



EXPRESS SCRIPTS®

**Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
January 26, 2017**

New Drug Evaluations

The Committee reviewed the following new drugs.

- A. **Eucrisa™ (crisaborole ointment, 2%, for topical use)** Anacor/Pfizer
- B. **Intrarosa™ (prasterone 6.5 mg vaginal inserts)** Endoceutics, Inc.
- C. **Rubraca™ (rucaparib tablets)** Clovis Oncology, Inc.
- D. **Spinraza™ (nusinersen injection for intrathecal use)** Biogen
- E. **Vemlidy® (tenofovir alafenamide tablets)** Gilead
- F. **Zinplava™ (bezlotoxumab injection for intravenous use)** Merck

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

- A. **Arymo™ ER** (morphine sulfate extended-release tablets) Egalet
- B. **Bonjesta™** (doxylamine succinate 20 mg and pyridoxine hydrochloride 20 mg extended-release tablets) Duchesnay
- C. **Esbriet®** (pirfenidone film-coated tablets) Genentech
- D. **Selzentry®** (maraviroc oral solution) ViiV
- E. **Soliqua™** (insulin glargine and lixisenatide injection for subcutaneous use) Sanofi
- F. **Synjardy® XR** (empagliflozin and metformin hydrochloride extended-release tablets) Boehringer Ingelheim/Lilly
- G. **Tirosint® -SOL** (levothyroxine sodium oral solution) Croomsources
- H. **Xultophy®** (insulin degludec and liraglutide injection for subcutaneous use) Novo Nordisk

New Indications for Existing Products

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

- A. **Adynovate® (Antihemophilic Factor [recombinant], PEGylated lyophilized powder for intravenous injection)** Baxalta – New indication for use in children and adults with hemophilia A (congenital factor VIII deficiency) for perioperative management.
- B. **Adynovate®** (Antihemophilic Factor [recombinant], PEGylated lyophilized powder for intravenous injection) Baxalta – Expanded age indication for use in young children (including those < 12 years of age) and adults with hemophilia A (congenital factor VIII deficiency) for on-demand treatment and control of bleeding episodes, perioperative management, and routine prophylaxis to reduce the frequency of bleeding episodes.
- C. **Avastin® (bevacizumab injection for intravenous infusion)** Genentech – New indication for use either in combination with carboplatin and paclitaxel or carboplatin and gemcitabine,



Public Information

followed by Avastin as a single agent, for patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

- D. Ceftin® (cefuroxime axetil tablets and powder for oral suspension)** GlaxoSmithKline and **Cefzil® (cefprozil tablets and oral suspension)** Corden Pharma – Removal of indication for the treatment of adult patients and pediatric patients (aged ≥ 13 years) with secondary bacterial infections of acute bronchitis caused by susceptible strains of bacteria.
- E. Darzalex® (daratumumab injection)** Janssen – New indication for use in combination with Revlimid® (lenalidomide capsules) and dexamethasone, or Velcade® (bortezomib injection) and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.
- F. Enbrel® (etanercept injection)** Amgen – Expanded age indication for the treatment of patients ≥ 4 years of age with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- G. FluLaval® Quadrivalent (influenza vaccine for intramuscular injection)** GlaxoSmithKline – Expanded age indication for use in persons aged ≥ 6 months for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.
- H. FluLaval® (influenza vaccine for intramuscular injection)** GlaxoSmithKline – Expanded age indication for use in persons aged ≥ 6 months for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.
- I. Genvoya® (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide tablets)** Gilead – Revised indication to include a minimum weight in the indication. Genvoya is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients ≥ 12 years of age weighing ≥ 35 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 at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Genvoya.
- J. Jardiance® (empagliflozin tablets)** Boehringer Ingelheim – New indication to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.
- K. Lucentis® (ranibizumab injection)** Genentech – New indication for the treatment of myopic choroidal neovascularization.
- L. Naftin® (naftifine hydrochloride) cream)** Merz – Expanded age for the treatment of tinea corporis caused by the organism *Trichophyton rubrum* to children ≥ 2 years of age.
- M. Opdivo® (nivolumab injection)** Bristol-Myers Squibb – New indication for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after platinum-based therapy.
- N. Renvela® (sevelamer carbonate tablet)** Genzyme – Expanded age indication for the control of serum phosphorus in adults and children ≥ 6 years of age with chronic kidney disease on dialysis.
- O. Ryzodeg® 70/30 (insulin degludec and insulin aspart injection)** Novo Nordisk – Expanded age indication to improve glycemic control in patients ≥ 1 year of age with diabetes mellitus.
- P. Saphris® (asenapine sublingual tablets)** Allergan – Revised indication for Bipolar I disorder which now states: acute monotherapy of manic or mixed episodes, in adults and pediatric patients 10 years to 17 years of age; adjunctive treatment to lithium or valproate in adults; and maintenance monotherapy treatment in adults.
- Q. Selzentry® (maraviroc tablets)** ViiV – Expanded age indication for use in combination with other antiretroviral agents for the treatment of only chemokine receptor type 5-tropic human immunodeficiency virus type 1 (HIV-1) infection in patients ≥ 2 years of age and weighing ≥ 10 kg.

- R. **Tresiba® (insulin degludec injection)** Novo Nordisk – Expanded age indication to improve glycemic control in patients ≥ 1 year of age with diabetes mellitus.
- S. **Various immediate-release (IR) opioid medications** (drugs affected by this labeling change can be found at the following Food and Drug Administration website: <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>) – Revised indication for the class of IR opioid analgesics. The indications are now for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Limitations of use: Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve IR opioid analgesics for use in patients for whom alternative analgesic treatment options (e.g., non-opioid analgesics) have not been tolerated, or are not expected to be tolerated, or have not provided adequate analgesia, or are not expected to provide adequate analgesia.

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