EVERNORTH HEALTH SERVICES

Express Scripts® Pharmacy Benefit Services
Pharmacy and Therapeutics (P&T) Committee
Proceedings
May 15, 2025

New Drug Evaluations

The Committee reviewed the following new drugs:

A. **Blujepa™ (gepotidacin tablets)** GlaxoSmithKline
B. **Encelto™ (revakinagene taroretcel-lwey intravitreal implant)** Neurotech
C. **Imaavy™ (nipocalimab-aahu intravenous infusion)** Johnson & Johnson
D. **Qfitlia™ (fitusiran subcutaneous injection)** Genzyme/Sanofi
E. **Vanrafia™ (atrasentan tablets)** Novartis
F. **Vykat™ XR (diazoxide choline extended-release tablets)** Soleno

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions:

A. **Arbli™ (losartan potassium oral suspension)** Scienture
B. **Atzumi™ (dihydroergotamine nasal powder)** Satsuma
C. **Egrifta WR™ (tesamorelin subcutaneous injection)** Theratechnologies
D. **Eliquis® (apixaban sprinkle capsules for oral suspension [0.15 mg])** Bristol Myers Squibb/Pfizer
E. **Eliquis® (apixaban tablets for oral suspension [0.5 mg])** Bristol Myers Squibb/Pfizer
F. **Epinephrine intravenous, intramuscular, subcutaneous injection** [Fresenius Kabi]
G. **HemiClor™ (chlorthalidone tablets, 12.5 mg)** PRM Pharma/Ingenus
H. **Jynneos® (Smallpox and Mpox Vaccine, Live, Non-replicating suspension for subcutaneous injection [freeze-dried formulation])** Bavarian Nordic
I. **Livmarli® (maralixibat tablets)** Mirum
J. **Lopressor® (metoprolol tartrate oral solution)** Validus
K. **Mezofy™ (aripiprazole oral film)** CMG Pharmaceutical
L. **Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection)** Argenx

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. **Amvuttra® (vutrisiran subcutaneous injection)** Alnylam – New indication for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular (CV) mortality, CV hospitalizations and urgent heart failure visits.
B. **Baqsimi® (glucagon nasal powder) Amphastar** – Expanded age indication to include pediatric patients 1 year to < 4 years of age. Beqsimi is now indicated for the treatment of severe hypoglycemia in adults and pediatric patients ≥ 1 year of age with diabetes.

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C. **Cabometyx® (cabozantinib tablets) Exelixis** – New indication for the treatment of previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors in adult and pediatric patients ≥ 12 years of age. Cabometyx also received a new indication for the treatment of previously treated, unresectable, locally advanced or metastatic, well-differentiated extra-pancreatic neuroendocrine tumors in adult and pediatric patients ≥ 12 years of age.

D. **Dextenza® (dexamethasone ophthalmic insert [0.4 mg])** Ocular Therapeutix – Expanded age indication to include pediatric patients for ocular inflammation and pain following ophthalmic surgery. Dextenza is now indicated for the treatment of ocular inflammation and pain following ophthalmic surgery in adults and pediatric patients. Dextenza received an additional expanded age indication to include pediatric patients for ocular itching associated with allergic conjunctivitis. Dextenza is now indicated for the treatment of ocular itching associated with allergic conjunctivitis in adults and pediatric patients ≥ 2 years of age.

E. **Dupixent® (dupilumab subcutaneous injection)** Sanofi/Regeneron – New indication for the treatment of chronic spontaneous urticaria in adults and pediatric patients ≥ 12 years of age who remain symptomatic despite H1 antihistamine treatment.

F. **Eliquis® (apixaban tablets [2.5 mg and 5 mg])** Bristol Myers Squibb/Pfizer – New indication for the treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in pediatric patients from birth and older after at least 5 days of initial anticoagulant treatment.

G. **Fabhalta® (iptacopan capsules) Novartis** – New indication for the treatment of complement 3 glomerulopathy in adults, to reduce proteinuria.

H. **Fylnetra® (pegfilgrastim-pbbk subcutaneous injection)** Amneal – New indication to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).

I. **Ibrance® (palbociclib capsules)** Pfizer – New indication for use in combination with Itovebi™ (inavolisib tablets) and fulvestrant for the treatment of endocrine-resistant, PIK3CA-mutated, hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-), locally advanced or metastatic breast cancer, as detected by a Food and Drug Administration (FDA)-approved test, following recurrence on or after completing adjuvant endocrine therapy.

J. **Iluvien® (fluocinolone acetonide intravitreal implant)** Ani Pharmaceuticals – New indication for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

K. **Imfinzi® (durvalumab intravenous infusion)** AstraZeneca – New indication for use in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent Imfinzi as adjuvant treatment following radical cystectomy, for the treatment of muscle invasive bladder cancer in adults.

L. **Isturisa® (osilodrostat tablets)** Recordati Rare Diseases – Expanded indication to include the treatment of Cushing's syndrome. Isturisa is now indicated for the treatment of endogenous hypercortisolemia in adults with Cushing's syndrome for whom surgery is not an option or has not been curative.

M. **Keytruda® (pembrolizumab intravenous infusion)** Merck – Conversion from accelerated to traditional (regular) approval for use in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic human epidermal growth factor receptor 2-positive gastric or gastroesophageal junction adenocarcinoma in adults whose tumors express programmed-death ligand-1 (PD-L1) [combined positive score ≥ 1] as determined by an FDA-approved test.

N. **Opdivo® (nivolumab intravenous infusion)** Bristol Myers Squibb – Revised indication and conversion from accelerated to traditional (regular) approval for use in combination with Yervoy® (ipilimumab injection) as a first-line treatment of unresectable or metastatic microsatellite

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instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC) in adult and pediatric patients ≥ 12 years of age. Opdivo received an additional revised indication and conversion from accelerated to traditional (regular) approval for use as a single agent for the treatment of MSI-H or dMMR metastatic CRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan in adult and pediatric patients ≥ 12 years of age. Opdivo received an additional conversion from accelerated approval to traditional (regular) approval for use in combination with Yervoy for the treatment of hepatocellular carcinoma in adults who have been previously treated with Nexavar® (sorafenib tablets). Opdivo received a new indication for use in combination with Yervoy® (ipilimumab injection) for the first-line treatment of unresectable or metastatic hepatocellular carcinoma in adults.

O. Pluvicto® (lutetium Lu 177 vipivotide tetraxetan intravenous injection) Novartis – New indication for the treatment of prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer in adults who have been treated with androgen receptor pathway inhibitor therapy and are considered appropriate to delay taxane-based chemotherapy.

P. Posfrea™ (palonosetron intravenous infusion) Avyxa Pharma – New pediatric indication for the prevention of acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including highly emetogenic cancer chemotherapy in pediatric patients 1 month to < 17 years of age.

Q. Prezcobix® (darunavir and cobicistat tablets) Janssen – Expanded pediatric weight indication to include pediatric patients weighing ≥ 25 kg to < 40 kg. Prezcobix is now indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus-1 in treatment-naïve and treatment-experienced adults and pediatric patients weighing ≥ 25 kg with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V).

R. Releuko® (filgrastim-ayow subcutaneous or intravenous injection) Amneal – New indication for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. Releuko received another new indication to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).

S. Rinvoq® (upadacitinib extended-release tablets) AbbVie – New indication for the treatment of giant cell arteritis in adults.

T. Rivfloza® (nedosiran subcutaneous injection) Novo Nordisk – Expanded age indication to include pediatric patients 2 years to < 9 years of age. Rivfloza is now indicated to lower urinary oxalate levels in children ≥ 2 years of age and adults with primary hyperoxaluria type 1 and relatively preserved kidney function (e.g., estimated glomerular filtration rate ≥ 30 mL/minute/1.73 m^2).

U. Sivextro® (tedizolid phosphate tablets) Merck – Expanded age and weight indication to include pediatric patients ≥ 35 kg. Sivextro is now indicated for the treatment of acute bacterial skin and skin structure infections caused by susceptible isolates of the following gram-positive microorganisms: Staphylococcus aureus (including methicillin-resistant and methicillin-susceptible isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), and Enterococcus faecalis, in adult and pediatric patients.

V. Uplizna® (inebilizumab-cdon intravenous infusion) Amgen – New indication for the treatment of Immunoglobulin G4-related disease in adults.

W. Valtoco® (diazepam nasal spray) Neurelis – Expanded age indication to include pediatric patients 2 years to < 6 years of age. Valtoco is now indicated for the acute treatment of intermittent,

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stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy ≥ 2 years of age.

X. **Vitrakvi® (larotrectinib capsules and oral solution)** Bayer – Conversion from accelerated to traditional (regular) approval for the treatment of solid tumors that have a neurotrophic receptor tyrosine kinase gene fusion in patients without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have no satisfactory alternative treatments or that have progressed following treatment in adults and pediatric patients. Select patients for therapy based on an FDA-approved test.
Y. **Welireg® (belzutifan tablets)** Merck – Revised indication to clarify that the use of the Welireg is intended for patients with advanced renal cell carcinoma (RCC) with a clear cell component. Welireg is now indicated for the treatment of advanced RCC in adults with a clear cell component following a programmed death receptor-1 or PD-L1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor.
Z. **Yervoy® (ipilimumab intravenous infusion)** Bristol Myers Squibb – Revised indication and conversion from accelerated to traditional (regular) approval for use in combination with Opdivo® (nivolumab injection) for the treatment of unresectable or metastatic MSI-H or dMMR CRC in adult and pediatric patients ≥ 12 years of age. Yervoy received another conversion from accelerated to traditional (regular) approval for use in combination with Opdivo for the treatment of hepatocellular carcinoma in adults who have been previously treated with Nexavar® (sorafenib tablets). Yervoy also received a new indication for use in combination with Opdivo® (nivolumab injection) for the first-line treatment of unresectable or metastatic hepatocellular carcinoma in adults.

New Biosimilars

The Committee reviewed the following new biosimilars:

A. **Bomyntra® (denosumab-bnht subcutaneous injection)** [Fresenius Kabi]
B. **Conexxence® (denosumab-bnht subcutaneous injection)** [Fresenius Kabi]
C. **Jobevne™ (bevacizumab-nwgd intravenous infusion)** [Bio-Thera Solutions]

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