EXPRESS SCRIPTS®

Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
September 8, 2016

New Drug Evaluations

The Committee reviewed the following new drugs.

A. Adlyxin™ (lixisenatide injection) Sanofi-Aventis
B. Rayaldee™ (calcifediol extended-release capsules) OPKO Pharmaceuticals, LLC
C. Relistor® (methylnaltrexone bromide tablets) Salix Pharmaceuticals/Valeant/Progenics
D. Xiidra™ (lifitegrast 5% ophthalmic solution) Shire

New Indications for Existing Products

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

A. Berinert® (C1 esterase inhibitor [human]) CSL Behring – Expanded age indication for the treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks in adult and pediatric patients. Previously, Berinert was indicated for the treatment of acute abdominal, facial, or laryngeal attacks of HAE in adult and adolescent patients.
B. Dexilant (dexlansoprazole delayed-release capsules) Takeda – Expanded age indication for patients ≥ 12 years of age for healing of all grades of erosive esophagitis (EE) for up to 8 weeks; to maintain healing of EE and relief of heartburn for up to 6 months in adults and 16 weeks in patients 12 to 17 years of age; and for the treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD) for 4 weeks. Previously, Dexilant capsules were indicated only in adults for these indications.
C. Dexilant SoluTab (dexlansoprazole delayed-release orally disintegrating tablets) Takeda – Expanded age indication for patients ≥ 12 years of age to maintain healing of EE and relief of heartburn for up to 6 months in adults and 16 weeks in patients 12 to 17 years of age and for the treatment of heartburn associated with symptomatic non-erosive GERD for 4 weeks. Previously, Dexilant SoluTabs were indicated only in adults for these indications.
D. Dysport® (abobotulinum-toxinA injection) Ipsen – New indication for the treatment of lower limb spasticity in pediatric patients 2 years of age and older.
E. Humira® (adalimumab injection) AbbVie – New indication for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients.
F. Keytruda® (pembrolizumab injection) Merck – New indication for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma with disease progression on or after platinum-containing chemotherapy.
G. Namzaric® (memantine and donepezil hydrochlorides extended-release capsules) Allergan – Expanded indication for the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on 10 mg of donepezil hydrochloride once daily (QD). Previously, Namzaric was indicated for the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on both memantine hydrochloride (immediate-release or extended-release) and donepezil hydrochloride 10 mg. For patients stabilized on donepezil 10 mg and not currently on memantine, the recommended starting dose is 7 mg/10 mg QD in the

evening, titrated up to the recommended maintenance dose of 28 mg/10 mg QD. Two additional strengths of Namzaric (memantine and donepezil hydrochloride extended-release capsules) will be available: 7 mg/10 mg and 21 mg/10 mg.

H. **Prevnar 13® (Pneumococcal 13-valent conjugate vaccine [diphtheria CRM197 protein] suspension for intramuscular injection) Pfizer** – Expanded age indication to include adult patients ages 18 to 49 years. In adults ≥ 18 years of age, Prevnar 13 is indicated for active immunization for the prevention of pneumonia and invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F. Previously, Prevnar 13 was indicated in adults ≥ 50 years of age.

I. **Synjardy® (empagliflozin and metformin hydrochloride tablets) Boehringer Ingelheim/Lilly** – Expanded indication to include treatment-naïve adults with type 2 diabetes mellitus. Synjardy is now indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin is appropriate. Previously, Synjardy was indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both empagliflozin and metformin.

J. **Trokendi XR® (topiramate extended-release capsules) Supernus** – Expanded age indication for use in patients ≥ 6 years of age as initial monotherapy for partial onset seizures (POS) or primary generalized tonic-clonic seizures. Previously, Trokendi XR was indicated as initial monotherapy in patients ≥ 10 years of age with POS or primary generalized tonic-clonic seizures.

K. **Xolair® (omalizumab for subcutaneous injection) Genentech** – Expanded age indication for patients ≥ 6 years of age with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Previously, Xolair was approved for patients ≥ 12 years of age for this indication.

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

A. **Afluria® Quadrivalent** (influenza vaccine suspension) Sequirus
B. **Belviq XR®** (lorcaserin extended-release tablets) Eisai/Arena
C. **Qbrelis™** (lisinopril oral solution) Silvergate
D. **Repatha® Pushtronex™** (evolocumab on-body infusor with prefilled cartridge) Amgen
E. **Syndros™** (dronabinol oral solution) Insys
F. **Troxyca® ER** (oxycodone hydrochloride and naltrexone hydrochloride extended-release capsules) Pfizer
G. **Viekira XR™** (dasabuvir, ombitasvir, paritaprevir, and ritonavir extended-release tablets) AbbVie