



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

**New Drug Evaluations**

The Committee reviewed the following new drugs.

- A. Eysuvis™ (loteprednol etabonate 0.25% ophthalmic suspension)** Kala Pharmaceuticals
- B. Gavreto™ (pralsetinib capsules)** Blueprint Medicines Corporation
- C. Gimoti™ (metoclopramide nasal spray)** Evoke Pharma
- D. Lampit® (nifurtimox tablets)** Bayer HealthCare Pharmaceuticals
- E. Milprosa™ (progesterone vaginal system)** Ferring Pharmaceuticals
- F. Mycapssa® (octreotide delayed-release capsules)** Chiasma
- G. Onureg® (azacitidine tablets)** Celgene Corporation
- H. Winlevi® (clascoterone cream 1%)** Cassiopea
- I. Xeglyze™ (abametapir lotion)** Dr. Reddy's Laboratories

**New Clinical Line Extensions**

The Committee reviewed the following new clinical line extensions.

- A. Alkindi® Sprinkle (hydrocortisone oral granules)** Eton Pharmaceuticals/Diurnal Limited
- B. MenQuadfi™ (Meningococcal [groups A, C, Y, W] conjugate vaccine solution for intramuscular injection)** Sanofi Pasteur
- C. Qdolo™ (tramadol hydrochloride oral solution)** Athena Bioscience
- D. Xeljanz® (tofacitinib oral solution)** Pfizer

**New Indications for Existing Products**

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

- A. Brilinta® (ticagrelor tablets)** AstraZeneca – New indication to reduce the risk of stroke in patients with acute ischemic stroke (National Institutes of Health Stroke Scale score ≤ 5) or high-risk transient ischemic attack.
- B. Haegarda® (C1 Esterase Inhibitor [Human] for subcutaneous use)** CSL Behring – Expanded age indication to include patients 6 to < 12 years of age. Haegarda is now indicated for routine prophylaxis to prevent Hereditary Angioedema attacks in patients ≥ 6 years of age.
- C. Ixinity® (coagulation Factor IX [recombinant] injection for intravenous use)** Aptevo BioTherapeutics – New indication for routine prophylaxis to reduce the frequency of bleeding episodes in adults and adolescents ≥ 12 years of age with hemophilia B.
- D. Kalydeco® (ivacaftor tablets and oral granules)** Vertex – Expanded age indication for use in children with cystic fibrosis (CF) 4 to < 6 months of age. Kalydeco is now indicated for the treatment of CF in patients ≥ 4 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.
- E. Keytruda® (pembrolizumab injection for intravenous use)** Merck – Revised indication for the treatment of relapsed or refractory classical Hodgkin lymphoma (cHL) in adults. Keytruda

has an additional revised indication for the treatment of refractory cHL, or cHL that has relapsed after two or more lines of therapy in pediatric patients.

- F. Nucala® (mepolizumab injection for subcutaneous use)** GlaxoSmithKline – New indication for the treatment of hypereosinophilic syndrome for  $\geq 6$  months in adult and pediatric patients  $\geq 12$  years of age without an identifiable non-hematologic secondary cause.
- G. Opdivo® (nivolumab injection for intravenous use) + Yervoy® (ipilimumab injection for intravenous use)** Bristol Myers Squibb – New indication for the combination use of Opdivo and Yervoy for the first-line treatment of unresectable malignant pleural mesothelioma in adults.
- H. Selzentry® (maraviroc tablets and oral solution)** ViiV Healthcare – Expanded indication to include patients weighing 2 to  $< 10$  kg. Selzentry is now indicated in combination with other antiretroviral agents for the treatment of only chemokine receptor type 5-tropic human immunodeficiency virus type 1 infection in adult and pediatric patients weighing at least 2 kg.
- I. Simponi Aria® (golimumab injection for intravenous use)** Janssen – New indication for the treatment of active polyarticular juvenile idiopathic arthritis in patients  $\geq 2$  years of age.
- J. Simponi Aria® (golimumab injection for intravenous use)** Janssen – Expanded age indication to include patients 2 to less than 18 years of age for the treatment of active psoriatic arthritis. Simponi Aria is now indicated for treatment of active psoriatic arthritis in patients  $\geq 2$  years of age.
- K. Totect® (dexrazoxane for injection for intravenous use)** Clinigen – New indication for reducing the incidence and severity of cardiomyopathy associated with doxorubicin administration in women with metastatic breast cancer who have received a cumulative doxorubicin dose of  $300 \text{ mg/m}^2$  and who will continue to receive doxorubicin therapy to maintain tumor control.
- L. Trelegy Ellipta® (fluticasone furoate, umeclidinium, and vilanterol inhalation powder)** GlaxoSmithKline/Innoviva – New indication for the maintenance treatment of asthma in patients  $\geq 18$  years of age.
- M. Ultravate® (halobetasol propionate 0.05% lotion)** Sun Pharmaceuticals – Expanded age indication to include pediatric patients 12 to  $< 18$  years of age. Ultravate is now indicated for plaque psoriasis in adult and pediatric patients  $\geq 12$  years of age.
- N. Wakix® (pitolisant tablets)** Harmony Biosciences – New indication for the treatment of cataplexy in adults with narcolepsy.
- O. Xeljanz® (tofacitinib tablets)** Pfizer – New indication for the treatment of active polyarticular course juvenile idiopathic arthritis in patients  $\geq 2$  years of age.

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