

## Summary of Utilization Management (UM) Program Changes

**July 2023**

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
<i>Filspari</i>	sparsentan	<p>Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) <math>\geq 1.5</math> g/g.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> <li>1) Diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy</li> <li>2) Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]</li> <li>3) Used to reduce proteinuria;</li> <li>4) Patient has an estimated glomerular filtration rate (eGFR) of greater than or equal to 30 mL/min/1.73 m<sup>2</sup>;</li> <li>5) Patient has been on a minimum 90-day trial of a maximally tolerated doses of one of the following: <ol style="list-style-type: none"> <li>a) An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)</li> <li>b) An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan);</li> </ol> </li> <li>6) Medication will not be used in combination with any of the following: <ol style="list-style-type: none"> <li>a) Angiotensin receptor blockers</li> <li>b) Endothelin receptor antagonists (ERAs) (e.g., ambrisentan, bosentan, Opsumit)</li> <li>c) Aliskiren;</li> </ol> </li> <li>7) Prescribed by or in consultation with a nephrologist</li> </ol>	New	10/1/2023
<i>Jaypirca</i>	pirtobrutinib	<p>For the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton Tyrosine Kinase (BTK) inhibitor.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> <li>1) Diagnosis of mantle cell lymphoma (MCL);</li> <li>2) Disease is one of the following: Relapsed or Refractory;</li> <li>3) Patient has received at least two prior therapies for MCL, one of which is a Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Imbruvica (ibrutinib), Calquence (acalabrutinib), Brukinsa (zanubrutinib)];</li> </ol>	New	10/1/2023

		<p>[Imbruvica (ibrutinib) listed as a drug example for Med D only]</p> <p>4) Prescribed by or in consultation with an oncologist.</p>		
<i>Orserdu</i>	elacestrant	<p>For the treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> <li>1) Diagnosis of breast cancer;</li> <li>2) Disease is one of the following: Advanced or Metastatic;</li> <li>3) Disease is estrogen receptor (ER)-positive;</li> <li>4) Disease is human epidermal growth factor receptor 2 (HER2)-negative;</li> <li>5) Presence of estrogen receptor (ESR1) mutation(s) as detected by an FDA-approved test;</li> <li>6) Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)];</li> <li>7) Prescribed by or in consultation with an oncologist</li> </ol>	New	10/1/2023
<i>Kevzara</i>	sarilumab	<p>Treatment of adult patients with polymyalgia rheumatica who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.</p> <p>Initial criteria requires:</p> <ol style="list-style-type: none"> <li>1) Diagnosis of polymyalgia rheumatica (PMR);</li> <li>2) One of the following: <ol style="list-style-type: none"> <li>a) Patient has had an inadequate response to corticosteroids (e.g., prednisone) OR</li> <li>b) Patient cannot tolerate tapering of corticosteroids (e.g., prednisone);</li> </ol> </li> <li>3) Prescribed by or in consultation with a rheumatologist</li> </ol>	Update	10/1/2023
<i>Rebyota</i>	fecal microbiota, live-jslm	<p>Criteria requires:</p> <ol style="list-style-type: none"> <li>1) Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following: <ol style="list-style-type: none"> <li>a) Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days</li> <li>b) A positive stool test for C.difficile toxin or toxigenic C.difficile</li> </ol> </li> <li>2) Patient is 18 years of age or older</li> <li>3) Patient has a history of one or more recurrent episodes of CDI</li> </ol>	Update	10/1/2023

		<p>4) Both of the following:</p> <p>a) Patient has completed at least 10 consecutive days of one of the following antibiotic therapies between 24 to 72 hours prior to initiating Rebyota: oral vancomycin or Dificid (fidaxomicin)</p> <p>b) 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)</p> <p>5) Prescribed by or in consultation with a gastroenterologist or infectious disease specialist</p>		
<i>Livmarli</i>	maralixibat	<p>Expanded indication: Treatment of cholestatic pruritus in patients with Alagille syndrome 3 months of age and older. Previously this was approved for patients age 1 year or age and older.</p> <p>Existing age criteria will be updated to require "Patient is 3 months of age or older."</p>	Update	10/1/2023
<i>Benlysta</i>	belimumab	<p>Guideline for subcutaneously administered product that can be self-administered.</p> <p>Initial criteria for Systemic Lupus Erythematosis (SLE) requires:</p> <ol style="list-style-type: none"> <li>1) Diagnosis of active lupus nephritis</li> <li>2) Autoantibody positive;</li> <li>3) Age 18 years or older</li> <li>4) Trial and failure, contraindication, or intolerance to two standard of care treatments for active SLE: hydroxychloroquine, corticosteroids, or immunosuppressants [such as methotrexate or azathioprine]</li> <li>5) Currently receiving at least one standard of care treatment for active SLE: hydroxychloroquine, corticosteroids, or immunosuppressants [such as methotrexate or azathioprine]</li> <li>6) Prescribed by or in consultation with a rheumatologist</li> </ol> <p>Initial criteria for Lupus nephritis requires:</p> <ol style="list-style-type: none"> <li>1) Diagnosis of active lupus nephritis</li> <li>2) Age 18 years or older</li> <li>3) Currently receiving standard of care treatment for active lupus nephritis (such as corticosteroids with mycophenolate or cyclophosphamide)</li> <li>4) Prescribed by or in consultation with a rheumatologist or nephrologist</li> </ol>	New	10/1/2023
<i>Furoscix</i>	furosemide	Medical records and/or paid receipts will need to be submitted to confirm patient is on maintenance oral diuretic therapy.	Update	10/1/2023
<i>Ferriprox</i>	deferiprone	Updated guideline with approved age. Oral solution is approved for ages 3 and older.	Update	10/1/2023

<i>Takhzyro</i>	lanadelumab-flyo	Updated guideline with approved age. Takhzyro is approved for ages 2 and older.	Update	10/1/2023
<i>Tegsedi</i>	inotersen	Updated Neuropathy Impairment Score (NIS) score in to require between 10 and 130 for Tegsedi to align with the clinical trials. Removed "Patient has not had a liver transplant" in criteria.	Update	10/1/2023