



EXPRESS SCRIPTS®

**Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
July 13, 2019**

New Drug Evaluations

The Committee reviewed the following new drugs.

- A. **Dengvaxia™ (dengue tetravalent vaccine [live] suspension for subcutaneous injection)** Sanofi Pasteur
- B. **Esperoct® (antihemophilic factor [recombinant] glycopegylated-exei injection for intravenous use)** Novo Nordisk
- C. **Nayzilam® (midazolam nasal spray)** UCB
- D. **Piqray® (alpelisib tablets)** Novartis Pharmaceuticals
- E. **Polivy™ (polatuzumab vedotin-piiq injection for intravenous use)** Genentech
- F. **Vyleesi™ (bremelanotide subcutaneous injection)** AMAG Pharmaceuticals, Inc.
- G. **Xpovio™ (selinexor tablets)** Karyopharm Therapeutics
- H. **Zolgensma® (onasemnogene abeparvovec-xioi suspension for intravenous infusion)** AveXis/Novartis

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

- A. **Ortikos™ (budesonide extended-release capsules)** Sun Pharma
- B. **Nucala® (mepolizumab injection for subcutaneous use)** GlaxoSmithKline
- C. **Ruzurgi™ (amifampridine tablets)** Jacobus Pharmaceutical Company
- D. **Slynd™ (drospirenone tablets)** Exeltis

New Biosimilars

The Committee reviewed the following new biosimilars.

- A. **Kanjinti™ (trastuzumab-anns injection for intravenous use)** Amgen
- B. **Zirabev™ (bevacizumab-bvzr injection for intravenous infusion)** Pfizer

New Indications for Existing Products

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

- A. **Bavencio® (avelumab injection for intravenous use)** – New indication for use in combination with Inlyta® (axitinib tablets) for the first-line treatment of patients with advanced renal cell carcinoma.
- B. **Biktarvy® (bictegravir, emtricitabine, and tenofovir alafenamide tablets)** – Expanded age indication to include pediatric patients weighing ≥ 25 kg. Biktarvy is now indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection



Public Information

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 with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy.

- C. **Botox[®] (onabotulinumtoxinA injection for intramuscular, intradetrusor, or intradermal use)** – New pediatric indication for the treatment of upper limb spasticity in pediatric patients 2 years to 17 years of age.
- D. **Cyramza[®] (ramucirumab injection for intravenous use)** – New indication for use as a single agent for the treatment of patients with hepatocellular carcinoma who have an alpha fetoprotein of ≥ 400 ng/mL and have been treated with Nexavar[®] (sorafenib tablets).
- E. **Darzalex[®] (daratumumab injection for intravenous use)** – New indication for the treatment of adult patients with multiple myeloma in combination with Revlimid and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy.
- F. **Doptelet[®] (avatrombopag tablets)** – New indication for the treatment of thrombocytopenia in adults with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.
- G. **Dupixent[®] (dupilumab injection for subcutaneous use)** – New indication as an add-on maintenance treatment in adults with inadequately controlled chronic rhinosinusitis with nasal polyposis.
- H. **Emflaza[®] (deflazacort tablets and oral suspension)** – Expanded age indication for children 2 years to less than 5 years of age. Emflaza is now indicated for the treatment of Duchenne muscular dystrophy in patients ≥ 2 years of age.
- I. **Emgality[®] (galcanezumab-gnlm injection for subcutaneous use)** – New indication for the treatment of episodic cluster headache in adults.
- J. **Eylea[®] (aflibercept injection)** – Expanded indication for the treatment of patients with diabetic retinopathy.
- K. **Fragmin[®] (dalteparin sodium injection for subcutaneous use)** – Expanded age indication for the treatment of symptomatic venous thromboembolism (VTE) to reduce the recurrence of VTE in pediatric patients ≥ 1 month of age.
- L. **Gattex[®] (teduglutide for injection)** – Expanded age indication for the treatment of patients ≥ 1 year of age with short bowel syndrome who are dependent on parenteral support.
- M. **Herzuma[®] (trastuzumab-pkrb for injection for intravenous use)** – New indication for use in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with human epidermal growth factor receptor 2 (HER2) overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease. New indication for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer as monotherapy following multi-modality anthracycline-based therapy.
- N. **Inflectra[™] (infliximab-dyyb injection for intravenous use)** – New indication for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients ≥ 6 years of age with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.
- O. **Jakafi[®] (ruxolitinib tablets)** – New indication for the treatment of steroid-refractory acute graft-versus-host disease in patients ≥ 12 years of age.
- P. **Keytruda[®] (pembrolizumab injection for intravenous use)** – New indication for use as monotherapy for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma whose tumors express programmed death-ligand 1 (PD-L1) [Combined Positive Score {CPS} ≥ 1] as determined by an FDA-approved test.
- Q. **Keytruda[®] (pembrolizumab injection for intravenous use)** – New indication as monotherapy for the treatment of patients with metastatic small cell lung cancer with disease

progression on or after platinum-based chemotherapy and at least one other prior line of therapy.

- R. **Livalo® (pitavastatin tablets)** – New indication as an adjunctive therapy to diet in pediatric patients ≥ 8 years of age with heterozygous familial hypercholesterolemia to reduce elevated total cholesterol, low-density lipoprotein cholesterol (LDL-C), and apolipoprotein B.
- S. **Lyrica® (pregabalin oral solution)** – Expanded age indication as adjunctive therapy for the treatment of partial onset seizures in patients ≥ 1 month of age.
- T. **Renflexis™ (infliximab-abda injection for intravenous use)** – New indication for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients ≥ 6 years of age with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.
- U. **Revlimid® (lenalidomide capsules)** – New indication for use in combination with a rituximab product for the treatment of adults with previously-treated follicular lymphoma.
- V. **Soliris® (eculizumab injection for intravenous use)** – New indication for the treatment of neuromyelitis optica spectrum disorder in adult patients who are anti-aquaporin-4 antibody positive.
- W. **Sorilux™ (calcipotriene foam)** – Expanded age indication to include patients 12 years to less than 18 years of age. Sorilux is now indicated for the topical treatment of plaque psoriasis of the scalp and body in patients ≥ 12 years of age.
- X. **Symdeko™ (tezacaftor/ivacaftor tablets; ivacaftor tablets)** – Expanded age indication for the treatment of patients with cystic fibrosis ≥ 6 years of age who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence.
- Y. **Tindamax® (tinidazole tablets)** – Expanded indication to include pregnant women in the indication for bacterial vaginosis. Tindamax is now indicated for the treatment of bacterial vaginosis (formerly referred to as Haemophilus vaginitis, Gardnerella vaginitis, nonspecific vaginitis, or anaerobic vaginosis) in adult women.
- Z. **Truxima® (rituximab-abbs injection for intravenous use)** – New indication for the treatment of adults with previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma (NHL) in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens. New indication for the treatment of adults with previously-untreated and previously-treated CD20-positive chronic lymphocytic leukemia in combination with fludarabine and cyclophosphamide.
- AA. **Xeomin® (incobotulinumtoxinA injection for intramuscular or intraglandular use)** – Expanded indication for the treatment of blepharospasm in adults. Previously, Xeomin was indicated for the treatment of adults with blepharospasm who were previously treated with Botox® (onabotulinumtoxinA injection).
- BB. **Venclexta® (venetoclax tablets)** – Expanded indication for use in combination with azacitidine, decitabine, or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia in adults who are ≥ 75 years of age or who have comorbidities that preclude use of intensive induction chemotherapy.
- CC. **Victoza® (liraglutide injection for subcutaneous use)** – Expanded age indication to include the treatment of pediatric patients 10 years to 17 years of age. Victoza is now indicated as an adjunct to diet and exercise to improve glycemic control in patients ≥ 10 years of age with type 2 diabetes mellitus.
- DD. **Vraylar® (cariprazine capsules)** – New indication for the treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults.

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