



Rx TWO PHARMACY SERVICES, INC.

MEDICATION NEWSLETTER

Volume 4 No. 3 phone (866) 739-7700 web: RxTwoPharmacy.com

Medicare & CMS News

CMS has entirely revised the State Operations Manual and these new guidelines went into effect December 18, 2006 and are being enforced during annual DHS surveys. 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 (this includes short-stay residents). 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, Clinical Studies and News:

A study published on June 5, 2007 in the *Annals of Internal Medicine* determined the risk for death at 30, 60, 120 and 180 days after the initial dispensing of antipsychotic medication to older adults. Study participants were 66 years of age or older with a concurrent diagnosis of dementia but no other psychotic disorders. Study participants did not receive antipsychotics in the year prior to the study enrollment. Comparisons of atypical vs. conventional antipsychotics and atypical vs. no antipsychotics were performed among 27,259 pairs of patients in the community and long-term care settings.

Results revealed that the risk for death was highest in patients taking conventional antipsychotics. However, there was still a statistically significant difference in risk in patients taking atypical antipsychotics compared to patients taking neither when evaluated over 30 days. Currently, no antipsychotics are FDA approved for the treatment of Dementia. For more information, visit www.annals.org/cgi/content/abstract/146/11/775

Lyrica is now the first FDA approved treatment for fibromyalgia, a mysterious syndrome marked by muscle pain and fatigue. Patients currently make so-called "off label" use of pain medications, antidepressants, muscle relaxants and sleep aids to treat the condition. Exercise and applying heat also can help. Fibromyalgia typically affects women, striking them with long-lasting or chronic pain, as well as muscle stiffness and tenderness, according to the FDA. Lyrica, known generically as pregabalin, previously won FDA approval to treat partial seizures, pain following the rash of shingles and pain associated with diabetes nerve damage. The FDA warned that common side effects include mild-to-moderate dizziness and sleepiness. Also, the agency said that Lyrica reduces pain and improves daily functions for some patients with fibromyalgia, but that not everyone derived benefit from the drug in studies.

Rosiglitazone (Avandia®) and Pioglitazone, (Actos®), have both received a request from the FDA for a black box warning following a study that analyzed the results of 42 previous studies of rosiglitazone. Although no studies were included using pioglitazone, the drug was also issued that same black box warning request due to its therapeutic similarity to rosiglitazone. Millions of people worldwide currently take rosiglitazone and any

conclusions that are drawn from these studies will have major implications. The meta-analysis study published recently in the *New England Journal of Medicine* found that rosiglitazone was associated with a significant increase in the risk of myocardial infarction (MI) and a nonsignificant increase in the risk of death from cardiovascular causes. An interim analysis of a rosiglitazone safety trial found no significant differences in overall risk of hospitalization or death from cardiovascular causes but an increased risk of heart failure associated with use of the antidiabetic drug. The problem most clinicians have with these reports is that they are not *proving* anything. The American Diabetes Association is recommending that any patient taking rosiglitazone or considering taking the medication consult their physician first to determine if the benefits outweigh the risks. Rosiglitazone and pioglitazone both currently include warnings to physicians and pharmacists that patients with significant heart failure should not be prescribed these drugs for the treatment of type II diabetes. For those patients with significant heart failure also taking rosiglitazone, they should be told to watch for fluid retention, trouble breathing, or sudden weight gain, as these may be symptoms of worsening heart failure. The FDA will continue to gather information regarding rosiglitazone and pioglitazone and is expected to address the issue this summer.

The FDA has approved twice-daily Zylflo-CR (Zileuton) extended-release tablets and should be available in the U.S. in the fall of 2007. Zylflo-CR and Zylflo (Zileuton tablets) are the only FDA-approved leukotriene synthesis inhibitors for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. Zylflo-CR and Zylflo are not indicated for use in the reversal of bronchospasm in acute asthma attacks, but can be continued during acute exacerbations of asthma. Leukotrienes are inflammatory mediators in asthma that can trigger asthma symptoms, including inflammation, swelling, bronchoconstriction and mucus secretion.

The FDA has approved Xyzal (levocetirizine dihydrochloride), a new once-daily prescription antihistamine that delivers a rapid and long-lasting effect for the relief of symptoms associated with seasonal and perennial allergic rhinitis and uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children six years of age and older. Studies in allergic rhinitis patients demonstrated Xyzal significantly reduced the symptoms of sneezing, itchy nose, runny nose, and itchy eyes. Studies in chronic idiopathic urticaria patients showed Xyzal significantly reduced the severity of itching and the number and size of wheals.

Neupro (Rotigotine transdermal system) has been approved by the FDA for the treatment of the signs and symptoms of early stage idiopathic Parkinson's disease, making it the first transdermal patch to receive approval for this indication. The patch is replaced every 24 hours, continuously delivering Rotigotine, a dopamine agonist, through the skin.

Generic Drug Approvals:

- Terbinafine (Lamisil) 250mg tablets
- Terbinafine (Lamisil) 1% cream (OTC)
- Zolpidem (Ambien) 5mg and 10mg tabs
- Famciclovir (Famvir) 125mg, 250mg and 500mg tablets (tentative approval)
- Cetirizine (Zyrtec) 5mg and 10mg tablets (tentative approval)
- Amlodipine Besylate (Norvasc) 2.5mg, 5mg and 10mg tablets
- Rabeprazole (Aciphex) 20mg delayed-release 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.

Prepared by Sailesh Patel, PharmD, FASCP
Vice President, Clinical Services