EXPRESS SCRIPTS®

# Express Scripts Holding Company
# Pharmacy and Therapeutics Committee
# Proceedings
# July 21, 2018

## New Drug Evaluations

The Committee reviewed the following new drugs.

A. **Braftovi™ (encorafenib capsules)** Array BioPharma
B. **Doptelet™ (avatrombopag tablets)** Dova Pharmaceuticals/AkaRx
C. **Epidiolex® (cannabidiol oral solution)** GW Pharmaceuticals
D. **Lokelma™ (sodium zirconium cyclosilicate for oral suspension)** AstraZeneca
E. **Lucemyra® (lofexidine tablets)** US WorldMeds
F. **Mektovi® (binimetinib tablets)** Array BioPharma
G. **Nocdurna® (desmopressin acetate sublingual tablets)** Ferring
H. **Olumiant® (baricitinib tablets)** Lilly
I. **Palyniq® (pegvaliase-pqpz injection for subcuteanous use)** BioMarin

## New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

A. **Aristada Initio™ (aripiprazole lauroxil extended-release injectable suspension for intramuscular use)** Alkermes
B. **Bendamustine hydrochloride injection for intravenous use** Eagle Pharms
C. **Consensi® (amlodipine and celecoxib tablets)** Kitov Pharmaceuticals
D. **Halobetason propionate topical foam, 0.05%** Therapeutics Inc.
E. **Imvexxy™ (estradiol vaginal inserts)** TherapeuticsMD
F. **Lamivudine and tenofovir disoproxil fumarate tablets, 300 mg/300 mg** Aurobindo Pharma
G. **LymePak (doxycycline hyclate tablets, 100 mg)** Chartwell Pharma
H. **Nuplazid® (pimavanserin capsules)** Acadia
I. **Prograf® Granules (tacrolimus for oral suspension)** Astellas
J. **Yonsa® (abiraterone acetate tablets)** Sun Pharma

## New Biosimilars

The Committee reviewed the following new biosimilars.

A. **Retacrit™ (epoetin alfa-epbx injection for intravenous or subcutaneous use)** Hospira/Pfizer
B. **Fulphila™ (pegfilgrastim-jmdb injection for subcutaneous use)** Amgen

**New Indications for Existing Products**

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

A. **Actemra® (tocilizumab injection for subcutaneous use)** Genentech – New indication for the subcutaneous form of Actemra for the treatment of active polyarticular juvenile idiopathic arthritis in patients ≥ 2 years of age.
B. **Alimta® (pemetrexed for injection for intravenous use)** Lilly – New indication in combination with carboplatin and Keytruda® (pembrolizumab injection for intravenous use) for the initial treatment of patients with metastatic, non-squamous non-small cell lung cancer.
C. **Arnuity™ Ellipta® (fluticasone furoate inhalation powder)** GlaxoSmithKline – Expanded age indication for the once daily (QD) maintenance treatment of asthma as prophylactic therapy in patients ≥ 5 years of age. Previously, Arnuity Ellipta was indicated for the QD maintenance treatment of asthma as prophylactic therapy in patients ≥ 12 years of age.
D. **Avastin® (bevacizumab solution for intravenous infusion)** Genentech – New indication for use in combination with carboplatin and paclitaxel, followed by Avastin as single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection.
E. **Briviact® (brivaracetam tablets and oral solution)** UCB – Expanded age indication as monotherapy and adjunctive therapy in the treatment of partial onset seizures in patients ≥ 4 years of age.
F. **Cimzia® (certolizumab pegol injection for subcutaneous use)** UCB – New indication for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
G. **Cinryze® (C1 esterase inhibitor [human] injection for intravenous use)** ViroPharma Biologics – Expanded age indication for routine prophylaxis against angioedema attacks to include pediatric patients 6 years to 11 years of age with hereditary angioedema (HAE). Previously, Cinryze was indicated for routine prophylaxis against angioedema attacks in adolescent (≥ 12 years of age) and adult patients with HAE.
H. **Gilenya® (fingolimod capsules)** Novartis – Expanded age indication for the treatment of relapsing multiple sclerosis (MS) in children and adolescents ≥ 10 years of age. Previously, Gilenya was indicated for the treatment of patients with relapsing forms of MS to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.
I. **Keytruda® (pembrolizumab injection for intravenous use)** Merck – New indication for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express programmed death-ligand 1 [combined positive score ≥ 1] as determined by a Food and Drug Administration (FDA)-approved test.
J. **Keytruda® (pembrolizumab injection for intravenous use)** Merck – New indication for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma, or who have relapsed after ≥ two prior lines of therapy.
K. **Keytruda® (pembrolizumab injection for intravenous use)** Merck – Revised indication for the treatment of patients with locally-advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express programmed death-ligand 1 [combined positive score ≥ 10], or in patients who are not eligible for any platinum-containing chemotherapy regardless of programmed death-ligand 1 status.
L. **Mircera® (methoxy polyethylene glycol-epoetin beta injection for intravenous or subcutaneous use)** Vifor Pharma – Expanded age indication for the treatment of anemia associated with chronic kidney disease in pediatric patients 5 years to 17 years of age on hemodialysis who are converting from another erythroid stimulating agent after their hemoglobin level was stabilized with an erythroid stimulating agent.

M. **Prograf® (tacrolimus capsules)** Astellas – Expanded age indication for the prophylaxis of organ rejection, in pediatric patients receiving allogeneic kidney transplant, liver transplants, and heart transplant, in combination with other immunosuppressants.

N. **Prograf® (tacrolimus injection for intravenous use)** Astellas – Expanded age indication for the prophylaxis of organ rejection, in pediatric patients receiving allogeneic kidney transplant, liver transplants, and heart transplant, in combination with other immunosuppressants.

O. **Prolia® (denosumab injection for subcutaneous use)** Amgen – New indication for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

P. **Rituxan® (rituximab injection for intravenous infusion)** Genentech – New indication for the treatment of adults with moderate to severe pemphigus vulgaris.

Q. **Tecentriq® (atezolizumab injection for intravenous use)** Genentech – Revised indication for the treatment of patients with locally-advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express programmed death-ligand 1 (PD-L1) [PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥5% of the tumor area] as determined by an FDA-approved test, or are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status, or have disease progression during or following any platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant chemotherapy.

R. **Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg tablets)** Gilead – Expanded age indication for use in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired human immunodeficiency virus-1 (HIV-1) in at-risk adults and adolescents weighing ≥ 35 kg. Individuals must have a negative HIV-1 test immediately prior to initiating Truvada for HIV-1 PrEP. If clinical symptoms consistent with acute viral infection are present and recent (< 1 month) exposures are suspected, delay starting PrEP for at least 1 month and reconfirm HIV-1 status or use a test cleared by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection.

S. **Venclexta® (venetoclax tablets)** AbbVie/Roche – Expanded indication for the treatment of patients with chronic lymphocytic leukemia or small lymphocytic lymphoma, with or without 17p deletion, who have received at least one prior therapy.

T. **Xeljanz® (tofacitinib tablets)** Pfizer – New indication for the treatment of adult patients who have moderate to severe forms of ulcerative colitis.

U. **Xeomin® (incobotulinumtoxinA injection for intramuscular or intraglandular use)** Merz – New indication for the treatment of chronic sialorrhea in adult patients.