



**Express Scripts, Inc.
Pharmacy and Therapeutics Committee
Proceedings
October 19 and 20, 2007**

New Drugs

The Committee reviewed the following new drugs.

- A. AzaSite™ (azithromycin ophthalmic solution 1%)**
- B. Selzentry™ (maraviroc tablets)**
- C. Endometrin® (progesterone vaginal inserts)**
- D. Reclast® (zoledronic acid injection)**
- E. Exelon® Patch (rivastigmine transdermal system [patch])**
- F. Perforomist® (formoterol fumarate inhalation solution)**
- G. Xyzal® (levocetirizine dihydrochloride tablets)**

New Indications for Existing Products

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

- A. FluMist® (influenza virus vaccine live, intranasal)** – Expanded age range now indicated for patients 2 to 49 years of age (previous age range was 5 to 49 years of age).
- B. Rhophylac® (Rho_(D) immune globulin intravenous [human])** – For Rho_(D)-positive non-splenectomized adult patients with chronic immune thrombocytopenic (ITP) to raise platelet counts.
- C. Risperdal®/Risperdal M-Tab® (risperidone tablets, oral solution, and disintegrating tablets)** – 1) Treatment of schizophrenia in adolescents (aged 13-17 years); 2) The short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder in children (aged 10-12 years) and adolescents (aged 13-17 years).
- D. Caduet® (amlodipine besylate/atorvastatin calcium tablets)** – Added the new indications wording approved for Lipitor in March 2007.
- E. Keppra® (levetiracetam injection)** – As adjunctive therapy in the treatment of myoclonic seizures in adults with juvenile myoclonic epilepsy.
- F. Evista® (raloxifene tablets)** – The reduction in risk of invasive breast cancer in PM women with osteoporosis. 2) The reduction in risk of invasive breast cancer in PM women at high risk of invasive breast cancer.
- G. Campath® (alemtuzumab injection)** – Expanded indication to include use as a single agent for treatment of B-cell chronic lymphocytic leukemia (B-CLL). Previous indication was for B-CLL patients who had been treated with an alkylating agent and who had failed fludarabine therapy.
- H. Taxotere® (docetaxel injection concentrate)** – Approved for an induction treatment in combination with cisplatin and 5-fluorouracil for patients with locally advanced squamous cell carcinoma of the head and neck prior to chemoradiotherapy and surgery.
- I. Erbitux® (cetuximab injection)** - Expanded indication to include use of Erbitux, as a single agent, for the treatment of EGFR-expressing metastatic colorectal cancer after failure of both irinotecan- and oxaliplatin-based regimens.

- J. Januvia™ (sitagliptin phosphate tablets)** – New wording for monotherapy and combination therapy: As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Januvia has not been studied in combination with insulin. The new regimens include as an adjunct to diet and exercise, initial therapy in combination with metformin; add-on therapy to sulfonylurea (glimepiride) when the single agent alone does not provide adequate glycemic control; and, add-on therapy to the combination of a sulfonylurea (glimepiride) and metformin when dual therapy does not provide adequate glycemic control.
- K. Lyrica™ (pregabalin capsules)** – Management of fibromyalgia.

New Clinical Line Extensions

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

- A. CaloMist™ (cyanocobalamin nasal spray)**
- B. Allegra ODT® (fexofenadine hydrochloride orally disintegrating tablets).**
- C. Privigen™ (immune globulin intravenous [human], 10% liquid)**
- D. Atralin™ (tretinoin gel 0.05%)**
- E. Sanctura XR™ (trospium chloride extended-release capsules)**
- F. Brand name to be determined (fenofibrate tablets)**
- G. Zingo™ (lidocaine hydrochloride monohydrate powder intradermal)**
- H. Fludarabine phosphate injection [ready-to-use solution]**
- I. Azor™ (amlodipine olmesartan medoxomil tablets).**
- J. Amlodipine orally disintegrating tablets**
- K. Afluria® (influenza virus vaccine injection)**
- L. Brand name to be determined (simvastatin orally disintegrating tablet)**

Medicare Six Classes of Clinical Concern

The Committee reviewed one new drug categorized in a Medicare Class of Clinical Concern which was not reviewed elsewhere.

- A. Ixempra™ Kit (ixabepilone for injection)**