



A Partnership for Medical Excellence

PHARMACY MONTHLY NEWSLETTER

MAY 10, 2009

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TOPICS IN EVERY ISSUE:

[In The News](#) | [Safety Updates](#) | [New Generic...](#) | [Emerging Therapies...](#) | [PharmD Monthly Q&A...](#) | [Disease State/Lit. Update](#) | [Formulary Updates](#)

In The News:

Queen Mary's School of Medicine, University of Edinburgh and other British groups, developed a **simple and convenient** algorithm to predict risk of developing type II DM in 10 years. It is called the **QDScore**. Details are published in British Medical Journal [[Link](#)].

- * 1st risk prediction algorithm to estimate 10 yr risk of DM using a prospective cohort study & including social deprivation & ethnicity
- * To date, NO trials or consensus has been conducted to suggest how this tool should be used
- * Also, authors from the Cleveland Clinic recently published a predicting tool for 6-yr mortality risk in patients with T2DM [[Link](#)]

A randomized trial of apparently health persons found that **Crestor® (rosuvastatin)** significantly reduced the occurrence of symptomatic **venous thromboembolism**. The analysis broke VTEs down by 4 specific types, only 2 of which showed statistically significant differences. Provoked venous thromboembolism (cancer, trauma, surgery, etc) and deep-vein thrombosis each showed significant benefits, whereas unprovoked venous thromboembolism and pulmonary embolism did NOT show significant differences.

- * Large cohort of 17,802 apparently healthy men & women w/ low LDL levels median baseline 108 mg/dL) and CRP of 2.0 or higher
- * High rosuvastatin dose was used, 20 mg daily (same as JUPITER study); study did NOT evaluate other doses
- * Benefits did NOT appear to be related to any changes in LDL, HDL or TGs (note: patients already within goal ranges at baseline)
- * NNT with rosuvastatin for 2 years to prevent 1 primary end point was 95, for 4 years it was 31

⚡ **Note:** Deaths from cancer were significantly lower in rosuvastatin group (38 vs. 54, p=0.02); finding was NOT commented on

FDA approved **Coartem®** (artemether-lumefantrine) for acute, uncomplicated malarial infections from *Plasmodium falciparum*, the most dangerous form, in patients of ≥5 kg of body weight. However, should **NOT** be used to prevent malaria OR for severe infection.

The FDA approved the TRIPLE drug combination **Exforge HCT®** (amlodipine/valsartan/hctz). It becomes the first and ONLY fixed combination formulation with 3 drugs indicated for hypertension. These 3 drugs fit the general JNC VII scheme, cost (insurance coverage) and ease of up/down titrations will be significant factors.

Metformin added to insulin, vs. placebo added to insulin, reduces the risk of **MACROvascular** disease after 4.3 years of follow up in 390 T2DM patients. Limiting the interpretation this was a secondary end-point, as the aggregate micro+macro was the primary end-point.

Pharmacy—Clinical Sound Bytes:

- **Cetraxal®** (ciprofloxacin otic solution, 0.2%) new formulation approved for acute otitis media [[Link](#)]
- **Edluar®** (sublingual zolpidem) new formulation approved, However, needed an FDA REMS as well [[Link](#)]
- **Diovan®** (valsartan) NOT effective for afib in the GISSI-AF trial [[Link](#)]
- FDA allows OTC sales of **Plan B** to girls ≥17 years old [[Link](#)]
- **Benzyl alcohol (tradename pending)** approved for head lice infestation in patients 6 months of age and older [[Link](#)]
- **Epipen®** was under-prescribed and most physicians improperly demonstrated its use in a recent study [[Link](#)]

[QDScore](#)
[Crestor for VTEs?](#)
[Coartem](#)
[Exforge HCT](#)
[Metformin MACROvascular](#)



Safety Updates:

[Submit ADR^s to MedWatch Online!](#)

- **Raptiva (efalizumab)** withdrawn due to the potential risk of developing progressive multifocal leukoencephalopathy (PML)
 - * It was indicated for a non-fatal condition but caused a fatal disease (rare) to which there is no known cure (Risks outweigh any benefit)
 - * By June 8, 2009, efalizumab will NO longer be available in the US
 - **Hydroxycut** diet products have been pulled from the market due to serious liver toxicity, 23 reports from jaundice to transplant to **death**. [Dear healthcare letter](#); [Consumer Q and A letter](#)
 - * Local Buffalo Link (distributed by Iovate Health Sciences USA of Blasdell, NY) [Ask RPh to submit ADR to Medwatch](#)
 - FDA updates early ongoing analysis of **Botox** and ADRs when drug effects go beyond injection site and states that products will be required to strengthen their labels, add a **black box warning** and develop Risk Evaluation and Mitigation Strategies (REMS).
 - **Emend® (aprepitant)** interacts with oral contraceptives, reducing ethinyl estradiol and norgestimate levels, effect may last for weeks.
 - Link to ALL latest labeling changes (i.e., post-marketing ADR updates) [[Link](#)]
- * Example; **Lipitor® (atorvastatin)** updated drug information to include 'hepatic failure' in adverse reaction section.

[Raptiva](#)
[Hydroxycut](#)
[Botox](#)
[Emend](#)



New Generic Approvals*:

[Each have a Medicare exception from Tier changes until 1/1/2010]

- Acetazolamide, generic for Diamox®
- Carbidopa/levodopa ODT, generic for Parcopa® approved but both brand and generic remain Tier 3
- Dexamethasone/tobramycin, generic for Tobradex®
- Protriptyline, generic for Vivactil®





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[Back to Page 1](#)

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Emerging Therapies & the Drug Pipeline:

[Saxagliptin](#)

Diabetes Type II— Onglyza (saxagliptin) is one of a slew of new dipeptidyl-peptidase IV (DPP-IV) inhibitors working their way to the market. Saxagliptin may be closer than the others because the FDA has recently stated that its cardiovascular data is acceptable. Currently Januvia® (sitagliptan) is the only DPP-IV inhibitor available in the US. The FDA has only recently insisted on cardiovascular safety data for diabetes drugs. Note that GLP-1 analogues (exenatide) are more efficacious but DPP-IV's appear to be better tolerated.

Pharm.D. Monthly Q&A Review:

[11-dehydro thromboxane B2 and CV risk](#)

Incoming e-mail Question:

[Aspirin resistance; Review Article](#)

“How do we evaluate a patient for aspirin resistance?”

[VerifyNow Aspirin Assay Details](#)

[AspirinWorks urine test details](#)

Excerpt of Outgoing e-mail Answer:

For review: There are at least 3 potential explanations for the emergence of aspirin resistance: 1) platelets can be activated by pathways that are not blocked by aspirin, 2) higher doses than 75—325 mg/d may be required in some patients to achieve the optimal antithrombotic effect of aspirin (though low-dose ASA blocks > 95% of COX-1 activity), 3) some patients may be able to generate thromboxane A₂ despite usual therapeutic doses of ASA.

- The extent of inhibition of thromboxane A₂ generation can be determined by measuring levels of urinary 11-dehydro thromboxane B₂, a stable metabolite of thromboxane A₂. (significant CV risk was tied to 11-dehydro thromboxane B₂ levels in at least 1 well designed cohort analysis)
- The best test of aspirin resistance appears to be the VerifyNow Aspirin Assay by Accumetrics Inc. (Platelet responsiveness is expressed in aspirin response units, with a cutoff for aspirin resistance at 550 or more aspirin response units)
- Another test is a point-of-care test using the PFA-100 device. Aspirin resistance measured by the PFA-100 has been only weakly correlated with an increase risk of clinical events in one observational cohort study.

Disease State Or Literature Update:

ACCF and AHA have jointly updated **CHF guidelines.**

- Entire new section, “**Recommendations for the Hospitalized Patient**”, listed by NYHA Class [AHA CHF 2009 Guidelines](#)
- “Focused update” style to facilitate a quicker response to new evidence
 - * Evidence is reviewed twice a year, updates initiated on as-needed basis as quickly as possible, while maintaining rigorous methodology already employed by ACCF/AHA
- **Select modifications, additions or deletions to the 2005 guidelines: (New for 2009)**
 1. **Modification:** Measurement of natriuretic peptides (BNP and NT-proBNP) can be useful in the evaluation of patients presenting in the urgent care setting in whom the clinical diagnosis of HF is uncertain. **Measurement of natriuretic peptides (BNP and NT-proBNP) can be useful in risk stratification** (Level A evidence)
 2. **Addition:** It is reasonable to treat patient with atrial fibrillation and HF with a strategy to maintain sinus rhythm or with a strategy to control ventricular rate alone (Level A evidence)
 3. **Addition:** The combination of hydralazine and nitrates is recommended to improve outcomes for patients self-described as African-Americans, with moderate-severe symptoms on optimal therapy with ACE inhibitors, beta blockers, and diuretics (Level B evidence)
 4. **Modification:** Routine intermittent infusions of **vasoactive and** positive inotropic agents are NOT recommended for patients with refractory end-stage HF (Level A evidence)
 5. **Modification (elevated from class IIa to I recommendation):** The combination of a fixed-dose of isosorbide dinitrate and hydralazine to a standard medical regimen for HF, including ACE inhibitors and beta blockers, is recommended in order to improve outcomes for patients self-described as African Americans, with NYHA functional class III or IV HF. Others may benefit similarly, but this has not yet been tested (Level A evidence)

Formulary Updates:

Tier changes:

Moved from Tier 2 to Tier 1: QVar®

Removal of Prior Authorization requirements:

Prandin, Prandimet, Ranexa, Suboxone, Janumet, Januvia

Additions:

Promacta, Banzel, Vimpat, Xenazine all added to Tier 2 w/ PAR,

Prandimet, Apriso both added to Tier 2



[Link to IHA Formulary](#)

[Tablet Splitting Program](#)

Reviewed by P+T but remain non-preferred (Tier 3)

Trilipix, Toviaz, Aczone, Zolpimist, Reprexain, Moxatag, Vanoxide HC, Naprelan SR, Millipred, Veripred 20