



EXPRESS SCRIPTS®

**Express Scripts Holding Company  
Pharmacy and Therapeutics Committee  
Proceedings  
July 9, 2016**

**New Drug Evaluations**

The Committee reviewed the following new drugs.

- A. **Afstyla**® (antihemophilic factor [recombinant] single chain for intravenous injection) CSL Behring
- B. **Bevespi Aerosphere**™ (glycopyrrolate and formoterol fumarate inhalation aerosol – AstraZeneca)
- C. **Epclusa**® (sofosbuvir/velpatasvir tablets) Gilead
- D. **Ocaliva**™ (obeticholic acid tablets) Intercept
- E. **Otovel**™ (ciprofloxacin/fluocinolone acetone) Arbor Pharmaceuticals
- F. **Probuphine**® (buprenorphine implant for subdermal administration – Braeburn Pharmaceuticals)
- G. **Tecentriq**™ (atezolizumab injection for intravenous use) Genentech [Roche]
- H. **Ultravate**® (halobetasol propionate lotion) Ranbaxy Laboratories
- I. **Vaxchora**™ (cholera vaccine, live, suspension for administration) PaxVac
- J. **Zinbryta**™ (daclizumab subcutaneous injection) Biogen/AbbVie

**New Indications for Existing Products**

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

- A. **Crestor**® (**rosuvastatin calcium tablets**) **AstraZeneca** – The age indication was expanded to children and adolescents 7 to 17 years of age with homozygous familial hypercholesterolemia (HoFH). For this indication, Crestor is indicated as adjunct to diet to reduce total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), non-high density lipoprotein cholesterol (non-HDL-C), and apolipoprotein B levels, either alone or with other lipid-lowering treatments (e.g., low-density lipoprotein apheresis).
- B. **Fanapt**® (**iloperidone tablets**) **Vanda** – The indication was expanded for the treatment of schizophrenia in adults, which now includes maintenance treatment.
- C. **Invokamet**® (**canagliflozin and metformin hydrochloride tablets**) **Janssen** – The indication was expanded as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Invokana® (canagliflozin tablets) and metformin is appropriate.
- D. **Lenvima**® (**lenvatinib capsules**) **Eisai** – New indication in combination with Afinitor® (everolimus tablets) for the treatment of patients with advanced renal cell cancer following one prior anti-angiogenic therapy.
- E. **Opdivo**® (**nivolumab injection**) **Bristol-Myers Squibb** – New indication for the treatment of patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation Adcetris® (brentuximab vedotin injection). This indication was approved under accelerated approval



Public Information

based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

- F. **Stivarga® (regorafenib tablets) Bayer** – There was a change to the patient population for the treatment of metastatic colorectal cancer (CRC). Stivarga is now indicated for the treatment of patients with metastatic CRC who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-epidermal growth factor receptor (EGFR) therapy. Previously, Stivarga's indication included the more limited population of KRAS wild-type.
- G. **Tivicay® (dolutegravir tablets) ViiV Healthcare** – The patient population was expanded to include the treatment of pediatric patients weighing  $\geq 30$  kg to  $< 40$  kg. Tivicay is now indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing  $\geq 30$  kg. Previously, Tivicay was only indicated in patients weighing  $\geq 40$  kg.

### **New Clinical Line Extensions**

The Committee reviewed the following new clinical line extensions.

- A. **Byvalson™** (nebivolol and valsartan tablets) Allergan
- B. **Flucelvax Quadrivalent™** (influenza vaccine) Seqirus
- C. **GoNitro™** (nitroglycerin sublingual powder) Espero Pharmaceuticals
- D. **Jentadueto® XR** (linagliptin and metformin hydrochloride extended-release tablets)  
Boehringer Ingelheim/Lilly

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