



EXPRESS SCRIPTS®

**Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
November 17, 2018**

New Drug Evaluations

The Committee reviewed the following new drugs.

- A. **Ajovy™ (fremanezumab-vfrm injection for subcutaneous use)** Teva
- B. **Arakoda™ (tafenoquine tablets)** 60 Degrees Pharmaceuticals
- C. **Arikayce® (amikacin liposome inhalation suspension for oral inhalation)** Insmed
- D. **Copiktra™ (duvelisib capsules)** Verastem
- E. **Delstrigo™ (doravirine/lamivudine/tenofovir disoproxil fumarate tablets)** Merck
- F. **Diacomit® (stiripentol capsules and powder for oral suspension)** Biocodex
- G. **Emgality™ (galcanezumab-gnlm injection for subcutaneous use)** Lilly
- H. **Libtayo® (cemiplimab-rwlc injection for intravenous use)** Regeneron/Sanofi-Genzyme
- I. **Lumoxiti™ (moxetumomab pasudotox-tdfk injection for intravenous use)** AstraZeneca
- J. **Oxervate™ (cenegermin-bkbj ophthalmic solution 0.002%)** Dompé farmaceutici S.p.A/Dompé USA
- K. **Nuzyra™ (omadacycline tablets)** 60 Degrees Pharmaceuticals
- L. **Pifeltro™ (doravirine tablets)** Merck
- M. **Revcovi™ (elapegademase-ivlr injection for intramuscular use)** Leadiant
- N. **Seysara™ (sarecycline tablets)** Allergan
- O. **Talzenna™ (talazoparib capsules)** Pfizer Inc.
- P. **Tegsedi™ (inotersen injection for subcutaneous use)** Ionis/Akcea Therapeutics
- Q. **Xofluza™ (baloxavir marboxil tablets)** Genentech
- R. **Xyosted™ (testosterone enanthate subcutaneous injection)** Antares Pharma
- S. **Vizimpro® (dacomitinib tablets)** Pfizer

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

- A. **Bijuva™ (estradiol 1 mg and progesterone 100 mg capsules)** TherapeuticsMD
- B. **Khazory™ (levoleucovorin injection for intravenous use)** Spectrum
- C. **Symjepi™ (epinephrine injection 0.15 mg for intramuscular or subcutaneous use [prefilled syringe])** Adamis
- D. **Qmiiz™ ODT (meloxicam orally-disintegrating tablet)** TerSera Therapeutics
- E. **Xelpros™ (latanoprost ophthalmic emulsion, 0.005%)** Sun Pharma
- F. **Yutiq™ (fluocinolone acetonide 0.18 mg intravitreal implant)** EyePoint

New Biosimilars

The Committee reviewed the following new biosimilar.

- A. **Hyrimoz™ (adalimumab-adaz injection for subcutaneous use)** Sandoz
- B. **Udenyca™ (pegfilgrastim-cbqv injection for subcutaneous use)** Coherus BioSciences



Public Information

New Indications for Existing Products

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

- A. Actemra® (tocilizumab injection for subcutaneous use)** Genentech – New indication for the subcutaneous form of Actemra for the treatment of active systemic juvenile idiopathic arthritis in patients ≥ 2 years of age.
- B. Afluria® (influenza vaccine)** Seqirus – Expanded age indication to include patients 6 months through 59 months of age. Afluria is now indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B present in the vaccine for use in persons ≥ 6 months of age.
- C. Afluria® Quadrivalent (influenza vaccine)** Seqirus – Expanded age indication to include patients 6 months through 59 months of age. Afluria Quadrivalent is now indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B present in the vaccine for use in persons ≥ 6 months of age.
- D. Coagadex® (coagulation Factor X [Human] lyophilized powder for solution for intravenous injection)** BPL USA – New indication in adults and children with hereditary Factor X deficiency for routine prophylaxis to reduce the frequency of bleeding episodes.
- E. Dupixent® (dupilumab injection for subcutaneous use)** Sanofi/Regeneron – New indication as an add-on maintenance therapy in patients with moderate to severe asthma ≥ 12 years of age with an eosinophilic phenotype or with oral corticosteroid-dependent asthma.
- F. Fycompa® (perampanel tablets and oral suspension)** Eisai – Expanded age indication for the treatment of partial-onset seizures (POS) in adolescents and children 4 to < 12 years with epilepsy. Fycompa is now indicated for the treatment of POS with or without secondarily generalized seizures in patients with epilepsy ≥ 4 years of age. Previously, Fycompa was indicated for the treatment of POS with or without secondarily generalized seizures in patients with epilepsy ≥ 12 years of age.
- G. Gardasil® 9 (human papillomavirus 9-valent vaccine, recombinant)** Merck – Expanded age indication to include women and men 27 years through 45 years of age. Gardasil 9 is now indicated in girls and women (and boys and men where noted with an *) 9 through 45 years of age for the prevention of the following diseases: cervical, vulvar, vaginal, and anal cancer* caused by Human Papillomavirus (HPV) types 16, 18, 31, 33, 45, 52, and 58; genital warts (condyloma acuminata)* caused by HPV types 6 and 11; and the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58: cervical intraepithelial neoplasia grade 2/3 and cervical adenocarcinoma in situ (AIS); cervical intraepithelial neoplasia grade 1; vulvar intraepithelial neoplasia grade 2 and grade 3; vaginal intraepithelial neoplasia grade 2 and grade 3; and anal intraepithelial neoplasia* grades 1, 2, and 3.
- H. Hemlibra® (emicizumab-kxwh injection for subcutaneous use)** Roche – Expanded indication to include patients without inhibitors. Hemlibra is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors. Previously, Hemlibra was indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors.
- I. Humira® (adalimumab injection for subcutaneous use)** AbbVie – Expanded age indication for uveitis to include children ≥ 2 years of age. Humira is now indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients ≥ 2 years of age. Previously, Humira was indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients.

- J. **Invokana® (canagliflozin tablets)** Janssen – New indication to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.
- K. **Invokamet® (canagliflozin and metformin hydrochloride tablets) Invokamet® XR (canagliflozin and metformin hydrochloride extended-release tablets)** Janssen – New indication to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.
- L. **Liletta® (levonorgestrel-releasing 52 mg intrauterine system)** Medicines360 – Expanded duration of use for the prevention of pregnancy for up to 5 years. The system should be replaced after 5 years if continued use is desired. Previously, Liletta was indicated for prevention of pregnancy for up to 4 years.
- M. **Lithium carbonate capsules, lithium carbonate tablets, and lithium oral solution 8 meq/5mL** West-Ward – Expanded age indication for patients ≥ 7 years of age. Lithium is now indicated as monotherapy for the treatment of acute manic and mixed episodes of bipolar I disorder in patients ≥ 7 years of age and for maintenance treatment of bipolar I disorder in patients ≥ 7 years of age. Previously, lithium was indicated for the treatment of manic episodes and as maintenance treatment for Bipolar I Disorder in patients ≥ 12 years of age.
- N. **Keytruda® (pembrolizumab injection for intravenous use)** Merck – New indication for use in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for the first-line treatment of patients with metastatic squamous non-small cell lung cancer.
- O. **Stiolto® Respiat® (tiotropium bromide & olodaterol inhalation spray)** Boehringer Ingelheim – Revised indication for long-term, once-daily maintenance treatment of patients with chronic obstructive pulmonary disease, including chronic bronchitis and/or emphysema. Previously, Stiolto Respiat was indicated for long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and/or emphysema.
- P. **Viramune XR® (nevirapine extended-release tablets)** Boehringer Ingelheim – Revised indication to include only pediatric patients with body surface area (BSA) ≥ 1.17 m². Viramune XR is now indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients ≥ 6 years of age with a BSA of ≥ 1.17 m². Previously, Viramune XR was indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in patients ≥ 6 years of age.
- Q. **Xarelto® (rivaroxaban tablets)** Janssen – New indication for use in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular death, myocardial infarction and stroke) in patients with chronic coronary artery disease or peripheral artery disease.
- R. **Xyrem® (sodium oxybate oral solution)** Jazz – Expanded age indication to include patients 7 years to 17 years of age. Xyrem is now indicated for the treatment of cataplexy or excessive daytime sleepiness in patients ≥ 7 years of age with narcolepsy. Previously, Xyrem was indicated for the treatment of cataplexy in narcolepsy and excessive daytime sleepiness in narcolepsy in adults.

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