



EXPRESS SCRIPTS®

**Express Scripts, Inc.  
Pharmacy and Therapeutics Committee  
Proceedings  
July 15, 2023**

**New Drug Evaluations**

The Committee reviewed the following new drugs:

- A. Abrysvo™ (respiratory syncytial virus vaccine intramuscular injection)** Pfizer
- B. Arexvy® (respiratory syncytial virus vaccine [adjuvanted] intramuscular injection)** GlaxoSmithKline
- C. Columvi™ (glofitamab-gxbm intravenous infusion)** Genentech
- D. Elevidys® (delandistrogene moxeparvovec-rokl intravenous infusion)** Sarepta
- E. Elfabrio® (pegunigalsidase alfa intravenous infusion)** Chiesi/Protalix
- F. Epkinly™ (epcoritamab-bysp subcutaneous injection)** Genmab
- G. Inpefa™ (sotagliflozin tablets)** Lexicon
- H. Litfulo™ (ritlecitinib capsules)** Pfizer
- I. Miebo™ (perfluorohexyloctane ophthalmic solution)** Bausch and Lomb
- J. Opvee® (nalmefene nasal spray)** Opiant/Indivior
- K. Roctavian® (valoctocogene roxaparvovec-rvox intravenous infusion)** Biomarin
- L. Rystiggo® (rozanolixizumab-noli subcutaneous infusion)** Argenx
- M. Veozah™ (fezolinetant tablets)** Astellas
- N. Vyjuvek™ (beremagene geperpavec-svdt gel for topical administration)** Krystal Biotech
- O. Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc injection)** Argenx

**New Clinical Line Extensions**

The Committee reviewed the following new clinical line extensions:

- A. Brixadi™ (buprenorphine extended-release subcutaneous injection)** Braeburn
- B. Cyclophosphamide intravenous injection** (Dr. Reddy's)
- C. Motpoly XR® (lacosamide extended-release capsules)** Aucta
- D. Paclitaxel protein-bound particles (albumin-bound) intravenous infusion** (Teva)
- E. Pemrydi RTU® (pemetrexed intravenous infusion)** Shilpa Medicare/Amneal
- F. Suflave® (polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride oral solution)** Braintree
- G. Vevye® (cyclosporine ophthalmic solution, 0.1%)** Novaliq
- H. Zolpidem tartrate 7.5 mg capsules** (Almatica)

**New Indications for Existing Products**

The Committee reviewed the following new indications for existing products: See product inserts for specific wording.

- A. Abrilada™ (adalimumab-afzb subcutaneous injection)** Pfizer – New indication for the treatment of moderate to severe hidradenitis suppurativa in adults.
- B. Ayvakit® (avapritinib tablets)** Blueprint Medicines – New indication for the treatment of indolent systemic mastocytosis in adults.
- C. Breo® Ellipta® (fluticasone furoate and vilanterol inhalation powder)** GlaxoSmithKline – Expanded age indication to include patients 5 to < 18 years of age for



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the maintenance treatment of asthma. Breo Ellipta is now indicated for the maintenance treatment of asthma in patients  $\geq 5$  years of age.

- D. Bylvay® (odevixibat oral pellets and capsules)** Ipsen – New indication for the treatment of cholestatic pruritus in patients  $\geq 12$  months of age with Alagille syndrome.
- E. Farxiga® (dapagliflozin tablets)** AstraZeneca – Expanded indication to include patients who have heart failure with mildly reduced ejection fraction or heart failure with preserved ejection fraction. Farxiga is now indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure.
- F. Hadlima™ (adalimumab-bwwd subcutaneous injection)** Organon – New indication for the treatment of moderate to severe hidradenitis suppurativa in adults.
- G. Imbruvica® (ibrutinib capsules, tablets, and oral suspension)** Pharmacyclics/Janssen – Removal of indication for the treatment of mantle cell lymphoma in adults who have received at least one prior therapy. Removal of indication for the treatment of marginal zone lymphoma in adults who require systemic therapy and have received at least one prior anti-CD20-based therapy.
- H. Injectafer® (ferric carboxymaltose intravenous injection or infusion)** Daiichi Sankyo – New indication for the treatment of iron deficiency in adults with heart failure categorized as New York Heart Association class II/III to improve exercise capacity.
- I. Jardiance® (empagliflozin tablets)** Boehringer Ingelheim – Expanded indication to include pediatric patients  $\geq 10$  years of age with type 2 diabetes mellitus. Jardiance is now indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients  $\geq 10$  years of age with type 2 diabetes mellitus.
- J. Lexapro® (escitalopram tablets and oral solution)** Allergan – Expanded age indication for generalized anxiety disorder (GAD) to include patients 7 to 17 years of age. Lexapro is now indicated for the treatment of GAD in adults and pediatric patients  $\geq 7$  years of age.
- K. Linzess® (linaclotide capsules)** Ironwood/Allergan – New indication for the treatment of functional constipation in pediatric patients 6 to 17 years of age.
- L. Lynparza® (olaparib tablets)** AstraZeneca/Merck – New indication in combination with abiraterone and prednisone or prednisolone for the treatment of deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer in adults.
- M. Paxlovid™ (nirmatrelvir tablets; ritonavir tablets, co-packaged)** Pfizer – Approved under a New Drug Application for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.
- N. Prevymis® (letermovir tablets)** Merck – New indication for prophylaxis of cytomegalovirus (CMV) disease in adult kidney transplant recipients at high risk (Donor CMV-seropositive/Recipient CMV-seronegative).
- O. Rexulti® (brexpiprazole tablets)** Otsuka/Lundbeck – New indication for the treatment of agitation associated with dementia due to Alzheimer's disease.
- P. Rinvoq® (upadacitinib extended-release tablets)** AbbVie – New indication for the treatment of moderately to severely active Crohn's disease in adults who have had an inadequate response or intolerance to one or more tumor necrosis factor inhibitors.
- Q. Synjardy® (empagliflozin and metformin hydrochloride)** Boehringer Ingelheim – Expanded age indication to include pediatric patients  $\geq 10$  years of age with type 2 diabetes mellitus. Synjardy is now indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients  $\geq 10$  years of age with type 2 diabetes mellitus.
- R. Talzenna® (talazoparib capsules)** Pfizer – New indication for use in combination with Xtandi® (enzalutamide capsules and tablets) for the treatment of homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer in adults.
- S. Triumeq® (abacavir, dolutegravir, lamivudine tablets) and Triumeq® PD (abacavir, dolutegravir, lamivudine tablets for oral suspension)** ViiV – Expanded



age indication to include pediatric patients  $\geq 3$  months of age and weighing  $\geq 6$  kg. Triumeq and Triumeq PD are now indicated for the treatment of human immunodeficiency virus infection in adults and in pediatric patients  $\geq 3$  months of age and weighing  $\geq 6$  kg.

### **New Biosimilar**

The Committee reviewed the following new biosimilar:

#### **A. Yuflyma® (adalimumab-aaty subcutaneous injection) Celltrion**

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