

# Express Scripts

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## Express Scripts Pharmacy and Therapeutics Committee Proceedings January 23, 2025

### New Drug Evaluations

The Committee reviewed the following new drugs:

- A. **Alhemo<sup>®</sup> (concizumab-mtci subcutaneous injection)** Novo Nordisk
- B. **Alyftrek<sup>™</sup> (vanzacaftor/tezacaftor/deutivacaftor tablets)** Vertex
- C. **Attruby<sup>™</sup> (acoramidis tablets)** BridgeBio
- D. **Aucatzyl<sup>®</sup> (obecabtagene autoleucel intravenous infusion)** Autolus
- E. **Bizengri<sup>®</sup> (zenocutuzumab-zbco intravenous infusion)** Merus/Partner
- F. **Crenessity<sup>™</sup> (crinecerfont capsules and oral solution)** Neurocrine Biosciences
- G. **Emrosi<sup>™</sup> (minocycline extended-release capsules [40 mg])** Journey Medical
- H. **Ensacove<sup>™</sup> (ensartinib capsules)** Xcovery
- I. **Opdivo Qvantig<sup>™</sup> (nivolumab and hyaluronidase-nvhy subcutaneous injection)**  
Bristol Myers Squibb and Halozyme
- J. **Revuforj<sup>®</sup> (revumenib tablets)** Neurotech
- K. **Ryoncil<sup>®</sup> (remestemcel-L-rknd intravenous infusion)** Mesoblast
- L. **Tryngolza<sup>™</sup> (olezarsen subcutaneous injection)** Ionis
- M. **Unloxcyt<sup>™</sup> (cosibelimab-ipdl intravenous infusion)** Checkpoint Therapeutics
- N. **Ziihera<sup>®</sup> (zanidatamab-hrii intravenous infusion)** Jazz

### New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions:

- A. **Beizray<sup>®</sup> (docetaxel intravenous infusion)** Zhuhai Beihai Biotech
- B. **Danziten<sup>™</sup> (nilotinib tablets)** Azurity/Merck
- C. **Imkeldi<sup>®</sup> (imatinib oral solution)** Shorla
- D. **Ontralfy<sup>™</sup> (tizanidine oral solution)** Fidelity BioPharma
- E. **Raldesy<sup>™</sup> (trazodone hydrochloride oral solution)** Kamat Pharmatech

### 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. **Arixtra<sup>®</sup> (fondaparinux sodium subcutaneous injection)** Mylan – New pediatric indication for the treatment of venous thromboembolism in pediatric patients  $\geq 1$  year of age weighing  $\geq 10$  kg.
- B. **Bimzelx<sup>®</sup> (bimekizumab-bkzx subcutaneous injection)** UCB – New indication for the treatment of moderate to severe hidradenitis suppurativa in adults.
- C. **Braftovi<sup>®</sup> (encorafenib capsule)** Array BioPharma/Pfizer – New indication for use in combination with Erbitux<sup>®</sup> (cetuximab intravenous [IV] infusion) and mFOLFOX6, for the treatment of metastatic colorectal cancer in patients with a BRAF V600E mutation, as detected by an FDA-approved test.



Public Information

- D. Epysqli® (eculizumab-aagh intravenous infusion)** Samsung Bioepis – New indication for the treatment of generalized myasthenia gravis in adults who are anti-acetylcholine receptor antibody positive.
- E. Fludarabine Phosphate intravenous infusion (Sandoz)** – Revised indication for use as a component of a combination regimen for the treatment of adults with B-cell chronic lymphocytic leukemia (CLL). There was also an additional revised indication for the treatment of B-cell CLL in adults who have not responded to, or whose disease has progressed during treatment with at least one alkylating-agent containing regimen.
- F. Gemtesa® (vibegron tablets)** Urovant – New indication for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia.
- G. Imcivree® (setmelanotide subcutaneous injection)** Rhythm – Expanded age indication to include pediatric patients 2 years to < 6 years of age. Imcivree is now indicated to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients ≥ 2 years of age with syndromic or monogenic obesity due to Bardet-Biedl syndrome or pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance.
- H. Imfinzi® (durvalumab intravenous infusion)** AstraZeneca – New indication for use as a single agent for the treatment of limited-stage small cell lung cancer in adults whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
- I. Invokamet® (canagliflozin and metformin hydrochloride tablets)** Janssen – Expanded age indication to include pediatric patients ≥ 10 years of age. Invokamet 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.
- J. Invokamet XR® (canagliflozin and metformin hydrochloride extended-release tablets)** Janssen – Expanded age indication to include pediatric patients ≥ 10 years of age. Invokamet XR 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.
- K. Invokana® (canagliflozin tablets)** Janssen – Expanded age indication to include pediatric patients ≥ 10 years of age. Invokana 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.
- L. Nemluvio® (nemolizumab-ilto subcutaneous injection)** Galderma – New indication for the treatment of moderate to severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies in adults and pediatric patients ≥ 12 years of age.
- M. Nuwiq® (antihemophilic factor [recombinant] intravenous infusion)** Octapharma – Expanded age indication to include patients < 2 years of age. Nuwiq is now indicated in pediatric and adult patients with hemophilia A for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.
- N. Omvoh® (mirikizumab-mrkz intravenous infusion and subcutaneous injection) Lilly [late distribution]** – New indication for the treatment of moderately to severely active Crohn's disease in adults.
- O. Repatha® (evolocumab subcutaneous injection)** Amgen – Revised (reworded) indication to reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults with established CV disease.
- P. Tevimbra® (tislelizumab-jsgr intravenous infusion)** Beigene – New indication for use in combination with platinum and fluoropyrimidine-based chemotherapy, for the first-line treatment of unresectable or metastatic human epidermal growth factor receptor 2

(HER2)-negative gastric or gastroesophageal junction adenocarcinoma in adults whose tumors express programmed death-ligand 1 (PD-L1)  $\geq 1$ .

- Q. Trikafta® (elexacacftor/tezacaftor/ivacaftor tablets or oral granules and ivacaftor tablets or oral granules)** Vertex – Expanded indication to include 94 additional responsive mutations.
- R. Trodelvy® (sacituzumab govitecan-hziy intravenous infusion)** Gilead – Removal of indication for the treatment of locally advanced or metastatic urothelial cancer in adults who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 or PD-L1 inhibitor.
- S. Vtama® (tapinarof 1% cream)** Dermavant – New indication for the topical treatment of atopic dermatitis in adult and pediatric patients  $\geq 2$  years of age.

### **New Biosimilars**

The Committee reviewed the following new biosimilars:

- A. Steqeyma™ (ustekinumab-stba intravenous infusion)** Celltrion
- B. Steqeyma™ (ustekinumab-stba subcutaneous injection)** Celltrion
- C. Yesintek™ (ustekinumab-kfce intravenous infusion)** Biocon Biologics
- D. Yesintek™ (ustekinumab-kfce subcutaneous injection)** Biocon Biologics

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