EXPRESS SCRIPTS®

Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
March 24, 2018

New Drug Evaluations

The Committee reviewed the following new drugs.

A. **Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide tablets)** Gilead
B. **Erleada™ (apalutamide tablets)** Janssen Pharmaceutical Companies
C. **Ilumya™ (tildrakizumab-asmn injection for subcutaneous use)** Merck
D. **Lutathera® (lutetium Lu 177 dotatate injection for intravenous use)** Advanced Accelerator Applications
E. **Makena® SC (hydroxyprogesterone caproate injection for subcutaneous use)** AMAG Pharmaceuticals
F. **Rhopressa® (netarsudil ophthalmic solution 0.02%)** Aerie Pharmaceuticals, Inc.
G. **Symdeko™ (tezacaftor/ivacaftor and ivacaftor tablets)** Vertex
H. **Trogarzo™ (ibalizumab-uiyk injection for intravenous use)** Thera Technologies
I. **Xepi™ (ozenoxacin cream 1%)** Medimetriks Pharmaceuticals

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

A. **Apadaz™ (benzhydrocodone and acetaminophen tablets)** Kempharm
B. **Bortezomib for injection for intravenous use** Fresenius Kabi
C. **Cimduo™ (lamivudine 300 mg and tenofovir disoproxil fumarate 300 mg tablets)** Matrix Laboratories
D. **Firvanq™ (vancomycin hydrochloride for oral solution)** CutisPharma
E. **Imbruvica® (ibrutinib tablets)** Pharmacyclics/Janssen
F. **(Metoprolol succinate extended-release capsules)** Sun Pharmaceutical
G. **Osmolex ER™ (amantadine extended-release tablets)** Osmotica
H. **Symfi Lo™ (efavirenz 400 mg, lamivudine 300 mg, and tenofovir disoproxil fumarate 300 mg tablets)** Mylan
I. **TriVisc™ (sodium hyaluronate injection)** OrthogenRx
J. **ZTlido™ (lidocaine topical system 1.8%)** Sorrento/Scilex

New Biosimilars

The Committee reviewed the following new biosimilars.

A. **Mvasi™ (bevacizumab-awwb solution for intravenous infusion)** Amgen
B. **Ogivri™ (trastuzumab-dkst for injection for intravenous use)** Mylan

New Indications for Existing Products

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

A. **Feraheme® (ferumoxytol injection for intravenous use)** AMAG Pharmaceuticals – New indication for the treatment of iron deficiency anemia in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron.
B. **Fluarix® Quadrivalent (influenza vaccine)** GlaxoSmithKline – The agent received an expanded age indication for people ≥ 6 months of age. Fluarix Quadrivalent is indicated for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine; it is approved for use in persons ≥ 6 months of age.
C. **Gilotrif® (afatinib tablets)** Boehringer Ingelheim – Expanded indication for the first-line treatment of patients with metastatic non-small cell lung cancer whose tumors have non-resistant epidermal growth factor receptor mutations as detected by a Food and Drug Administration-approved test.
D. **Imfinzi® (durvalumab injection for intravenous use)** AstraZeneca – New indication for the treatment of patients with unresectable Stage III non-small cell lung cancer whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
E. **Latuda® (lurasidone hydrochloride tablets)** Sunovion – Expanded age indication as monotherapy for the treatment of children and adolescents 10 years to 17 years of age with major depressive episodes associated with bipolar I disorder (bipolar depression).
F. **Luzu™ (luliconazole cream, 1% for topical use)** Medicis – Expanded age indication for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms *Trichophyton rubrum* and *Epidermophyton floccosum*, in patients ≥ 12 years of age. Previously, Luzu was indicated for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms *T. rub*rum and *E. floccosum*, in patients ≥ 18 years of age.
G. **Lynparza® (olaparib tablets)** AstraZeneca/Merck – New indication for use in patients with deleterious or suspected deleterious germline BRCA-mutated, human epidermal growth factor receptor 2-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting.
H. **Norditropin® (somatropin injection, for subcutaneous use)** Novo Nordisk – New indication for the treatment of pediatric patients with idiopathic short stature, height standard deviation score < -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range.
I. **Norditropin® (somatropin injection, for subcutaneous use)** Novo Nordisk – New indication for the treatment of pediatric patients with growth failure due to Prader-Willi syndrome.
J. **Trisenox® (arsenic trioxide injection)** Teva – New indication for use in combination with tretinoin for treatment of adults with newly-diagnosed low-risk acute promyelocytic leukemia (APL) whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression.
K. **Trulance® (plecanatide tablets)** Synergy – New indication for the treatment of irritable bowel syndrome with constipation in adults.
L. **Verzenio™ (abemaciclib tablets)** Lilly – New indication in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer.
M. **Zomacton® (somatropin for injection for subcutaneous use)** Ferring – New indication for the replacement of growth hormone in adults with growth hormone deficiency.
N. **Zytiga® (abiraterone acetate tablets)** Janssen – New indication in combination with prednisone for the treatment of patients with metastatic high-risk castration-sensitive prostate cancer.

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