

**Express Scripts® Pharmacy Benefit Services
Pharmacy and Therapeutics (P&T) Committee
Proceedings
September 18, 2025**

New Drug Evaluations

The Committee reviewed the following new drugs:

- A. Anzupgo® (delgocitinib 2% cream) LEO**
- B. Modeyso™ (dordaviprone capsules) Jazz**
- C. Lynozyfic™ (linvoseltamab-gcpt intravenous infusion) Regeneron**
- D. Hernexeos® (zongertinib tablets) Boehringer Ingelheim**
- E. Wayrilz™ (rilzabrutinib tablets) Genzyme/Sanofi**
- F. Papzimeos™ (zopapogene imadenovec-drba subcutaneous injection) Precigen**
- G. Brinsupri™ (brensocatib tablets) Insamed**
- H. Leqembi® IQLIK™ (lecanemab-irmb subcutaneous injection) Eisai/Biogen**
- I. Dawnzera™ (donidalorsen subcutaneous injection) Ionis**
- J. Sephience™ (sepiapterin oral powder) PTC 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. Actemra® (tocilizumab intravenous infusion) Genentech** – Expanded age indication to include pediatric patients 2 years to < 18 years of age for the treatment of coronavirus disease 2019 (COVID-19). Actemra intravenous (IV) is now indicated for the treatment of COVID-19 in hospitalized patients ≥ 2 years of age who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.
- B. Ajovy® (fremanezumab-vfrm subcutaneous injection) Teva** – New indication for the preventive treatment of episodic migraine in patients who are ≥ 6 years of age and who weigh ≥ 45 kg.
- C. Alhemo® (concizumab-mtci subcutaneous injection) Novo Nordisk** – New indication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ≥ 12 years of age with hemophilia A (congenital factor VIII deficiency) without FVIII inhibitors and hemophilia B (congenital factor IX deficiency) without FIX inhibitors.
- D. Avtozma® (tocilizumab-anoh intravenous infusion) Celltrion** – New indication for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients ≥ 2 years of age.
- E. Biktarvy® (bictegravir, emtricitabine, and tenofovir alafenamide tablets) Gilead** – New indication for use as a complete regimen for the treatment of human immunodeficiency virus type 1 infection in adults and pediatric patients weighing at least 14 kg with antiretroviral treatment history who are not virologically suppressed, with no known or suspected substitutions associated with resistance to the integrase strand inhibitor class, emtricitabine, or tenofovir.
- F. Comirnaty® (COVID-19 vaccine [mRNA] intramuscular injection) Pfizer/BioNTech** – Revised patient population limiting the approved patient populations. Comirnaty is 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 5 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

- G. Doptelet® (avatrombopag tablets) AkaRx** – New indication for the treatment of thrombocytopenia in pediatric patients ≥ 6 years of age with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.
- H. Empaveli® (pegcetacoplan subcutaneous infusion) Apellis** – New indication for the treatment of C3 glomerulopathy or primary immune-complex membranoproliferative glomerulonephritis in adult and pediatric patients ≥ 12 years of age, to reduce proteinuria.
- I. Kerendia® (finerenone tablets) Bayer** – New indication to reduce the risk of cardiovascular (CV) death, hospitalization for heart failure, and urgent heart failure visits in adults with heart failure with left ventricular ejection fraction (LVEF) $\geq 40\%$.
- J. Leqvio® (inclisiran subcutaneous injection) Novartis** – Expanded indication to be used alone, without addition of statin therapy. Leqvio is now indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).
- K. Otezla® (apremilast tablets) Amgen** – Expanded age indication to include pediatric patients ≥ 6 years of age and weighing ≥ 20 kg with active psoriatic arthritis. Otezla is now indicated for the treatment of active psoriatic arthritis in adults and pediatric patients ≥ 6 years of age and weighing at least 20 kg.
- L. Phyrago® (dasatinib tablets) Handa Therapeutics** – New indication for the treatment of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic phase in pediatric patients ≥ 1 year of age. Also, Phyrago received another new indication for the treatment of newly diagnosed Ph+ acute lymphoblastic leukemia in combination with chemotherapy in pediatric patients ≥ 1 year of age.
- M. Repatha® (evolocumab subcutaneous injection) Amgen** – Expanded indication to be used alone, without addition of other LDL-C-lowering therapies. Repatha is now indicated as an adjunct to diet and exercise to reduce LDL-C in adults with hypercholesterolemia; in adults and pediatric patients ≥ 10 years of age with HeFH; and in adults and pediatric patients ≥ 10 years of age with homozygous familial hypercholesterolemia. Repatha also received another expanded indication to include any adult at increased risk of major adverse CV events. Repatha is now indicated to reduce the risk of major adverse CV events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults at increased risk for these events.
- N. Sirturo® (bedaquiline tablets) Janssen** – Expanded age indication to include pediatric patients 2 years to < 5 years of age and weighing at least 8 kg. Sirturo is now indicated as part of combination therapy for the treatment of pulmonary tuberculosis due to Mycobacterium tuberculosis resistant to at least rifampin and isoniazid in adults and pediatric patients ≥ 2 years of age and weighing at least 8 kg.
- O. Skytrofa® (lonapegsomatropin-tcgd subcutaneous injection) Ascendis Pharma** – New indication for replacement of endogenous growth hormone in adults with growth hormone deficiency.
- P. Wegovy® (semaglutide subcutaneous injection) Novo Nordisk** – New indication in combination with a reduced calorie diet and increased physical activity for the treatment of non-cirrhotic metabolic dysfunction-associated steatohepatitis, formerly known as non-alcoholic steatohepatitis, with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults.

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions:

- A. Atmeksi® (methocarbamol oral suspension)** Rosemont
- B. Avgemsi™ (gemcitabine intravenous infusion)** Ricon/Avyxa
- C. Bendamustine hydrochloride intravenous infusion** (Dr. Reddy's)
- D. Camcevi® ETM (leuprolide subcutaneous injection)** Foresee
- E. Doptelet® Sprinkle (avatrombopag oral granules)** AkaRx
- F. Escitalopram 15 mg capsules** (Almatica)
- G. Hymovis® One (viscoelastic hyaluronan injection)** Fidia
- H. Kyxata™ (carboplatin intravenous infusion)** Avyxa Pharma
- I. Otezla XR™ (apremilast extended-release tablets)** Amgen
- J. Sdamlo® (amlodipine oral solution)** Brilliant Pharma
- K. Vostally® (ramipril oral solution)** Rosemont
- L. Vyscoxa™ (celecoxib oral suspension)** Carwin

New Biosimilars

The Committee reviewed the following new biosimilars:

- A. BILDYOS® (denosumab-nxyp subcutaneous injection)** Shanghai Henlius Biotech/Organon
- B. BILPREVDA® (denosumab-nxyp subcutaneous injection)** Shanghai Henlius Biotech/Organon
- C. KIRSTY™ (insulin aspart-xjhz subcutaneous or intravenous injection)** Biocon Biologics