

**Summary of Utilization Management (UM) Program Changes**

**April (2<sup>nd</sup> Posting) 2020**

<b>Brand Name</b>	<b>Generic Name</b>	<b>Utilization Update Summary</b>	<b>Type</b>	<b>Effective Date</b>
<b>Adakveo</b>	crizanlizumab	<p>New product indicated to reduce the frequency of vaso-occlusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease (SCD). Initial criteria requires:</p> <ol style="list-style-type: none"> <li>1) Diagnosis of sickle cell disease;</li> <li>2) Patient is 16 years of age or greater;</li> <li>3) Documentation of 2 vaso-occlusive events that required medical facility visits and treatments in the past 12 months (e.g., sickle cell crisis, acute pain episodes, acute chest syndrome, hepatic sequestration, splenic sequestration, priapism);</li> <li>4) Trial and failure, contraindication, or intolerance to one of the following: hydroxyurea or L-glutamine (i.e., Endari); and</li> <li>5) Prescribed by or in consultation with one of the following: hematologist/oncologist or a specialist with expertise in the diagnosis and management of sickle cell disease.</li> </ol>	New	6/15/2020
<b>Oxbryta</b>	voxelotor	<p>New product indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 12 years of age and older.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> <li>1) Diagnosis of sickle cell disease;</li> <li>2) Patient is 12 years of age or greater;</li> <li>3) Documentation of 1 vaso-occlusive crisis (VOC) event within the past 12 months (e.g., sickle cell crisis, acute painful crisis, acute chest syndrome);</li> <li>4) Documentation of hemoglobin level that does not exceed 10.5 g/dL prior to therapy initiation;</li> <li>5) Trial and failure, contraindication, or intolerance to hydroxyurea; and</li> <li>6) Prescribed by or in consultation with one of the following: hematologist/oncologist or a specialist with expertise in the diagnosis and management of sickle cell disease.</li> </ol>	New	6/15/2020
<b>Givlaari</b>	givosiran	<p>New product indicated for the treatment of adults with acute hepatic porphyria (AHP).</p>	New	6/15/2020

		<p>Initial criteria requires:</p> <ol style="list-style-type: none"> <li>1) Diagnosis of acute hepatic porphyria (i.e., acute intermittent porphyria, hereditary coproporphyria, variegate porphyria, ALA dehydrase deficient porphyria);</li> <li>2) Patient has active disease with at least two documented porphyria attacks within the past 6 months;</li> <li>3) Provider attestation documenting elevated urinary or plasma levels of one of the following within the past 12 months: a) Porphobilinogen (PBG), or b) Delta-aminolevulinic acid (ALA);</li> <li>4) Patient has not had/will not be anticipating liver transplantation; and</li> <li>5) Prescribed by or in consultation with a gastroenterologist or a specialist with expertise in the diagnosis and management of acute hepatic porphyria.</li> </ol>		
<b>Reblozyl</b>	luspatercept	<p>New product indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> <li>1) One of the following: a) Both of the following: Diagnosis of beta thalassemia major AND patient requires regular red blood cell (RBC) transfusions, OR b) Diagnosis of transfusion-dependent beta thalassemia; and</li> <li>2) Prescribed by or in consultation with a hematologist.</li> </ol>	New	6/15/2020
<b>Vumerity</b> (part of Multiple Sclerosis criteria)	diroximel fumarate	<p>Diagnosis of a relapsing form of multiple sclerosis (MS) and a trial of at least 4 weeks or contraindication to at least two of the following disease-modifying therapies for MS: Aubagio, Avonex, Copaxone/Glatopa, Extavia, Gilenya, Plegridy, and Tecfidera.</p>	New	6/15/2020
<b>Egrifta SV</b>	tesamorelin	<p>New 2 mg single-dose vial formulation of Egrifta indicated for reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.</p> <p>This new formulation will have the same criteria as the original Egrifta 1 mg vial. QL will apply of 1 vial per day.</p>	Update	6/15/2020
<b>defasirox</b>	defasirox	<p>New generic of Jadenu 90 and 360 mg tablets. Approved for the treatment of chronic iron overload due to blood</p>	Update	6/15/2020

		<p>transfusions (transfusional hemosiderosis) and for the treatment of chronic iron overload in non-transfusion-dependent thalassemia syndromes. (Brand Jadenu also available as 180 mg tablets, and 90 mg, 180 mg and 360 mg sprinkle granules).</p> <p>These new generics will be added to the deferasirox prior authorization guideline with criteria to mirror the other generic deferasirox products (generics of Exjade). For branded Exjade and Jadenu, a trial of a generic deferasirox product is still required.</p>		
<b>Zejula</b>	Niraparib	<p>Indicated for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either: (1) a deleterious or suspected deleterious BRCA mutation, or (2) genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy.</p> <p>Initial criteria requires:  1) Diagnosis of one of the following: advanced ovarian cancer, advanced fallopian tube cancer, or advanced peritoneal cancer;  2) Patient has been treated with 3 (three) or more prior chemotherapy regimens;  3) Patient's cancer is associated with homologous recombination deficiency (HRD) positive status defined by ONE of the following: a) A deleterious or suspected deleterious BRCA mutation, or b) Both of the following: Genomic instability and cancer has progressed more than 6 months after response to the last platinum-based chemotherapy (e.g., cisplatin, carboplatin); and  4) Prescribed by or in consultation with an oncologist.</p>	Update	6/15/2020
<b>Corlanor</b>	ivabradine	<p>Prior authorization criteria will be added for a common, but non-FDA approved use: inappropriate sinus tachycardia (IST).</p> <p>Criteria for approval for IST requires:</p>	Update	6/15/2020

		<p>1) Diagnosis of IST confirmed by both of the following: a) Sinus heart rate greater than 100 beats per minute at rest, and b) An average 24 hour heart rate greater than 90 beats per minute;</p> <p>2) Documentation that other causes of sinus tachycardia have been ruled out (e.g., hyperthyroidism, anemia, illicit stimulant drug use, caffeine, etc.);</p> <p>3) Documentation that symptoms of IST are causing significant functional impairment or distress (e.g., palpitations, light-headedness, fainting, chest pain, difficulty breathing, etc.); and</p> <p>4) Prescribed by or in consultation with a cardiologist.</p>		
<b>Sunosi</b>	solriamfetol	<p>Update for the narcolepsy indication:</p> <p>1) Trial and failure, contraindication, or intolerance to One of the following: modafinil or armodafinil, AND One of the following: a) Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant, OR b) History of or potential for a substance use disorder.</p> <p>2) Update initial authorization duration to 6 months (previously 12 months).</p>	Update	6/15/2020
<b>Xyrem</b>	sodium oxybate	<p>Update for the narcolepsy indications:</p> <p>1) For the narcolepsy without cataplexy indication:</p> <p>Trial and failure, contraindication, or intolerance to both of the following: a) modafinil or armodafinil AND b) Sunosi, AND One of the following: a) Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant, OR b) History of or potential for a substance use disorder.</p> <p>2) Update initial authorization duration to 6 months for both narcolepsy indications, with and without cataplexy (previously 12 months).</p>	Update	6/15/2020
<b>Wakix</b>	pitolisant	<p>Criteria will read:</p> <p>Trial and failure, contraindication or intolerance to both of the following: a) generic modafinil or generic armodafinil, AND b) Sunosi; and</p> <p>One of the following: a) Trial and failure, contraindication, or intolerance to a generic amphetamine (e.g., amphetamine,</p>	Update	6/15/2020

		dextroamphetamine) or methylphenidate based stimulant, OR b) history of or potential for a substance use (previously stated "abuse") disorder.		
<b>Focalin SR</b> and generics	dexmethylphenidate	Modify the QL to 1 capsule per day (previously 2 capsules per day). Patients can use one 40 mg capsule instead of two 20 mg capsules as product is dosed once daily.	Update	6/15/2020