Express Scripts, Inc.
Pharmacy and Therapeutics Committee
Proceedings
September 9, 2021

New Drug Evaluations

The Committee reviewed the following new drugs:

A. **Comirnaty™ (COVID-19 vaccine suspension for intramuscular injection)** Pfizer and BioNTech
B. **Kerendia™ (finerenone tablets**) Bayer
C. **Nexviazyme™ (avalglucosidase alfa-ngpt intravenous infusion)** Genzyme
D. **Rezurock™ (belumosudil tablets)** Kadmon Pharmaceuticals
E. **Rylaze™ (asparaginase erwinia chrysanthemi [recombinant]-rywn intramuscular injection)** Jazz Pharmaceuticals
F. **Saphnelo™ (anifrolumab-fnia intravenous infusion)** AstraZeneca
G. **Skytrofa® (lonapegsomatropin-tcgd subcutaneous injection)** Ascendis Pharma
H. **Welireg™ (belzutifan tablets)** Merck

New Clinical Line Extension

The Committee reviewed the following new clinical line extension:

A. **Twyneo® (tretinoin/benzoyl peroxide cream, 0.1%/0.3%)** Galderma/Sol-Gel Technologies

New Indications for Existing Products

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

A. **ArmonAir® RespiClick® (fluticasone propionate inhalation powder)** Teva – Expanded age indication to include patients 4 to 11 years of age. ArmonAir RespiClick is now indicated for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients ≥ 4 years of age.
B. **Bydureon® (exenatide extended-release subcutaneous injection)** AstraZeneca – Expanded age indication to be used in pediatric patients ≥ 10 years of age with type 2 diabetes. Bydureon is now indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients ≥ 10 years of age with type 2 diabetes mellitus.
C. **Bydureon® BCise® (exenatide extended-release subcutaneous injectable suspension)** AstraZeneca – Expanded age indication to be used in pediatric patients ≥ 10 years of age with type 2 diabetes. Bydureon BCise is now indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients ≥ 10 years of age with type 2 diabetes mellitus.
D. **Darzalex Faspro® (daratumumab and hyaluronidase-fihj subcutaneous injection)** Janssen Biotech – Expanded indication for the treatment of multiple myeloma in combination with Pomalyst® (pomalidomide capsules) and dexamethasone in patients who have received at least one prior line of therapy including Revlimid® (lenalidomide capsules) and a proteosome inhibitor.
E. **Drizalma Sprinkle™ (duloxetine delayed-release capsules)** Sun Pharma – New indication for the treatment of fibromyalgia in adults.

F. **Evomela® (melphalan injection)** Acrotech Biopharma – Removal of indication for the palliative treatment of multiple myeloma in patients for whom oral therapy is not appropriate.
G. **Keytruda® (pembrolizumab intravenous infusion)** Merck – Expanded indication for use as monotherapy for the treatment of locally advanced cutaneous squamous cell carcinoma that is not curable by surgery or radiation.
H. **Keytruda® (pembrolizumab intravenous infusion)** Merck – New indication for the treatment of high-risk early-stage triple-negative breast cancer in combination with chemotherapy as neoadjuvant treatment and then continued as a single agent as adjuvant treatment after surgery in adults.
I. **Keytruda® (pembrolizumab intravenous infusion)** Merck – New indication for use in combination with Lenvima® (lenvatinib capsules), for the first-line treatment of advanced renal cell carcinoma in adults.
J. **Jardiance® (empagliflozin tablets)** Boehringer Ingelheim – New indication to reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction.
K. **Jemperli™ (dostarlimab-gxly intravenous infusion)** GlaxoSmithKline/AnaptysBio – New indication for the treatment of adult patients with mismatch repair deficient recurrent or advanced solid tumors, as determined by an Food and Drug Administration (FDA)-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.
L. **Lenvima® (lenvatinib capsules)** Eisai – New indication for use in combination with Keytruda® (pembrolizumab injection), for the first-line treatment of advanced renal cell carcinoma in adults.
M. **Lexette™ (halobetasol propionate topical foam)** Mayne Pharma – Expanded age indication to include pediatric patients 12 to 17 years of age. Lexette is now indicated for the topical treatment of plaque psoriasis in patients ≥ 12 years of age.
N. **Mirena® (levonorgestrel-releasing intrauterine system)** Bayer – Extended duration of use for up to 7 years. Mirena is now indicated for prevention of pregnancy for up to 7 years; replace after the end of the seventh year.
O. **Nucala® (mepolizumab subcutaneous injection)** GlaxoSmithKline – New indication as an add-on maintenance treatment of chronic rhinosinusitis with nasal polyps in patients ≥ 18 years of age with inadequate response to nasal corticosteroids.
P. **Octagam® (immune globulin intravenous [human], 10%)** Octapharma – New indication for the treatment of dermatomyositis in adults.
Q. **Opdivo® (nivolumab intravenous infusion)** Bristol Myers Squibb – New indication for the adjuvant treatment of patients with urothelial carcinoma who are at high risk of recurrence after undergoing radical resection of urothelial carcinoma.
R. **Opdivo® (nivolumab intravenous infusion**) Bristol Myers Squibb – Removal of indication as a single agent, for the treatment of hepatocellular carcinoma in patients who have been previously treated with Nexavar® (sorafenib tablets).
S. **Padcev® (enfortumab vedotin-ejfv intravenous infusion)** Astellas/Seagen – New indication for locally advanced or metastatic urothelial cancer in adults who are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.
T. **Prograf® (tacrolimus capsules) and Prograf® Granules (tacrolimus oral suspension)** Astellas – Expanded indication for the prevention of rejection in lung transplantation. Prograf is now indicated for the prophylaxis of organ rejection, in adult and pediatric patients receiving allogeneic kidney transplant, liver transplant, heart transplant, or lung transplant in combination with other immunosuppressants.
U. **Shingrix® (zoster vaccine recombinant, adjuvanted)** GlaxoSmithKline – Expanded indication for the prevention of herpes zoster (shingles) in adults ≥ 18 years of age who are or will be at increased risk of herpes zoster due to immunodeficiency or immunosuppression caused by known disease or therapy.
V. **Solosec® (secnidazole oral granules)** Lupin – New indication for the treatment of trichomoniasis caused by Trichomonas vaginalis in adults. Because trichomoniasis is a sexually transmitted disease with potentially serious sequelae, treat partners of infected patients simultaneously in order to prevent reinfection.

W. Tibsovo® (ivosidenib tablets) Servier – New indication for the treatment of previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 mutation as detected by an FDA-approved test in adults.

X. Xarelto® (rivaroxaban tablets) Janssen – Expanded indication for use in combination with aspirin, to reduce the risk of major thrombotic vascular events (myocardial infarction, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in patients with peripheral artery disease (PAD), including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic PAD.

Y. Xywav™ (calcium, magnesium, potassium, and sodium oxybates oral solution) Jazz – New indication for the treatment of idiopathic hypersomnia in adults.