlatinib	Expanded indication for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. Criteria update requires: -Criteria that required trial of specific prerequisite therapies will be removed. - ALK-positive tumor criteria will be updated to state that the diagnosis must include an FDA-approved test For patients new to treatment with Lorbrena, a trial of of Alunbrig or Alecensa is required.	Update	10/15/2021
Nplate	romiplostim	New indication to increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation. Criteria update requires: 1. Diagnosis of hematopoietic syndrome of acute radiation syndrome; 2. Patient is acutely exposed to myelosuppressive doses of radiation; and 3. Prescribed by a hematologist/oncologist.	Update	10/15/2021
Forteo in Teriparatide Products	teriparatide	Criteria update: trial of brand Teriparatide **and** Tymlos for the treatment of postmenopausal women with osteoporosis at high risk for fracture. For all other indications, a trial of brand Teriparatide product will be required	Update	10/15/2021
Cabenuva, Vocabria	cabotegravir / rilpirivine; cabotegravir	Clarified requirement that a patient's current HIV regimen must be stable, uninterrupted for at least 6 months. Prescriber must attest that the patient would benefit from a long-acting injectable therapy over standard oral regimens.	Update	10/15/2021
Ferriprox	Deferiprone	The minimum trial of another drug chelation therapy is at least 30 days	Update	10/15/2021