



EXPRESS SCRIPTS®

**Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
September 20, 2018**

New Drug Evaluations

The Committee reviewed the following new drugs.

- A. Azedra® (iobenguane I-131 injection for intravenous use)** Progenics Pharmaceuticals, Inc.
- B. Galafold™ (migalastat capsules)** Amicus Therapeutics
- C. Jivi® (antihemophilic factor [recombinant] PEGylated-aucl lyophilized powder for solution for intravenous use)** Bayer HelathCare
- D. Mulpleta® (lusutrombopag tablets)** Shionogi/Quotient Science
- E. Onpattro™ (patisiran for intravenous infusion)** Alnylam
- F. Orilissa™ (elagolix tablets)** AbbVie Inc.
- G. Poteligeo® (mogamulizumab-kpkc injection for intravenous use)** Kyowa Kirin, Inc.
- H. Qbrexa™ (glycopyrronium cloth .4% for topical use)** Dermira
- I. Takhzyro™ (lanadelumab-flyo for subcutaneous injection)** Shire
- J. Tibsovo® (ivosidenib tablets)** Agios

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

- A. Altreno™ (tretinoin lotion)** Valeant/Dow
- B. Cassipa® (buprenorphine 16 mg and naloxone 4 mg sublingual film)** Teva
- C. Cequa™ (cyclosporine ophthalmic solution 0.09%)** Sun Pharma
- D. Efavirenz 600 mg, lamivudine 300 mg, and tenofovir disoproxil fumarate 300 mg tablets** Aurobindo Pharma
- E. Infugem™ (gemcitabine in sodium chloride injection for intravenous use)** Sun Pharmaceutical
- F. Inveltys™ (loteprednol etabonate ophthalmic suspension, 1%)** Kala Pharmaceuticals
- G. Jornay PM™ (methylphenidate extended-release capsules)** Ironshore
- H. Lamivudine 150 mg, nevirapine 200 mg, and zidovudine 300 mg tablets** Micro Labs
- I. Orkambi® (lumacaftor/ivacaftor oral granules)** Vertex
- J. Panzyga® (immune globulin intravenous, human - ifas, 10% liquid preparation)** Octapharma
- K. Perseris™ (risperidone extended-release injectable suspension for subcutaneous use)** Indivior
- L. Symtuza™ (darunavir, cobicistat, emtricitabine mg and tenofovir alafenamide)** Janssen
- M. Synjoynt™ (sodium hyaluronate 1% injection)** Teva
- N. Tiglutik™ (riluzole oral suspension)** ITF Pharma

New Biosimilars

The Committee reviewed the following new biosimilar.



Public Information

A. Nivestym™ (filgrastim-aafi injection for intravenous or subcutaneous use)
Hospira/Pfizer

New Indications for Existing Products

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

- A. Atripla® (efavirenz, emtricitabine, and tenofovir disoproxil fumarate tablets)** Gilead – Revised (reworded) indication to change from a minimum patient age to a minimum patient weight. Atripla is indicated as a complete regimen or in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 infection in adults and pediatric patients weighing ≥ 40 kg.
- B. Granix® (tbo-filgrastim injection for subcutaneous use)** Teva – Expanded age indication to include pediatric patients. Granix is indicated to reduce the duration of severe neutropenia in adult and pediatric patients ≥ 1 month of age with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.
- C. Imbruvica® (ibrutinib capsules)** Pharmacyclics/Janssen – Expanded indication in combination with rituximab for the treatment of adult patients with Waldenström’s macroglobulinemia. Imbruvica is indicated for the treatment of adult patients with Waldenström’s macroglobulinemia. Previously, Imbruvica was indicated as monotherapy for the treatment of adult patients with Waldenström’s macroglobulinemia.
- D. Intelence® (etravirine tablets)** Janssen – Expanded age indication to include pediatric patients 2 years to < 6 years of age and weighing ≥ 10 kg. Intelence is indicated for treatment of human immunodeficiency virus type 1 infection in treatment-experienced patients ≥ 2 years of age with viral strains resistant to a non-nucleoside reverse transcriptase inhibitor and other antiretroviral agents.
- E. Kalydeco® (ivacaftor tablets and oral granules)** Vertex – Expanded age indication for the treatment of cystic fibrosis in patients ≥ 12 months of age who have one mutation in the cystic fibrosis transmembrane regulator gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data.
- F. Keytruda® (pembrolizumab injection for intravenous use)** Merck – Expanded indication in combination with Alimta® (pemetrexed injection for intravenous use) and platinum chemotherapy, for the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer, with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations.
- G. Kisqali® (ribociclib tablets)** Novartis – Expanded patient population to include pre/perimenopausal women for use in combination with an aromatase inhibitor. Kisqali is now indicated for the treatment of pre/perimenopausal or postmenopausal women, with hormone receptor-positive, human epidermal growth factor receptor 2-negative, advanced or metastatic breast cancer, as initial endocrine-based therapy.
- H. Kisqali® (ribociclib tablets)** Novartis – New indication for use in combination with Faslodex® (fulvestrant injection) for the treatment of postmenopausal women with hormone receptor-positive, human epidermal growth factor receptor 2-negative, advanced or metastatic breast cancer, as initial endocrine based therapy or following disease progression on endocrine therapy.
- I. Lenvima® (lenvatinib capsules)** Eisai/Merck – New indication for the first-line treatment of patients with unresectable hepatocellular carcinoma.
- J. Lotemax® (loteprednol etabonate ophthalmic gel)** Valeant – Expanded age indication to include pediatric patients beginning at birth. Lotemax is indicated for the treatment of postoperative inflammation and pain following ocular surgery.

- K. Nuvessa™ (metronidazole vaginal gel 1.3%)** Actavis Pharma – Expanded age indication for the treatment of bacterial vaginosis in females ≥ 12 years of age.
- L. Opdivo® (nivolumab injection for intravenous use)** Bristol-Myers Squibb – New indication in combination with Yervoy® (ipilimumab injection) for the treatment of adults and pediatric patients ≥ 12 years of age with microsatellite instability-high or DNA mismatch repair deficient, metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.
- M. Opdivo® (nivolumab injection for intravenous use)** Bristol-Myers Squibb – New indication for the treatment of patients with metastatic small cell lung cancer with progression after platinum-based chemotherapy and at least one other line of therapy.
- N. Orkambi® (lumacaftor/ ivacaftor tablets)** Vertex – Expanded age indication for the treatment of cystic fibrosis in patients ≥ 2 years of age who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator gene.
- O. Prepopik® (sodium picosulfate, magnesium oxide, and anhydrous citric acid for oral solution)** Ferring – Expanded age indication for cleansing of the colon as a preparation for colonoscopy in adults and pediatric patients ≥ 9 years of age.
- P. Signifor® LAR (pasireotide injectable suspension for intramuscular use)** Novartis – New indication for the treatment of adult patients with Cushing’s disease for whom pituitary surgery is not an option or has not been curative.
- Q. Timoptic-XE® (timolol maleate ophthalmic gel forming solution)** Valeant – Expanded age of use to include pediatric patients ≥ 2 years of age. Timoptic-XE is indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.
- R. Xtandi® (enzalutamide capsules)** Astellas – Expanded indication to include men with non-metastatic castration-resistant prostate cancer.
- S. Yervoy® (ipilimumab injection for intravenous use)** Bristol-Myers Squibb – New indication in combination with Opdivo® (nivolumab injection) for the treatment of adult and pediatric patients 12 years of age and older with microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.
- T. Zomacton® (somatropin for injection for subcutaneous use)** Ferring – New pediatric indication for the treatment of idiopathic short stature (ISS), height standard deviation score ≤ -2.25 and associated with growth rates unlikely to permit attainment of adult height in the normal range.
- U. Zomacton® (somatropin for injection for subcutaneous use)** Ferring – New pediatric indication for the treatment of short stature associated with Turner syndrome.
- V. Zomacton® (somatropin for injection for subcutaneous use)** Ferring – New pediatric indication for the treatment of short stature born small for gestational age with no catch-up growth by 2 years to 4 years of age.
- W. Zomacton® (somatropin for injection for subcutaneous use)** Ferring – New pediatric indication for the treatment of short stature or growth failure in short stature homeobox-containing gene deficiency.

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