Summary of Utilization Management (UM) Program Changes

September 2021

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Margenza	margetuximab-cmkb	Indicated in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. Initial criteria requires: 1) Diagnosis of breast cancer; 2) Disease is human epidermal growth factor receptor 2 (HER2)-positive; 3) Disease is metastatic; 4) Used in combination with chemotherapy (e.g. capecitabine, eribulin, gemcitabine, vinorelbine); 5) Patient has received two or more prior anti-HER2 regimens (e.g., pertuzumab + trastuzumab + docetaxel, ado-trastuzumab emtansine, etc.), at least one of which was for metastatic disease; and 6) Prescribed by an oncologist.	New	11/1/2021
Pepaxto	melphalan flufenamide	Indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. Initial criteria requires: 1) Diagnosis multiple myeloma (MM); 2) Disease is relapsed or refractory; 3) Patient has received at least four prior lines of therapy; 4) Disease is refractory to all of the following: a) A proteasome inhibitor (e.g., bortezomib, carfilzomib), b) An immunomodulatory agent (e.g., lenalidomide, thalidomide), and c) A CD38-directed monoclonal antibody (e.g. daratumumab); 5) Used in combination with dexamethasone; and 6) Prescribed by an oncologist/hematologist.	New	11/1/2021
Nulibry	fosdenopterin	Indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A. Initial criteria requires: 1) Submission of documentation (e.g., chart notes) confirming both of the following: a) Diagnosis of molybdenum cofactor deficiency (MoCD) Type A, and b) Genetic mutation in the MOCS1 gene; 2) Patient has clinical and/or laboratory signs and symptoms consistent with MOCD Type A (e.g., seizures, limb/axial hypertonia, elevated levels of urinary sulfite/SSC [s-sulfocysteine] or xanthine in blood/urine, low uric acid in blood/urine); and	New	11/1/2021

		3) Prescribed by a physician who specializes in the treatment of inherited metabolic disorders.		
Actemra	tocilizumab	Actemra subcutaneous injection has been approved for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD). Actemra is also approved for rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, and cytokine release syndrome. Initial criteria for SSc-ILD requires: 1) Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following: a) Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity), AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (e.g., fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD, OR ii) In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD; and 2) Prescribed by a pulmonologist or rheumatologist. For the Systemic Juvenile Idiopathic Arthritis indication, methotrexate has been added as another initial option for required drug trial before Actemra.	Update	11/1/2021
Arcalyst	rilonacept	Treatment of recurrent pericarditis and reduction in risk of recurrence in adults and pediatric patients 12 years and older. Arcalyst is also indicated for Cryopyrin-Associated Periodic Syndromes (CAPS) and Deficiency of IL-1 Receptor Antagonist (DIRA). Initial criteria for pericarditis requires: 1) Diagnosis of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart; 2) Prescribed by a cardiologist; and 3) Trial and failure of at least one of the following: a) nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen), b) colchicine, or c) corticosteroids (e.g., prednisone).	Update	11/1/2021
Tecfidera	dimethyl fumarate	Brand Tecfidera is now nonformulary. Brand Tecfidera will require trial of BOTH of the following: 1) generic dimethyl fumarate, and 2) either Bafiertam or Vumerity. Tecfidera has been moved from the Multiple Sclerosis Guideline to its own guideline.	New	11/1/2021
Cystaran, Cystadrops	cysteamine eye drops	Requirement for use in conjunction with oral cysteamine has been removed.	Update	11/1/2021

Remicade Renflexis in Infliximab Products	infliximab	For approval of Remicade and Renflexis [both are infliximab], a trial and failure of ONE (instead of two) of the following: Avsola, Renflexis [also infliximab products] is required.	Update	11/1/2021
Truvada and Viread in Healthcare Reform Copay Waiver Review	emtricitabine-tenofovir disoproxil fumarate; tenofovir disoproxil fumarate	For the pre-exposure prophylaxis criteria section to clarify that there are no additional requirements beyond diagnosis that need to be met for the generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg and tenofovir disoproxil fumarate 300mg products. Original intent has not changed. Wording is below. 1) Member is taking as effective antiretroviral therapy for preexposure prophylaxis (PrEP); and 2) One of the following a) Request is for generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg or generic tenofovir disoproxil fumarate 300mg; or b) History of contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg (Applies to Brand Truvada 200-300 mg and Descovy only); or c) History of contraindication or intolerance to generic tenofovir disoproxil fumarate 300mg (Applies to Brand Viread 300mg only).	Update	11/1/2021
Actemra	adalimumab	Indication expanded for use in pediatric patient ages 5 and up for the treatment of moderately to severely active ulcerative colitis. Based on FDA label changes, the indications for Crohn's disease (CD) and Ulcerative colitis (UC) have been simplified. Crohn's Disease: Indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older. Ulcerative Colitis: Indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older. Limitations of use: The effectiveness of Humira has not been established in patients who have lost response to or were intolerant to TNF blockers. Since the CD indication no longer mentions a previous trial of infliximab, criteria for CD will be no longer require a trial of infliximab.	Update	11/1/2021
Mitoxantrone	mitroxantrone	For the Multiple Sclerosis indication: A trial and failure of two drugs will be required, instead of two and prescribed by a neurologist.	Update	11/1/2021
Nexavar	sorafenib	Criteria for renal cell carcinoma no longer requires patient to have a relapse after surgical removal of the tumor or be Stage IV disease.	Update	11/1/2021
Tysabri	natalizumab	Multiple Sclerosis: Updated diagnosis criteria to align with package insert. Must be prescribed by a neurologist.	Update	11/1/2021

		Crohn's Disease: Updated diagnosis to align with package insert.		