EXPRESS SCRIPTS®

Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
March 16, 2019

New Drug Evaluations

The Committee reviewed the following new drugs.

A. **Annovera™ (segesterone acetate and ethinyl estradiol vaginal system)** Therapeutics MD, Inc.
B. **Cablivi® (caplacizumab-yhdp injection for intravenous or subcutaneous use)** Genzyme
C. **Egaten™ (triclabendazole tablet)** Novartis
D. **Krintafel™ (tafenoquine tablets)** GlaxoSmithKline
E. **Primaquine® (primaquine phosphate tablets)**
F. **Spravato™ (esketamine nasal spray)** Janssen
G. **Zerviate™ (cetirizine 0.24% ophthalmic solution)** Akorn

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

A. **Adhansia XR™ (methylphenidate hydrochloride extended-release capsules)** Purdue Pharma
B. **Evekeo ODT™ (amphetamine sulfate orally disintegrating tablets)** Arbor Pharms
C. **Gloperba® (colchicine oral solution)** Romeg Therapeutics
D. **Licart™ (diclofenac epolamine topical system)** IBSA Institut Biochimique
E. **Lotemax® SM (loteprednol etabonate ophthalmic gel, 0.38%)** Bausch and Lomb
F. **Tosymra™ (sumatriptan nasal spray)** Dr. Reddys Labs
G. **Vaxelis™ (diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus, haemophilus b conjugate [meningococcal protein conjugate] and hepatitis B [recombinant] vaccine for intramuscular injection)** Sanofi/Merck

New Biosimilars

The Committee reviewed the following new biosimilar.

A. **Ontruzant® (trastuzumab-dttb injection for intravenous use)** Merck

New Indications for Existing Products

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

A. **Adacel® (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis [Tdap] vaccine adsorbed suspension for intramuscular injection)** Sanofi – Expanded indication to include repeat vaccination to help protect against tetanus, diphtheria and pertussis. Adacel is now indicated for active booster immunization against tetanus, diphtheria, and pertussis in individuals 10 through 64 years of age.

B. **Alimta® (pemetrexed for injection for intravenous use)** Lilly – Expanded indication in combination with Keytruda® (pembrolizumab 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.
C. **Biltricide® (praziquantel tablets)** Bayer Healthcare – Expanded age indication to include children 1 year to < 4 years of age. Biltricide is indicated in patients ≥ 1 year of age for the treatment of the following infections: schistosomiasis due to all species of schistosoma (for example, Schistosoma mekongi, Schistosoma japonicum, Schistosoma mansoni and Schistosoma hematobium), and clonorchiasis and opisthorchiasis due to the liver flukes, Clonorchis sinensis/Opisthorchis viverrini (approval of this indication was based on studies in which the two species were not differentiated).
D. **Cabometyx® (cabozantinib tablets)** Exelixis – New indication for patients with hepatocellular carcinoma who have been previously treated with Nexavar® (sorafenib tablets).
E. **Docetaxel injection for intravenous use (formerly Docefrez®)** Sun Pharma – New indications: for use in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-positive breast cancer; for use in combination with cisplatin and fluorouracil for the treatment of patients with advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for advanced disease; and for use in combination with cisplatin and fluorouracil for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.
F. **Dyanavel™ XR (amphetamine extended-release oral suspension)** Tris – Expanded age indication to include adults. Dyanavel XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder in patients ≥ 6 years of age.
G. **Flector® (diclofenac epolamine topical system)** Pfizer – Expanded age indication to include pediatric patients. Flector is now indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions in adults and pediatric patients ≥ 6 years of age.
H. **Imbruvica® (ibrutinib capsules and tablets)** Pharmacyclics/Janssen – Expanded indication for use in combination with Gazyva® (obinutuzumab injection for intravenous use) for adult patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). Imbruvica is indicated for the treatment of adult patients with CLL/SLL. Previously, Imbruvica was only for use as a single agent or in combination with bendamustine and rituximab for CLL/SLL).
I. **Keytruda® (pembrolizumab injection for intravenous use)** Merck – New indication for the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection.
J. **Kisqali® Femara® Co-Pack (ribociclib tablets; letrozole tablets)** Novartis – Expanded patient population to include pre/perimenopausal women. Kisqali Femara Co-Pack is now indicated as initial endocrine-based therapy for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2), advanced or metastatic breast cancer.
K. **Lonsurf® (trifluridine and tipiracil tablets)** Taiho Oncology – New indication for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, human epidermal growth factor receptor 2 (HER2)/neu-targeted therapy.
L. **Osphena® (ospemifene tablets)** Shionogi/Duchesnay – New indication for the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.
M. **Soliqua® (insulin glargine and lixisenatide injection)** Sanofi – Expanded indication to include patients uncontrolled on oral antidiabetic medicines. Soliqua is now indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

N. **Uloric® (febuxostat tablet)** Takeda – Restriction of indication due to the results of a cardiovascular safety study. Uloric is now indicated for the chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable.

O. **Vfend® (voriconazole powder for oral suspension)** Pfizer – Expanded age indication to include patients 2 years to < 12 years of age. Vfend is indicated in adults and pediatric patients (≥ 2 years of age) for the treatment of invasive apergillosis; candidemia in non-neutropenic patients and the following Candida infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and wounds; esophageal candidiasis; and serious fungal infections caused by Scedosporium apiospermum (asexual form of Pseudallescheria boydii) and Fusarium spp. including Fusarium solani, in patients intolerant of, or refractory to, other therapy.

P. **Xultophy® (insulin degludec and liraglutide injection for subcutaneous use)** Novo Nordisk – Expanded indication to include patients uncontrolled on oral antidiabetic medicines. Xultophy is now indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.