

CPS Insider is a quarterly client newsletter produced by the University of Massachusetts Medical School (UMMS) Clinical Pharmacy Services (CPS).

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Noteworthy

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 CPS' plan for RetroDUR,
 MTM and DSM programs



Heads Up!

Topics for the Upcoming
 Issue: An update on flu
 and asthma guidelines

New Generics

- **Terbinafine (Lamisil®)**
 Approved 7/2/2007
- **Pantoprazole (Protonix®)**
 Approved 8/6/2007
- **Famciclovir (Famvir®)**
 Approved 8/24/2007
- **Carvedilol (Coreg®)**
 Approved 9/5/2007

Drug Watch



Selzentry® (maraviroc)

Approved: 8/6/2007
 Manufacturer: Pfizer
 Formulation: Tablet

Maraviroc is a CCR5 co-receptor antagonist that selectively binds to human chemokine receptor CCR5 located on cell membranes. This action prevents the interaction between HIV-1 gp120 and CCR5, which is necessary for the CCR5-tropic HIV-1 to enter cells. Maraviroc is FDA-approved for use, in combination with other antiretroviral agents, in treatment-experienced adults who are infected with CCR5-tropic detectable HIV-1; these patients must also have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents. In combination with CYP3A inhibitors, the recommended dose is 150mg twice daily. When used in combination with tipranavir/ritonavir, nevirapine, all nucleoside reverse transcriptase inhibitors, and enfuvirtide, the recommended dose is 300mg twice daily. Lastly, in combination with CYP3A inducers, the recommended dose is 600mg twice daily.

The FDA issued a black box warning of potential hepatotoxicity. Patients who develop signs of hepatitis or allergic reactions following maraviroc use should be evaluated immediately. Other common adverse events that occur with higher frequency include cough, pyrexia, upper respiratory infection, rash, musculoskeletal symptoms, abdominal pain, and dizziness.



Somatuline® (lanreotide)

Approved: 8/30/2007
 Manufacturer: Tercica
 Formulation: Injection

Lanreotide is a synthetic octapeptide analogue of somatostatin. It works by reducing the growth hormone (GH) secretion in addition to the levels of insulin-like growth factor 1.

Lanreotide is FDA-approved for the long-term treatment of acromegaly in patients who have either had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option.

Dosing for lanreotide is 90 mg initially given via the deep subcutaneous route every 4 weeks for 3 months. Maintenance dose after 3 months is adjusted based on GH levels.

The most common adverse events include bradycardia, alopecia, diarrhea, abdominal pain and cholelithiasis.

There are no major drug-drug interactions. Lanreotide may inhibit secretion of insulin and glucagon and decrease relative bioavailability of cyclosporine.

New FDA-Approved Indications

- **Reclast® (zoledronic acid)**
Approved on **8/17/2007**. For the treatment of osteoporosis in postmenopausal women
- **Risperdal® (risperidone)**
Approved on **8/22/2007**. Treatment of schizophrenia in adults and adolescents 13 to 17 years old, alone, or in combination with lithium or valproate, for the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder in adults, and as monotherapy in children and adolescents aged 10 to 17 years old.
- **Evista® (raloxifene)**
Approved on **9/14/2007**. For reducing the risk of invasive breast cancer in postmenopausal women with osteoporosis and in postmenopausal women at high risk for invasive breast cancer
- **FluMist® (influenza virus vaccine, live)**
Approved on **9/19/2007**. For use in children between ages of 2 and 5.

New Formulations and Dosages

- **Tamiflu® (oseltamivir)**
30mg, 45mg capsules
Approved **7/2/2007**
- **Exelon® (rivastigmine)**
4.6mg, 9.5mg transdermal patch
Approved **7/6/2007**
- **Allegra ODT® (fexofenadine)**
Orally disintegrating tablets
Approved **7/26/2007**
- **Sanctura XR® (trospium)**
Extended-release capsule
Approved **8/3/2007**

Information available at: www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm



Clinical Notes

AMERICAN DIABETES ASSOCIATION: STANDARDS OF MEDICAL CARE IN DIABETES—1/2007

Additions

- **Treatment algorithm: metabolic management of Type 2 Diabetes Mellitus (DM)**
 - Following a definitive diagnosis of DM, initial therapy should include lifestyle interventions and metformin
 - No therapy changes are needed if A1C <7%. However, if A1C ≥7%, a second agent (e.g., basal insulin, sulfonylurea, or glitazone*) should be added
 - Depending on subsequent A1C levels and patient response, a third agent may be required to lower A1C levels to a goal of <7%
- **Recommendation:** an emergency disaster kit should be available with critically important items (i.e. test strips, lancets, syringes, glucagons, etc.) during natural disasters
- **Table of therapeutic options, diabetic peripheral neuropathy:** Options include tricyclic drugs, anticonvulsants, 5-hydroxy-tryptamine and norepinephrine uptake inhibitors, or substance P inhibitors
- **Celiac disease in Type 1 DM Recommendation:** Children with positive antibodies should be referred to a gastroenterologist for evaluation and be placed on a gluten-free diet by a dietician

Revisions

- **Discussion of medical nutrition therapy**
 - Lifestyle changes should be the primary weight loss method
 - Components of daily food intake:
 - Fat <7% of total calories (minimize trans fat)
 - Total carbohydrate <130g/day is not recommended in overweight patients
 - Sweeteners are safe within the daily intake level established by the FDA
 - Moderate alcohol consumption is recommended (≤1 glass/day in women and ≤2 glasses/day in men)
 - Lack of evidence supporting routine supplementation with antioxidants such as vitamin C, E and carotene.
 - Recommendation for diabetic patients with nephropathy: reduce protein intake to 0.8-1 g/kg/day in early stages of chronic kidney disease and 0.8 g/kg/day in later stages of chronic kidney disease. Protein restriction may improve measures of renal function

*See advisory on Avandia® on page 3

For additional information, please visit: http://professional.diabetes.org/CPR_search.aspx

Advisories

Zelnorm® (tegaserod maleate)

On 7/27/2007, the FDA announced that the re-introduction of tegaserod into the market would be permitted under an investigational new drug protocol. On March 30, 2007, the FDA requested that Novartis suspend sales of tegaserod due to a safety analysis concluding that the agent may increase the risk of heart attacks, stroke, and unstable angina. The use of this agent is now restricted to the treatment of irritable bowel syndrome with constipation, and chronic idiopathic constipation in women <55 years of age. The physician must indicate reasons of medical necessity and the patient must sign consent materials.

Prilosec® (omeprazole), Nexium® (esomeprazole)

On 8/9/2007, the FDA issued an early communication about the ongoing review of new safety data for the proton pump inhibitors, omeprazole and esomeprazole. The results from the study of omeprazole and analyses from an ongoing study of esomeprazole raised concerns that long-term use of omeprazole or esomeprazole may increase the risk of heart attacks, heart failure, and heart-related sudden death. The FDA concluded that preliminary data do not suggest an increased risk of heart problems.

Avandia® (rosiglitazone), Actos® (pioglitazone), Avandaryl® (rosiglitazone/glimepiride), Avandamet® (rosiglitazone/metformin), Duetact® (pioglitazone/glimepiride)

On 8/14/2007, the FDA determined that a boxed warning on the risks of heart failure was needed for the thiazolidinedione class following a review of postmarketing adverse event reports. The strengthened warning advises healthcare professionals to observe patients carefully for signs and symptoms of heart failure. The use of these drugs should be reconsidered in patients who develop symptoms of heart failure. This topic remains controversial.



From The Hill

Federal

Implications of SCHIP Reauthorization and CMS Guidance

The reauthorization of the State Children's Health Insurance Program (SCHIP) and a new guidance issued by the Centers for Medicare and Medicaid Services (CMS) may significantly affect state reform efforts as well as state efforts to expand insurance coverage to residents. SCHIP was established to provide insurance coverage to "targeted low-income children" who are uninsured and not eligible for Medicaid. In 2007, this typically included families with incomes up to 200% federal poverty line (FPL) for a family of four; however 23 states provided coverage above this amount. Differences between House and Senate bills were reconciled, and the House favored the recent bill 265 to 159. However, President Bush has vetoed the bill as promised. The recently vetoed bill prohibited states from using the program to aid families who make more than three times the FPL, or about \$60,000 a year for a family of four. However, the majority of funding was expected to aid families earning substantially less. Furthermore, a new guidance issued by the CMS on August 17, 2007 limits states' ability to expand SCHIP coverage to children with family incomes above 250% of the FPL.

State

Massachusetts: The Department of Public Health's Bureau of Health Care Quality is developing proposed regulations regarding new retail health clinics. Reportedly, CVS Pharmacy executives are planning to open the first in-store clinic in Weymouth, MA. Other pharmacies are in the planning stages of developing in-store clinics as well. In-store clinics are open for extended hours and on weekends where patients can meet with certified nurse practitioners for 15 minute visits without scheduling an appointment. These clinics offer a range of services with prices ranging from \$30-\$100. A public hearing on the proposed regulations is to be scheduled.

Alabama: Proposed Alabama legislation regarding Generic Drug Access adjourned in the House. This proposition would have prohibited a pharmacist from substituting any anti-epileptic drug without the consent of the prescribing physician and patient.

For more information, please visit: www.kff.org/medicaid/upoad/7576.pdf and www.washingtonpost.com/content/article/2007/10/04/AR2007100401921_pf.html

Pipeline

Isentress® (raltegravir)

September 2007- The Antiviral Drugs Advisory Committee of the FDA has recommended accelerated FDA approval of raltegravir. The drug is used in combination with other antiretroviral therapy (ART) for the treatment of HIV infection in treatment-experienced patients with ongoing viral replication despite existing therapy. The mechanism of action is unique in that it inhibits the activity of integrase enzymes, thereby preventing HIV DNA from entering cell DNA. If approved, raltegravir will be a first-in-class integrase inhibitor.

New Combination

The FDA has accepted a new drug application for combination allergy product of Claritin® and Singulair®. The Schering-Plough/Merck Pharmaceuticals manufactured product will seek approval for loratadine/montelukast for the treatment of nasal allergy symptoms.

Noteworthy

What's New at CPS?

Clinical Pharmacy Services (CPS) has begun the development and expansion of additional clinical programs including, Retrospective Drug Utilization Review (RetroDUR), Medication Therapy Management (MTM), and Disease State Management (DSM).

RetroDUR programs are put in place to improve quality, safety, and cost-effectiveness of medication therapy by retrospectively identifying patterns of care that are not in accordance with nationally accepted clinical guidelines or best practices. Managed care organizations are provided a unique opportunity to influence and optimize health care outcomes.

MTM programs offer a service that focuses on optimizing therapeutic outcomes for individual patients. It encompasses activities such as monitoring and assessing therapeutic responses, formulating treatment plans, conducting comprehensive medication reviews, and providing patient education, among many others.

DSM programs involve collaboration among health care professionals to identify patients, with complex chronic diseases, who will benefit from comprehensive disease management.

CPS is building a strong foundation of programs that focus on optimal therapeutic outcomes and cost management using evidence based medicine. Workgroups have been established to develop these programs for use with current and future clients.



UMMS Clinical Pharmacy Services: Who We Are and What We Do

The University of Massachusetts Medical School (UMMS) Clinical Pharmacy Services (CPS) is a comprehensive prescription drug management program developed in 1999 as part of UMMS' Commonwealth Medicine division, primarily to provide drug utilization review for Massachusetts Medicaid. Today, CPS brings exceptional depth and experience in the development and implementation of unique, client-customized managed care-related clinical pharmacy functions including, but not limited to, evidence-based formulary support, drug utilization review, medication therapy management, clinical call center support and provider/patient education. 'CPS Insider' is an educational resource produced quarterly in an effort to deliver critical information at the highest level of quality to our clients. We hope that you find this resource of value and welcome your suggestions for improvement.



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