EXPRESS SCRIPTS®

Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
November 12, 2016

New Drug Evaluations

The Committee reviewed the following new drugs.

A. Exondys 51™ (eteplirsen injection for intravenous [IV] use) Sarepta Therapeutics, Inc.
B. Kyleena™ (levonorgestrel-releasing intrauterine system) Bayer
C. Lartruvo™ (olaratumab injection for IV use) Eli Lilly & Co.
D. Stelara® (ustekinumab for IV infusion) Jansen Biotech/Johnson and Johnson
E. Sustol® (granisetron extended-release subcutaneous injection) Heron Therapeutics

New Indications for Existing Products

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

A. Arzerra® (ofatumumab injection) Novartis – New indication for use in combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed chronic lymphocytic leukemia.
B. Blincyto® (blinatumomab injection) Amgen – Expanded age indication for the treatment of pediatric patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia.
C. Equetro® (carbamazepine extended-release capsules) Validus – New indication for the treatment of the pain associated with trigeminal neuralgia. Beneficial results have also been reported in glossopharyngeal neuralgia. This drug is not a simple analgesic and should not be used for the relief of trivial aches or pains.
D. Equetro® (carbamazepine extended-release capsules) Validus – New indication for the treatment of partial seizures with complex symptomatology (e.g., psychomotor, temporal lobe), generalized tonic-clonic seizures (grand mal), and mixed seizure patterns, which include the seizure types listed here or other partial or generalized seizures.
E. Ilaris® (canakinumab injection) Novartis – New indication for Tumor Necrosis Factor Receptor-Associated Periodic Syndrome.
F. Ilaris® (canakinumab injection) Novartis – New indication for Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency.
G. Ilaris® (canakinumab injection) Novartis – New indication for Familial Mediterranean Fever.
H. Keytruda® (pembrolizumab injection) Merck – New indication for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high programmed death ligand 1 (PD-L1) expression (Tumor Proportion Score [TPS] ≥ 50%) as determined by an FDA-approved test, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
I. Keytruda® (pembrolizumab injection) Merck – Revised indication to add level of PD-L1 expression for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥1%) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations

should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.

J. **Orkambi® (lumacaftor/ivacaftor tablets)** Vertex – Expanded age indication for the treatment of cystic fibrosis in patients ≥ 6 years of age who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator gene.
K. **Plavix® (clopidogrel bisulfate tablets)** Sanofi/Bristol-Myers Squibb – Revised (reworded) indications for acute coronary syndrome and recent myocardial infarction, recent stroke, or established peripheral arterial disease.
L. **Rexulti® (brexpiprazole tablets)** Otsuka/Lundbeck – Expanded indication for the treatment of schizophrenia in adults, which now includes maintenance treatment.
M. **Stelara® (ustekinumab subcutaneous injection)** Janssen – New indication for the treatment of adult patients with moderately to severely active Crohn's disease who have failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker OR who have failed or were intolerant to treatment with one or more TNF blockers.
N. **Tecentriq® (atezolizumab injection for IV use)** Genentech – New indication for the treatment of patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Tecentriq.
O. **Tarceva® (erlotinib tablets)** Genentech – Modified indication limiting its use for the treatment of metastatic NSCLC to patients whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations. Tarceva is now indicated for the treatment of patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen.
P. **Zemplar® (paricalcitol capsules)** AbbVie – Expanded age indication for pediatric patients ≥ 10 years of age for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stages 3 and 4 and CKD Stage 5 in patients on hemodialysis or peritoneal dialysis.

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

A. **Cuvitru™** (immune globulin subcutaneous [human], 20% solution) Shire
B. **Epaned®** (enalapril maleate oral solution) Silvergate
C. **Flublok®** Quadrivalent (influenza vaccine intramuscular injection) Protein Sciences
D. **Invokamet® XR** (canagliflozin and metformin hydrochloride extended-release tablets) Janssen
E. **Vermox™** Chewable (mebendazole 500 mg chewable tablets) Janssen
F. **Yosprala™** (aspirin and omeprazole delayed-release tablets) Aralez Pharmaceuticals