



**Express Scripts, Inc.
Pharmacy and Therapeutics Committee
Proceedings
July 12, 2008**

Drug Evaluations

The Committee reviewed the following new drugs.

- A. Relistor® (methylnaltrexone bromide subcutaneous injection) - Wyeth**
- B. Hycamtin® (topotecan capsules) – GlaxoSmithKline**

New Indications for Existing Products

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

- A. Keppra® (levetiracetam injection) - UCB Pharma** – For use as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and children 16 years of age and older with idiopathic.
- B. Herceptin® (trastuzumab intravenous infusion) - Genentech** – Expanded for the adjuvant treatment of human epidermal growth factor receptor 2 (HER2) overexpressing node-positive or node-negative (estrogen receptor [ER]/progesterone receptor [PR] negative or with one high-risk feature) breast cancer in conjunction with either regimen: 1) doxorubicin, cyclophosphamide, and docetaxel, or 2) docetaxel and carboplatin. Also, this label revision clarified the metastatic breast cancer indication in combination with paclitaxel to note it is indicated for first-line treatment.
- C. Reclast® (zoledronic acid injection) - Novartis** – Expanded the treatment of osteoporosis indication to add: In patients at high risk of fracture, defined as a recent low-trauma hip fracture, Reclast reduces the incidence of new clinical fractures. Also added detail to better define postmenopausal osteoporosis as diagnosed by bone mineral density or prevalent vertebral fracture.
- D. Doxil® (doxorubicin hydrochloride liposome injection for intravenous infusion) – Ortho Biotech** - Revised indication wording for the acquired immune deficiency syndrome (AIDS)-related Kaposi's Sarcoma indication. Previous indication wording: Treatment of AIDS-related Kaposi's sarcoma in patients with disease that has progressed on prior combination chemotherapy or in patients who are intolerant to such therapy. New indication wording: Treatment of AIDS-related Kaposi's sarcoma in patients after failure of prior systemic chemotherapy or intolerance to such therapy.
- E. Genotropin® (somatropin [rDNA origin] injection [lyophilized powder and MiniQuick two-chamber cartridge]) – Pfizer** - Treatment of idiopathic short stature, also called non-growth hormone-deficient short stature, defined by height standard deviation score ≤ -2.25 , and associated with growth rates unlikely to permit attainment of adult height in the normal range, in pediatric patients whose epiphyses are not closed for whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means.
- F. Cymbalta® (duloxetine hydrochloride delayed-release capsules) - Eli Lilly** - For the management of fibromyalgia.

- G. **Avodart[®] (dutasteride capsules) - GlaxoSmithKline** - For use in combination with the alpha-blocker tamsulosin (Flomax[®]) for the treatment of symptomatic benign prostatic hypertrophy in men with an enlarged prostate.
- H. **Velcade[®] (bortezomib for injection) - Millennium Pharmaceuticals** - Revised indication wording for the multiple myeloma (MM) indication. Previous indication wording: Treatment of patients with MM who have received at least one prior therapy. New indication wording: Treatment of patients with MM.
- I. **Kaletra[®] (lopinavir and ritonavir tablet/ oral solution) - Abbott Laboratories** - Expanded to include pediatric patients aged 14 days to 6 months of age and children 12 to 18 years of age for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection.
- J. **Aptivus[®] (tipranavir capsules) - Boehringer Ingelheim** - Expanded indication to include pediatric patients aged 2 to 18 years of age for co-administration with ritonavir for combination antiretroviral treatment of HIV-1 infected pediatric patients who are treatment-experienced and infected with HIV-1 strains resistant to more than one protease inhibitor.
- K. **Viramune[®] (nevirapine tablets/oral suspension) - Boehringer Ingelheim** - Expanded to include pediatric patients down to the age of 15 days (previously was indicated down to 2 years of age) for use in combination with other antiretroviral agents for the treatment of HIV-1 infection.
- L. **Concerta[®] (methylphenidate hydrochloride extended-release tablets) - McNeil Pediatrics** - Treatment of attention deficit hyperactivity disorder in adults up to the age of 65 years.
- M. **Aciphex[®] (rabeprazole sodium delayed-release tablets) - Eisai Inc** - Short-term (up to 8 weeks) of treatment of gastroesophageal reflux disease in adolescents aged 12 years of age and above.

New Clinical Line Extensions

The Committee reviewed new clinical line extensions.

- A. **Xyntha[™] (antihemophilic factor [recombinant], plasma/albumin-free for intravenous use, freeze dried powder) - Wyeth**
- B. **Requip[®] XL[™] (ropinirole extended-release tablets) - GlaxoSmithKline**
- C. **Pentacel[®] (diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and Haemophilus b conjugate [tetanus toxoid conjugate] vaccine) - Sanofi Pasteur**
- D. **Aptivus[®] (tipranavir oral solution) - Boehringer Ingelheim**
- E. **PrandiMet[™] (repaglinide and metformin hydrochloride tablets) - Novo Nordisk**
- F. **Kinrix[™] (diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine suspension for intramuscular injection) - GlaxoSmithKline**