Summary of Utilization Management (UM) Program Changes

May #2 2022

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Adbry	tralokinumab-ldrm	Treatment of moderate-to-severe atopic dermatitis in adults 18 years or older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Initial criteria requires: 1) Diagnosis of moderate to severe atopic dermatitis; 2) One of the following: a) > 10% body surface area (BSA) involvement, or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25; 3) Patient is 18 years of age or older; 4) Prescribed by a dermatologist or allergist/immunologist; 5) Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least TWO of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, d) Eucrisa (crisaborole) ointment 6) Trial and failure of Dupixent (dupilumab)	New	8/1/2022
Acthar (in Repository Corticotropin Gel Products)	purified corticotropin	Criteria for MS exacerbations will be updated as noted below in red. One of the following: a) Patient is new to therapy with corticotropin b) Trial and failure, contraindication, or intolerance to treatment with two high dose corticosteroid treatments (e.g., prednisone, IV methylprednisolone) OR a) Patient's multiple sclerosis exacerbations have been treated in the past with corticotropin b) Patient has benefitted from treatment with corticotropin for acute exacerbations of multiple sclerosis c) Medication is being used to treat a new exacerbation of multiple sclerosis	Update	8/1/2022
Vyvgart	efgartigimod alfa-fcab	Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. Initial criteria requires: 1) Diagnosis of generalized myasthenia gravis (gMG); 2) Patient is anti-acetylcholine receptor (AChR) antibody positive; 3) Prior to administration, patient must be on a stable dose of at least ONE of the following therapies for the treatment of gMG: acetylcholinesterase (AChE) inhibitors (e.g., pyridostigmine), steroids, or non-steroidal immunosuppressive therapies (NSISTs) [e.g., azathioprine, cyclosporine, cyclophosphamide); 4) One of the following: a) Prescribed medication will be administered at 10mg/kg as an intravenous infusion over one hour once weekly for 4 weeks, or	New	8/1/2022

		b) In patients weighing 120 kg or more, prescribed medication will be administered at 1200mg per infusion over one hour once weekly for 4 weeks; and 5) Prescribed by a neurologist.		
Infliximab (in Infliximab Products)	infliximab	New unbranded Infliximab product that is interchangeable with Remicade. This new Infliximab product will be added to the existing PA guidelines to mirror Remicade. For Commercial, Infliximab will be non-preferred and require trial of Avsola or Inflectra.	Update	8/1/2022
Kisqali (in Kisqali, Kisqali Femara Copack)	ribociclib	Treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with: an aromatase inhibitor as initial endocrine-based therapy; or fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men (previously approved in women for this indication). Criteria will be updated to include men in addition to pre/perimenopausal women.	Update	8/1/2022
Kisqali Femara Copack (in Kisqali, Kisqali Femara Copack)	Ribociclib, letrozole	Initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer (previously approved in women for this indication). Criteria will be updated to add "Pre/perimenopausal women and men should be concurrently treated with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide)" to align with the dosing recommendations.	Update	8/1/2022
Rituxan (in Rituximab Products)	rituximab	Expanded indication for Non-Hodgkin's lymphoma to include the treatment of pediatric patients aged 6 months and older with previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy. National cancer guidelines indicate that a biosimilar may be a substitute for rituximab, so this allows use of all rituximab products for these new indications. Existing NHL sections will be updated to include the following criteria to allow a pathway to approval for these new indications: a) Diagnosis of one of the following previously untreated, advanced stage indications: CD-20-positive DLBCL, BL, BLL, or B-AL; b) Patient is 6 months of age or older; c) Use in combination with chemotherapy.	Update	8/1/2022
Truxima (in Rituximab Products)	rituximab-abbs	The section for Truxima that applies for Rheumatoid Arthritis will be updated. If being requested for continuation of therapy to bypass trial of preferred agents, confirmation that the patient is having a	Update	8/1/2022

		positive clinical response while on therapy will be required.		
Orencia	abatacept	Prophylaxis of acute graft versus host disease, in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation from a matched or 1 allele-mismatched unrelated-donor. Initial criteria requires: 1) Used for prophylaxis of acute graft versus host disease (aGVHD); 2) Patient is 2 years of age and older; 3) Patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor; 4) Recommended antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation (e.g., acyclovir) will be administered prior to Orencia and continued for six months after HSCT; and 5) Used in combination with both of the following: calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate.	Update	8/1/2022
Zepatier	elbasvir-grazoprevir	Treatment of chronic hepatitis C virus (HCV) genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg. Criteria will be updated to require that patients are: 12 years of age or older or have a weight of at least 30 kg in order to align with the updated indication.	Update	8/1/2022
Asceniv *Cutaquig* *Panzyga* (in Immune Globulins)	Immune globulins	Criteria will be updated to remove the continuation of therapy allowance for the non-preferred immune globulins (Asceniv, Cutaquig, Panzyga). All patients (new and existing) will be required to try the preferred alternatives, unless there is a reason these would be inappropriate.	Update	8/1/2022
Azole Antifungals	multiple	Updates include added age criteria to target drugs where applicable (i.e., Noxafil tablet/suspension, Vfend tablet/suspension, Cresemba capsules). For Sporanox (itraconazole) fingernail and toenail onychomycosis criteria, added a minimum trial duration for oral terbinafine (6-week for fingernail; 12-week for toenail). Removed Noxafil (posaconazole) tablet from oropharyngeal candidiasis criteria and removed Noxafil oral suspension from therapy of systemic fungal infections criteria to align with FDA indications for specific formulations.	Update	8/1/2022
Gaucher Disease Agents	multiple	Added age criterion: 4 years of age or older for Elelyso and VPRIV, 2 years of age or older for Cerezyme, 18 years of age or older for Zavesca/miglustat to align with FDA labels.	Update	8/1/2022
Promacta	eltrombopag	Added 'Persistent ITP' to diagnosis criteria.	Update	8/1/2022

Soliris	eculizumab	Added specialist requirements to initial criteria of paroxysmal nocturnal hemoglobinuria (hematologist or oncologist) and atypical hemolytic uremic syndrome (hematologist or nephrologist).	Update	8/1/2022
Sprycel	dasatinib	Pediatric age definition is now 1 year of age and older.	Update	8/1/2022
Topical Antifungals	multiple	For all onychomycosis criteria for brand/generic Kerydin, Jublia, added a minimum trial duration for oral terbinafine (6 weeks for fingernail; 12 weeks for toenail). For Jublia criteria, added a minimum 48-week trial duration for brand Kerydin.	Update	8/1/2022
Applicable to FEHB members only: *Xenical* *Wegovy* *Saxenda* (in Anorexiants)	orlistat liraglutide semaglutide	Criteria for additional drugs will be added to the Anorexiant guideline: 1) Treatment for appetite suppression or weight loss 2) Ages 18 and up for Xenical and Wegovy; ages 12 and up for Saxenda 3) Submission of medical or other records documenting lifestyle intervention methods within the last 12 months AND continuing lifestyle changes for 6 months prior to medication 4) BMI is 30 kg/m^2 or higher OR BMI is 27 kg/m^2 if patient has a weight-related medical condition (such as high blood pressure, high cholesterol, diabetes, sleep apnea) For Saxenda in patients 12 up to 18 years of age: weight is at least 60 kg and BMI is elevated (based on chart in product information) equivalent to an adult BMI of 30 kg/m^2 or higher	Update	6/15/2022