



EXPRESS SCRIPTS®

**Express Scripts Holding Company  
Pharmacy and Therapeutics Committee  
Proceedings  
January 17, 2019**

**New Drug Evaluations**

The Committee reviewed the following new drugs.

- A. **Aemcolo™ (rifamycin delayed-release tablets)** Aries Pharmaceuticals, Inc.
- B. **Asparlas™ (calaspargase pegol-mknl injection for intravenous use)** Servier Pharmaceuticals
- C. **Daurismo™ (glasdegib tablets)** Pfizer
- D. **Elzonris™ (tagraxofusp-erzs injection for intravenous use)** Stemline Therapeutics
- E. **Firdapse® (amifampridine phosphate tablets)** Catalyst Pharmaceuticals
- F. **Gamifant™ (emapalumab-lzsg injection for intravenous infusion)** Sobi
- G. **Inbrija™ (levodopa inhalation powder for oral inhalation use)** Acorda
- H. **Lorbrena® (lorlatinib tablets)** Pfizer Inc.
- I. **Motegrity™ (prucalopride tablets)** Shire/Takeda Pharmaceuticals
- J. **Ultomiris™ (ravulizumab-cwvz injection for intravenous use)** Alexion Pharmaceuticals
- K. **Vitrakvi® (larotrectinib capsules and oral solution)** Loxo Oncology, Inc. and Bayer Healthcare Pharmaceuticals, Inc.
- L. **Xospata® (gilteritinib tablets)** Astellas
- M. **Yupelri™ (revefenacin inhalation solution)** Theravance/Mylan Specialty

**New Clinical Line Extensions**

The Committee reviewed the following new clinical line extensions.

- A. **Bryhali™ (halobetasol propionate 0.01% lotion)** Bausch Health
- B. **Cutaquig® (immune globulin subcutaneous [human] – hipp 16.5% solution)** Octapharma
- C. **Ezallor™ (rosuvastatin capsules)** Sun Pharma
- D. **ProAir® Digihaler™ (albuterol sulfate inhalation powder [90 mcg albuterol base/inhalation])** Teva
- E. **Sympazan™ (clobazam oral film)** Aquestive
- F. **Temixys™ (lamivudine 300 mg and tenofovir disoproxil fumarate 300 mg tablets)** Celltrion
- G. **Tolsura™ (itraconazole capsules)** Mayne Pharma

**New Biosimilars**

The Committee reviewed the following new biosimilar.

- A. **Herzuma® (trastuzumab-pkrb injection for intravenous use)** Celltrion
- B. **Truxima® (rituximab-abbs injection for intravenous use)** Celltrion



Public Information

## **New Indications for Existing Products**

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

- A. Adcetris® (brentuximab vedotin injection for intravenous use)** Seattle Genetics – New indication for use in combination with CHP (cyclophosphamide, doxorubicin, prednisone) in adults with previously-untreated systemic anaplastic large cell lymphoma or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified.
- B. Astagraf XL® (tacrolimus extended-release capsules)** Astellas – Expanded age indication to include pediatric patients  $\geq 4$  years of age who are able to swallow capsules intact and Prograf® (tacrolimus) capsules in adult and pediatric organ transplant patients. Astagraf XL is now indicated for the prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants in adult and pediatric patients.
- C. Complera® (emtricitabine, rilpivirine, tenofovir disoproxil fumarate tablets)** Gilead – Revised indication to include a minimum weight in the indication. Complera is indicated for use as a complete regimen for the treatment of human immunodeficiency type 1 (HIV-1) infection in patients weighing  $\geq 35$  kg as initial therapy in those with no antiretroviral (ARV) treatment history and with HIV-1 RNA  $\leq 100,000$  copies/mL at the start of therapy, or to replace a stable ARV regimen in those who are virologically suppressed (HIV-1 RNA  $< 50$  copies/mL) on a stable ARV regimen for at least 6 months with no treatment failure and no known substitutions associated with resistance to the individual components of Complera.
- D. Empliciti® (elotuzumab injection for intravenous use)** Bristol-Myers Squibb – New indication for use in combination with Pomalyst® (pomalidomide capsules) and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.
- E. Envarsus XR® (tacrolimus extended-release tablets)** Veloxis – New indication to prevent organ rejection in de novo kidney transplant patients in combination with other immunosuppressants.
- F. Intelence® (etravirine tablets)** Janssen – Revised indication (rewording) for use in combination with other ARV agents for the treatment of HIV-1 infection in ARV treatment-experienced adults and pediatric patients  $\geq 2$  years of age.
- G. Keytruda® (pembrolizumab injection for intravenous use)** Merck – Two new indications were granted: 1) for the treatment of patients with hepatocellular carcinoma who have been previously treated with Nexavar; and 2) for the treatment of adult and pediatric patients with recurrent locally-advanced or metastatic Merkel cell carcinoma.
- H. Lynparza® (olaparib tablets)** AstraZeneca/Merck – New indication for use in patients who are in complete or partial response to first-line platinum-based chemotherapy as maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer.
- I. Nplate® (romiplostim injection for subcutaneous use)** Amgen – Expanded indication for the treatment of pediatric patients  $\geq 1$  year of age with immune thrombocytopenia for  $\geq 6$  months who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.
- J. Odefsey® (emtricitabine, rilpivirine, and tenofovir alafenamide tablets)** Gilead – Revised indication to include a minimum weight in this indication. Odefsey is indicated for use as a complete regimen for the treatment of HIV-1 infection in patients weighing  $\geq 35$  kg as initial therapy in those with no ARV treatment history and with HIV-1 RNA  $\leq 100,000$  copies/mL at the start of therapy, or to replace a stable ARV regimen in those who are virologically-suppressed (HIV-1 RNA  $< 50$  copies/mL) on a stable ARV regimen for at least 6 months with no treatment



failure and no known substitutions associated with resistance to the individual components of Odefsey.

- K. Oralair® (Sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens allergen extract sublingual tablet)** Stallergenes – Expanded age indication to include patients 5 to 9 years of age. Oralair is now indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific immunoglobulin E antibodies for any of the five grass species contained in this product for patients 5 through 65 years of age.
- L. Oxtellar XR® (oxcarbazepine extended-release tablets)** Supernus – Expanded age indication to include monotherapy for the treatment of partial-onset seizures in patients ≥ 6 years of age.
- M. Promacta® (eltrombopag tablets)** Novartis – New indication for use in combination with standard immunosuppressive therapy for the first-line treatment of adult and pediatric patients ≥ 2 years of age with severe aplastic anemia.
- N. Ravicti® (glycerol phenylbutyrate oral liquid)** Horizon Pharma – Expanded age indication to include pediatric patients < 2 months of age. Ravicti is indicated for use as a nitrogen-binding agent for chronic management of patients with urea cycle disorders who cannot be managed by dietary protein restriction and/or amino acid supplementation alone.
- O. Sprycel® (dasatinib tablets)** Bristol-Myers Squibb – Expanded indication for the treatment of pediatric patients ≥ 1 year of age with newly-diagnosed Philadelphia chromosome-positive Acute Lymphocytic Leukemia in combination with chemotherapy.
- P. Tecentriq® (atezolizumab injection for intravenous use)** Genentech – New indication for use in combination with Avastin (bevacizumab), paclitaxel, and carboplatin for the first-line treatment of patients with metastatic non-squamous non-small cell lung cancer with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations.
- Q. Venclexta® (venetoclax tablets)** AbbVie/Genentech – Expanded indication for use in combination with azacitidine, decitabine, or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia in adults who are ≥ 75 years of age or who have comorbidities that preclude use of intensive induction chemotherapy.
- R. Viread® (tenofovir disoproxil fumarate tablets and oral powder)** Gilead – Expanded age indication to include pediatric patients ≥ 2 years of age weighing ≥ 10 kg for the treatment of chronic hepatitis B virus.

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