



EXPRESS SCRIPTS®

**Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
May 16, 2019**

New Drug Evaluations

The Committee reviewed the following new drugs.

- A. **Balversa™ (erdafitinib tablets)** Janssen
- B. **Evenity™ (romosozumab-aqqg injection for subcutaneous use)** Amgen
- C. **Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk injection for subcutaneous use)** Genentech
- D. **Mavenclad® (cladribine tablets)** EMD Serono
- E. **Mayzent® (siponimod tablets)** Novartis
- F. **Skyrizi™ (risankizumab-rzaa subcutaneous injection)** AbbVie
- G. **Sunosi™ (solriamfetol tablets)** Jazz Pharmaceuticals
- H. **Vyndaqel® (tafamidis meglumine capsules)** and **Vyndamax™ (tafamidis capsules)** Pfizer
- I. **Zulresso™ (brexanolone injection for intravenous use)** Sage Therapeutics

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

- A. **Asceniv™ (immune globulin intravenous, human – slra 10% liquid)** ADMA Biologics
- B. **Corlanor® (ivabradine oral solution)** Amgen
- C. **Dovato™ (dolutegravir and lamivudine tablets)** ViiV Healthcare
- D. **Duaklir® Pressair® (aclidinium bromide and formoterol fumarate inhalation powder)** AstraZeneca
- E. **Duobrii™ (halobetasol propionate/tazarotene lotion, 0.01%/0.045%)** Bausch Health
- F. **Jatenzo® (testosterone undecanoate capsules)** Clarus
- G. **Qternmet® XR (dapagliflozin, saxagliptin and metformin hydrochloride extended release tablets)** AstraZeneca
- H. **Rocklatan™ (netarsudil and latanoprost ophthalmic solution)** Aerie Pharmaceuticals
- I. **Welchol® (colesevelam hydrochloride chewable bars)** Daiichi Sankyo
- J. **Zykadia® (ceritinib tablets)** Novartis

New Biosimilars

The Committee reviewed the following new biosimilar.

- A. **Eticovo™ (etanercept-ykro injection for subcutaneous use)** Samsung Bioepis
- B. **Trazimera™ (trastuzumab-qyyp 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.



Public Information

- A. **Benlysta® (belimumab injection for intravenous infusion)** – Expanded age indication for the treatment of patients ≥ 5 years of age with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.
- B. **Cimzia® (certolizumab pegol injection for subcutaneous use) UCB** – New indication the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
- C. **Corlanor® (ivabradine tablets) Amgen** – New indication for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients ≥ 6 months of age, who are in sinus rhythm with an elevated heart rate.
- D. **Dupixent® (dupilumab injection for subcutaneous use) Sanofi/Regeneron** – Expanded age indication to include patients 12 years of age to < 18 years of age with atopic dermatitis. Dupixent is now indicated for the treatment of 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.
- E. **Faslodex® (fulvestrant injection for intramuscular use) AstraZeneca** – New indication for hormone receptor positive, human epidermal growth factor receptor 2 negative advanced or metastatic breast cancer in postmenopausal women in combination with Kisqali® (ribociclib tablets) as initial endocrine-based therapy or following disease progression on endocrine therapy.
- F. **Ibrance® (palbociclib capsules) Pfizer** – Expanded indication to include men with advanced or metastatic breast cancer. Ibrance is now indicated for the treatment of adult patients with hormone receptor positive, human epidermal growth factor receptor 2 negative, advanced, or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men or Faslodex® (fulvestrant injection) in patients with disease progression following endocrine therapy.
- G. **Kadcyla® (ado-trastuzumab emtansine injection for intravenous use)** – New indication for use as a single agent, for the adjuvant treatment of patients with human epidermal growth factor receptor 2 positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.
- H. **Kalydeco® (ivacaftor tablets and oral granules) Vertex** – Expanded age indication for use in children with cystic fibrosis (CF) 6 months to < 12 months of age. Kalydeco is now indicated for the treatment of CF in patients ≥ 6 months of age who have one mutation in the cystic fibrosis transmembrane conductance regulator gene that is responsive to Kalydeco based on clinical and/or in vitro assay data.
- I. **Keytruda® (pembrolizumab injection for intravenous use) Merck** – Expanded indication for use as a single agent for the first-line treatment of patients with stage III non-small cell lung cancer (NSCLC), who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) $\geq 1\%$] as determined by an Food and Drug Administration (FDA)-approved test, with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations.
- J. **Keytruda® (pembrolizumab injection for intravenous use) Merck** – New indication in combination with Inlyta® (axitinib tablets), for the first-line treatment of patients with advanced renal cell carcinoma.
- K. **Mavyret® (glecaprevir and pibrentasvir tablets) AbbVie** – Expanded age indication to treat all six genotypes of hepatitis C virus (HCV) in children 12 to 17 years of age. Mavyret is now indicated for the treatment of adult and pediatric patients ≥ 12 years of age or weighing ≥ 45 kg with chronic HCV genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) and with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.
- L. **Opdivo® (nivolumab injection for intravenous use) Bristol-Myers Squibb** – Revised wording of indications for melanoma into a single approved indication. Opdivo is now indicated

as a single agent or administered with Yervoy® (ipilimumab injection) for the treatment of patients with unresectable or metastatic melanoma.

- M. Praluent® (alirocumab injection for subcutaneous use) Sanofi/Regeneron** – New indication to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- N. Praluent® (alirocumab injection for subcutaneous use) Sanofi/Regeneron** – Revised indication 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 cholesterol.
- O. Qtern® (dapagliflozin and saxagliptin tablets) AstraZeneca** – Revised indication as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- P. Tecentriq® (atezolizumab injection for intravenous use) Genentech** – New indication for use in combination with Abraxane® (paclitaxel protein-bound particles for injectable suspension), for the treatment of adult patients with unresectable locally-advanced or metastatic triple-negative breast cancer whose tumors express programmed death-ligand 1 (PD-L1) [PD-L1 stained tumor-infiltrating immune cells covering $\geq 1\%$ of the tumor area], as determined by an FDA-approved test.
- Q. Tecentriq® (atezolizumab injection for intravenous use) Genentech** – New indication for use in combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer.
- R. Tibsovo® (ivosidenib tablets) Agios Pharmaceuticals** – New indication for the treatment of newly-diagnosed acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation as detected by an FDA-approved test in adult patients who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.
- S. Welchol® (colesevelam hydrochloride tablets and packet for oral suspension) Daiichi Sankyo** – Revised indication for use to reduce low-density lipoprotein cholesterol (LDL-C) levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia who are unable to reach LDL-C target levels despite an adequate trial of dietary therapy and lifestyle modification.
- T. Zelnorm® (tegaserod maleate tablets) US WorldMeds** – Reintroduction of Zelnorm and revised indication for the treatment of adult women < 65 years of age with irritable bowel syndrome with constipation.

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