Express Scripts® Pharmacy Benefit Services
Pharmacy and Therapeutics (P&T) Committee
Proceedings
January 22, 2026

New Drug Evaluations

The Committee reviewed the following new drugs:

A. **Aqvesme™ (mitapivat tablets)** Agios
B. **Cardamyst™ (etripamil nasal spray)** Milestone
C. **Exdensur® (depemokimab-ulaa subcutaneous injection)** GlaxoSmithKline
D. **Fesilty® (fibrinogen [human] intravenous infusion)** Grifols
E. **Hyrnuo® (sevabertinib tablets)** Bayer
F. **Itvisma® (onasemnogene abeparvovec-brve intrathecal injection)** Novartis
G. **Komzifti™ (ziftomenib capsules)** Kura Oncology/Kyowa Kirin
H. **Kygevvi™ (doxecitine and doxribtimine powder for oral solution)** UCB
I. **Lerochol™ (lerodalcibep-liga subcutaneous injection)** LIB
J. **Lunsumio Velo™ (mosunetuzumab-axgp subcutaneous injection)** Genentech
K. **Myqorzo™ (aficamten tablets)** Cytokinetics
L. **Redemplo® (plozasiran subcutaneous injection)** Arrowhead
M. **Rybrevant Faspro™ (amivantamab and hyaluronidase-lpuj subcutaneous injection)** Janssen
N. **Wegovy® (semaglutide tablets)** NovoNordisk
O. **Voyxact® (sibeprenlimab-szsi subcutaneous injection)** Otsuka
P. **Yartemlea® (narsoplimab-wuug intravenous infusion)** Omeros

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. **Accrufer® (ferric maltol capsules) Shield** – Expanded age indication for pediatric patients ≥ 10 years of age. Accrufer is now indicated for the treatment of iron deficiency in adult and pediatric patients ≥ 10 years of age.
B. **Addyi™ (flibanserin tablet) Sprout** – Expanded indication for hypoactive sexual desire disorder (HSDD) to include postmenopausal women < 65 years of age. Addyi is now indicated for the treatment of women < 65 years of age with acquired, generalized HSDD as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is not due to: a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance.
C. **Akeega® (niraparib/abiraterone acetate tablets) Janssen** – New indication for metastatic castration-sensitive prostate cancer (mCSPC). Akeega, a poly (ADP-ribose) polymerase (PARP) inhibitor plus a cytochrome P450 (CYP)17 inhibitor, is now indicated in combination with prednisone for the treatment of deleterious or suspected deleterious BRCA2-mutated mCSPC in adults.
D. **Blujepa® (gepotidacin tablets) GlaxoSmithKline** – New indication for the treatment of gonorrhea in adults and pediatric patients ≥ 12 years of age. Blujepa is now indicated for

treatment of uncomplicated urogenital gonorrhea caused by susceptible strains of Neisseria gonorrhoeae in adult and pediatric patients ≥ 12 years of age weighing ≥ 45 kg who have limited or no alternative options.

E. **Breyanzi® (lisocabtagene maraleucel intravenous infusion) Juno** – New indication for the treatment of relapsed or refractory marginal zone lymphoma in adults who have received at least two prior lines of systemic therapy.
F. **Cablivi® (caplacizumab-yhdp intravenous infusion and subcutaneous injection) Genzyme/Sanofi** – Expanded age indication for acquired thrombotic thrombocytopenic purpura (aTTP) in adolescent patients ≥ 12 years of age. Cablivi is now indicated for the treatment of aTTP in adults and pediatric patients ≥ 12 years of age in combination with plasma exchange and immunosuppressive therapy.
G. **Darzalex Faspro® (daratumumab and hyaluronidase-fihj subcutaneous injection) Janssen** – Darzalex Faspro received conversion from accelerated to traditional (regular) approval for the treatment of newly diagnosed light chain amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone in adults.
H. **Elevidys® (delandistrogene moxeparvovec-rokl intravenous infusion) Sarepta** – Removal of indication for the treatment of Duchenne muscular dystrophy (DMD) in individuals ≥ 4 years of age who are non-ambulatory and have a confirmed mutation in the DMD gene. Elevidys remains indicated for the treatment of DMD in individuals ≥ 4 years of age who are ambulatory and have a confirmed mutation in the DMD gene.
I. **Enhertu® (fam-trastuzumab deruxtecan-nxki intravenous infusion) AstraZeneca/Daiichi Sankyo** – New indication for first-line treatment of unresectable or metastatic human epidermal growth factor receptor 2 (HER2) positive (immunohistochemistry [IHC] 3+ or in situ hybridization [ISH]+) breast cancer. Enhertu is now indicated in combination with pertuzumab for unresectable or metastatic HER2-positive (IHC 3+ or ISH+) breast cancer, as determined by a Food and Drug Administration (FDA)-approved test, as first-line therapy in adults.
J. **Epkinly® (epcoritamab-bysp subcutaneous injection) Genmab** – New indication for the treatment of relapsed or refractory follicular lymphoma in combination with lenalidomide and rituximab in adults.
K. **Eylea® HD (aflibercept intravitreal injection) Regeneron** – New indication for the treatment of macular edema following retinal vein occlusion.
L. **Furoscix® (furosemide subcutaneous injection) scPharmaceuticals** – Expanded age indication for pediatric patients weighing ≥ 43 kg with edema. Furoscix is now indicated for the treatment of edema in pediatric patients weighing ≥ 43 kg and in adults with chronic heart failure or chronic kidney disease, including the nephrotic syndrome.
M. **Idacio® (adalimumab-aacf subcutaneous injection) Fresenius Kabi** – Expanded age indication for uveitis in pediatric patients ≥ 2 years of age. Idacio is now indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in patients ≥ 2 years of age. Also, Idacio received an expanded age indication for hidradenitis suppurativa in adolescent patients ≥ 12 years of age. Idacio is now indicated for the treatment of moderate to severe hidradenitis suppurativa in patients ≥ 12 years of age.
N. **Imdelltra® (tarlatamab-dlle intravenous infusion) Amgen** – Imdelltra received conversion from accelerated to traditional (regular) approval for the treatment of extensive stage small cell lung cancer with disease progression on or after platinum-based chemotherapy in adults.
O. **Imfinzi® (durvalumab intravenous infusion) AstraZeneca** – New indication for use in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel as neoadjuvant and adjuvant

treatment, followed by single-agent Imfinzi, for the treatment of resectable gastric or gastroesophageal junction adenocarcinoma in adults.

P. Jascayd® (nerandomilast tablets) Boehringer Ingelheim – New indication for the treatment of progressive pulmonary fibrosis in adults.

Q. Jaypirca® (pirtobrutinib tablets) Eli Lilly – Expanded indication for earlier treatment for chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL). Jaypirca is now indicated for relapsed or refractory CLL/SLL in adults who have previously been treated with a covalent Bruton tyrosine kinase inhibitor. Jaypirca also received conversion of accelerated approval to traditional (regular) approval for the CLL/SLL indication.

R. Keytruda® (pembrolizumab intravenous infusion) and Keytruda Qlex™ (pembrolizumab and berahyaluronidase alfa-pmph subcutaneous injection) Merck – New indication for the treatment of muscle invasive bladder cancer, in combination with Padcev® (enfortumab vedotin intravenous infusion), as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment for adults who are ineligible for cisplatin-containing chemotherapy.

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

T. Mounjaro® (tirzepatide subcutaneous injection) Eli Lilly – Expanded age indication for pediatric patients ≥ 10 years of age for type 2 diabetes mellitus. Mounjaro 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.

U. Nexletol® (bempedoic acid tablets) Esperion – Revised (reworded) indication to reduce the risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, stroke, or coronary revascularization) in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking a statin). Nexletol also received another revised (reworded) indication as an adjunct to diet and exercise, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

V. Nexlizet® (bempedoic acid and ezetimibe tablets) Esperion – Expanded indication to be used alone, without addition of statin therapy. Nexlizet is now indicated as an adjunct to diet and exercise to reduce LDL-C in adults with hypercholesterolemia, including HeFH.

W. Omisirge® (omidubicel-onlv intravenous infusion) Gamida – New indication for severe aplastic anemia. Omisirge is now indicated for the treatment of severe aplastic anemia following reduced intensity conditioning in adults and pediatric patients ≥ 6 years of age.

X. Opdivo Qvantig™ (nivolumab and hyaluronidase-nvhy subcutaneous injection) Bristol-Myers Squibb – Five expanded age indications to include pediatric patients ≥ 12 years of age weighing ≥ 30 kg as follows: 1) Opdivo Qvantig is now indicated for use as monotherapy, for the treatment of unresectable or metastatic microsatellite instability-high or mismatch repair deficient colorectal cancer in adults and pediatric patients ≥ 12 years of age who weigh ≥ 30 kg following treatment with Opdivo® (nivolumab intravenous infusion) and Yervoy® (ipilimumab) combination therapy; 2) Opdivo Qvantig is now indicated for use as monotherapy, for the treatment of metastatic colorectal cancer in adults and pediatric patients ≥ 12 years of age who weigh ≥ 30 kg that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan; 3) Opdivo Qvantig is now indicated for use as monotherapy, for the treatment of unresectable or metastatic melanoma as monotherapy in adults and pediatric patients ≥ 12 years of age who weigh ≥ 30 kg; 4) Opdivo Qvantig is now indicated for use as monotherapy, for the treatment of

unresectable or metastatic melanoma in adults and pediatric patients ≥ 12 years of age who weigh ≥ 30 kg following treatment with Opdivo IV and Yervoy combination therapy; and 5) Opdivo Qvantig is now indicated for use as monotherapy, as adjuvant treatment for the treatment of completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma in adults and pediatric patients ≥ 12 years of age who weigh ≥ 30 kg.

Y. Orladeyo® (berotralstat oral capsules and pellets) BioCryst – Expanded age indication to include pediatric patients 2 years to < 12 years of age. Orladeyo is now indicated for prophylaxis to prevent attacks of hereditary angioedema in adults and pediatric patients ≥ 2 years of age.

Z. Padcev® (enfortumab vedotin-ejfv intravenous infusion) Astellas/Seagen – New indication for use in combination with Keytruda® (pembrolizumab intravenous infusion) or Keytruda Qlex™ (pembrolizumab and berahyaluronidase alfa-pmph subcutaneous injection), as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment, for the treatment of muscle invasive bladder cancer in adults who are ineligible for cisplatin-containing chemotherapy.

AA. Rubraca® (rucaparib tablets) pharmaand Schwiez GmbH/Tolmar – Expanded indication for earlier treatment of prostate cancer. Rubraca, a PARP inhibitor, is now indicated for the treatment of metastatic castration-resistant prostate cancer (mCRPC) associated with a deleterious BRCA mutation (germline and/or somatic) in adults who have been treated with androgen receptor-directed therapy. Also, Rubraca received conversion of accelerated approval to traditional (regular) approval for the mCRPC indication. Previously, this indication was approved under accelerated approval based on objective response rate and duration of response; continued approval for this indication was contingent upon verification and description.

BB. Tecentriq Hybreza® (atezolizumab and hyaluronidase-tqjs subcutaneous injection) Genentech – Expanded age indication to include pediatric patients ≥ 12 years of age and weighing ≥ 40 kg. Tecentriq Hybreza is now indicated as monotherapy, for the treatment of unresectable or metastatic alveolar soft part sarcoma in adults and pediatric patients ≥ 12 years of age and weighing ≥ 40 kg.

CC. Thrombate III (antithrombin III [Human] intravenous infusion) Grifol – Expanded age indication to include pediatric patients. Thrombate III is now indicated for the treatment and prevention of thromboembolism and the prevention of peri-operative and peri-partum thromboembolism in adult and pediatric patients with hereditary antithrombin deficiency.

DD. Uplizna® (inebilizumab-cdon intravenous infusion) Amgen – New indication for the treatment of generalized myasthenia gravis. Uplizna is now indicated for the treatment of generalized myasthenia gravis in adults who are anti-acetylcholine receptor or anti-muscle specific tyrosine kinase (MuSK) antibody positive.

EE. Vraylar® (cariprazine capsules) AbbVie – Expanded age indication for pediatric patients 13 years to 17 years of age for the treatment of schizophrenia. Vraylar is now indicated for the treatment of schizophrenia in adults and pediatric patients ≥ 13 years of age. Additionally, Vraylar received an expanded age indication for pediatric patients 10 years to 17 years of age for the treatment of bipolar mania. Vraylar is now indicated for the acute treatment of mania or mixed episodes associated with bipolar I disorder in adults and pediatric patients ≥ 10 years of age.

FF. Zynyz® (retifanlimab-dlwr intravenous infusion) Incyte – Zynz received conversion of accelerated approval to traditional (regular) approval for the treatment of adults with metastatic or recurrent locally advanced Merkel cell carcinoma

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions:

A. **Daybue® Stix (trofinetide powder for oral solution)** Acadia
B. **Orladeyo® (berotralstat oral pellets)** BioCryst

New Biosimilars
The Committee reviewed the following new biosimilars:

A. **Armlupeg™ (pegfilgrastim-unne subcutaneous injection)** Lupin
B. **Boncresa™ (denosumab-mobz subcutaneous injection)** Amneal
C. **Jubereq® (denosumab-desu subcutaneous injection)** Accord BioPharma
D. **Nufymco® (ranibizumab-leyk intravitreal injection)** Formycon AG
E. **Osvyrti® (denosumab-desu subcutaneous injection)** Accord BioPharma
F. **Oziltus™ (denosumab-mobz subcutaneous injection)** Amneal
G. **Poherdy® (pertuzumab-dpzb intravenous infusion)** Organon