



EXPRESS SCRIPTS®

**Express Scripts, Inc.
Pharmacy and Therapeutics Committee
Proceedings
November 17, 2011**

New Drug Evaluations

The Committee reviewed the following new drugs.

- A. Ferriprox® (deferiprone tablets – Apotex Inc.)**
- B. Potiga™ (ezogabine tablets – GlaxoSmithKline/Valeant)**

New Indications for Existing Products

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

- A. Afluria® (influenza virus vaccine) CSL Limited** - Change in age indication for immunization of persons ≥ 5 years against influenzal disease caused by influenza virus subtypes A and type B present in the vaccine.
- B. Amturnide™ (aliskiren, amlodipine, and hydrochlorothiazide tablets) Novartis** - Outcome claims language approved (no controlled trials demonstrating risk reduction with Amturnide). Indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from many pharmacologic classes, including amlodipine and hydrochlorothiazide. There are no controlled trials demonstrating risk reduction with Amturnide.
- C. Byetta® (exenatide injection) Amylin/Eli Lilly** - Revised limitation of use for existing indication. The concurrent use of Byetta with prandial insulin has not been studied and cannot be recommended.
- D. Cialis® (tadalafil tablets) Eli Lilly** – For the treatment of the signs and symptoms of benign prostatic hyperplasia.
- E. Cialis® (tadalafil tablets) Eli Lilly** - For the treatment of erectile dysfunction and the signs and symptoms of benign prostatic hyperplasia.
- F. Erbitux® (cetuximab injection, for intravenous infusion) Bristol-Myers Squibb/Eli Lilly** - For first-line treatment of patients with recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck in combination with platinum-based therapy with 5-FU.
- G. Remicade® (infliximab injection, for intravenous use) Janssen Biotech** - For reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients ≥ 6 years of age with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.
- H. Soliris® (eculizumab concentrated solution for intravenous infusion) Alexion** - For the treatment of patients with atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy.
- I. Tekamlo™ (aliskiren and amlodipine tablets) Novartis** - Outcome claims language approved (no controlled trials demonstrating risk reduction with Tekamlo). Indicated for the treatment of hypertension, alone or with other antihypertensive agents, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in

controlled trials of antihypertensive drugs from many pharmacologic classes, including amlodipine. There are no controlled trials demonstrating risk reduction with Tekamlo.

- J. **Tekturna® (aliskiren tablets) Novartis** - Outcome claims language approved (no controlled trials demonstrating risk reduction with Tekturna). Indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from many pharmacologic classes. There are no controlled trials demonstrating risk reduction with Tekturna.
- K. **Tekturna HCT® (aliskiren and hydrochlorothiazide tablets) Novartis** - Outcome claims language approved (no controlled trials demonstrating risk reduction with Tekturna HCT). Indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from many pharmacologic classes, including hydrochlorothiazide. There are no controlled trials demonstrating risk reduction with Tekturna HCT.
- L. **Valturna® (aliskiren and valsartan tablets) Novartis** - Outcome claims language approved (no controlled trials demonstrating risk reduction with Valturna). Indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from many pharmacologic classes, including the angiotensin receptor blocker class to which the valsartan component of this drug principally belongs. There are no controlled trials demonstrating risk reduction with Valturna.
- M. **Xarelto® (rivaroxaban tablets) Janssen** – To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

- A. **Combivent® Respimat® (ipratropium bromide and albuterol inhalation spray) Boehringer Ingelheim**
- B. **ConZip™ (tramadol hydrochloride extended-release capsules) Cipher Pharmaceuticals / Vertical Pharmaceuticals**
- C. **Gammaked® (immune globulin injection [human] 10% caprylate/chromatography purified) Talecris/Kedrion**
- D. **Juvisync™ (sitagliptin and simvastatin tablets) Merck**