



EXPRESS SCRIPTS®

**Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
May 18, 2017**

New Drug Evaluations

The Committee reviewed the following new drugs.

- A. **Alunbrig™ (brigatinib tablets)** ARIAD/Takeda Pharmaceuticals
- B. **Austedo™ (deutetrabenazine tablets)** Teva
- C. **Bavencio® (avelumab injection for intravenous use)** EMD Serono/Pfizer
- D. **Ingrezza™ (valbenazine capsules)** Neurocrine Biosciences
- E. **Kisqali® (ribociclib tablets)** Novartis
- F. **Ocrevus™ (ocrelizumab intravenous infusion)** Genentech/Roche
- G. **Rydapt® (midostaurin capsules)** Novartis
- H. **Tymlos™ (abaloparatide subcutaneous injection)** Radius Pharmaceuticals
- I. **Xadago® (safinamide tablets)** US Worldmeds/Newron
- J. **Zejula™ (niraparib capsules)** Tesaro, Inc.

New Biosimilar

The Committee reviewed the following new biosimilar.

- A. **Renflexis® (infliximab-abda for injection for intravenous use)** Samsung Bioepis/Merck

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

- A. **Roxybond™ (oxycodone hydrochloride tablets)** Inspirion Delivery Sciences
- B. **Xatmep™ (methotrexate oral solution, 2.5 mg/mL)** Silvergate Pharmaceuticals

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)** EMD Serono/Pfizer – New indication for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- B. **Bunavail® (buprenorphine and naloxone buccal film)** BioDelivery Sciences International – Revised indication for the treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support.
- C. **Harvoni® (ledipasvir 90 mg/sofosbuvir 400 mg tablets)** Gilead – Expanded age indication for the treatment of pediatric patients ≥ 12 years of age or weighing ≥ 35 kg with



Public Information

chronic hepatitis C virus genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis.

- D. **Ibrance® (palbociclib capsules)** Pfizer – Revised indication for the treatment of hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine based therapy in postmenopausal women.
- E. **Keytruda® (pembrolizumab injection)** Merck – New indication for the treatment of adult and pediatric patients with refractory classical Hodgkin lymphoma, or who have relapsed after ≥ three prior lines of therapy.
- F. **Lucentis® (ranibizumab injection)** Genentech – Expanded indication for the treatment of all forms of diabetic retinopathy.
- G. **Opdivo® (nivolumab injection)** Bristol-Myers Squibb – Revised indication for the treatment of adult patients with classical Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and Adcetris® (brentuximab vedotin injection), or three or more lines of systemic therapy that includes autologous HSCT.
- H. **Orencia® (abatacept SC injection)** Bristol-Myers Squibb – New indication for Orencia SC injection for reducing signs and symptoms in patients ≥ 2 years of age with moderately to severely active polyarticular juvenile idiopathic arthritis as monotherapy or used concomitantly with methotrexate.
- I. **Oudexy® XR (topiramate extended-release capsules, generics)** Upsher-Smith – New indication for use as prophylaxis of migraine headache in adults and adolescents ≥ 12 years of age.
- J. **Ravicti® (glycerol phenylbutyrate oral liquid)** Horizon Pharma – Expanded age indication for use as a nitrogen-binding agent for chronic management of patients ≥ 2 months of age with urea cycle disorders who cannot be managed by dietary protein restriction and/or amino acid supplementation alone.
- K. **Sovaldi® (sofosbuvir tablets)** Gilead – Expanded age indication for the treatment of chronic hepatitis C virus genotype 2 or 3 infection in pediatric patients ≥ 12 years of age, or weighing ≥ 35 kg, without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.
- L. **Stivarga® (regorafenib tablets)** Bayer – New indication for the treatment of patients with hepatocellular carcinoma who have been previously treated with Nexavar® (sorafenib tablets).
- M. **Tecentriq® (atezolizumab injection for intravenous use)** Genentech – Expanded indication for the treatment of people with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin chemotherapy.
- N. **Trokendi XR® (topiramate extended-release capsules)** Supernus – New indication for use as prophylaxis of migraine headache in adults and adolescents ≥ 12 years of age.
- O. **Timoptic® in Ocudose® 0.25% and 0.5% (timolol maleate ophthalmic solution)** Aton – Expanded age indication for use in pediatric patients ≥ 2 years of age in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

All trademarks are the property of their respective owners.