Express Scripts® Pharmacy Benefit Services
Pharmacy and Therapeutics (P&T) Committee
Proceedings
November 22, 2025

New Drug Evaluations

The Committee reviewed the following new drugs:

A. Clotic™ (clotrimazole 1% otic solution) Carwin
B. Enbumyst™ (bumetanide nasal spray) Corstasis
C. Forzinity™ (elamipretide subcutaneous injection) Stealth
D. Inlexzo™ (gemcitabine intravesical system) Janssen/Johnson & Johnson
E. Inluriyo™ (imlunestrant tablets) Eli Lilly
F. Jascayd® (nerandomilast tablets) Boehringer Ingelheim
G. Keytruda Qlex™ (pembrolizumab and berahyaluronidase alpha-pmph subcutaneous injection) Merck
H. Lynkuet® (elinzanetant capsules) Bayer
I. Palsonify™ (paltusotine tablets) Crinetics
J. Rhapsido® (remibrutinib tablets) Novartis
K. Zegfrovy™ (sunvozertinib tablets) Dizal [Jiangsu] Pharmaceuticals

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. Amjevita® (adalimumab-atto subcutaneous injection) Amgen; Cyltezo® (adalimumab-adbm subcutaneous injection); Boehringer Ingelheim; Hyrimoz® (adalimumab-adaz subcutaneous injection) Sandoz; Simlandi® (adalimumab-ryvk subcutaneous injection) Alvotech; and Yuflyma® (adalimumab-aaty subcutaneous injection) Celltrion – Expanded age indication for uveitis in pediatric patients ≥ 2 years of age. These biosimilars to Humira® (adalimumab subcutaneous [SC] injection) are now indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients ≥ 2 years of age. Additionally, these agents received an expanded age indication for hidradenitis suppurativa in adolescent patients ≥ 12 years of age. These biosimilars to Humira are now indicated for the treatment of moderate to severe hidradenitis suppurativa in patients ≥ 12 years of age.
B. Axtle™ (pemetrexed intravenous infusion) Avyxa Pharma – New indication in combination with Keytruda® (pembrolizumab intravenous [IV] infusion) and platinum chemotherapy, for the initial treatment of metastatic non-squamous non-small cell lung cancer (NSCLC), in patients with no EGFR or ALK genomic tumor aberrations.
C. Blenrep® (belantamab mafodotin-blmf intravenous infusion) GlaxoSmithKline – New indication for use in combination with bortezomib and dexamethasone for the treatment of relapsed or refractory multiple myeloma in adults who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.
D. Caplyta® (lumateperone capsules) Intra-Cellular Therapies – New indication for adjunctive therapy with antidepressants for the treatment of major depressive disorder in adults.

E. **Contrave® (naltrexone hydrochloride and bupropion hydrochloride extended-release tablets) Currax** – 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. Contrave 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 with obesity or overweight in the presence of at least one weight-related comorbid condition.

F. **Darzalex Faspro® (daratumumab and hyaluronidase-fihj subcutaneous injection) Janssen** – New indication for use as monotherapy for the treatment of high-risk smoldering multiple myeloma in adults.

G. **Evkeeza® (evinacumab-dgnb intravenous infusion) Regeneron** – Expanded age indication to include pediatric patients from 1 year to less than 5 years of age with homozygous familial hypercholesterolemia (HoFH). Evkeeza is now indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies to reduce LDL-C in those with HoFH who are adults or in pediatric patients ≥ 1 year of age.

H. **Gazyva® (obinutuzumab intravenous infusion) Roche** – New indication for the treatment of active lupus nephritis in adults who are receiving standard therapy.

I. **Koselugo® (selumetinib capsules) AstraZeneca** – Expanded age indication to include pediatric patients 1 year to < 2 years of age. Koselugo is now indicated for the treatment of neurofibromatosis type 1 in pediatric patients ≥ 1 year of age who have symptomatic, inoperable plexiform neurofibromas.

J. **Libtayo® (cemiplimab-rwlc intravenous infusion) Regeneron** – New indication for the adjuvant treatment of cutaneous squamous cell carcinoma in adults at high risk of recurrence after surgery and radiation.

K. **Linzess® (linaclotide capsules) AbbVie** – Expanded age indication to include pediatric patients ≥ 7 years of age with irritable bowel syndrome with constipation (IBS-C). Linzess is now indicated for the treatment of IBS-C in adults and pediatric patients ≥ 7 years of age.

L. **Olpruva™ (sodium phenylbutyrate oral suspension) Acer Therapeutics** – Expanded age indication to include patients ≥ 1 year of age weighing ≥ 7 kg for urea cycle disorders (UCDs). Olpruva is now indicated for the chronic management of UCDs involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase, or arginosuccinic acid synthetase in adults and pediatric patients ≥ 1 year of age who weigh ≥ 7 kg as an adjunctive therapy to standard of care (which includes dietary management).

M. **Opdivo Qvantig™ (nivolumab and hyaluronidase-nvhy subcutaneous injection) Bristol-Myers Squibb** – New indication for use as monotherapy, for the treatment of unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC) in adults following treatment with Opdivo® (nivolumab IV infusion) and Yervoy® (ipilimumab IV infusion) combination therapy.

N. **Opzelura™ (ruxolitinib cream) Incyte** – Expanded age indication to include pediatric patients 2 years to < 12 years of age. Opzelura is now indicated for the short-term and non-continuous chronic treatment of mild to moderate eczema (atopic dermatitis) in non-immunocompromised adults and children ≥ 2 years of age whose disease is not well controlled with topical prescription therapies or when those therapies are not recommended.

O. **Praluent® (alirocumab subcutaneous injection) Regeneron** – Expanded indication to be used alone, without addition of other LDL-C-lowering therapies. Praluent is now indicated as an adjunct to diet and exercise to reduce LDL-C in adults with hypercholesterolemia; adults and pediatric patients ≥ 8 years of age with heterozygous familial hypercholesterolemia (HeFH); and adults with HoFH. In addition, Praluent received another expanded indication to include any adult

at increased risk of major adverse cardiovascular (CV) events. Praluent is now indicated to reduce the risk of major adverse CV events (coronary heart disease death, myocardial infarction, stroke, and unstable angina requiring hospitalization) in adults at increased risk for these events.

P. **Revuforj® (revumenib tablets) Syndax** – New indication for the treatment of relapsed or refractory acute myeloid leukemia with a susceptible nucleophosmin 1 mutation in adult and pediatric patients ≥ 1 year of age who have no satisfactory alternative treatment options.

Q. **Rinvoq® (upadacitinib extended-release tablets) AbbVie** – Expanded indication for moderately to severely active ulcerative colitis in adults, that if tumor necrosis factor (TNF) blockers are clinically inadvisable, patients should have received at least one approved systemic therapy prior to use of Rinvoq. Rinvoq also received an additional expanded indication for moderately to severely active Crohn's disease in adults, that if TNF blockers are clinically inadvisable, patients should have received at least one approved systemic therapy prior to use of Rinvoq.

R. **Rybelsus® (semaglutide tablets) Novo Nordisk** – New indication to reduce the risk of major adverse CV events (CV death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus who are at high risk for these events.

S. **Simponi® (golimumab subcutaneous injection) Janssen Biotech** – Expanded age and revised indication to include pediatric patients weighing ≥ 15 kg with moderately to severely active ulcerative colitis. Simponi SC is now indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients weighing ≥ 15 kg.

T. **Tecentriq® (atezolizumab intravenous infusion) Genentech** – New indication for the maintenance treatment of extensive-stage small cell lung cancer, in combination with Zepzelca® (lurbinectedin IV infusion), in adults whose disease has not progressed after first-line induction therapy with Tecentriq or Tecentriq Hybreza™ (atezolizumab and hyaluronidase-tqjs SC injection), carboplatin and etoposide.

U. **Tecentriq Hybreza™ (atezolizumab and hyaluronidase-tqjs subcutaneous injection) Genentech** – New indication for the maintenance treatment of extensive-stage small cell lung cancer, in combination with Zepzelca® (lurbinectedin IV infusion), in adults whose disease has not progressed after first-line induction therapy with Tecentriq® (atezolizumab IV infusion) or Tecentriq Hybreza, carboplatin and etoposide.

V. **Tezspire® (tezepelumab-ekko subcutaneous injection) AstraZeneca** – New indication for the add-on maintenance treatment of inadequately controlled chronic rhinosinusitis with nasal polyps in adult and pediatric patients ≥ 12 years of age.

W. **Tremfya® (guselkumab subcutaneous injection) Janssen** – Expanded indication for the administration of Tremfya by SC injection during induction, when followed by SC injection during maintenance, for the treatment ulcerative colitis. Tremfya is now indicated for the treatment of moderately to severely active ulcerative colitis in adults with administration by SC injection or IV infusion for induction dosing followed by SC injection during maintenance dosing.

X. **Tremfya® (guselkumab subcutaneous injection) Janssen** – Expanded age indication to include pediatric patients ≥ 6 years of age and weighing ≥ 40 kg with plaque psoriasis. Tremfya is now indicated for the treatment of moderate to severe plaque psoriasis in adults and pediatric patients ≥ 6 years of age who also weigh ≥ 40 kg and who are candidates for systemic therapy or phototherapy.

Y. **Tremfya® (guselkumab subcutaneous injection) Janssen** – Expanded age indication to include pediatric patients ≥ 6 years of age and weighing ≥ 40 kg with psoriatic arthritis. Tremfya is now indicated for the treatment of active psoriatic arthritis in adults and pediatric patients ≥ 6 years of age who also weigh ≥ 40 kg.

Z. **Uzedy® (risperidone extended-release subcutaneous injection) Teva** – New indication as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder in adults.

AA. **Vonvendi® (von Willebrand factor [recombinant] intravenous injection) Baxalta/Shire** – Expanded indication to include adults with von Willebrand disease (VWD) for routine prophylaxis without specification of the VWD type. Vonvendi is now indicated for routine prophylaxis to reduce the frequency of bleeding episodes in adults. Additionally, there was an expanded age indication to include pediatric patients. Vonvendi is now indicated for perioperative management of bleeding in adults and pediatric patients with VWD and for on-demand treatment and control of bleeding episodes in adults and pediatric patients diagnosed with VWD.

BB. **Vyjuvek™ (beremagene geperpavec-svdt biological suspension mixed with excipient gel for topical application) Krystal Biotech** – Expanded age indication to include pediatric patients 0 months to < 6 months of age. Vyjuvek is now indicated for the treatment of wounds in adult and pediatric patients with dystrophic epidermolysis bullosa with mutation(s) in the collagen type VII alpha 1 chain gene.

CC. **Winrevair™ (sotatercept-csrk subcutaneous injection) Merck** – Revised indication to include components of clinical worsening events: hospitalization for pulmonary arterial hypertension (PAH), lung transplantation and death. Winrevair is now indicated for the treatment of PAH (Group 1 pulmonary hypertension) in adults to improve exercise capacity and World Health Organization functional class and reduce the risk of clinical worsening events including hospitalization for PAH, lung transplantation and death.

DD. **Xeljanz® (tofacitinib tablet and oral solution) Pfizer** – Expanded age indication to include pediatric patients for the treatment of active psoriatic arthritis. Xeljanz is now indicated for the treatment of psoriatic arthritis in adult and pediatric patients ≥ 2 years of age who have had an inadequate response or intolerance to one or more TNF inhibitors.

EE. **Zepzelca® (lurbinectedin intravenous infusion) Jazz/PharmaMar** – New indication for the maintenance treatment of extensive-stage small cell lung cancer, in combination with Tecentriq® (atezolizumab IV infusion) or Tecentriq Hybreza™ (atezolizumab and hyaluronidase-tqjs SC injection), in adults whose disease has not progressed after first-line induction therapy with Tecentriq or Tecentriq Hybreza, carboplatin, and etoposide.

FF. **Zoryve® (roflumilast 0.05% topical cream) Arcutis Biotherapeutics** – Expanded age indication and a new strength cream (0.05%) for pediatric patients 2 years to 5 years of age for atopic dermatitis. Zoryve 0.05% cream is indicated for the topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 years to 5 years of age.

<u>New Clinical Line Extensions</u>

The Committee reviewed the following new clinical line extensions:

A. **Bondlido® (lidocaine 10% topical system)** MEDRx
B. **Javadin™ (clonidine hydrochloride oral solution)** Azurity
C. **Koselugo® (selumetinib oral granules)** AstraZeneca
D. **Lasix® Onyu (furosemide subcutaneous infusion)** SQ Innovation
E. **Qivigy® (immune globulin intravenous [human]-kthm 10% liquid)** Kedrion
F. **Subvenite® (lamotrigine oral suspension)** OWP Pharmaceuticals
G. **Zolymbus™ (bimatoprost 0.01% ophthalmic gel)** Thea Pharma

New Biosimilars
The Committee reviewed the following new biosimilars:

A. **Aukelso™ (denosumab-kyqq subcutaneous injection)** Biocon Biologics
B. **Bosaya™ (denosumab-kyqq subcutaneous injection)** Biocon Biologics
C. **Enoby™ (denosumab-qdbe subcutaneous injection)** Hikma/Gedeon Richter
D. **Eydenzelt® (aflibercept-boav intravitreal injection)** Celltrion
E. **Xtenbo™ (denosumab-qbde subcutaneous injection)** Hikma/Gedeon Richter