



EXPRESS SCRIPTS®

**Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
March 19, 2016**

New Drug Evaluations

The Committee reviewed the following new drugs.

- A. **Basaglar**® (insulin glargine injection) Eli Lilly/Boehringer Ingelheim
- B. **Briviact**® (brivaracetam tablets, oral solution, and injection) UCB Pharma
- C. **Idelvion**® (coagulation Factor IX [recombinant] albumin fusion protein for intravenous injection) Baxalta
- D. **Vistogard**® (uridine triacetate oral granules) Wellstat Therapeutics Corporation
- E. **Vonvendi**™ (von Willebrand factor [recombinant] for intravenous injection) Baxalta
- F. **Xuriden**™ (uridine triacetate oral granules) Wellstat Therapeutics Corporation
- G. **Zepatier**™ (grazoprevir/elbasvir tablets) Merck
- H. **Zurampic**® (lesinurad tablets) AstraZeneca

New Indications for Existing Products

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

- A. **Afinitor**® (everolimus tablets) Novartis – New indication for the treatment of adult patients with progressive, well-differentiated, nonfunctional neuroendocrine tumors of gastrointestinal or lung origin that are unresectable, locally advanced or metastatic disease.
- B. **Arzerra**® (ofatumumab injection) Novartis – New indication for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia.
- C. **Botox**® (onabotulinumtoxinA injection) Allergan – New indication for the treatment of lower limb spasticity in adults to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus).
- D. **Complera**® (emtricitabine, rilpivirine, tenofovir disoproxil fumarate tablets) Gilead – Expanded age indication for use as a complete regimen for the treatment of human immunodeficiency virus-1 (HIV-1) infection in patients ≥ 12 years of age with no antiretroviral treatment history and with HIV-1 RNA ≤ 100,000 copies/mL at the start of therapy, and in certain virologically-suppressed (HIV-1 RNA < 50 copies/mL) patients on a stable antiretroviral regimen at start of therapy in order to replace their current antiretroviral treatment regimen. Previously, Complera was only indicated in adults.
- E. **Cosentyx**® (secukinumab injection) Novartis – New indication for the treatment of adults with active ankylosing spondylitis.
- F. **Cosentyx**® (secukinumab injection) Novartis – New indication for the treatment of adults with active psoriatic arthritis.
- G. **Daklinza**™ (daclatasvir tablets) Bristol-Myers Squibb – New indication for use with Sovaldi, with or without ribavirin, for the treatment of patients with chronic hepatitis C virus genotype 1.



Public Information

- H. **Daklinza™** (daclatasvir tablets) Bristol-Myers Squibb – Expanded indication for use with Sovaldi, with or without ribavirin, for the treatment of patients with chronic hepatitis C virus genotype 3 with decompensated (Child-Pugh B or C) cirrhosis. Previously, Daklinza was indicated for use with Sovaldi for the treatment of chronic hepatitis C virus genotype 3 infection.
- I. **Emend®** (fosaprepitant dimeglumine for injection) Merck – Revised indication for Emend injection in combination with other antiemetic agents, for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). Previously, Emend injection was indicated in adults for use in combination with other antiemetic agents for the prevention of nausea and vomiting associated with initial and repeat courses of MEC.
- J. **Faslodex®** (fulvestrant injection) AstraZeneca – New indication for use in combination with Ibrance® (palbociclib capsules) in women with hormone receptor positive, human epidermal growth factor receptor 2 negative- advanced or metastatic breast cancer whose disease has progressed following endocrine therapy.
- K. **Flebogamma 10% DIF** (immune globulin intravenous [Human]) Instituto Grifols – New indication for the treatment of patients ≥ 2 years of age with chronic primary immune thrombocytopenia to raise platelet counts.
- L. **Gazyva®** (obinutuzumab injection) Genentech – New indication for use in combination with Treanda® (bendamustine injection) followed by Gazyva monotherapy, for the treatment of patients with follicular lymphoma who relapsed after, or are refractory to, a rituximab-containing regimen.
- M. **Halaven®** (eribulin mesylate injection) Eisai – New indication for the treatment of patients with unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.
- N. **Harvoni®** (ledipasvir/sofosbuvir tablet) Gilead – Expanded indication for use in patients with chronic hepatitis C virus with advanced liver disease. Harvoni in combination with ribavirin for 12 weeks was approved for use in chronic hepatitis C virus genotype 1- or 4-infected liver transplant recipients without cirrhosis or with compensated cirrhosis (Child-Pugh A), and for HCV genotype 1-infected patients with decompensated cirrhosis (Child-Pugh B or C), including those who have undergone liver transplantation.
- O. **Hiberix®** (Haemophilus b conjugate vaccine [tetanus toxoid conjugate]) GlaxoSmithKline Biologicals – Expanded age indication for active immunization as a booster dose for the prevention of invasive disease caused by Haemophilus influenzae type b. Hiberix is approved for use in children 6 weeks through 4 years of age (prior to fifth birthday).
- P. **Ibrance®** (palbociclib capsules) Pfizer – New indication for the treatment of hormone receptor-positive, human epidermal growth factor receptor 2-negative- advanced or metastatic breast cancer in combination with Faslodex® (fulvestrant injection) in women with disease progression following endocrine therapy.
- Q. **Imbruvica®** (ibrutinib capsules) Janssen/Pharmacyclics – Expanded indication for the treatment of patients with chronic lymphocytic leukemia (CLL). This indication now includes treatment-naive patients. Previously, Imbruvica was indicated for the treatment of patients with CLL who have received at least one prior therapy.
- R. **Complera®** (emtricitabine, rilpivirine, tenofovir disoproxil fumarate tablets) Gilead – Expanded age indication for use as a complete regimen for the treatment of human immunodeficiency virus-1 (HIV-1) infection in patients ≥ 12 years of age with no antiretroviral treatment history and with HIV-1 RNA $\leq 100,000$ copies/mL at the start of therapy, and in certain virologically-suppressed (HIV-1 RNA < 50 copies/mL) patients on a stable antiretroviral regimen at start of therapy in order to replace their current antiretroviral treatment regimen. Previously, Complera was only indicated in adults.
- S. **Opdivo®** (nivolumab injection) Bristol-Myers Squibb – Expanded indications for both the Opdivo and Yervoy® (ipilimumab injection for intravenous use) regimen and Opdivo as a

single-agent regimen, which are now indicated in patients with unresectable or metastatic melanoma, regardless BRAF status.

- T. **Prilosec**[®] (omeprazole magnesium for delayed-release oral suspension and delayed-release capsules) AstraZeneca – Expanded age indication for short-term treatment (6 weeks) of erosive esophagitis due to acid-mediated gastroesophageal reflux disease in patients 1 month to < 1 year of age.

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

- A. **Aczone**[®] (dapson 7.5% gel) Allergan
- B. **Adzenys XR-ODT**[™] (amphetamine extended-release orally disintegrating tablets) Neos Therapeutics
- C. **Dexilant SoluTab** (dexlansoprazole delayed-release orally disintegrating tablets [ODT]) Takeda
- D. **Emverm**[™] (mebendazole 100 mg chewable tablets) Impax/Ameda
- E. **Odefsey**[®] (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir alafenamide 25 mg tablets) Gilead
- F. **Onzetra**[™] **Xsail**[™] (sumatriptan nasal powder) Avanir
- G. **Sernivo**[™] (betamethasone dipropionate spray, 0.05%) Promius
- H. **Xeljanz XR**[®] (tofacitinib citrate extended-release 11 mg tablets) Pfizer
- I. **Zembrace**[™] **SymTouch**[™] (sumatriptan 3 mg injection) Dr. Reddy's Labs

All trademarks are the property of their respective owners.