



EXPRESS SCRIPTS®

**Express Scripts, Inc.
Pharmacy and Therapeutics Committee
Proceedings
October 17, 2009**

New Drug Evaluations

The Committee reviewed the following new drugs.

- A. **Sabril® (vigabatrin tablets and oral solution) - Lundbeck**
- B. **Embeda™ (morphine sulfate and naltrexone hydrochloride extended-release capsules) - King Pharmaceuticals**
- C. **Tyvaso™ (treprostinil inhalation solution) – United Therapeutics**
- D. **Fanapt™ (iloperidone tablets) - Vanda Pharmaceuticals**
- E. **Saphris® (asenapine sublingual tablets) - Schering-Plough**
- F. **Invega® Sustenna™ (paliperidone palmitate extended-release injectable suspension) – Janssen**
- G. **Dysport™ (abobotulinumtoxinA for injection) – Ipsen**
- H. **Intuniv™ (guanfacine extended-release tablets) – Shire Pharmaceuticals**
- I. **Bepreve™ (bepotastine besilate ophthalmic solution 1.5%) – ISTA Pharmaceuticals, Inc**
- J. **Stelara™ (ustekinumab injection) – Centocor Ortho Biotech**

New Indications for Existing Products

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

- A. **Havrix® (Hepatitis A vaccine [inactivated], suspension for intramuscular suspension) GlaxoSmithKline** - For active immunization against disease caused by hepatitis A virus (HAV) for persons ≥ 12 months of age (previously was for persons ≥ 2 years of age).
- B. **Welchol® (colesevelam hydrochloride tablets and powder for oral suspension) Daiichi Sankyo, Inc.** – As monotherapy or in combination with a statin to reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains ≥ 190 mg/dL or b. LDL-C remains ≥ 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) OR two or more other CVD risk factors are present in the pediatric patient.
- C. **Helixate® FS (anithemophilic factor [recombinant], formulated with sucrose, lyophilized powder for reconstitution, for intravenous use) CSL Behring** - For routine prophylactic treatment to reduce the frequency of bleeding episodes and the risk of joint damage in children with no pre-existing joint damage.
- D. **Xyzal® (levocetirizine tablets and oral solution) Sanofi-aventis** - For the relief of symptoms associated with perennial allergic rhinitis (PAR) and uncomplicated skin manifestations of chronic idiopathic urticaria (hives) in children 6 months of age and older; and for the relief of symptoms associated with seasonal allergic rhinitis (SAR) in children 2 years of age and older.

- E. **Valcyte[®] (valganciclovir tablets) Roche Laboratories Inc.** - For the prevention of cytomegalovirus disease in kidney and heart transplant patients, 4 months to 16 years of age, at high risk.

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

- A. **TobraDex[®] ST (tobramycin 0.3%/dexamethasone 0.05% ophthalmic suspension) Alcon**
- B. **Hiberix[®] (Haemophilus b conjugate vaccine [tetanus toxoid conjugate] solution for intramuscular injection) GlaxoSmithKline**
- C. **Colcrys[™] (colchicine tablets) Mutual Pharmaceutical Company, Inc.**
- D. **Zenpep[™] (pancrelipase delayed-release capsules) Mutual Pharmaceutical Company, Inc.**
- E. **Astepro[®] (azelastine hydrochloride 0.15% nasal spray) MEDA Pharmaceuticals**
- F. **Valturna[®] (aliskiren and valsartan tablets) Novartis**
- G. **Gammaplex[®] (immune globulin intravenous [human]) Bio Products Laboratory**
- H. **Renvela[®] (sevelamer carbonate for oral suspension) Genzyme**
- I. **Metozolv[™] ODT (metoclopramide hydrochloride orally disintegrating tablets) Salix Pharmaceuticals, Inc.**
- J. **Valcyte[®] (valganciclovir oral solution) Roche Laboratories Inc.**