Express Scripts® Pharmacy Benefit Services
Pharmacy and Therapeutics (P&T) Committee
Proceedings
July 19, 2025

New Drug Evaluations

The Committee reviewed the following new drugs:

A. **Andembry® (garadacimab subcutaneous injection)** CSL Behring
B. **Avmapki™ Fakzynja™ Co-Pack (avutometinib capsules; defactinib tablets [co-packaged])** Verastem
C. **Ekterly® (sebetralstat tablets)** KalVista
D. **Emrelis™ (telisotuzumab vedotin-tllv intravenous infusion)** AbbVie
E. **Enflonsia™ (clesrovimab-cfor intramuscular injection)** Merck
F. **Harliku™ (nitisinone 2 mg tablets)** Cycle
G. **Ibtrozi™ (taletrectinib capsules)** Nuvation Bio
H. **Nuvaxovid® (COVID-19 vaccine [adjuvanted] intramuscular injection)** Novavax
I. **Penpulimab-kcqx intravenous infusion** - Akeso
J. **Tryptyr® (acoltremon 0.003% ophthalmic solution)** Alcon
K. **Yeztugo® (lenacapavir tablets and subcutaneous injection)** Gilead
L. **Yutrepia™ (treprostinil inhalation powder)** Liquidia
M. **Zevaskyn™ (prademagene zamikeracel gene-modified cellular sheets)** Abeona
N. **Zusduri™ (mitomycin intravesical solution)** UroGen

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions:

A. **Arynta™ (lisdexamfetamine dimesylate oral solution)** Azurity
B. **Brekiya® (dihydroergotamine mesylate subcutaneous injection)** Amneal
C. **Brukinsa® (zanubrutinib tablets)** BeOne Medicines
D. **Gammagard Liquid ERC® (immune globulin infusion [human] 10% solution for intravenous or subcutaneous use)** Takeda
E. **Khindivi® (hydrocortisone oral solution)** Eton
F. **mNexspike (COVID-19 vaccine [mRNA] intramuscular injection)** Moderna
G. **Widaplik™ (telmisartan, amlodipine and indapamide tablets)** George Medicines

New Indication for Existing Products

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

A. **Benlysta® (belimumab subcutaneous injection)** GlaxoSmithKline – Expanded age indication for Benlysta subcutaneous (SC) to include patients 5 years to 17 years of age for the treatment of active lupus nephritis. Benlysta SC is now indicated for the treatment of active lupus nephritis in patients ≥ 5 years of age who are receiving standard therapy.

B. **Datroway® (datopotamab deruxtecan-dlnk intravenous infusion)** Daiichi Sankyo – New indication for the treatment of locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer in adults who have received prior EGFR-directed therapy and platinum-based chemotherapy.
C. **Descovy® (emtricitabine and tenofovir alafenamide tablets)** Gilead – Expanded indication to expand the use of Descovy in pediatric patients with human immunodeficiency virus type 1 (HIV-1) in combination with darunavir and cobicistat. Descovy is now indicated for the treatment of HIV-1 infection in pediatric patients weighing ≥ 14 kg to < 35 kg in combination with other antiretrovirals (ARVs), including darunavir and cobicistat but not other protease inhibitors that require a cytochrome P450 (CYP)3A inhibitor.
D. **Dupixent® (dupilumab subcutaneous injection)** Sanofi/Regeneron – New indication for the treatment of bullous pemphigoid in adults.
E. **Fenoglide® (fenofibrate tablets)** Salix**; Fibricor® (fenofibric acid tablets)** Athena Bio-Science**; Lipofen® (fenofibrate capsules)** ANI**; Tricor® (fenofibrate tablets)** AbbVie**, and Trilipix® (fenofibric acid delayed-release capsules)** AbbVie – Revised indication to address new clinical data available for the fenofibrate class and to conform with current labeling guidance. These products are now indicated as adjunctive therapy to diet to reduce elevated low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia when use of recommended LDL-C lowering therapy is not possible. Also, there was a revised (reworded) indication to address new clinical data available for the fenofibrate class and to conform with current labeling guidance. These products are now indicated as adjunctive therapy to diet to reduce triglyceride levels in adults with severe hypertriglyceridemia (triglycerides ≥ 500 mg/dL).
F. **Gamifant® (emapalumab-lzsg intravenous infusion)** Sobi/Swedish Orphan Biovitrum – New indication for treatment of hemophagocytic lymphohistiocytosis/macrophage activation syndrome in known or suspected Still's disease, including systemic juvenile idiopathic arthritis, in adult and pediatric (newborn and older) patients with an inadequate response or intolerance to glucocorticoids.
G. **Jivi® (antihemophilic factor [recombinant], PEGylated-aucl intravenous infusion)** Bayer – Expanded age indication to include pediatric patients 7 years to 12 years of age. Jivi is now indicated for use in previously treated adults and adolescents ≥ 7 years of age with hemophilia A (congenital Factor VIII deficiency) for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.
H. **Keytruda® (pembrolizumab intravenous infusion)** Merck – New indication for the treatment of resectable locally advanced head and neck squamous cell carcinoma in adults whose tumors express programmed death-ligand 1 (PD-L1) [combined positive score {CPS} ≥ 1] as determined by an Food and Drug Administration (FDA)-approved test, as a single agent as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy with or without cisplatin and then as a single agent. Keytruda also received a revised indication to reflect the gastric or gastroesophageal junction (GEJ) adenocarcinoma population (i.e., PD-L1 [CPS ≥ 1]) with a favorable risk-benefit assessment. Keytruda is now indicated for use in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of locally advanced unresectable or metastatic human epidermal growth factor receptor 2-negative GEJ adenocarcinoma in adults whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test. Keytruda also was given a revised indication to reflect the esophageal or GEJ carcinoma population (i.e., PD-L1 [CPS ≥1]) with a favorable risk-benefit assessment. Keytruda is now indicated for use in locally advanced or metastatic esophageal or GEJ (tumors with epicenter 1 cm to 5 cm above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation in combination

with platinum- and fluoropyrimidine-based chemotherapy for patients with tumors that express PD-L1 (CPS ≥ 1). Keytruda also received another revised indication to clarify one of the cervical cancer indications without expanding the indicated population. Keytruda is now indicated for use in combination with chemoradiotherapy for the treatment of locally advanced cervical cancer involving the lower third of the vagina, with or without extension to pelvic sidewall, or hydronephrosis/non-functioning kidney, or spread to adjacent pelvic organs (FIGO 2014 Stage III-IVA).

I. **Mavyret® (glecaprevir/pibrentasvir tablets and oral pellets)** AbbVie – Expanded indication to include the acute treatment of hepatitis C virus (HCV). Mavyret is now indicated for the treatment of acute or chronic HCV genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) in adults and pediatric patients ≥ 3 years of age.
J. **MenQuadfi® (meningococcal [Groups A, C, Y, W] conjugate vaccine)** Sanofi – Expanded age indication to include pediatric patients 6 weeks through 23 months of age. MenQuadfi is now indicated for active immunization for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y in individuals ≥ 6 weeks of age.
K. **mResvia® (respiratory syncytial virus vaccine intramuscular injection)** Moderna – New indication for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 18 years through 59 years of age who are at increased risk for LRTD caused by RSV.
L. **Monjuvi® (tafasitamab-cxix intravenous infusion)** Incyte – New indication for use in combination with lenalidomide and rituximab, for the treatment of relapsed or refractory follicular lymphoma in adults.
M. **Nubeqa® (darolutamide tablets)** Bayer – New indication for the treatment of metastatic castration-sensitive prostate cancer (CSPC) in adults. Nubeqa also received a revised indication to update terminology used in the indication from "hormone-sensitive" to "castration-sensitive" prostate cancer. Nubeqa is now indicated for the treatment of metastatic CSPC in combination with docetaxel in adults.
N. **Nucala® (mepolizumab subcutaneous injection)** GlaxoSmithKline – New indication for the add-on maintenance treatment of inadequately controlled chronic obstructive pulmonary disease and an eosinophilic phenotype in adults.
O. **Opdivo® (nivolumab intravenous infusion)** Bristol Myers Squibb – Revised indication to reflect the unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) population (i.e., PD-L1 [CPS ≥ 1]) with a favorable risk-benefit assessment. Opdivo is now indicated for use in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of unresectable advanced or metastatic ESCC in adults whose tumors express PD-L1 (≥ 1). Opdivo was given another revised indication to reflect the unresectable advanced or metastatic ESCC population (i.e., PD-L1 [CPS ≥ 1]) with a favorable risk-benefit assessment. Opdivo is now indicated in combination with Yervoy® (ipilimumab injection), for the first-line treatment of unresectable advanced or metastatic ESCC in adults whose tumors express PD-L1 (≥ 1). An additional revised indication was granted to Opdivo to reflect the advanced or metastatic gastric cancer, GEJ cancer, and esophageal adenocarcinoma population (i.e., PD-L1 ≥ 1) with a favorable risk-benefit assessment. Opdivo is now indicated in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the treatment of advanced or metastatic gastric cancer, GEJ cancer, and esophageal adenocarcinoma in adults whose tumors express PD-L1 (≥ 1).
P. **Riabni™ (rituximab-arrx intravenous infusion)** Amgen – New indication for the treatment of moderate to severe pemphigus vulgaris in adults.
Q. **Ruxience™ (rituximab-pvvr intravenous infusion)** Pfizer – New indication for the treatment of moderate to severe pemphigus vulgaris in adults.

R. **Saxenda® (liraglutide subcutaneous injection)** Novo Nordisk – Revised indication to reduce body weight such that reference to specific body mass index has been removed, and rather than referencing chronic weight management the revised indication is to reduce weight and maintain weight reduction long-term. Saxenda is now indicated in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients ≥ 12 years of age with body weight > 60 kg and obesity and in adults with overweight in the presence of at least one weight-related comorbid condition.

S. **Spikevax® (coronavirus disease 2019 [COVID-19] Vaccine [mRNA] intramuscular injection)** Moderna – Expanded age indication for use in pediatric patients 6 months to < 12 years of age to prevent coronavirus disease 2019 (COVID-19). Spikevax is now indicated for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 in individuals who are ≥ 65 years of age or who are 6 months through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

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

U. **Truxima® (rituximab-abbs injection for intravenous use)** Teva – New indication for the treatment of moderate to severe pemphigus vulgaris in adults.

V. **Tybost® (cobicistat tablets)** Gilead – Expanded weight indication to include pediatric patients ≥ 14 kg to < 35 kg when used in combination with atazanavir and other ARVs, except for tenofovir alafenamide. Tybost is now indicated to increase systemic exposure of atazanavir (once daily [QD] dosing regimen) in combination with other ARVs in the treatment of human immunodeficiency virus type 1 (HIV-1) infection in pediatric patients weighing ≥ 14 kg. Tybost also received another expanded weight indication to include pediatric patients weighing ≥ 15 kg to < 40 kg when used in combination with darunavir and other antiretroviral agents. Tybost is now indicated to increase systemic exposure of darunavir (QD dosing regimen) in combination with other antiretroviral agents in the treatment of HIV-1 infection in pediatric patients weighing ≥ 15 kg.

W. **Welireg® (belzutifan tablets)** Merck – New indication for the treatment of locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma in adults and pediatric patients ≥ 12 years of age.

X. **Yervoy® (ipilimumab intravenous infusion)** Bristol Myers Squibb – Revised indication to reflect the unresectable advanced or metastatic ESCC population (i.e., PD-L1 [CPS ≥ 1]) with a favorable risk-benefit assessment. Yervoy is now indicated for use in combination with Opdivo® (nivolumab injection), for the first-line treatment of unresectable advanced or metastatic ESCC in adults whose tumors express PD-L1 (≥ 1).

Y. **Zejula® (niraparib tablets)** GlaxoSmithKline – Revised indication to narrow the indication for first-line maintenance treatment of advanced ovarian cancer to those with homologous recombination deficiency (HRD)-positive tumors only. Zejula is now indicated for the maintenance treatment of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in adults who are in a complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with HRD-positive status defined by either a deleterious or suspected deleterious BReast CAncer susceptibility gene mutation, and/or genomic instability.

Z. **Zoryve® (roflumilast 0.3% topical foam)** Arcutis Biotherapeutics – New indication for the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients ≥ 12 years of age. Zoryve 0.3% cream is also FDA approved for treatment of plaque psoriasis, including intertriginous areas, in adults and pediatric patients > 6 years of age.

AA. **Zynyz® (retifanlimab-dlwr intravenous infusion)** Incyte – New indication for use in combination with carboplatin and paclitaxel (platinum-based chemotherapy) for the first-line

treatment of inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC) in adults. Zynyz also received another new indication as a single agent for the treatment of locally recurrent or metastatic SCAC in adults with disease progression or intolerance to platinum-based chemotherapy.

New Biosimilars

The Committee reviewed the following new biosimilars:

A. **Starjemza™ (ustekinumab-hmny subcutaneous injection)** [Bio-Thera Solutions/Hikma]
B. **Starjemza™ (ustekinumab-hmny intravenous infusion)** [Bio-Thera Solutions/Hikma]