EXPRESS SCRIPTS®

Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
May 13, 2021

New Drug Evaluations

The Committee reviewed the following new drugs:

A. **Abecma™ (idecabtagene vicleucel suspension for intravenous infusion)** Bristol-Myers Squibb/Celgene and bluebird bio
B. **Fotivda® (tivozanib capsules)** AVEO
C. **Jemperli™ (dostarlimab intravenous infusion)** GlaxoSmithKline
D. **Nulibry™ (fosdenopterin intravenous infusion)** Origin Biosciences
E. **Ponvory™ (ponesimod tablets)** Janssen
F. **Qelbree™ (viloxazine extended-release capsules)** Supernus
G. **Zegalogue® (dasiglucagon subcutaneous injection)** Zealand

New Clinical Line Extensions

The Committee reviewed the following new clinical line extension:

A. **Azstarys™ (serdexmethylphenidate and dexmethylphenidate capsules)** Corium
B. **Myrbetriq® Granules (mirabegraon for extended-release oral suspension)** Astellas
C. **Roszet™ (rosuvastatin and ezetimibe tablets)** Althera Pharmaceuticals

New Indications for Existing Products

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

A. **Arcalyst® (rilonacept injection for subcutaneous use) Kiniksa Pharmaceuticals/Regeneron** – New indication for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children ≥ 12 years of age.
B. **BeneFIX® (coagulation Factor IX [recombinant] injection for intravenous use) Wyeth** – Removal of indication for routine prophylaxis to reduce the frequency of bleeding episodes in children (< 16 years of age) with hemophilia B.
C. **Blincyto® (blinatumomab for injection for intravenous use) Amgen** – Revised indication to add CD-19 positive to the indication for minimal residual disease positive acute lymphoblastic leukemia (ALL). Blincyto is now indicated for the treatment of CD-19 positive B-cell precursor ALL in first or second complete remission with minimal residual disease ≥ 0.1% in adults and children.
D. **Diastat® (diazepam rectal gel) Bausch Health** – Reworded indication for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy ≥ 2 years of age.
E. **Diovan® (valsartan tablets) Novartis** – Expanded age indication to include pediatric patients 1 to less than 6 years of age. Diovan is now indicated for the treatment of hypertension, to lower blood pressure in adults and pediatric patients ≥ 1 year of age.

F. **Evekeo ODT® (amphetamine sulfate orally disintegrating tablets) Arbor** – Expanded age indication to include patients 3 to 5 years of age. Evekeo ODT is now indicated for the treatment of attention deficit hyperactivity disorder in pediatric patients 3 to 17 years of age.
G. **Fabrazyme® (agalsidase beta injection for intravenous use) Genzyme** – Expanded age indication to include patients 2 to < 8 years of age. Fabrazyme is now indicated for the treatment of confirmed Fabry disease in adult and pediatric patients ≥ 2 years of age.
H. **Ixinity® (coagulation Factor IX [recombinant] injection for intravenous use) Aptevo BioTherapeutics** – Removal of indication for routine prophylaxis to reduce the frequency of bleeding episodes in pediatric patients ≥ 12 years of age with hemophilia B.
I. **Keytruda® (pembrolizumab injection for intravenous use) Merck** – Expanded indication for the treatment of locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) [tumors with epicenter 1 to 5 cm above the GEJ] carcinoma that is not amendable to surgical resection or definitive chemoradiation, in combination with platinum- and fluoropyrimidine-based chemotherapy or as a single agent after one or more prior lines of systemic therapy for patients with tumors of squamous cell histology that express programmed death-ligand 1 [Combined Positive Score ≥ 10] as determined by an FDA-approved test.
J. **Keytruda® (pembrolizumab injection for intravenous use) Merck** – Removal of indication as monotherapy for metastatic small cell lung cancer with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy.
K. **Lupron Depot-Ped® (leuprolide acetate for depot suspension for intramuscular use) AbbVie** – Expanded age indication to include patients 1 to less than 2 years of age. Lupron Depot-Ped is indicated for the treatment of pediatric patients with central precocious puberty.
L. **Methotrexate injection for intravenous, intramuscular, subcutaneous, or intrathecal use (Hospira)** – Revisions to indications to remove the lung cancer and hydatidiform mole indications; substitution of the currently accepted clinical term "gestational trophoblastic neoplasia" for the previously approved indications of "gestational choriocarcinoma" and "chorioadenoma destruens"; and modifications to broaden the lymphoma indication to non-Hodgkin lymphoma to include all histologic subsets (previous indications were for the treatment of advanced non-Hodgkin lymphoma, Burkitt lymphoma, and mycosis fungoides).
M. **Myrbetriq® (mirabegron extended-release tablets) Astellas** – New pediatric indication for the treatment of neurogenic detrusor overactivity in pediatric patients ≥ 3 years of age and weighing ≥ 35 kg.
N. **Opdivo® (nivolumab injection for intravenous use) Bristol Myers Squibb** – New indication for the treatment of advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma in combination with fluoropyrimidine- and platinum-containing chemotherapy.
O. **Opdivo® (nivolumab injection for intravenous use) Bristol Myers Squibb** – Removal of 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.
P. **Praluent® (alirocumab injection for subcutaneous use) Regeneron** – New indication for use as an adjunct to other low density lipoprotein cholesterol (LDL-C)-lowering therapies for the treatment of homozygous familial hypercholesterolemia in adults to reduce LDL-C.
Q. **Ragwitek® (short ragweed pollen allergen extract tablet for sublingual use) ALK-Abelló** – Expanded age indication to include children and adolescents 5 to 17 years of age. Ragwitek is now indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific immunoglobulin E antibodies for short ragweed pollen in persons 5 through 65 years of age.
R. **Sarclisa® (isatuximab-irfc injection for intravenous use) sanofi-aventis** – New indication for use in combination with Kyprolis® (carfilzomib injection) and dexamethasone, for the treatment of relapsed or refractory multiple myeloma in adults who have received one to three prior lines of therapy.
S. **Tecentriq® (atezolizumab injection for intravenous use) Genentech** – Removal of indication for the treatment of metastatic urothelial carcinoma in patients previously treated with

chemotherapy (have disease progression during or following any platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant chemotherapy).

T. Trodelvy® (sacituzumab govitecan-hziy for injection for intravenous use) Immunomedics – New indication for the treatment of locally advanced or metastatic urothelial cancer in adults who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 or programmed death-ligand 1 inhibitor.

U. Tyvaso® (treprostinil inhalation solution) United Therapeutics – New indication for the treatment of patients with pulmonary hypertension associated with interstitial lung disease; World Health Organization [WHO] Group 3) to improve exercise ability.

V. Vyxeos® (daunorubicin and cytarabine liposome for injection for intravenous use) Jazz Pharmaceuticals – Expanded age indication to include pediatric patients ≥ 1 year of age. Vyxeos is now indicated for the treatment of newly-diagnosed therapy-related acute myeloid leukemia or acute myeloid leukemia with myelodysplasia-related changes in adults and pediatric patients ≥ 1 year of age.

W. Yescarta® (axicabtagene ciloleucel suspension for intravenous infusion) Kite/Gilead – New indication for the treatment of relapsed or refractory follicular lymphoma in adults after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate.