



Family Medicine Clinical Pharmacy Forum

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Family Medicine Clinical Pharmacy Forum is a brief bi-monthly publication from the Family Medicine clinical pharmacists distributed to faculty and residents of the Department of Family Medicine. Our intent is to provide timely information on broad-based issues of pharmacotherapy, as well as regulatory and practiced-based issues affecting you as a prescriber. If you have suggestions for things you would like to see, please contact us.

Pharmacotherapy Issues.

RotaTeq®

In February 2006, the FDA approved a new live, oral vaccine for the prevention of rotavirus gastroenteritis in infants. The CDC reports that over 55,000 hospitalizations occur each year as a result of a rotavirus infection. RotaTeq® prevented 74 percent of all rotavirus gastroenteritis cases, but it also prevented 98 percent of all severe cases. RotaTeq® has not been associated with an increased risk of intussusception which was a problem with an earlier vaccine for rotavirus infections.

The vaccine is given orally in three doses. Infants are to receive these doses between the ages of 6 weeks and 32 weeks. The vaccine manufacturer has committed to a post-licensure safety study of approximately 44,000 children.

Torcetrapib/atorvastatin Clinical Trials Stopped

The Data Safety Monitoring Board for this trial reported to Pfizer on December 2, 2006 that there was an unacceptable increase in mortality in their outcome study for torcetrapib/atorvastatin as compared to atorvastatin alone. Torcetrapib was first drug of its class; inhibiting the cholesteryl ester transfer protein. Previous study results had shown torcetrapib to increase HDL by 61% when combined with a statin. Pfizer subsequently suspended all studies involving torcetrapib.

Sitagliptin (Januvia®)

Sitagliptin, a new oral antiglycemic agent was approved by the FDA on October 17, 2006. This drug comes from a new drug class called dipeptidyl peptidase-4 (DPP-4) inhibitors. DPP-4 is an enzyme responsible for the breakdown of incretin hormones, glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic peptide (GIP). GLP-1 and GIP work by increasing insulin secretion following food intake. They also work by reducing glucagon secretion and slowing gastric emptying. Inhibiting DPP-4 potentiates the action of these two hormones. Sitagliptin is approved as monotherapy or as add-on therapy in combination with metformin or thiazolidinediones to improve blood glucose in type 2 diabetes. Studies have shown sitagliptin can lower HbA_{1C} levels by about 0.7%, with combination therapy yielding slightly better lowering. Sitagliptin appears to be a well-tolerated; has a low risk of

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hypoglycemia (5%) and no weight gain. . DPP-4 is responsible for the metabolism of many peptides and it is also involved with T-cell activation. The long term side effects of inhibiting this enzyme are still under investigation. It is administered as a once-daily 100mg oral dose. Decreases in dose are required in renal insufficiency. DPP-4 is responsible for the metabolism of many peptides and it is also involved with T-cell activation. The long term side effects of inhibiting this enzyme and its possible consequence on T-cell activation are still under investigation. It is expected to be priced comparably to the thiazolidinediones..

Zostavax®

In May of 2006, the FDA approved Zostavax®, a live attenuated varicella-zoster virus vaccine, for the prevention of herpes zoster in people over the age of 60. The ACIP issued a statement recommending that all adults >60 years of age be vaccinated whether or not they report having had herpes zoster. The Shingles Prevention Study Group was a double-blind RCT that found a 51 percent reduction of herpes zoster cases in the Zostavax® group as compared to placebo, with the greatest reductions occurring in patients less than 80 years old. There was a 55 percent decrease in the number of cases with postherpetic neuralgia in the Zostavax® group in the 70-79 year age group. Zostavax® is contraindicated in patient populations with a history of anaphylactic reaction to gelatin or neomycin, immunodeficiency states, untreated TB, or women who are or plan to become pregnant in the next 3 months. Common side effects include: erythema, pain, tenderness, and swelling at the injection site with and overall incidence of local reactions reaching almost 30%. As of December 2006, Zostavax® is a Medicare Part D coverage drug, which prevents billing through an outpatient physician clinic. The administrative aspects of providing this vaccine in many settings continues to be a challenge.

Practice-Based Issues.

Influenza vaccination: It is not too late to recommend influenza vaccination for your patients who have not yet been immunized. Activity throughout Iowa continues to be reported as Sporadic, with 3 different vaccine-covered strains having been isolated. The clinical implication of this is that a patient could possibly get 3 separate episodes of influenza. Vaccine efficacy is attained within 2-3 weeks and flu season officially extends through March.

Smoking Cessation and Iowa Medicaid

Effective January 1, 2007, the Iowa Medicaid Program is expanding coverage to support pharmacotherapy strategies for smoking cessation. A few key elements of the program include:

- 1) Bupropion SR 150mg products with an FDA indication for smoking cessation will be covered *without* prior authorization (PA).

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- 2) Over-the-counter nicotine replacement patches and gum will be covered *with* a PA for members 18 years of age or older with a diagnosis of nicotine dependence and enrollment in the Quitline Iowa program for counseling.
- 3) The maximum allowed duration of therapy is 12 weeks within a 12-month period.
- 4) For prior authorizations (PA) and additional physician information, Quitline Iowa can be reached at 1-319-384-4845 or www.quitlineiowa.org.

Iowa Medicaid PDL for 2007

Noteworthy changes to the Medicaid PDL for 2007 include the following:

Non-preferred status: Avelox®, Actonel®, Xalatan®

Preferred status: Levaquin®, Advair HFA®, Boniva®

Regulatory Issues.

Drug/Medical Supply Counterfeiting

Counterfeit drugs and/or medical supplies may not be a large problem in the United States, but significant instances of counterfeiting continue to occur. The recent introduction of counterfeit One Touch Ultra Blood Glucose meter strips into the marketplace serves as a reminder to consider the possibility of counterfeit products. Health care providers should encourage patients to be aware of any changes in medications they are currently taking. Patients should look for alterations in packaging, labeling, color, taste, shape of the pill, or any unanticipated effects possibly due to the drug. In the past few months, information linking numerous “Canadian” websites to the sale of counterfeit drugs has come to light. The list includes: Lipitor, Crestor, Zetia, Diovan, Hyzaar, Actonel, Nexium, Celebrex, Arimidex, and Propecia. Physicians, pharmacists and patients can be proactive in the fight against counterfeit drugs by only acquiring medication from reputable wholesalers or distribution centers. Additional information on counterfeit drugs can be found at www.fda.gov.

Medicare Part D

The open enrollment period for changing or initiating Part D coverage is 11/15/2006-12/31/2006. As eligible participants join a plan or change plans, there may be an increase in Therapeutic Interchange or Prior Authorization requests in January and early February of 2007. For participants that did not change plans, contractual changes with a pharmaceutical manufacturer may also lead to these types of requests as well.

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FDA proposes new labeling for OTC analgesics

The FDA is proposing new labeling for over the counter analgesics including acetaminophen and non-steroidal anti-inflammatory drugs. The proposal includes highlighting the risk of liver toxicity associated with acetaminophen and the risks of gastrointestinal bleeding in persons over 60 years of age with NSAID's. The agency is taking public comment on the proposed changes. The full press release can be found at www.fda.gov/bbs/topics/NEWS/2006/NEW01533.html.

Research.

The collaborative Blood Pressure Adherence Study is actively recruiting patients at the Statewide programs. Contact your study nurse coordinator, principal physician investigator or clinical pharmacist for additional information.

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