

Summary of Utilization Management (UM) Program Changes

March 2023

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
<i>Imjudo</i>	tremellimumab-actl	<p>In combination with durvalumab is indicated for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC).</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> 1) Diagnosis of unresectable hepatocellular carcinoma (uHCC); 2) Used in combination with Imfinzi (durvalumab); 3) Prescribed by or in consultation with one of the following: a) hepatologist or b) oncologist 	New	5/15/2023
<i>Relyvrio</i>	sodium phenylbutyrate / taurursodiol	<p>For the treatment of amyotrophic lateral sclerosis (ALS) in adults.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> 1) Diagnosis of amyotrophic lateral sclerosis (ALS); 2) Diagnosis of ALS is further supported by neurogenic changes in electromyography (EMG); 3) Patient has had ALS symptoms for less than or equal to 18 months; 4) Patient has a percent (%) forced vital capacity (%FVC) or slow vital capacity (%SVC) greater than or equal to 60% at the start of treatment; 5) Patient does not require permanent noninvasive ventilation or invasive ventilation; 6) Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS 	New	5/15/2023
<i>Furoscix</i>	furosemide	<p>For the treatment of congestion due to fluid overload in adult patients with New York Heart Association (NYHA) Class II and Class III chronic heart failure.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> 1) Diagnosis of chronic heart failure; 2) Patient has New York Heart Association (NYHA) Class II or III; 3) Patient is currently on maintenance oral diuretic therapy (e.g., bumetanide, furosemide, torsemide); 4) Provider attests that patient will be closely monitored for fluid, electrolyte, and metabolic abnormalities throughout therapy (e.g., hypokalemia, hypovolemia, hyponatremia) 	New	5/15/2023

<i>Pedmark</i>	sodium thiosulfate	<p>Indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> 1) Diagnosis of solid tumors; 2) Disease is both of the following: a) Localized, b) Non-Metastatic; 3) Used for the prevention of ototoxicity due to cisplatin-based chemotherapy; 4) Patient is 1 month of age or older; 5) Prescribed by or in consultation with an oncologist 	New	5/15/2023
<i>Lytgobi</i>	futibatinib	<p>For the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> 1) Diagnosis of intrahepatic cholangiocarcinoma; 2) Disease is one of the following: a) Unresectable, b) Locally advanced, or c) Metastatic; 3) Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangements; 4) Patient has been previously treated (e.g., chemotherapy); 5) Prescribed by or in consultation with one of the following: a) Hepatologist, b) Gastroenterologist, or c) Oncologist 	New	5/15/2023
<i>Cotellic</i>	cobimetinib	<p>As a single agent, is indicated for the treatment of adult patients with histiocytic neoplasms.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> 1) Diagnosis of histiocytic neoplasm; 2) Used as monotherapy; 3) Prescribed by or in consultation with a hematologist/oncologist 	Update	5/15/2023
<i>Retevmo</i>	selpercatinib	<p>For the treatment of adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> 1) Diagnosis of solid tumors; 2) Disease is one of the following: a) Locally Advanced or b) Metastatic; 3) Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s); 	Update	5/15/2023

		<p>4) One of the following: a) Disease has progressed on or following prior systemic treatment (e.g., chemotherapy) OR b) There are no satisfactory alternative treatment options 5) Prescribed by or in consultation with an oncologist</p> <p>Program update for Non-Small Cell Lung Cancer, Medullary Thyroid Cancer, and Thyroid Cancer. Criteria will be updated as follows:</p> <p>Criteria for <i>Non-Small Cell Lung Cancer</i> will be updated to include "locally advanced" as an additional option to confirm disease severity. Clarification that the presence of RET gene fusion-positive tumor(s) may be detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) will also be added.</p> <p>Criteria for <i>Medullary Thyroid Cancer</i> and <i>Thyroid Cancer</i> will be updated to include age criterion that confirms patient is 12 years of age or older and clarification that the presence of RET gene fusion-positive tumor(s) may be detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).</p>		
<i>Rinvoq</i>	upadacitinib	<p>For the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.</p> <p>Initial criteria requires: 1) Diagnosis of active non-radiographic axial spondyloarthritis; 2) Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints); 3) Prescribed by or in consultation with a rheumatologist; 4) Minimum duration of one month trial and failure, contraindication, or intolerance to two NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses;</p>	Update	5/15/2023

		<p>5) Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia);</p> <p>6) Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)</p>		
<i>Makena</i> in Hydroxyprogesterone Caproate Products	hydroxyprogesterone caproate	Due to efficacy concerns expressed by the FDA Advisory Committee, Makena and generic hydroxyprogesterone 250 mg/mL injection (generic Makena) criteria will be revised to include the following requirement "Provider attests and is aware of the FDA's advisory committee recommendation to withdraw medication due to lack of efficacy shown in post-market data."	Update	5/15/2023
<i>Stelara</i>	ustekinumab	<p>For the Stelara subcutaneous (SC) formulation only, initial criteria for Crohn's disease and Ulcerative Colitis will be revised as follows to reduce redundancy as the same requirements have already been asked in the Stelara IV initial criteria.</p> <p>Crohn's disease initial criteria will be revised as follows:</p> <ol style="list-style-type: none"> 1) Diagnosis of moderately to severely active Crohn's disease; 2) Will be used as a maintenance dose following the intravenous induction dose 3) Prescribed by or in consultation with a gastroenterologist <p>Ulcerative Colitis initial criteria will be revised as follows:</p> <ol style="list-style-type: none"> 1) Diagnosis of moderately to severely active ulcerative colitis; 2) Will be used as a maintenance dose following the intravenous induction dose 3) Prescribed by or in consultation with a gastroenterologist 	Update	5/15/2023
<i>Apretude</i> in Cabotegravir Containing Agents	cabotegravir	<p>Initial criteria HIV-1 Pre-Exposure Prophylaxis will be revised as follows:</p> <p>Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:</p> <ol style="list-style-type: none"> a) Trial of, contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg OR b) Both of the following: <ol style="list-style-type: none"> i) Patient would benefit from long-acting injectable therapy over standard oral regimens ii) Patient would be adherent to testing and dosing schedule 	Update	5/15/2023