EXPRESS SCRIPTS®

Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
May 17 and 18, 2018

New Drug Evaluations

The Committee reviewed the following new drugs.

A. **Aimovig™ (erenumab-aooe injection for subcutaneous use)** Amgen
B. **Akynzeo® IV (fosnetupitant and palonosetron injection for intravenous use)** Helsinn
C. **Crysvita® (burosumab-twza injection for subcutaneous use)** Ultragenyx
D. **Jynarque™ (tolvaptan tablets for oral use)** Otsuka
E. **Tavalisse™ (fostamatinib disodium hexahydrate tablets)** Rigel Pharmaceuticals/Patheon Whitby

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

A. **Symfi™ (600 mg efavirenz, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate tablets)** Mylan
B. **Plenvu® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution)** Salix/Valeant
C. **hydrocodone bitartrate and guaifenesin tablets**, CII ECI Pharmaceuticals
D. **Zypitamag® (pitavastatin magnesium tablets)** Zydus Pharm
E. **Nikita® (pitavastatin sodium tablets)** Lupin

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 use in combination with chemotherapy in adult patients with previously untreated Stage III or IV classical Hodgkin lymphoma.
B. **Afinitor Disperz® (everolimus tablets for oral suspension)** Novartis – New indication for the adjunctive treatment of adult and pediatric patients ≥ 2 years of age with tuberous sclerosis complex-associated partial-onset seizures.
C. **Antivert® (meclizine tablets, generics)** Casper Pharma – Removal of indication for the prevention and treatment of the nausea, vomiting, dizziness associated with motion sickness.
D. **Blincyto® (blinatumomab for injection for intravenous use)** Amgen – New indication for the treatment of B-cell precursor acute lymphoblastic leukemia in first or second complete remission with minimal residual disease (MRD) ≥ 0.1% in adults and children. This indication was approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

E. **Bydureon® (exenatide extended-release injectable suspension)** AstraZeneca – Expanded indication as an add-on therapy to basal insulin in adults with type 2 diabetes mellitus with inadequate glycemic control.
F. **Darzalex® (daratumumab injection for intravenous use)** Janssen – New indication for use in combination with Velcade® (bortezomib for injection for subcutaneous or intravenous use), melphalan and prednisone for the treatment of patients with newly-diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
G. **Emend® (fosaprepitant injection for intravenous use)** Merck – Expanded age indication for use in combination with other antiemetics in patients ≥ 6 months of age for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly-emetogenic chemotherapy including high-dose cisplatin and for delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.
H. **Hizentra® (immune globulin subcutaneous [human] 20% liquid)** CSL Behring – New indication for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy as maintenance therapy to prevent relapse of neuromuscular disability and impairment.
I. **Kymriah® (tisagenlecleucel suspension for intravenous infusion)** Novartis – New indication for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.
J. **Leukine® (sargramostim injection, for subcutaneous or intravenous use)** Sanofi-Aventis – New indication to increase survival in adult and pediatric (from birth to 17 years of age) patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome).
K. **Lyrica® (pregabalin capsules and oral solution)** Pfizer – Expanded age indication as adjunctive therapy for the treatment of partial onset seizures in patients ≥ 4 years of age.
L. **Mekinist® (trametinib tablets)** Novartis – New indication in combination with Tafinlar® (dabrafenib capsules), for the treatment of patients with locally-advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation and with no satisfactory locoregional treatment options.
M. **Mekinist® (trametinib tablets)** Novartis – New indication, in combination with Tafinlar® (dabrafenib capsules), for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an Food and Drug Administration (FDA)-approved test, and involvement of lymph node(s), following complete resection.
N. **Myrbetriq® (mirabegron extended-release tablets)** Astellas – New indication for use in combination with the muscarinic antagonist Vesicare® (solifenacin succinate tablets) for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency.
O. **Opdivo® (nivolumab injection)** Bristol-Myers Squibb – New indication in combination with Yervoy® (ipilimumab injection) for previously untreated patients with intermediate and poor risk advanced renal cell carcinoma.
P. **Potassium chloride extended-release tablets and capsules (e.g., Micro-K®, K-Tab®, Klor-Con®, generics)** various – Revised indication for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient.
Q. **Rubraca® (rucaparib tablets)** Clovis – New indication for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
R. **Rubraca® (rucaparib tablets)** Clovis – New indication for the treatment of adult patients with deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies.

S. **Tafinlar® (dabrafenib capsules)** Novartis – New indication, in combination with Mekinist® (trametinib tablets), for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by a Food and Drug Administration (FDA)-approved test, and involvement of lymph node(s), following complete resection.

T. **Tafinlar® (dabrafenib capsules)** Novartis – New indication in combination with Mekinist® (trametinib tablets), for the treatment of patients with locally-advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation and with no satisfactory locoregional treatment options.

U. **Tagrisso® (osimertinib tablets)** AstraZeneca – New indication for the first-line treatment of patients with metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor mutations (exon 19 deletions or exon 21 L858R substitution mutations), as detected by an FDA-approved test.

V. **Tasigna® (nilotinib capsules)** Novartis – New indication for pediatric patients with resistant chronic phase Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML). Tasigna is now indicated for the treatment of pediatric patients ≥ 1 year of age with chronic phase Ph+ CML with resistance or intolerance to prior tyrosine kinase inhibitor therapy.

W. **Tasigna® (nilotinib capsules)** Novartis – Expanded age indication for newly-diagnosed pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML). Tasigna is now indicated for the treatment of adult and pediatric patients ≥ 1 year of age with newly-diagnosed Ph+ CML in chronic phase.

X. **Trelegy Ellipta® (fluticasone furoate, umeclidinium, and vilanterol inhalation powder)** GlaxoSmithKline/Innoviva – Revised indication for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Trelegy Ellipta is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.

Y. **Vonvendi® (von Willebrand factor [recombinant] for intravenous injection**) Baxalta/Shire – New indication for perioperative management of bleeding in adults (≥ 18 years of age) with von Willebrand disease.

Z. **Yervoy® (ipilimumab injection)** Bristol Myers Squibb – New indication in combination with Opdivo® (nivolumab injection) for previously untreated patients with intermediate and poor risk advanced renal cell carcinoma.

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