



Rx TWO PHARMACY SERVICES, INC. MEDICATION NEWSLETTER

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Medicare & CMS News

The U.S. Troops Readiness, Veterans Care, Katrina recovery and Iraq Accountability Appropriations Act of 2007 contained a provision that required all written, non-electronic prescriptions be executed on "tamper-resistant" prescription pads in order for Medicaid outpatient drugs to be reimbursed by the federal government. This requirement would not apply: when the prescription is communicated by the prescriber to the pharmacy electronically, verbally, or by fax; a managed care entity pays for the prescription; or in most situations when drugs are provided in certain institutional and clinical facilities. The provision was set to become effective on October 1, 2007, however, this deadline has since been delayed by the Senate and House of Representatives until April 1, 2008. The very short time frame for implementation was not sufficient enough to educate prescribers and pharmacists about this provision nor allow adequate time for printing and distributing supplies of these special prescriptions pads to all prescribers. The impact of this provision in this constricted period of time could have caused major disruptions in the provision of medications to Medicaid patients. More background information on this issue is available at this ASCP Briefing Room: <http://www.ascp.com/advocacy/briefing/tamper.cfm>

New FDA Approved Medications, Warnings, Indications, Formulations, Clinical Studies and News:

The FDA has approved Afluria, an additional seasonal influenza vaccine for the immunization of people ages 18 and older.

Afluria is intended to protect adults from influenza type A and type B flu viruses. Influenza is a contagious respiratory illness that can cause annual epidemics. The approval of Afluria, manufactured in Australia, brings the number of seasonal influenza manufacturers licensed for the U.S. market to six. Based on current manufacturing trends, the Centers for Disease Control and Prevention estimates that the six manufacturers will supply a record 132 million doses of influenza vaccine for the 2007-2008 influenza season.

The FDA has approved AZOR (amlodipine and olmesartan medoxomil) for the treatment of hypertension. AZOR is a convenient, once daily, single tablet combination of amlodipine, the number one prescribed calcium channel blocker (CCB) on the market, and olmesartan medoxomil, the active ingredient in Benicar®, an angiotensin receptor blocker (ARB). AZOR is indicated for the treatment of hypertension, alone or with other antihypertensive agents. AZOR is not indicated for the initial therapy of hypertension.

The FDA has approved Symbicort (budesonide/formoterol) for the maintenance treatment of asthma in patients 12 and older. Symbicort is a twice daily asthma medication combining budesonide (a corticosteroid) and formoterol (a rapid and long-acting beta-2 agonist) into one inhaler. It is NOT indicated for the relief of acute bronchospasm or in patients whose asthma can be successfully managed by inhaled corticosteroids along with occasional use of inhaled short-acting beta-agonists. Symbicort is available in two strengths: 80/4.5 (80 mcg budesonide, 4.5

mcg formoterol) and 160/4.5 (160 mcg budesonide, 4.5 mcg formoterol).

The FDA has determined that an updated label with a boxed warning on the risks of heart failure was needed for the entire thiazolidinedione class of antidiabetic drugs. This class includes Avandia (rosiglitazone), Actos (pioglitazone) Avandaryl (rosiglitazone and glimepiride), Avandamet (rosiglitazone and metformin), and Duetact (pioglitazone and glimepiride). These drugs are used in conjunction with diet and exercise, to improve blood sugar control in adults with type 2 (non-insulin-dependent) diabetes. The information will be included in the form of a "boxed" warning –the FDA's strongest form of a warning. The strengthened warning advises health care professionals to observe patients carefully for the signs and symptoms of heart failure, including excessive, rapid weight gain, shortness of breath, and edema after starting drug therapy. Patients with these symptoms who then develop heart failure should receive appropriate management of the heart failure and use of the drug should be reconsidered. People who have questions should contact their health care providers to discuss alternative treatments. The warning also states that these drugs should not be used by people with serious or severe heart failure who have marked limits on their activity and who are comfortable only at rest or who are confined to bed or a chair.

The FDA has approved use of the five-day, once-daily regimen of LEVAQUIN (levofloxacin) 750 mg I.V. and oral, for the treatment of complicated urinary tract infections (cUTI) and acute pyelonephritis (AP). This latest approval is based on results of a double-blind, randomized clinical trial involving 1,109 patients with either cUTI or AP which assessed the efficacy and safety of LEVAQUIN (750 mg/once daily/five days) versus ciprofloxacin (Cipro) (400/500 mg/twice daily/10 days). Microbiologic eradication and clinical success rates were similar in both treatment groups demonstrating the resolution of, or improvement in, urinary symptoms for both LEVAQUIN (750 mg/once daily/five days) and

ciprofloxacin (400/500 mg/twice daily/10 days) groups.

In July 2007, the FDA approved Exelon Patch (Rivastigmine transdermal system) indicated for treatment of mild to moderate dementia of the Alzheimer's' type and that associated with Parkinson's disease. This approval was based on results from the international IDEAL (Investigation of Transdermal Exelon in Alzheimer's disease) study, which involved nearly 1,200 patients with mild to moderate Alzheimer's disease. The patch showed similar efficacy to the highest doses of Exelon capsules, as well as significant improvement in memory and the ability to perform everyday activities compared to placebo. In addition, the study demonstrated three times fewer reports of gastrointestinal side-effects (nausea and vomiting) with the patch than the oral form of the medication. Treatment is started with the Exelon Patch 4.6 mg/24 hours which should be replaced every 24 hours. After a minimum of four weeks and if well tolerated, this dose should be increased to Exelon Patch 9.5 mg/24 hours, which is the recommended effective dose.

Recent Generic Drug Approvals:

- Rabeprazole (Aciphex) 20mg tabs
- Pantoprazole (Protonix) 20mg, 40mg tabs
- Zolpidem (Ambien) 5mg and 10mg tabs
- Carvedilol (Coreg) 3.125mg, 6.25mg, 12.5mg and 25mg tablets
- Cetirizine (Zyrtec) 5mg and 10mg tablets (tentative approval)
- Amlodipine Besylate (Norvasc) 2.5mg, 5mg and 10mg tablets

Rx Two Pharmacy Services, Inc. was formed by a group of dedicated and seasoned LTC pharmacy professionals with the goal of providing comprehensive pharmacy services for our contracted nursing centers and their residents by utilizing state of the art computer technology and good old fashioned hard work.

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