EXPRESS SCRIPTS®

Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
January 25, 2018

New Drug Evaluations

The Committee reviewed the following new drugs.

A. Fasenra™ (benralizumab injection for subcutaneous use) AstraZeneca
B. Hemlibra® (emicizumab-kxwh injection for subcutaneous use) Genentech/Roche/Chugai
C. Heplisav-B™ (hepatitis B vaccine [recombinant] adjuvanted solution for intramuscular injection) Dynavax Technologies Corporation
D. Lonhala™ Magnair™ (glycopyrrolate inhalation solution) Sunovion
E. Luxturna™ (voretigene neparvovec-rzyl intraocular suspension for subretinal injection) Spark Therapeutics
F. Mepsevii™ (vestronidase alfa-vjbk injection for intravenous use) Ultragenyx Pharmaceutical Inc.
G. Ozempic® (semaglutide injection for subcutaneous use) Novo Nordisk
H. Prevymis™ (letermovir tablets) Merck
I. Steglatro™ (ertugliflozin tablets) Merck
J. Sublocade™ (buprenorphine extended-release injection for subcutaneous use) Indivior
K. Vyzulta™ (latanoprostene bunod ophthalmic solution 0.024%) Bausch & Lomb/Valeant

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

A. Abilify Mycite® (aripiprazole tablets with sensor) Otsuka/Proteus
B. Admelog® (insulin lispro injection for subcutaneous or intravenous use) Sanofi Aventis
C. Auvi-Q® (epinephrine 0.1 mg injection for intramuscular or subcutaneous use) Kaleo
D. Balcoltra™ (levonorgestrel and ethinyl estradiol tablets and ferrous bisglycinate tablets) Neuvosyn Laboratories
E. Cinvanti™ (aprepitant injectable emulsion for intravenous use) Heron Therapeutics
F. Clenpiq™ (sodium picosulfate, magnesium oxide, and anhydrous citric acid oral solution) Ferring
G. Impoyz™ (clobetasol propionate cream, 0.025%) Promius
H. Juluca® (dolutegravir and rilpivirine tablets) ViiV Healthcare
I. Prexxartan® (valsartan oral solution) Carmel Biosciences
J. Segluromet™ (ertugliflozin and metformin hydrochloride tablets) Merck
K. Siklos™ (hydroxyurea tablets) Addmedica
L. Steglujan™ (ertugliflozin and sitagliptin tablets) Merck
M. Tekturna® (aliskiren oral pellets) Noden Pharma
N. Visco-3™ (sodium hyaluronate injection for intra-articular injection) Bioventus

New Biosimilar

The Committee reviewed the following new biosimilar.

A. **Ixifi™ (infliximab-qbtx injection for intravenous use)** Pfizer

New Indications for Existing Products

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

A. **Adcetris® (brentuximab vedotin injection for intravenous use)** Seattle Genetics – New indication for the treatment of adults with primary cutaneous anaplastic large cell lymphoma and CD30-expressing mycosis fungoides who have received prior systemic therapy.
B. **Auryxia® (ferric citrate tablets)** Keryx – New indication for the treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis.
C. **Avastin® (bevacizumab solution for intravenous infusion)** Genentech – Revised indication for the treatment of recurrent glioblastoma in adults. Previously, Avastin was indicated for the treatment of glioblastoma with progressive disease in adult patients following prior therapy as a single agent. The effectiveness of Avastin in glioblastoma was based on an improvement in objective response rate; no data had demonstrated an improvement in disease-related symptoms or increased survival with Avastin.
D. **Bosulif® (bosutinib tablets)** Pfizer – New indication for the treatment of adults with newly-diagnosed chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia.
E. **Cabometyx® (cabozantinib tablets)** Exelixis – Revised indication for the treatment of patients with advanced renal cell carcinoma. Previously, Cabometyx was indicated for the treatment of patients with advanced renal cell carcinoma who have received prior anti-angiogenic therapy.
F. **Faslodex® (fulvestrant injection for intramuscular use)** AstraZeneca – New indication for treatment of hormone-receptor positive, human epidermal growth factor receptor 2 negative advanced or metastatic breast cancer in combination with Verzenio™ (abemaciclib tablets) in women with disease progression after endocrine therapy.
G. **Gazyva® (obinutuzumab injection for intravenous use)** Genentech – New indication for the treatment of adults with previously untreated stage II bulky, III or IV follicular lymphoma, in combination with chemotherapy followed by Gazyva monotherapy in patients achieving at least a partial remission.
H. **Isentress® (raltegravir tablets, chewable tablets, and oral suspension)** Merck – Expanded patient population in combination with other antiretroviral agents for the treatment of HIV-1 infection in pediatric patients weighing ≥ 2 kg. Previously, Isentress was indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in pediatric patients ≥ 4 weeks of age.
I. **Levo-T® (levothyroxine sodium tablets)** Alara Pharmaceutical – Removal of indication for the treatment of various types of euthyroid goiter, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's thyroiditis), multinodular goiter. The Limitations of Use now state that Levo-T is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients as there are no clinical benefits and overtreatment with Levo-T may induce hyperthyroidism. Levo-T is also not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis.
J. **Nucala® (mepolizumab injection for subcutaneous use)** GlaxoSmithKline – New indication for the treatment of adults with eosinophilic granulomatosis with polyangiitis.
K. **Opdivo® (nivolumab injection for intravenous use)** Bristol-Myers Squibb – New indication for the adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.
L. **Perjeta® (pertuzumab injection for intravenous use)** Genentech – New indication for the adjuvant treatment of patients with human epidermal growth factor receptor 2 positive early

breast cancer at high risk of recurrence in combination with Herceptin® (trastuzumab injection) and chemotherapy.

M. **Procysbi® (cysteamine bitartrate delayed-release capsules)** Horizon Pharma – Expanded age indication to include pediatric patients 1 year to 2 years of age. Procysbi is now indicated for the treatment of nephropathic cystinosis in adults and pediatric patients ≥ 1 year of age.

N. **Repatha® (evolocumab injection for subcutaneous use)** Amgen – New indication to prevent heart attacks, strokes and coronary revascularizations in adults with established cardiovascular disease.

O. **Repatha® (evolocumab injection for subcutaneous use)** Amgen – Expanded indication in primary hyperlipidemia. New wording of the indication is as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low density lipoprotein.

P. **Sprycel® (dasatinib tablets)** Bristol-Myers Squibb – Expanded age indication for the treatment of pediatric patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase.

Q. **Sutent® (sunitinib malate capsules)** Pfizer – New indication for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma following nephrectomy.

R. **Taltz® (ixekizumab injection for subcutaneous use)** Lilly – New indication for the treatment of adults with active psoriatic arthritis.

S. **Tekturna® (aliskiren tablets)** Noden Pharma – Expanded age indication for the treatment of hypertension in adults and children ≥ 6 years of age, to lower blood pressure.

T. **Tivicay® (dolutegravir tablets)** ViiV Healthcare – New indication in combination with Edurant® (rilpivirine tablets) as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen for ≥ 6 months with no history of treatment failure or known substitutions associated with resistance to either antiretroviral agent.

U. **Triumeq® (abacavir, dolutegravir, and lamivudine tablets)** ViiV Healthcare – Expanded patient population for the treatment of HIV-1 infection in adults and in pediatric patients weighing ≥ 40 kg. Triumeq alone is not recommended in patients with resistance-associated integrase substitutions or clinically-suspected integrase strand transfer inhibitor resistance because the dose of dolutegravir in Triumeq is insufficient in these subpopulations.

V. **Xeljanz® (tofacitinib tablets)** Pfizer – New indication for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs.

W. **Xeljanz® XR (tofacitinib extended-release tablets)** Pfizer – New indication for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs.

X. **Xgeva® (denosumab injection for subcutaneous use)** Amgen – Expanded indication for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.