

Summary of Utilization Management (UM) Program Changes

October #2 2021

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
<i>Lumakras</i>	sotorasib	<p>For the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test who have received at least one prior systemic therapy.</p> <p>Initial criteria requires: 1) Diagnosis of non-small cell lung cancer (NSCLC); 2) Disease is one of the following: locally advanced or metastatic; 3) Tumor is KRAS G12C-mutated as detected by an approved lab test; 4) Patient has received at least one prior systemic therapy (e.g., cisplatin/pemetrexed, atezolizumab, nivolumab, capmatinib); and 5) Prescribed by an oncologist.</p>	New	1/1/2022
<i>Myfembree</i>	relugolix / estradiol / norethindrone	<p>Myfembree is a new product indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.</p> <p>Myfembree will be added to the Oriahnn guideline and have the same requirements.</p> <p>Initial criteria requires: 1) Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); 2) Patient is premenopausal; 3) One of the following: a) History of inadequate control of bleeding following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: i) Combination (estrogen/progestin) contraceptive, ii) Progestins, or iii) Tranexamic acid; OR b) Patient has had a previous interventional therapy to reduce bleeding; and 4) Treatment duration of therapy has not exceeded a total of 24 months.</p>	New	1/1/2022
<i>Ayvakit</i>	avapritinib	<p>Treatment of adult patients with advanced systemic mastocytosis (AdvSM). AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), and mast cell leukemia (MCL).</p> <p>Initial criteria for this new indication requires: 1) Diagnosis of advanced systemic mastocytosis (AdvSM); 2) Patient has one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL); and</p>	Update	1/1/2022

		3) Prescribed by an oncologist/hematologist.		
<p><i>Noxafil</i> <i>Sporonox</i> <i>Vfend</i> <i>Cresemba</i>)</p>	<p><i>posaconazole</i> <i>itraconazole</i> <i>voriconazole</i> <i>isavuconazonium</i></p>	<p>Noxafil (posaconazole): Oropharyngeal candidiasis: 1) Diagnosis of oropharyngeal candidiasis AND 2) Trial and failure or lack of susceptibility to fluconazole</p> <p>Prophylaxis of invasive fungal infection: 1) Used as prophylaxis to invasive fungal infection caused by: Aspergillus or Candida AND 2) ONE of the following: a) At high risk of infection due to hematopoietic stem cell transplant with graft-versus-host disease or blood-related cancers with prolonged low white blood cells due to chemotherapy OR b) Prior fungal infection requiring secondary prevention treatment.</p> <p>Treatment of invasive aspergillosis: Diagnosis of invasive aspergillosis</p> <p>Sporonox (itraconazole): The trial and failure of fluconazole will be changed to a trial and failure of fluconazole OR lack of susceptibility to fluconazole.</p> <p>Vfend (voriconazole): Invasive Aspergillosis and Serious Fungal Infections: 1) Diagnosis of invasive aspergillosis OR 2) Diagnosis of serious fungal infections (e.g. Seceosporium apiospermum, Fusarium species) AND 3) Patient is intolerant of, or not effectively treated with other therapy</p> <p>Candidemia in non-neutropenic patients and other deep tissue Candida infections: 1) Diagnosis of candidemia or deep tissue candida infection 2) Patient does not have very low white blood cells 3) ONE of the following a) Trial and failure of fluconazole OR b) Lack of susceptibility to fluconazole</p> <p>Esophageal Candidiasis: 1) Diagnosis of esophageal candidiasis 2) ONE of the following: a) Candidiasis is resistant to treatment with fluconazole OR b) Lack of susceptibility to fluconazole</p> <p>Cresemba (isavuconazonium) Diagnosis of invasive aspergillosis OR invasive mucormycosis</p>	Update	1/1/2022

<i>Trikafta</i>	elexacaftor / tezacaftor / ivacaftor; ivacaftor	Expanded indication for the treatment of cystic fibrosis in patients <u>aged 6 years and older</u> who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on in vitro data.	Update	1/1/2022
<i>Praluent Repatha in PCSK9 Inhibitors</i>	alirocumab evolocumab	The requirement of a specialist prescriber has been removed.	Update	1/1/2022
<i>Ocaliva</i>	obeticholic acid	Based on a new FDA warning: 1) Patient does not have evidence of advanced cirrhosis (i.e. cirrhosis with current or prior evidence of hepatic decompensation including encephalopathy or coagulopathy); and 2) Patient does not have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia).	Update	1/1/2022
<i>Firazyr in Hereditary Angioedema Agents</i>	icatibant	Approval for brand Firazyr with require a trial and failure of generic icatibant.	Update	1/1/2022
<i>Mifergot Cafergot Ergomar</i>	ergotamine/caffeine ergotamine/caffeine ergotamine	These medications will be added to the guideline that contains dihydroergotamine injection and nasal spray. Initial criteria requires: 1) Diagnosis of migraine headaches, with or without aura 2) Will be used for acute treatment of migraine 3) Patient is 18 years of age or older 4) Trial and failure of two triptan medications OR contraindication to triptans 5) If patient has 4 or more headache days per month, a) patient must have current treatment with amitriptyline or venlafaxine or have a contraindication to these medications OR b) patient must have current treatment with divalproex sodium or topiramate or have a contraindication to these medications c) patient must have current treatment with a beta blocker (such as propranolol or atenolol) or have a contraindication to these medications 6) Prescribed by a specialist (neurologist, pain specialist or headache specialist).	Update	1/1/2022
<i>Addyi (only for applicable plans)</i>	flibanserin	Updated criteria to align with prescribing information: Medication request is not due to: a co-existing medical or psychiatric condition, problems within relationship, or effects of a medication or other drug substance.	Update	1/1/2022
<i>Arcalyst</i>	riloncept	For Cryopyrin-Associated Periodic Syndromes, the age requirement has been removed.	Update	1/1/2022
<i>Growth Hormones</i>		Where applicable, diagnostic laboratory testing has been updated: Growth Hormone Releasing Hormone has been removed; Arginine to Growth Hormone Releasing Hormone stimulation test has been	Update	1/1/2022

		removed; Arginine stimulation test has been removed; and Macimorelin stimulation test with cutoff value has been added.		
<i>Hetlioz</i>	tasimelteon	A neurologist has been added as an option to the specialist prescriber section for Non-24 sleep-wake cycle and Smith-Magenis syndrome.	Update	1/1/2022