EXPRESS SCRIPTS®

Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
July 9, 2020

New Drug Evaluations

The Committee reviewed the following new drugs.

A. **Darzalex Faspro™ (daratumumab and hyaluronidase-fihj injection for subcutaneous use)** Janssen Biotech
B. **Ervebo® (Ebola Zaire live vaccine suspension for intramuscular injection)** Merck
C. **Fensolvi® (leuprolide acetate injectable suspension for subcutaneous use)** Tolmar
D. **Fintepla® (fenfluramine oral solution)** Zogenix
E. **Kynmobi™ (apomorphine sublingual film)** Sunovion Pharmaceuticals
F. **Ongentys® (opicapone capsules)** Neurocrine Biosciences
G. **Oriahnn™ (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules)** AbbVie Inc.
H. **Qinlock™ (ripretinib tablets)** Deciphera Pharmaceuticals, LLC
I. **Retevmo™ (selpercatinib capsules)** Eli Lilly and Company
J. **Tabrecta™ (capmatinib tablets)** Novartis Pharmaceutical
K. **Uplizna™ (inebilizumab-cdon injection for intravenous infusion)** Viela Bio
L. **Vesicare LS™ (solifenacin succinate oral suspension)** Astellas
M. **Zepzelca™ (lurbinectedin injection for intravenous use)** Jazz Pharmaceuticals
N. **Zilxi™ (minocycline 1.5% topical foam)** Foamix Pharmaceuticals

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

A. **Elyxyb™ (celecoxib oral solution)** Dr Reddy's Labs
B. **Impeklo™ (clobetasol propionate lotion, 0.05%)** Mylan
C. **Lyumjev™ (insulin lispro-aabc injection for subcutaneous or intravenous use)** Lilly
D. **Pemfexy™ (pemetrexed injection for intravenous use)** Eagle Pharmaceuticals
E. **Semglee™ (insulin glargine injection for subcutaneous use)** Mylan/Biocon
F. **Tivicay PD® (dolutegravir tablets for oral suspension)** ViiV Healthcare
G. **Tyblume™ (levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg tablets)** Exeltis USA

New Biosimilar

The Committee reviewed the following new biosimilar.

A. **Nyvepria™ (pegfilgrastim-apgf injection for subcutaneous use)** Pfizer

New Indications for Existing Products

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

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A. **Alunbrig® (brigatinib tablets)** Takeda – Expanded indication to include the first-line treatment of anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer in adults, as detected by a Food and Drug Administration-approved test.
B. **Avastin® (bevacizumab solution for intravenous infusion) + Tecentriq® (atezolizumab injection for intravenous use)** Genentech – New indication for the use of Avastin and Tecentriq in combination for the treatment of patients with unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy.
C. **Brilinta® (ticagrelor tablets)** AstraZeneca – New indication to reduce the risk of a first myocardial infarction or stroke in patients with coronary artery disease at high risk for such events.
D. **Cosentyx® (secukinumab injection for subcutaneous use)** Novartis – New indication for the treatment of active non-radiographic axial spondyloarthritis in adults with objective signs of inflammation.
E. **Crysvita® (burosumab-twza injection for subcutaneous use)** Ultragenyx/Kyowa Kirin – New indication for treatment of anti-human fibroblast growth factor 23-related hypophosphatemia in tumor-induced osteomalacia associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients ≥ 2 years of age.
F. **Cyramza® (ramucirumab injection for intravenous use)** Lilly – New indication for use in combination with erlotinib, for first-line treatment of metastatic non-small cell lung cancer in patients whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 (L858R) mutations.
G. **Dupixent® (dupilumab injection for subcutaneous use)** Sanofi/Regeneron – Expanded age indication for the treatment of patients ≥ 6 years of age with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable, with or without topical corticosteroids. Previously, Dupixent was indicated for patients ≥ 12 years of age with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable, with or without topical corticosteroids.
H. **Erelzi™ (etanercept-szzs injection for subcutaneous use)** Sandoz/Novartis – Expanded age indication to include patients 4 years to 17 years of age with plaque psoriasis. Erelzi is now indicated for the treatment of chronic moderate to severe plaque psoriasis in patients ≥ 4 years of age who are candidates for systemic therapy or phototherapy. Previously, Erelzi was only approved in adults for this indication.
I. **Gardasil® 9 (human papillomavirus 9-valent vaccine, recombinant)** Merck – Expanded indication to include prevention of oropharyngeal and other head and neck cancers caused by Human Papillomavirus types 16, 18, 31, 33, 45, 52, and 58.
J. **Farxiga® (dapagliflozin tablets)** AstraZeneca – New indication to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (New York Heart Association class II-IV) with reduced ejection fraction.
K. **Ilaris® (canakinumab injection for subcutaneous use)** Novartis – Expanded indication to include the new population of patients with active Adult-Onset Still's Disease (AOSD). Both, Systemic Juvenile Idiopathic Arthritis (SJIA) and AOSD, are referred to as Still's Disease. Ilaris is now indicated for the treatment of active Still's Disease, including AOSD and SJIA in patients ≥ 2 years of age.
L. **Inlyta® (axitinib tablets)** Pfizer – New indications for use in combination with Bavencio® (avelumab injection) or with Keytruda® (pembrolizumab injection) for the first-line treatment of advanced renal cell carcinoma.
M. **Keytruda® (pembrolizumab injection for intravenous use)** Merck – New indication as monotherapy for the treatment of unresectable or metastatic tumor mutational burden-high [≥ 10 mutations/megabase] solid tumors, as determined by a Food and Drug Administration-approved test, in adult and pediatric patients that have progressed following prior treatment and who have no satisfactory alternative treatment options.
N. **Lynparza® (olaparib tablets)** AstraZeneca – New indication for the treatment of deleterious or suspected deleterious germline or somatic homologous recombination repair gene-mutated

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metastatic castration-resistant prostate cancer in adults who have progressed following prior treatment with Xtandi® (enzalutamide capsules) or abiraterone.

O. Lynparza® (olaparib tablets) AstraZeneca – New indication for use in combination with bevacizumab injection for the maintenance treatment of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer in adults who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency-positive status defined by either a deleterious or suspected deleterious breast cancer susceptibility gene [BRCA] mutation, and/or genomic instability.

P. Mylotarg™ (gemtuzumab ozogamicin injection for intravenous use) Pfizer – Expanded age indication to include pediatric patients ≥ 1 month of age. Mylotarg is now indicated for the treatment of newly-diagnosed CD33-positive acute myeloid leukemia in adults and pediatric patients ≥ 1 month of age.

Q. Opdivo® (nivolumab injection for intravenous use) + Yervoy® (ipilimumab injection for intravenous use) Bristol Myers Squibb – New indication for the use of Opdivo and Yervoy in combination for the first-line treatment of metastatic non-small cell lung cancer in adults whose tumors express programmed death-ligand 1 [≥ 1%] as determined by a Food and Drug Administration-approved test, with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations.

R. Opdivo® (nivolumab injection for intravenous use) + Yervoy® (ipilimumab injection for intravenous use) Bristol Myers Squibb – New indication for the combination use of Opdivo, Yervoy, and two cycles of platinum-doublet chemotherapy, for the first-line treatment of metastatic or recurrent non-small cell lung cancer in adults, with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations.

S. Opdivo® (nivolumab injection for intravenous use) Bristol Myers Squibb – New indication for the treatment of patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based chemotherapy.

T. Pomalyst® (pomalidomide capsules) Bristol Myers Squibb – New indication for the treatment of acquired immune deficiency syndrome-related Kaposi sarcoma in adults after failure of highly active antiretroviral therapy and Kaposi sarcoma in adults who are human immunodeficiency virus-negative.

U. Rubraca® (rucaparib tablets) Clovis – New indication for the treatment of deleterious breast cancer susceptibility gene [BRCA] mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer in adults who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

V. Sirturo® (bedaquiline tablets) Janssen – Expanded age indication to include children 5 years to 11 years of age for use as part of combination therapy in the treatment of pulmonary multi-drug resistant tuberculosis in adults and pediatric patients (≥ 5 years of age and weighing ≥ 15 kg). Reserve Sirturo for use when an effective treatment regimen cannot otherwise be provided.

W. Taltz® (ixekizumab injection for subcutaneous use) Lilly – New indication for the treatment of active non-radiographic axial spondyloarthritis in adults with objective signs of inflammation.

X. Tazverik® (tazemetostat tablets) Epizyme – New indication for the treatment of adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by a Food and Drug Administration-approved test and who have received at least two prior systemic therapies.

Y. Tecentriq® (atezolizumab injection for intravenous use) Genentech – New indication as monotherapy for the first-line treatment of metastatic non-small cell lung cancer in adults whose tumors have high programmed death-ligand 1 (PD-L1) expression (PD-L1 stained ≥ 50% of tumor cells or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by a Food and Drug Administration-approved test, with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations.

Z. Tivicay® (dolutegravir tablets) ViiV Healthcare – New indication for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 infection in adults (treatment-naïve or -experienced) and in pediatric patients (treatment-naïve or -experienced but integrase strand transfer inhibitor-naïve) ≥ 4 weeks of age and weighing ≥ 3 kg.

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