Express Scripts, Inc.
Pharmacy and Therapeutics Committee
Proceedings
January 18, 2024

New Drug Evaluations
The Committee reviewed the following new drugs:

A. **Adzynma™ (ADAMTS13 recombinant-krhn intravenous infusion)** Takeda
B. **Augtyro™ (repotrectinib capsules)** Bristol-Myers Squibb
C. **Casgevy™ (exagamglogene autotemcel intravenous infusion)** Vertex/CRISPR Therapeutics
D. **Filsuvez® (birch triterpenes topical gel)** Lichtenheldt GmbH/Chiesi
E. **Fruzaqla™ (fruquintinib capsules)** Takeda
F. **Iwilfin™ (eflornithine tablets)** US WorldMeds
G. **Ixchiq® (Chikungunya virus vaccine intramuscular injection [live])** Valneva
H. **Loqtorzi™ (toripalimab-tpzi intravenous infusion)** Coherus Biosciences
I. **Lyfgenia® (lovotibeglogene autotemcel intravenous infusion)** bluebird bio
J. **Ogsiveo™ (nirogacestat tablets)** SpringWorks
K. **Ryzneuta® (efbemalenograstim alfa-vuxw subcutaneous injection)** Evive/Acrotech
L. **Truqap™ (capivasertib tablets)** AstraZeneca
M. **Wainua™ (eplontersen subcutaneous injection)** AstraZeneca
N. **Zoryve® Foam (roflumilast 0.3% topical foam)** Arcutis

New Clinical Line Extensions
The Committee reviewed the following new clinical line extensions:

A. **Abacavir and lamivudine tablets for oral suspension** (Mylan)
B. **Alvaiz™ (eltrombopag choline tablets)** Teva
C. **Alyglo™ (immune globulin intravenous, human-stwk, 10% solution)** GC Biopharma
D. **Phyrago® (dasatinib tablets)** Nanocopoeia
E. **Zituvimet™ (sitagliptin and metformin hydrochloride tablets)** Zydus

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

A. **Adbry® (tralokinumab-ldrm subcutaneous injection)** Leo Pharma – Expanded age indication to include pediatric patients 12 to 17 years of age with moderate to severe atopic dermatitis. Adbry is now indicated for the treatment of moderate to severe atopic dermatitis in patients ≥ 12 years of age whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry can be used with or without topical corticosteroids.
B. **Bivigam® (immune globulin intravenous [human], 10% liquid)** ADMA Biologics – Expanded age indication to include pediatric patients 2 years to < 6 years of age. Bivigam is now indicated for the treatment of primary humoral immunodeficiency in adults and pediatric patients ≥ 2 years of age. This includes, but is not limited to, the humoral

immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

C. **Cresemba® (isavuconazonium sulfate capsules)** Astellas – Expanded age indication for Cresemba capsules in children 6 to < 18 years of age who weigh ≥ 16 kg for the treatment of invasive aspergillosis and invasive mucormycosis. Cresemba capsules are now indicated for the treatment of invasive aspergillosis and invasive mucormycosis in adults and pediatric patients ≥ 6 years of age who weigh ≥ 16 kg.

D. **Jaypirca® (pirtobrutinib tablets)** Lilly – New indication for the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in adults who have received at least two prior lines of therapy, including a Bruton's tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 inhibitor.

E. **Keytruda® (pembrolizumab intravenous infusion)** Merck – New indication for use in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of locally advanced unresectable or metastatic human epidermal growth factor receptor 2-negative gastric or gastroesophageal junction adenocarcinoma in adults.

F. **Keytruda® (pembrolizumab intravenous infusion)** [Merck] **and Padcev® (enfortumab vedotin-ejfv intravenous infusion)** [Astellas] – Expanded indication for combination use of Keytruda and Padcev for the treatment of locally advanced or metastatic urothelial cancer in adults.

G. **Lescol® XL (fluvastatin extended-release tablets)** Sandoz/Pfizer – Revised indication to remove the dyslipidemia language and non-low-density lipoprotein cholesterol (LDL-C) parameters. Lescol XL is now indicated to reduce the risk of undergoing coronary revascularization procedures and slow the progression of coronary atherosclerosis in adults with clinically evident coronary heart disease; as an adjunct to diet to reduce LDL-C in adults with primary hyperlipidemia; and as an adjunct to diet to reduce LDL-C in adults and pediatric patients ≥ 10 years of age with heterozygous familial hypercholesterolemia (HeFH) who require 80 mg of fluvastatin daily.

H. **Nexletol® (bempedoic acid tablets)** Esperion Therapeutics – Revised indication to remove the qualification of "maximally tolerated" from the description of statin therapy. Nexletol is now indicated as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with HeFH or atherosclerotic cardiovascular disease, who require additional lowering of LDL-C.

I. **Nexlizet® (bempedoic acid and ezetimibe tablets)** Esperion Therapeutics – Revised indication to remove the qualification of "maximally tolerated" from the description of statin therapy. Nexlizet is now indicated as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with HeFH or atherosclerotic cardiovascular disease, who require additional lowering of LDL-C.

J. **Nikita™ (pitavastatin tablets)** Lupin – Revised indication to allow expanded use in patients with primary hyperlipidemia. Nikita is now indicated as an adjunct to diet to reduce LDL-C in adults with primary hyperlipidemia.

K. **Opioids, extended-release products** (various manufacturers) – Revised indication for the extended-release opioids for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

L. **Tarpeyo® (budesonide 4 mg delayed-release capsule)** Calliditas Therapeutics – Expanded indication to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy who are at risk for disease progression. Also, Tarpeyo's approval was converted from accelerated to regular approval. The conversion from accelerated approval to regular approval was based on 15 months of follow-up in the NefIgArd trial.

M. **Welireg® (belzutifan tablets)** Merck – New indication for the treatment of advanced renal cell carcinoma in adults following a programmed death receptor-1 or programmed death-ligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor.

N. Wilate® (von Willebrand Factor/coagulation Factor VIII complex [human]) Octapharma – New indication in children and adults with von Willebrand disease (VWD) for routine prophylaxis to reduce the frequency of bleeding episodes. Wilate is indicated in this clinical scenario in children 6 years of age and older and adults with VWD.

O. Xtandi® (enzalutamide capsules and tablets) Astellas – New indication for the treatment of non-metastatic castration-sensitive prostate cancer in patients with biochemical recurrence at high risk for metastasis (high-risk biochemical recurrence).

P. Yuflyma® (adalimumab-aaty subcutaneous injection) Celltrion – New indication for the treatment of non-infectious intermediate, posterior, and panuveitis in adults.

New Biosimilar

The Committee reviewed the following new biosimilar:

A. Avzivi® (bevacizumab-tnjn intravenous infusion) Bio-Thera Solutions