



EXPRESS SCRIPTS®

**Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
November 18, 2017 Meeting**

New Drug Evaluations

The Committee reviewed the following new drugs.

- A. Aliqopa™ (copanlisib injection for IV use) Bayer
- B. Benznidazole tablets – Exelti
- C. Calquence® (acalabrutinib capsules) AstraZeneca
- D. Fiasp® (insulin aspart injection for subcutaneous or intravenous use) NovoNordisk
- E. Kymriah™ (tisagenlecleucel suspension for IV infusion) Novartis Oncology
- F. Mylotarg™ (gemtuzumab ozogamicin for injection for IV use) Wyeth Pharmaceutical/Pfizer
- G. Rebinyn® (coagulation Factor IX [recombinant] glycoPEGylated intravenous injection) NovoNordisk
- H. Shingrix™ (zoster vaccine recombinant, adjuvanted suspension for intramuscular [IM] injection) GlaxoSmithKline
- I. Solosec® (secnidazole oral granules) Symbiomix Therapeutics LLC
- J. Varubi® IV (rolapitant injection emulsion) Tesaro
- K. Verzenio™ (abemaciclib tablets) Eli Lilly and Company
- L. Xhance™ (fluticasone propionate nasal spray) OptiNose
- M. Yescarta™ (axicabtagene ciloleucel suspension for IV infusion) Kite Pharma/Gilead

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

- A. Adzenys ER™ (amphetamine extended-release oral suspension) Neos Therapeutics
- B. Bydureon® BCise™ (exenatide extended-release injectable suspension for SC use) AstraZeneca
- C. Durolane® (hyaluronic acid intraarticular injection) Bioventus
- D. Lyrica® CR (pregabalin extended-release tablets) Pfizer
- E. Prolastin®-C Liquid (alpha1-proteinase inhibitor [human] injection) Grifols
- F. Tracleer® (bosentan tablets for oral suspension) Actelion
- G. Trelegy Ellipta® (fluticasone furoate, umecclidinium, and vilanterol inhalation powder) GlaxoSmithKline/Innoviva
- H. Zilretta™ (triamcinolone acetonide extended-release injectable suspension, for intra-articular use) Flexion Therapeutics

New Biosimilar

The Committee reviewed the following new biosimilar.

- A. Cyltezo™ (adalimumab-adbm subcutaneous injection) Boehringer Ingelheim



Public Information

New Indications for Existing Products

The Committee reviewed the following new indications for existing products: See product inserts for specific wording.

- A. **Afluria® Quadrivalent (influenza vaccine for intramuscular injection)** Seqirus USA Inc. – Expanded age indication for active immunization against influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine in persons ≥ 5 years of age.
- B. **Alecensa® (alectinib capsules)** Genentech – Expanded indication to include first-line therapy for the treatment of patients with anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer as detected by an Food and Drug Administration (FDA)-approved test.
- C. **Aptiom® (eslicarbazepine acetate tablets)** Sunovion – Expanded age indication for the treatment of partial-onset seizures in patients ≥ 4 years of age.
- D. **Austedo® (deutetrabenazine tablets)** Teva – New indication for the treatment of tardive dyskinesia in adults.
- E. **Actemra® (tocilizumab intravenous injection)** Genentech – New indication for Actemra intravenous injection for the treatment of chimeric antigen receptor T-cell therapy cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients ≥ 2 years of age.
- F. **Briviact® (brivaracetam tablets, oral solution, and injection)** UCB – New indication for use as monotherapy for partial-onset (focal) seizures in patients ≥ 16 years of age with epilepsy.
- G. **Descovy® (emtricitabine and tenofovir alafenamide tablets)** Gilead – Expanded patient population to include pediatric patients weighing ≥ 25 kg. Descovy is now indicated, in combination with other antiretroviral agents, for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and pediatric patients weighing ≥ 35 kg, and also in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor, for the treatment of HIV-1 infection in pediatric patients weighing ≥ 25 kg and < 35 kg.
- H. **Genvoya® (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide tablets)** Gilead – Expanded age indication to include patients 6 years to 12 years of age who weigh ≥ 25 kg. Genvoya is now indicated as a complete regimen for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and pediatric patients weighing ≥ 25 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen for ≥ 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Genvoya.
- I. **Keytruda® (pembrolizumab injection)** Merck – New indication for the treatment of recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express programmed death-ligand 1 as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, human epidermal growth factor receptor 2 (HER2)/neu-targeted therapy.
- J. **Lomotil® (diphenoxylate hydrochloride and atropine sulfate tablets)** GD Searle – Change to patient population to pediatric patients ≥ 13 years of age. Lomotil is now indicated as adjunctive therapy in the management of diarrhea in patients ≥ 13 years of age.
- K. **Lynparza® (olaparib capsules)** AstraZeneca/Merck – Rewording of the indication to synch up the indications for the capsules and the tablets. Lynparza capsules are now indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-

mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy..

- L. **Opdivo® (nivolumab injection)** Bristol-Myers Squibb – New indication for the treatment of patients with hepatocellular carcinoma who have been previously treated with Nexavar® (sorafenib tablets).
- M. **Privigen® [Immune Globulin intravenous (Human), 10% Liquid]** CSL Behring – New indication for the treatment of adults with chronic inflammatory demyelinating polyneuropathy to improve neuromuscular disability and impairment.
- N. **Qvar® (beclomethasone dipropionate inhalation aerosol)** Teva – Removed indication for patients requiring oral corticosteroid therapy for asthma, and also the statement that many of these patients may be able to reduce or eliminate their requirement for oral corticosteroids over time.
- O. **Oxytrol® (oxybutynin transdermal system)** Allergan – Change to patient population to limit use to men. Prescription Oxytrol is now indicated for the treatment of overactive bladder in men with symptoms of urge urinary incontinence, urgency, and frequency.
- P. **Simponi Aria® (golimumab intravenous injection)** Janssen Biotech – New indication for the treatment of adult patients with active psoriatic arthritis with or without methotrexate or other non-biologic disease-modifying antirheumatic drugs.
- Q. **Simponi Aria® (golimumab intravenous injection)** Janssen Biotech – New indication for the treatment of adult patients with active ankylosing spondylitis with or without methotrexate or other non-biologic disease-modifying antirheumatic drugs.
- R. **Soliris® (eculizumab injection)** Alexion – New indication for the treatment of adult patients with generalized myasthenia gravis who are anti-acetylcholine receptor antibody positive.
- S. **Somatuline® Depot (lanreotide injection)** Ipsen – New indication for the treatment of carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analogue rescue therapy.
- T. **Stelara® (ustekinumab subcutaneous injection)** Janssen Biotech – Expanded age indication for the treatment of patients ≥ 12 years of age with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- U. **Symbicort® (budesonide and formoterol fumarate dihydrate inhalation aerosol)** AstraZeneca – New indication for Symbicort 160 mcg/4.5 mcg to reduce exacerbations of chronic obstructive pulmonary disease.
- V. **Tracleer® (bosentan tablets)** Actelion – New pediatric indication for the treatment of pulmonary arterial hypertension (PAH) [World Health Organization {WHO} Group 1] in pediatric patients ≥ 3 years of age with idiopathic or congenital PAH to improve pulmonary vascular resistance, which is expected to result in an improvement in exercise ability.
- W. **Vimpat® (lacosamide tablets and oral solution)** UCB – Expanded age indication for the treatment of partial-onset seizures in patients ≥ 4 years of age.
- X. **Zelboraf® (vemurafenib tablet)** Genentech – New indication for the treatment of patients with Erdheim-Chester Disease with BRAF V600 mutation.

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