



EXPRESS SCRIPTS®

**Express Scripts, Inc.  
Pharmacy and Therapeutics Committee  
Proceedings  
January 17, 2008**

**New Drugs**

The Committee reviewed the following new drugs.

- A. **Kuvan™ (sapropterin tablets)**
- B. **Tasigna® (nilotinib capsules)**
- C. **Somatuline® Depot (lanreotide injection)**
- D. **Lamisil® Oral Granules (terbinafine oral granules)**
- E. **Iquix® (levofloxacin ophthalmic solution 1.5%)**
- F. **Isentress™ (raltegravir tablets)**

**New Indications for Existing Products**

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

- A. **Menactra® (meningococcal [groups A, C, Y and W-135] polysaccharide diphtheria toxoid conjugate vaccine intramuscular injection)** – Expanded age range, now indicated for patients aged 2 to 55 years old (previously was 11-55 years old).
- B. **Renagel® (sevelamer hydrochloride tablets)** – Expanded indication to control serum phosphorus in patients with chronic kidney disease (CKD) on peritoneal dialysis. Previous indication wording was for patients with CKD on hemodialysis.
- C. **Abilify® (aripiprazole tablets, oral solution, and injection intramuscular)/ Abilify Discmelt™ (aripiprazole orally disintegrating tablets)** – 1) Expanded indication to include treatment of schizophrenia in adolescents (aged 13-17 years old). 2) For use as an adjunctive treatment to antidepressants for major depressive disorder in adults.
- D. **Crestor® (rosuvastatin calcium tablets)** - Indicated as adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower total cholesterol and low-density lipoprotein cholesterol (LDL-C) to target levels.
- E. **Seroquel XR™ (quetiapine fumarate extended-release tablets)** - Maintenance treatment of schizophrenia.
- F. **Avalide® (irbesartan/ hydrochlorothiazide tablets)** - 1) May be used in patients whose blood pressure is not adequately controlled on monotherapy. 2) May be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.
- G. **Nexavar® (sorafenib tablets)** - Treatment of patients with unresectable hepatocellular carcinoma.
- H. **Cymbalta® (duloxetine hydrochloride delayed-release capsules)** - Maintenance treatment of major depressive disorder.
- I. **Diovan® (valsartan tablets)** - Expanded indication to include treatment of hypertension in children aged 6-16 years old.
- J. **Derma-Smoothe®/FS® (fluocinolone acetonide topical oil)** - Expanded age indication for the topical treatment of moderate to severe atopic dermatitis in pediatric

patients to 3 months and older for up to 4 weeks. (Previous indication age range was for patients aged 2 years and older.)

- K. Thyrogen<sup>®</sup> (thyrotropin alfa for injection)** - For use as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of metastatic thyroid cancer.
- L. Effexor XR<sup>®</sup> (venlafaxine hydrochloride extended-release capsules)** - Expanded labeling language for the treatment of social anxiety disorder to allow for long-term treatment (beyond 12 weeks).
- M. Hepsera<sup>®</sup> (adefovir dipivoxil tablets)** - Expanded indication to include treatment of chronic hepatitis B in patients aged 12 years and older with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases or histologically-active disease. Previously Hepsera was only indicated for use in adults.
- N. Ambien CR<sup>™</sup> (zolpidem tartrate extended-release tablets)** - Expanded indication labeling to add detail that clinical trials performed in support of efficacy were up to 24 weeks (using patient-reported assessment in adult patients only) in duration. Previous clinical trials noted in support of efficacy were up to 3 weeks (with formal assessments done after 2 weeks of therapy). The initial indication remains the same: treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

#### **New Clinical Line Extensions**

The Committee reviewed new clinical line extensions for the following products.

- A. Proquad<sup>®</sup> (measles, mumps, rubella and varicella virus vaccine live injection)**
- B. Combigan<sup>™</sup> (brimonidine tartrate 0.2%/ timolol maleate 0.5% ophthalmic solution)**
- C. Protonix<sup>®</sup> (pantoprazole delayed-release oral suspension) Wyeth**