Summary of Utilization Management (UM) Program Changes

February #2 2022

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Opzelura	ruxolitinib	First drug in class to be indicated for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with older topical prescription therapies or when those therapies are not advisable. Initial criteria requires: 1) Diagnosis of mild to moderate atopic dermatitis; 2) One of the following: a) Greater than or equal to 3% body surface area (BSA) involvement, OR b) Involvement of sensitive body areas (e.g., face, hands, feet, scalp, groin); 3) Patient is 12 years of age or older; 4) Prescribed by one of the following: Dermatologist or Allergist/Immunologist; 5) Trial and failure of a minimum 30-day supply of non-pharmacologic topical therapies (e.g., moisturizers) 6) Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least TWO of the following: a) Medium or higher potency topical corticosteroid, b) Elidel (pimecrolimus) topical cream, c) Tacrolimus topical ointment; d) Eucrisa (crisaborole) ointment; 7) Patient is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine); and 8) Opzelura will only be used for short-term and/or non-continuous chronic treatment.	New	5/1/2022
Bylvay	odevixibat	Initial criteria requires: 1) Diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1, 2, or 3, confirmed by one of the following: a) Diagnostic test (e.g., liver function test, liver ultrasound and biopsy, bile analysis), or b) Genetic testing; 2) Patient is experiencing both of the following: a) Moderate to severe pruritus (itching), and b) Patient has a serum bile acid concentration above the upper limit of the normal 3) Patient is 3 months of age or older 4) Patient has had an inadequate response to at least TWO of the following treatments used for the relief of pruritus: ursodeoxycholic acid (e.g., Ursodiol), Antihistamines (e.g., diphenhydramine, hydroxyzine), rifampin, Bile acid sequestrants (e.g., Questran, Colestid, Welchol);	Update	5/1/2022

		5) Prescribed dose is consistent with FDA-approved package labeling and does not exceed a total daily dose of 6 mg; and 6) Prescribed by a hepatologist (liver specialist).		
Welireg	belzutifan	Treatment of adult patients with von Hippel-Lindau (VhL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery. Initial criteria requires: 1) Diagnosis of von Hippel-Lindau (VHL) disease; 2) Patient requires therapy for one of the following; Renal cell carcinoma (RCC), Central nervous system (CNS) hemangioblastoma, Pancreatic neuroendocrine tumor (pNET); 3) Patient does not require immediate surgery; and 4) Prescribed by an oncologist.	New	5/1/2022
Livmarli	maralixibat	Treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older. Initial criteria requires: 1) Both of the following: a) Diagnosis of Alagille Syndrome (ALGS), and b) Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene; 2) Documentation of ONE of the following: a) Total serum bile acid > 3x the upper limit of normal (ULN), b) Conjugated bilirubin > 1 mg/dL, c) Fat soluble vitamin deficiency otherwise unexplainable, or d) Gammaglutamyl transpeptidase (GGT) > 3x ULN; 3) Patient is experiencing moderate to severe cholestatic pruritus (itching); 4) Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus: ursodeoxycholic acid (e.g., Ursodiol), Antihistamines (e.g., diphenhydramine, hydroxyzine), rifampin, Bile acid sequestrants (e.g., Questran, Colestid, Welchol); 5) Patient is 1 year of age or older; and 6) Prescribed by a hepatologist (liver specialist).	New	5/1/2022
Exkivity	mobocertinib succinate	Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. Initial criteria requires: 1) Diagnosis of non-small cell lung cancer (NSCLC); 2) Disease is one of the following: locally advanced or metastatic; 3) Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive 4) Patient has progressed on or following prior treatment with a platinum-containing regimen (e.g., carboplatin, cisplatin); and 5) Prescribed by an oncologist.	New	5/1/2022

Tivdak	tisotumab vedotin-tftv	Treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Initial criteria requires: 1) Diagnosis of cervical cancer; 2) Disease is one of the following: a) recurrent or b) metastatic; 3) Disease has progressed on or after chemotherapy; and 4) Prescribed by an oncologist.	New	5/1/2022
Qulipta (in CGRP Inhibitors)	atogepant	This is the second oral CGRP antagonist approved for the preventive treatment of episodic migraine in adults. Criteria for Qulipta will be added into the CGRP Inhibitors guideline. Initial criteria requires: 1) BOTH of the following: a) Diagnosis of episodic migraines, and b) Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month; 2) Patient is 18 years of age or older; 3) TWO of the following: a) History of failure (after at least a two-month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine) OR patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine), b) History of failure (after at least a two-month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) OR patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate), or c) History of failure (after at least a two-month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol OR patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol; d) History of failure (after at least a two-month trial) or intolerance to Atacand (candesartan) OR patient has a contraindication to Atacand (candesartan); 4) Prescribed by one of the following specialists: neurologist, pain specialist, headache specialist; and 5) Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines.	Update	5/1/2022
Aimovig *Emgality* *Ajovy* *Vyeptil* *Nurtec ODT (in CGRP Inhibitors)* *Ubrelvy*	multiple	Due to the new approval of Qulipta, an oral CGRP inhibitor indicated for prevention of episodic migraines, criteria was updated for Aimovig, Emgality, Ajovy, Vyepti, and Nurtec to clarify that only 1 CGRP inhibitor should be used for preventive treatment. Criteria will state: "Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines." ----------	Update	5/1/2022

		Indication: Prevention Aimovig, Emgality 120 mg/mL, Ajovy*, Vyepti, Nurtec: Add Atacand (candesartan) as an alternative for the prevention of migraines. TWO of the following: a) History of failure (after at least a two-month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine) or a contraindication to both b) History of failure (after at least a two-month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) or a contraindication to both c) History of failure (after at least a two-month trial) or intolerance to one of the following beta blockers (atenolol, propranolol, nadolol, timolol, or metoprolol) or a contraindication to all listed beta blockers *d) History of failure (after at least a two-month trial) or intolerance to Atacand (candesartan) or a contraindication to Atacand (candesartan)* Indication: Acute Treatment Nurtec, Ubrelvy: Add Atacand (candesartan) as an alternative for the prevention of migraines, to be used as concurrent therapy unless contraindicated in patients who have 4 or more headache days per month. If patient has 4 or more headache days per month, patient must meet ONE of the following: a) Currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications b) Currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications c) Currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications *d) Currently being treated with a Atacand (candesartan) unless there is a contraindication or intolerance to this medication*		
Trudhesa (in Dihydroergotamine Products)	dihydroergotamine	Nasal formulation of dihydroergotamine (DHE) indicated for the acute treatment of migraine with or without aura in adults. Trudhesa will be added into the existing PA guideline with criteria to mirror the other dihydroergotamine agents.	Update	5/1/2022
Dihydroergotamine Products	dihydroergotamine	Criteria will be updated for all DHE products to add candesartan as an additional conventional treatment option for the prevention of migraine (aligns with the CGRPs). Commercial: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45	Update	5/1/2022

		injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, Migergot suppository, Brand Migranal nasal spray, Generic dihydroergotamine mesylate nasal spray, Trudhesa If patient has 4 or more headache days per month, patient must meet one of the following: a) Currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications b) Currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications c) Currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications *d) Currently being treated with a Atacand (candesartan) unless there is a contraindication or intolerance to this medication.*		
Cabometyx	cabozantinib	Treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible. Initial criteria requires: 1) Diagnosis of differentiated thyroid cancer (DTC); 2) Disease is locally advanced or metastatic; 3) Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib]); 4) Disease or patient is refractory to radioactive iodine treatment or ineligible; and 5) Prescribed by an oncologist.	Update	5/1/2022
Brukinsa	zanubrutinib	Two new indications for Brukinsa: 1) Treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen, and 2) Treatment of adult patients with Waldenström's macroglobulinemia (WM). Initial criteria for <u>Waldenstrom's macroglobulinemia</u> requires: 1) Diagnosis of Waldenstrom's macroglobulinemia/Lymphoplasmacytic lymphoma; and 2) Prescribed by a hematologist/oncologist. Initial criteria for <u>Marginal Zone Lymphoma</u> requires: 1) Diagnosis of Marginal Zone Lymphoma; 2) Disease is relapsed or refractory; 3) Patient has received at least one anti-CD20 based regimen such as rituximab or obinutuzumab; and 4) Prescribed by a hematologist/oncologist.	Update	5/1/2022

Jakafi	ruxolitinib	Treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older. Initial authorization requires: 1) Diagnosis of chronic graft-versus-host disease; 2) Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.); and 3) Prescribed by one of the following: Hematologist, Oncologist, or Physician experienced in the management of transplant patients.	Update	5/1/2022
Strensiq	asfotase alfa	Initial criteria requires: 1) ALL of the following: a) Diagnosis of Perinatal/infantile-onset HPP (hypophosphatemia) or Juvenile-onset HPP; and b) Onset of clinical signs and symptoms of hypophosphatasia prior to age 18 years (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, low trauma fractures); and c) Radiographic evidence supporting the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., infantile rickets, craniosynostosis, non-traumatic fractures, osteoporosis or low bone mineral content for age [as detected by DEXA]); and d) ONE of the following: i) Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age and gender-adjusted normal range, AND Patient has an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level]), OR ii) Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing; 2) Prescribed by a specialist experienced in the treatment of inborn errors of metabolism; 3) Provide patient's weight to verify that the requested dose will not exceed the following: 9 mg/kg per week for perinatal/infantile-onset HPP or 6 mg/kg per week for juvenile-onset HPP; and 4) One of the following: a) Patient is prescribed Strensiq 18 mg/0.45 mL, Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials, OR b) Patient is prescribed Strensiq 80 mg/0.8 mL vial and Patient's weight is greater than or equal to 40 kg.	Update	5/1/2022
Revatio (in Pulmonary Arterial Hypertension Agents)	sildenafil	Update to require a trial and failure of generic sildenafil before approval of the brand.	Update	5/1/2022
Dupixent	dupilumab	Use for chronic rhinosinusitis with nasal polyps criteria has been updated.	Update	5/1/2022

		Initial criteria additionally requires: 1) Presence of at least TWO of the following symptoms for at least 12 weeks: a) Nasal blockage/obstruction/congestion b) Nasal discharge (anterior/posterior nasal drip) c) Facial pain/pressure d) Reduction or loss of smell 2) Systemic corticosteroid treatment for nasal polyps at least once in the last two years or prior nasal polyp surgery at least 6 months ago For the treatment of Oral Corticosteroid Dependent Asthma and Eosinophilic Asthma, the age limit has been lowered to 6 years.		
Xolair	omalizumab	Use for nasal polyps criteria has been updated. Initial criteria additionally requires: 1) Presence of at least TWO of the following symptoms for at least 12 weeks: a) Nasal blockage/obstruction/congestion b) Nasal discharge (anterior/posterior nasal drip) c) Facial pain/pressure d) Reduction or loss of smell 2) Systemic corticosteroid treatment for nasal polyps at least once in the last two years or prior nasal polyp surgery at least 6 months ago	Update	5/1/2022
Lenvima	levatinib	New indication for first-line treatment of adult patients with advanced renal cell carcinoma in combination with Keytruda. Initial criteria for this new indication requires: 1) Diagnosis of renal cell carcinoma 2) Used in conjunction with Keytruda (pembrolizumab) 3) Prescribed by an oncologist	Update	5/1/2022