



Rx TWO PHARMACY SERVICES, INC.

MEDICATION NEWSLETTER

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Medicare & CMS News

CMS has entirely revised the State Operations Manual and these new guidelines went into effect December 18, 2006. The Unnecessary Medications Guidelines includes a 36 page medication table page that includes medications that are problematic to the nursing home population. For Pharmacy Services, regulatory guidance has been combined into three remaining tags: F425 Pharmacy Services, F425 Drug Regimen Review, and F431 Labeling and Storage of Drugs and Biologicals. One significant requirement is that every resident's medication regimen must be reviewed by a pharmacist. Rx Two consultant pharmacists can help you comply with this new requirement by performing weekly off-site MRR's. The full text of these documents can be accessed on the ASCP Web site at:

<http://www.ascp.com/som>

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

The FDA has approved Janumet, the first and only tablet combining a dipeptidyl peptidase-4 (DPP-4) inhibitor, sitagliptin (also known as Januvia), and metformin for the treatment of type 2 diabetes. Janumet has been approved, as an adjunct to diet and exercise, to improve blood glucose control in adult patients with type 2 diabetes who are not adequately controlled on metformin or sitagliptin alone, or in patients already being treated with the combination of sitagliptin and metformin. Janumet should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Janumet, like metformin, is dosed twice daily with meals. Consistent with the labeling for metformin alone, the labeling for Janumet contains a

boxed warning for lactic acidosis, a rare, but serious, metabolic complication that can occur due to metformin accumulation during treatment with Janumet.

Novartis is complying with a request from the FDA to suspend US marketing and sales of Zelnorm (tegaserod maleate), a treatment for irritable bowel syndrome (IBS) with constipation and chronic constipation. A small (but not statistically significant) imbalance in cases of angina pectoris was recorded and included in the US label when Zelnorm was approved in 2002. A recent analysis of the entire clinical database revealed a statistically significant imbalance in the incidence of cardiovascular ischemic events in patients taking Zelnorm compared to those taking placebo. These events included myocardial infarction, stroke, and unstable angina pectoris.

The FDA announced on April 6, 2007 that companies must stop manufacturing and distributing unapproved suppository drug products containing trimethobenzamide hydrochloride. These products are used to treat nausea and vomiting in adults and children. Drugs containing trimethobenzamide in suppository form lack evidence of effectiveness. These products have been marketed under various names, including Tigan, Tebamide, and Trimazide.

The FDA notified healthcare professionals and patients that companies that manufacture and distribute Permax (pergolide) have agreed to withdraw the drug from the market. Pergolide is a dopamine agonist (DA) used with levodopa and carbidopa to manage the signs and symptoms of Parkinson's disease. Results of two new studies showed that some patients with Parkinson's disease treated with pergolide had serious damage to their heart

valves when compared to patients who did not receive the drug. These two studies confirm earlier studies that also described this problem.

The FDA has approved Tekturna (aliskiren) tablets for the treatment of hypertension, which affects an estimated 25 percent of Americans and causes increased risk of stroke, heart attack, kidney failure, heart failure and death. Tekturna, a new molecular entity, is the first high blood pressure drug approved by FDA that inhibits renin, a kidney enzyme associated with the regulation of blood pressure. Tekturna acts at the beginning of the blood pressure regulation process, while other available high blood pressure medications act at later stages. Tekturna was effective across all demographic subgroups, but African American patients tended to have smaller reductions in blood pressure than Caucasians and Asians, as is generally true for drugs that affect the renin-angiotensin system, a component of blood pressure regulation.

The FDA has approved Lipitor (Atorvastatin) tablets to reduce the risk of nonfatal heart attacks, fatal and non-fatal strokes, certain types of heart surgery, hospitalization for heart failure, and chest pain in patients with heart disease. Lipitor is the first cholesterol-lowering medication to receive FDA approval for the reduction of the risk of hospitalization for heart failure. This new approval expands the use of Lipitor to patients at high risk for cardiovascular events because of established heart disease such as prior heart attack, prior heart surgery, or chest pain with evidence of clogged arteries. Previously, Lipitor was approved to reduce cardiovascular events in patients without heart disease.

The FDA has notified health care professionals of the results from a large clinical trial evaluating use of an erythropoiesis-stimulating agent (ESA) to treat anemia in cancer patients not receiving chemotherapy. In this study, patients received either the ESA Aranesp (darbepoetin alfa) according to the approved dosing regimen, or placebo. Patients treated

with Aranesp had a higher death rate and no reduction in the need for transfusions compared to those treated with placebo. The findings in the Aranesp study may apply to other ESAs. Additionally, the findings show that treating anemic cancer patients not currently on chemotherapy with an ESA may offer no benefit and may cause serious harm.

Glaxo SmithKline recently notified health care professionals of the results of the "ADOPT" study of 4,360 patients with recently diagnosed type 2 diabetes mellitus followed for 4-6 years to compare glycemic control with rosiglitazone relative to metformin and glyburide monotherapies. Significantly more female patients who received rosiglitazone experienced fractures of the upper arm, hand, or foot, than did female patients who received either metformin or glyburide. GSK is suggesting health care professionals consider the risk of fracture when initiating or treating female patients with type 2 diabetes mellitus with rosiglitazone.

Generic Drug Approvals:

- Citalopram (Celexa) 10mg, 20mg and 40mg tablets
- Irbesartan (Avapro) 75mg, 150mg and 300mg tablets
- Zolpidem (Ambien) 5mg and 10mg tabs (tentative approval)
- Galantamine (Razadyne) 4mg, 8mg and 12mg tablets (tentative approval)
- Ciprofloxacin-ER (Cipro-XR) 500mg and 1000mg tabs
- Amlodipine Besylate (Norvasc) 2.5mg, 5mg and 10mg tablets (tentative approval)

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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