



Rx TWO PHARMACY SERVICES, INC.

MEDICATION NEWSLETTER

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Medicare & CMS News

Eight of the top 10 Medicare prescription drug plans will cover fewer medications in 2008 than in 2007, according to a new analysis by Avalere Health. Overall, the top 10 plans reduced the size of their formularies by 26% for 2008. Much of the decrease in coverage is attributable to a decision by Centers for Medicare & Medicaid Services (CMS) to no longer include drugs lacking Food and Drug Administration (FDA) approval on the CMS list of formulary-approvable drugs. Often referred to as "DESI" drugs (Drug Efficacy Study Implementation), these medications did not undergo the full FDA review now required for both safety and efficacy because they were marketed prior to 1962. More information about these drugs is available at:

<http://www.ascp.com/medicarerx/marketdunapproveddrugs.cfm>

A law passed last year amending the California Health and Safety Code for Residential Care Facilities for the Elderly is effective January 1, 2008. The law requires that such facilities:

- (1) Ensure that each employee of the facility who assists residents with the self-administration of medications meet specified training requirements outlined in the law
- (2) Maintain certain records and documentation related to the training
- (3) That care for 16 or more persons, maintain documentation that demonstrates that a consultant pharmacist or nurse has reviewed the facility's medication management program and procedures at least twice a year.

A copy of this can be accessed online at:

http://www.leginfo.ca.gov/pub/05-06/bill/asm/ab_2601-2650/ab_2609_bill_20060929_chaptered.pdf.

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

The FDA has approved the novel beta blocker Bystolic (nebivolol) for the treatment of hypertension. Bystolic is a once daily medication that can be used alone or in combination with other hypertension treatments. In an extensive clinical trial program involving more than 2,000 patients, Bystolic demonstrated significant reductions in sitting diastolic and systolic blood pressure in a general hypertensive population, which included 26 percent Black, 54 percent male, 19 percent elderly and 8 percent diabetic patients. The studies also found that Bystolic was well tolerated, with the most common adverse events reported as headache, fatigue and dizziness. Like other beta blockers, Bystolic decreases heart rate and myocardial contractility, and suppresses renin activity. Bystolic is a selective beta 1 blocker at doses less than or equal to 10 mg per day and has the added pharmacological properties of producing vasodilation and reducing total peripheral resistance. Bystolic is contraindicated in severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless a permanent pacemaker is in place), severe hepatic impairment (Child-Pugh >B), and in patients who are hypersensitive to any component of this product.

The FDA has approved the switch from prescription to over-the-counter (OTC) status for Zyrtec (Cetirizine Hydrochloride). The generic product will be marketed under various store and generic brand labels and will be available in a 5mg and 10mg chewable tablet and a 1mg/ml syrup. Zyrtec is an antihistamine and is indicated for allergy and hives relief.

A study in the December 4, 2007 issue of *Annals of Internal Medicine* reports that three medications accounted for one-third of emergency department visits for adverse drug events. Warfarin (17.3%), insulin (13.0%), and digoxin (3.2%) were the top three. By contrast, the combined list of medications considered potentially inappropriate according to the Beers criteria resulted in only 3.6% of emergency department visits. Considering frequency of prescribing, the risk of emergency department visits from warfarin, insulin, and digoxin is 35 times greater than the risk of visits from Beers criteria medications. An abstract of the article is at:

<http://www.annals.org/cgi/content/abstract/147/11/755>

In November 2007, the FDA approved Mircera (Methoxy polyethylene glycol-epoetin beta) indicated for the treatment of anemia associated with chronic renal failure in adult patients, including patients on dialysis or not on dialysis. Mircera is an erythropoietin-receptor activator, with greater activity than erythropoietin, which interacts with erythroid progenitor cells to increase red blood cell production. The recommended starting dose for patients not currently receiving an erythropoiesis-stimulating agent (ESA) is 0.6 mcg/kg IV or subcutaneously once every 2 weeks. Once the hemoglobin (Hgb) level is between 10 and 12 g/dL, the every two week dose should be doubled and given once a month. In patients currently treated with an ESA, Mircera should be administered IV or subcutaneously every 2 weeks or monthly depending on the total weekly ESA dose.

On 10/18/07, Exubera (insulin recombinant human, powder for inhalation) was discontinued by the manufacturer citing poor acceptance by patients and physicians. Patients on Exubera should be transitioned to alternate glucose lowering medications, Exubera will not be available for sale after 1/16/08.

The FDA issued an update that highlights important information on appropriate prescribing, dose selection, and the safe use of the fentanyl

transdermal system (patch). The FDA continues to receive reports of death and life-threatening adverse events related to fentanyl overdose that have occurred when the fentanyl patch was used to treat pain in opioid-naive patients and when opioid-tolerant patients have applied more patches than prescribed, changed the patch too frequently, and exposed the patch to a heat source. The fentanyl patch is only indicated for use in patients with persistent, moderate to severe chronic pain who have been taking a regular, daily, around-the-clock narcotic pain medicine for longer than a week and are considered to be opioid-tolerant. Patients must avoid exposing the patch to excessive heat as this promotes the release of fentanyl from the patch and increases the absorption of fentanyl through the skin which can result in fatal overdose. Directions for prescribing and using the fentanyl patch must be followed exactly to prevent death or other serious side effects from fentanyl overdose.

Recent Generic Drug Approvals:

- Donepezil (Aricept) 5mg and 10mg tabs (tentative approval)
- Escitalopram (Lexapro) 5mg, 10mg and 20mg tabs (tentative approval)
- Risedronate (Actonel) 5mg, 30 mg, 35mg tablets
- Oxcarbazepine (Trileptal) 150mg, 300mg, 600mg tablets
- Rivastigmine (Exelon) 1.5mg, 3mg, 4.5mg, 6mg BASE capsules
- Nifedipine extended release (Procardia XL) 90mg tablet
- Ipratropium/Albuterol Inhalation (0.5mg/3mg) Solution (Duoneb)
- Granisetron hydrochloride (Kytril) 1mg 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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