Express Scripts
By EVERNORTH

Express Scripts
Pharmacy and Therapeutics Committee
Proceedings
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New Drug Evaluations

The Committee reviewed the following new drugs:

A. **Ctexli™ (chenodiol tablets)** Mirum
B. **Datroway® (datopotamab deruxtecan-dlnk intravenous infusion)** Daiichi Sankyo
C. **Gomekli™ (mirdametinib capsule and tablets for oral suspension)** SpringWorks Therapeutics
D. **Grafapex™ (treosulfan intravenous infusion)** Medexus
E. **Journavx™ (suzetrigine tablets)** Vertex
F. **Miudella® (copper intrauterine system)** Sebela
G. **Onapgo™ (apomorphine subcutaneous infusion)** Supernus
H. **Romvimza™ (vimseltinib capsules)** Deciphera/Ono Pharma
I. **Trodelvy® (sacituzumab govitecan-hziy intravenous infusion)** Gilead
J. **Vimkunya™ (chikungunya vaccine [recombinant] intramuscular injection)** Bavarian Nordic A/S

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions:

A. **Brynovin™ (sitagliptin oral solution)** Azurity
B. **Evrysdi® (risdiplam tablets)** Genentech
C. **Inzirqo™ (hydrochlorothiazide oral suspension)** ANI Pharmaceuticals
D. **Nilotinib capsules** (Cipla)
E. **Penmenvy™ (meningococcal groups A, B, C, W and Y vaccine)** GlaxoSmithKline
F. **Symbravo® (meloxicam and rizatriptan tablets)** Axsome Therapeutics

New Indications for Existing Products

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

A. **Adcetris® (brentuximab vedotin intravenous infusion)** Pfizer – New indication for use in combination with lenalidomide and a rituximab product for the treatment of relapsed or refractory large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma, after two or more lines of systemic therapy in adults who are not eligible for autologous hematopoietic stem cell transplantation (HSCT) or chimeric antigen receptor T-cell therapy.
B. **Calquence® (acalabrutinib tablets)** AstraZeneca – New indication for use in combination with bendamustine and rituximab for the treatment of previously untreated mantle cell lymphoma in adults who are ineligible for autologous HSCT.
C. **Enhertu® (fam-trastuzumab deruxtecan-nxki intravenous infusion)** AstraZeneca/Daiichi Sankyo – New indication for the treatment of unresectable or

metastatic hormone receptor-positive human epidermal growth factor receptor 2 (HER2)-low (immunohistochemistry [IHC] 1+ or IHC 2+/in situ hybridization negative) or HER2-ultralow (IHC 0 with membrane staining) breast cancer in adults, as determined by a Food and Drug Administration (FDA)-approved test, that has progressed on one or more endocrine therapies in the metastatic setting.

D. Ezallor Sprinkle™ (rosuvastatin capsules) Sun – Revised indication with regard to major adverse cardiovascular (CV) events endpoints. Ezallor Sprinkle is now indicated to reduce the risk of major adverse CV events (CV death, nonfatal myocardial infarction, nonfatal stroke, or an arterial revascularization procedure) in adults without established coronary heart disease who are at increased risk of CV disease based on age, high-sensitivity C-reactive protein ≥ 2 mg/L, and at least one additional CV risk factor.

E. Furoscix® (furosemide subcutaneous injection) scPharmaceuticals – Expanded indication to include the treatment of edema in patients with chronic kidney disease, including nephrotic syndrome. Furoscix is now indicated for the treatment of edema in adults with chronic heart failure or chronic kidney disease, including the nephrotic syndrome.

F. Lumakras® (sotorasib tablets) Amgen – New indication in combination with Vectibix® (panitumumab intravenous infusion) for the treatment of Kirsten RAt Sarcoma virus (KRAS) G12C-mutated metastatic colorectal cancer, as determined by an FDA-approved test, in adults who have received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy.

G. Neffy® (epinephrine nasal spray) ARS Pharmaceuticals – Expanded age indication for pediatric patients ≥ 4 years of age who weigh 15 kg to < 30 kg, for emergency treatment of Type I allergic reactions. Neffy is now indicated for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult and pediatric patients ≥ 4 years of age who weigh ≥ 15 kg.

H. Odactra® (house mite allergen extract sublingual tablets) ALK-Abellò – Expanded age indication to include pediatric patients 5 years to < 12 years of age. Odactra is now indicated as immunotherapy for the treatment of house dust mite-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive in vitro testing for immunoglobulin E antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or by positive skin testing to licensed house dust mite allergen extracts in individuals 5 years through 65 years of age.

I. Odefsey® (emtricitabine, rilpivirine, and tenofovir alafenamide tablets) Gilead Sciences – Expanded pediatric weight indication to include patients ≥ 25 kg to < 35 kg. Odefsey is now indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least ≥ 25 kg as initial therapy in those with no antiretroviral treatment history with HIV-1 RNA ≤ 100,000 copies/mL or to replace a stable antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA < 50 copies/mL) for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Odefsey.

J. Ozempic® (semaglutide subcutaneous injection) Novo Nordisk – New indication to reduce the risk of sustained estimated glomerular filtration rate decline, end-stage kidney disease, and CV death in adults with type 2 diabetes mellitus and chronic kidney disease (CKD).

K. Soliris® (eculizumab intravenous infusion) Alexion – Expanded age indication for the treatment of generalized myasthenia gravis (gMG) in pediatric patients ≥ 6 years of age. Soliris is now indicated for the treatment of gMG in adults and pediatric patients ≥ 6 years of age who are anti-acetylcholine receptor antibody positive.

L. Spravato® (esketamine nasal spray) Janssen – Expanded indication to include monotherapy. Spravato is now indicated for the treatment of treatment-resistant depression in adults as monotherapy or in conjunction with an oral antidepressant.

M. Sublocade® (buprenorphine extended-release subcutaneous injection) Indivior – Revised indication for use in patients who have initiated treatment with a single dose of a

transmucosal buprenorphine product (i.e., rapid initiation protocol). Sublocade is now indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.

N. Susvimo® (ranibizumab ocular implant) Genentech/Roche – New indication for the treatment of diabetic macular edema in patients who have previously responded to at least two intravitreal injections of a vascular endothelial growth factor inhibitor medication.

O. Tevimbra® (tislelizumab-jsgr intravenous infusion) Beigene – New indication for use in combination with platinum-containing chemotherapy, for the first-line treatment of unresectable or metastatic esophageal squamous cell carcinoma in adults whose tumors express programmed death-ligand 1 (≥ 1).

P. Tremfya® (guselkumab intravenous infusion or subcutaneous injection) Janssen – New indication for the treatment of moderately to severely active Crohn's disease in adults.

Q. Tyenne® (tocilizumab-aazg intravenous or subcutaneous injection) Fresenius Kabi – New indication for the treatment of chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients ≥ 2 years of age. Also, Tyenne received a new indication for the treatment of coronavirus disease 2019 in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.

R. Vectibix® (panitumumab intravenous infusion) Amgen – New indication for use in combination with Lumakras® (sotorasib tablets), for the treatment of KRAS G12C-mutated metastatic colorectal cancer, as determined by an FDA-approved test, in adults who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

S. Xromi® (hydroxyurea oral solution) Nova – Expanded age indication to include pediatric patients ≥ 2 years of age. Xromi is now indicated to reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients ≥ 6 months of age with sickle cell anemia with recurrent moderate to severe painful crises.

New Biosimilars

The Committee reviewed the following new biosimilars:

A. Avtozma® (tocilizumab-anoh intravenous infusion) Celltrion
B. Avtozma® (tocilizumab-anoh subcutaneous injection) Celltrion
C. Merilog™ (insulin aspart-szjj subcutaneous injection) sanofi-aventis
D. Omlyclo® (omalizumab-igec subcutaneous injection) Celltrion
E. Ospomyv™ (denosumab-dssb subcutaneous injection) Samsung Bioepsis
F. Osenvelt® (denosumab-bmwo subcutaneous injection) Celltrion
G. Stoboclo® (denosumab-bmwo subcutaneous injection) Celltrion
H. Xbryk™ (denosumab-dssb subcutaneous injection) Samsung Bioepsis