

**Express Scripts® Pharmacy Benefit Services
Pharmacy and Therapeutics (P&T) Committee
Proceedings
July 18, 2026**

New Drug Evaluations

The Committee reviewed the following new drugs:

- A. Baxfendy™ (baxdrostat tablets)** AstraZeneca
- B. Beqalzi™ (sonrotoclax tablets)** BeOne Medicines
- C. Decnupaz™ (pivekimab sunirine-pvzy intravenous infusion)** AbbVie
- D. Hepcludex® (bulevirtide-gmod subcutaneous injection)** Gilead
- E. Lumvoa™ (veligrotug-vvze intravenous infusion)** Viridian
- F. Utebzi® (tebipenem pivoxil tablets)** GlaxoSmithKline
- G. Xocova® (ensitrelvir tablets)** Shionogi
- H. Xtoro™ (finafloxacin 0.3% otic suspension)** Fonseca Biosciences

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. Afrezza® (insulin human inhalation powder)** MannKind – Expanded age indication for pediatric patients ≥ 6 years of age to improve glycemic control in patients with diabetes mellitus.
- B. Bizengri® (zenocutuzumab-zbco intravenous infusion)** Partner Therapeutics – New indication for the treatment of adults with advanced, unresectable or metastatic cholangiocarcinoma harboring a neuregulin 1 gene fusion with disease progression on or after prior systemic therapy.
- C. Capvaxie® (pneumococcal 21-valent conjugate vaccine intramuscular injection)** Merck – Expanded age indication for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 36B in pediatric patients ≥ 2 years of age through 17 years of age who are at increased risk for pneumococcal disease.
- D. Datroway® (datopotamab deruxtecan-dlnk intravenous infusion)** Daiichi Sankyo – New indication for the treatment of unresectable or metastatic triple-negative breast cancer in adults who are not candidates for programmed death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1) inhibitor therapy.
- E. Enhertu® (fam-trastuzumab deruxtecan-nxki intravenous infusion)** Daiichi Sankyo – New indications for HER2-positive early breast cancer: 1) Enhertu followed by a taxane, trastuzumab, and pertuzumab is indicated for the neoadjuvant treatment of adults with HER2-positive (IHC 3+ or ISH+) Stage II or III breast cancer as determined by a Food and Drug Administration (FDA)-authorized test; and 2) Enhertu is indicated for the adjuvant treatment of adults with HER2-positive (IHC 3+ or ISH+) breast cancer who have residual invasive disease following neoadjuvant trastuzumab (with or without pertuzumab) and taxane-based treatment.

- F. Fasenra® (benralizumab subcutaneous injection)** AstraZeneca – New indication for the treatment of patients ≥ 12 years of age with hypereosinophilic syndrome without an identifiable non-hematologic secondary cause.
- G. Hympavzi® (marstacimab-hncq subcutaneous injection)** Pfizer – Expanded indication for the routine prophylaxis to prevent or reduce with frequency of bleeding episodes in patients with hemophilia A or hemophilia B with factor VIII or factor IX inhibitors, respectively. Also, Hympavzi received an expanded pediatric age indication for patients 6 years to < 12 years of age who have hemophilia A or B.
- H. Ibrance® (palbociclib tablets and capsules)** Pfizer – New indication for Ibrance in combination with trastuzumab, with or without Perjeta (pertuzumab IV infusion), and endocrine therapy for the maintenance treatment of adults with hormone receptor (HR)-positive, HER2-positive locally advanced or metastatic breast cancer following induction treatment.
- I. Imfinzi® (durvalumab intravenous infusion)** AstraZeneca – New indication for use in combination with Bacillus Calmette-Guerin (BCG) for the treatment of BCG-naïve, high-risk non-muscle-invasive bladder cancer in adults.
- J. Inqovi® (decitabine-cedazuridine tablets)** Taiho Oncology – New indication for use in combination with Venclexta (venetoclax tablets) for the treatment of newly diagnosed acute myeloid leukemia in adults ≥ 75 years of age, or who have comorbidities that preclude the use of intensive induction chemotherapy.
- K. Keytruda® (pembrolizumab intravenous infusion) Merck and Keytruda Qlex® (pembrolizumab and berahyaluronidase alfa-pmph subcutaneous injection) Merck** – New indication in combination with Welireg (belzutifan tablets) for the adjuvant treatment of renal cell carcinoma with a clear cell component in adults at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions. Additionally, Keytruda and Keytruda Qlex received a new indication for use in combination with Trodelvy (sacituzumab govitecan-hziy IV infusion), for the first-line treatment of adult with unresectable locally advanced for metastatic triple-negative breast cancer whose tumors express PD-L1 combined positive score (CPS) ≥ 10 as determined by an FDA-authorized test.
- L. Linzess® (linaclotide capsules)** AbbVie – Expanded age indication for pediatric patients ≥ 2 years of age for the treatment of functional constipation.
- M. Ocrevus® (ocrelizumab intravenous infusion)** Genentech – New indication for the treatment of relapsing-remitting multiple sclerosis in pediatric patients ≥ 10 years of age who weigh ≥ 25 kg.
- N. Skyrizi® (risankizumab-rzaa subcutaneous injection)** AbbVie – Expanded age indication for the treatment of moderate to severe plaque psoriasis in adults and pediatric patients ≥ 6 years of age who are candidates for systemic therapy or phototherapy.
- O. Skyrizi® (risankizumab-rzaa subcutaneous injection)** AbbVie – Expanded age indication in active psoriatic arthritis in pediatric patients ≥ 6 years of age.
- P. Tecelra® (afamitresgene autoleucel intravenous infusion)** US World Meds – Converted its prior accelerated approval to a full approval of Tecelra for the treatment of patients with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. Additionally, Tecelra received an expanded age indication to include pediatric patients ≥ 12 years of age in the indication above.
- Q. Tecentriq® (atezolizumab intravenous infusion) Genentech and Tecentriq Hybreza™ (atezolizumab and hyaluronidase-tqjs subcutaneous injection) Genentech** – New indication

as adjuvant treatment for muscle invasive bladder cancer after cystectomy in adults who have circulating tumor DNA molecular residual disease as determined by an FDA-authorized test.

- R. Tofidence® (tocilizumab-bavi intravenous infusion)** Organon – New indication for the treatment of cytokine release syndrome in adults and pediatric patients ≥ 2 years of age with chimeric antigen receptor (CAR) T cell-induced severe or life threatening cytokine release syndrome. Also, Tofidence received an expanded age indication for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adult and pediatric patients ≥ 2 years of age who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.
- S. Tremfya® (guselkumab subcutaneous injection)** Janssen – Expanded labeling to include inhibition of progression of structural joint damage in adults who have active psoriatic arthritis.
- T. Trodelvy® (sacituzumab govitecan-hziy intravenous infusion)** Immunomedics/Gilead – New expanded indications in adults with triple-negative breast cancer. Trodelvy is now indicated for use in the first-line setting in locally advanced or metastatic triple-negative breast cancer. Additionally, Trodelvy received another new indication is for use in combination with Keytruda (pembrolizumab IV infusion) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmpH SC injection) for the first-line treatment of unresectable locally advanced or metastatic triple-negative breast cancer in adults whose tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-authorized test.
- U. Truqap® (capivasertib tablets)** AstraZeneca – New indication, in combination with abiraterone and prednisone, for the treatment of metastatic androgen pathway modulation-naïve or -sensitive prostate cancer (previously referred to as metastatic hormone-sensitive prostate cancer) in adults that is PTEN-deficient as detected by an FDA-authorized test.
- V. Tryngolza® (olezarsen subcutaneous injection)** Ionis – New indication to reduce triglycerides and the risk of acute pancreatitis in adults with severe hypertriglyceridemia (triglycerides greater than or equal to 500 mg/dL).
- W. Tyenne® (tocilizumab-aazg intravenous infusion)** Fresenius Kabi – Expanded age indication for the treatment of COVID-19 in hospitalized pediatric patients ≥ 2 years of age who are receiving systemic corticosteroids and require supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.
- X. Tzield® (teplizumab-mzwv intravenous infusion)** Provention/Sanofi – New indication to delay the decline in endogenous insulin production in pediatric patients ≥ 8 years of age and ≤ 17 years of age recently diagnosed with Stage 3 type 1 diabetes. This indication is approved under accelerated approval based on evidence of reduced C-peptide decline. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- Y. Uptravi® (selexipag tablets)** Actelion – New pediatric indication for Uptravi tablets for the treatment of pulmonary arterial hypertension (PAH) [World Health Organization Group 1] in pediatric patients ≥ 2 years of age. Uptravi reduces N-terminal pro-B-type natriuretic peptide and is expected to delay disease progression and reduce the risk of hospitalization for PAH.
- Z. Vyvgart® (efgartigimod alfa-fcab intravenous injection) Argenx and Vyvgart Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection) Argenx** – New indication for patients ≥ 18 years of age for the treatment of generalized myasthenia gravis. Of note, this includes all types of adults who have generalized myasthenia gravis (e.g., those who are anti-acetylcholine receptor [AChR] antibody-negative, anti-muscle-specific tyrosine kinase [MuSK] antibody-positive, anti-antibody-positive low density lipoprotein receptor-related protein

4 [LRP4], and triple seronegative [with no detectable autoantibodies against AChR, MuSK, or LRP4]).

- AA. Welireg® (belzutifan tablets)** Merck – New indication, in combination with Keytruda (pembrolizumab IV infusion) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph SC injection), for the adjuvant treatment of clear cell renal cell carcinoma in adults at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.
- BB. Xeomin® (incobotulinumtoxin A injection)** Merz – Expanded label and removal of exclusion for use for the treatment of upper limb spasticity in pediatric patients 2 years of age and older to not exclude spasticity caused by cerebral palsy. The updated indication is for the treatment or improvement of upper limb spasticity in patients 2 years of age and older.
- CC. Zegalogue® (dasiglucagon subcutaneous injection)** Zealand – Expanded indication for the treatment of severe hypoglycemia in pediatric patients with diabetes who weigh at least 20 kg.
- DD. Zoryve (roflumilast cream 0.3%)** Arcutis – Expanded age indication for the treatment of pediatric patients ≥ 2 years to 5 years of age with plaque psoriasis.

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions:

- A. Aprepitant Injectable Emulsion (Azurity)**
- B. Cavhanza™ (nilotinib orally disintegrating tablets)** Flex Pharma
- C. Duloxetine Delayed-Release Capsules (Almatica)**
- D. Navitrox™ (fosaprepitant intravenous injection)** Avyxa
- E. Tiocystin® (tiopronin tablets)** Casper Pharma
- F. Trimbow® (beclomethasone dipropionate, formoterol fumarate, glycopyrrolate oral inhalation aerosol)** Chiesi

New Biosimilars

The Committee reviewed the following new biosimilars:

- A. Ennumo™ (pegfilgrastim-pccg subcutaneous injection)** Accord Biopharma
- B. Immgolis™ (golimumab-sldi subcutaneous injection)** Accord BioPharma
- C. Immgolis Intrī™ (golimumab-sldi intravenous infusion)** Accord BioPharma
- D. Ranluspec® (ranibizumab-hkdz intravitreal injection)** Lupin