

Summary of Utilization Management (UM) Program Changes

December 2023

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Veozah	fezolinetant	<p>Indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> 1) Diagnosis of moderate to severe vasomotor symptoms due to menopause; 2) Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to both of the following: <ol style="list-style-type: none"> a) Menopausal hormone therapy (e.g., Premarin, Bijuva, Estrogel, etc.) b) Non-hormonal therapy (e.g. paroxetine mesylate, venlafaxine, clonidine, etc.) 	New	2/15/2024
Vowst in Fecal Microbiota Agents	fecal microbiota spores, live-brpk	<p>Indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI).</p> <p>Criteria requires:</p> <ol style="list-style-type: none"> 1) Diagnosis of recurrent Clostridioides difficile infection (CDI) as defined by both of the following: <ol style="list-style-type: none"> 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) Patient has a history of two or more recurrent episodes of CDI within 12 months; 4) All of the following: <ol style="list-style-type: none"> a) Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst: oral vancomycin OR Difidid (fidaxomicin); b) Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst; c) 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 one of the following: a) Gastroenterologist or b) Infectious disease specialist 	New	2/15/2024

<p><i>Lumryz</i> in Sodium Oxybate Containing Agents</p>	<p>sodium oxybate</p>	<p>New extended-release oral solution. Indicated for the treatment of 1) Narcolepsy Type 1: Cataplexy in adults with narcolepsy; 2) Narcolepsy Type 2: Excessive daytime sleepiness (EDS) in adults with narcolepsy.</p> <p>The following criteria will apply: Narcolepsy with Cataplexy (Narcolepsy Type 1) Initial criteria requires: 1) Diagnosis of narcolepsy as confirmed by sleep study 2) Symptoms of cataplexy are present; 3) Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present; 4) Trial and failure, contraindication or intolerance to Wakix 5) Prescribed by or in consultation with one of the following: a) Neurologist, b) Psychiatrist, c) Sleep Medicine Specialist</p> <p>Narcolepsy without Cataplexy (Narcolepsy Type 2) Initial criteria requires: 1) Diagnosis of narcolepsy as confirmed by sleep study 2) Symptoms of cataplexy are absent; 3) Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present 4) BOTH of the following: a) Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight) or intolerance to TWO of the following: i) Generic modafinil or armodafinil, ii) Sunosi, iii) Wakix b) One of the following i) Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant OR ii) History of or potential for a substance use disorder; 5) Prescribed by or in consultation with one of the following: a) Neurologist, b) Psychiatrist, c) Sleep Medicine Specialist</p>	<p>Update</p>	<p>2/15/2024</p>
<p><i>Mekinist</i></p>	<p>trametinib</p>	<p>Indicated, in combination with dabrafenib, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.</p> <p>For this new indication, criteria requires: 1) Diagnosis of low-grade glioma; 2) Patient is 1 year of age or older; 3) Patient requires systemic therapy;</p>	<p>Update</p>	<p>2/15/2024</p>

		<p>4) Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at an approved lab facility</p> <p>5) Medication is used in combination with Tafinlar (dabrafenib);</p>		
<i>Tafinlar</i>	dabrafenib	<p>Indicated, in combination with trametinib, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.</p> <p>For this new indication, criteria requires:</p> <ol style="list-style-type: none"> 1) Diagnosis of low-grade glioma; 2) Patient is 1 year of age or older; 3) Patient requires systemic therapy; 4) Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at an approved lab facility 5) Medication is used in combination with Mekinist (trametinib) 	Update	2/15/2024
<i>Tezspire</i> (self-administered product only)	tezepelumab-ekko	Requirement to try other asthma biologics before Tezspire has been removed.	Update	2/15/2024
<i>Ayvakit</i>	avapritinib	<p>Newly indicated for the treatment of adult patients with indolent systemic mastocytosis (ISM).</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> 1) Diagnosis of indolent systemic mastocytosis (ISM); 2) Platelet count is greater than $50 \times 10^9/L$ 	Update	2/15/2024
<i>Lynparza</i>	olaparib	<p>New indication to be used in combination with abiraterone and prednisone or prednisolone, for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> 1) Diagnosis of metastatic castration-resistant prostate cancer (mCRPC); 2) Presence of a deleterious or suspected deleterious BRCA-mutation as detected by an FDA-approved test or a test performed at an approved lab; 3) Used in combination with abiraterone and one of the following: a) prednisone or b) prednisolone 	Update	2/15/2024
<i>Braftovi</i>	encorafenib	Melanoma criteria will be updated to add an additional trial and failure, contraindication or intolerance to one of the following: Tafinlar or Zelboraf. Continuation of current therapy is allowed.	Update	2/15/2024
<i>Mektovi</i>	binimetinib	Criteria will be updated to add an additional trial and failure, contraindication	Update	2/15/2024

		or intolerance to one of the following: Cotellic or Makinist. Continuation of therapy is allowed.		
<i>Nexlitol/Nexlizet</i>	bempedoic acid; bempedoic acid/ezetimibe	Criteria will be updated for patients who are on maximally tolerated statin therapy who require additional non-statin therapy as follows: Both of the following: 1) Documentation of one of the following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days: a) LDL-C between 55-99 mg/dL and 99 mg/dL with ASCVD b) LDL-C between 100 mg/dL and 129 mg/dL without ASCVD; 2) One of the following: a) Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy OR b) Patient has a history of contraindication, or intolerance to ezetimibe	Update	2/15/2024
<i>Xyosted</i> in Testosterone Products	testosterone enanthate	Xyosted will require a trial of generic testosterone cypionate or generic testosterone enanthate injection	Update	2/15/2024
<i>Liqrev</i> in Pulmonary Arterial Hypertension Agents	sildenafil	Liqrev will mirror existing Revatio [another liquid formulation of sildenafil] oral suspension criteria. In addition, brand Liqrev will require a trial and failure, or intolerance to generic sildenafil oral suspension	Update	2/15/2024
<i>Sogroya Ngenla</i> in Growth Hormones	somapacitan-beco somatrogon-ghla	Both drugs will have the same criteria as Skytrofa for pediatric growth hormone deficiency.	Update	1/1/2024
<i>Kalydeco</i>	ivacaftor	Expanded age indication: For the treatment of cystic fibrosis in patients age 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data. Previously, this indication was approved in patients 4 months and older.	Update	2/15/2024
<i>Iressa</i>	gefitinib	New generic will be added to guideline with existing criteria to apply. Brand Iressa criteria will be updated to require a trial and failure, or intolerance to its generic.	Update	2/15/2024
<i>Cotellic</i>	cobimetinib	A specialist prescriber is no longer required	Update	2/15/2024
<i>Piqray</i>	alpelisib	A specialist prescriber is no longer required	Update	2/15/2024
<i>Qinlock</i>	ripretinib	A specialist prescriber is no longer required	Update	2/15/2024
<i>Rubraca</i>	rucaparib	A specialist prescriber is no longer required	Update	2/15/2024
<i>Temodar</i>	temozolomide	A specialist prescriber is no longer required	Update	2/15/2024
<i>Tibsovo</i>	ivosidenib	A specialist prescriber is no longer required	Update	2/15/2024