



A Partnership for Medical Excellence

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PHARMACY MONTHLY NEWSLETTER

MARCH 5, 2009

TOPICS IN EVERY ISSUE:

In The News	Safety Updates	New Generic...	Emerging Therapies...	PharmD Monthly Q&A...	Disease State/Lit. Update	Formulary Updates
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In The News:

- A comparison of **weight-loss diets**, published in NEJM, finds that there was NO difference in type of diet used, only that **reduced calories** provided clinically meaningful weight loss. Attendance at group education sessions was found to be strongly associated w/ weight loss. Weight loss averaged only 4 kg over 2 years, but DID result in significant benefit w/ lipids and fasting insulin levels.
 - * 811 overweight adults randomly assigned to 1 of 4 diets, similar foods used but in different fat/carb/protein ratios
 - * Intervention included goal of 90 minutes of physical activity per week, and 80% completed trial
 - * Each patient received a caloric prescription that provided a 750 kcal/day deficit from baseline
- The still investigational glucagon-like peptide 1, **liraglutide** (similar to Byetta (exenatide)), proved safe and effective for initial treatment of T2DM in a 52-week phase III, double-blind, parallel-treatment trial. Importantly, this trial also showed liraglutide provided **greater reductions** in A1C, weight, hypoglycemia, and blood pressure than **glimepiride**. Furthermore, this trial was conducted to investigate its use as INITIAL therapy, vs. adjunct therapy as with exenatide's current FDA indication. ["LEAD-3 Mono" trial].
 - * 746 patients w/early T2DM randomized to once daily liraglutide 1.2 mg, 1.8 mg, or glimepiride 8 mg
 - * At 52wks, A1C decreased by 0.51% w/glimepiride, by 0.84% w/ liraglutide 1.2 mg, and by 1.24% w/liraglutide 1.8 mg
- A 2 year, randomized, double-blind, placebo-controlled trial suggests that the long-term combined structure-modifying and symptom-modifying effects of **chondroitin sulfate (CS)** 4 and 6 may be a disease-modifying agent in patients with knee osteoarthritis.
 - * n=622, 800 mg/day (n=309), placebo (n=313) for 2 years follow up
 - * % of patients w/significant radiographic progression had greater reduction in CS group vs. placebo (41% vs. 28%, P<0.0005)
- FDA approves **Uloric® (febuxostat)** for the chronic management of hyperuricemia in patients with gout. It was studied in multiple clinical trials in more than 4,000 patients, and in some for up to 5 years.
 - * Significant advantages over allopurinol include NO dosage adjustments for renal impairment, 80 mg febuxostat was found **SUPERIOR** to 40 mg febuxostat or allopurinol 300/200 in achieving primary end-point of <6.0 mg/dL serum UA.
 - * Rashes have been reported during pre-approval trials, no cases of SJS to date vs. allopurinol

Pharmacy—Clinical Sound Bytes:

- Study finds that clinicians override most medication alerts, including severe and drug allergy alerts, indicating that alerts are inadequate to protect patient safety. [[Link](#)]
- Homocysteine alone accurately predicts CV risk in those ≥75, classic risk factors in Framingham score did NOT. [[Link](#)]
- American Pain Society & AAPM publish clinical guidelines: chronic opioid therapy in chronic non-cancer pain. [[Link](#)]
- Symbicort gains FDA indication for COPD. [[Link](#)]. Apidra (insulin glulisine) now available in pre-filled pen formulation, Apidra SoloSTAR [[Link](#)].

[NEJM Wt Loss](#)

[Liraglutide](#)
[Chondroitin for OA](#)
[Uloric®](#)

Safety Updates:

Submit ADR^s to MedWatch Online!

- The FDA is requiring a new black box warning for **metoclopramide**-containing products, citing the risk of developing **tardive dyskinesia** with long-term OR high-dose use. In addition, manufacturers of the drugs will have to implement a REMS (risk evaluation and mitigation strategy). They state that, "chronic use of metoclopramide therapy should be avoided in all but rare cases where the benefit is believed to outweigh the risk." Those at greatest risk are the elderly, especially older women, and people who have been on the drug for a long time.
- **Zonegran (zonisamide)** products, FDA approved as adjunct for partial seizures and used off-label for migraines or Parkinson disease, will get a labeling revision to include the warning of **metabolic acidosis**. Per FDA:
 - * If metabolic acidosis develops & persists, consideration should be given to reducing the dose of zonisamide, or to d/c zonisamide using **dose tapering** & modifying the patient's treatment as appropriate. If the decision is made to continue patients with persistent acidosis on zonisamide, then alkali treatment should be considered.
- The FDA has warned that **medicated patches** that contain metal in their non-adhesive backing may cause skin burning when undergoing an MRI. The FDA is compiling a list of these and ensuring labeling revisions. Until then they are advising that patients should be facilitated (appropriately) to be able to remove any medicated patch prior to the MRI.

[Metoclopramide](#)
 ->[Journal article](#)
[Zonisamide](#)
[Patches & MRI](#)

[Ask RPh to submit ADR to Medwatch](#)

New Generic Approvals*:

Venlafaxine XR, generic for Effexor XR, NOT AB rated and remains Tier 3 on IHA

Independent Health
Dedicated to Making a Difference

- **HFA inhaler transition time is here!** Generic inhalers (with CFCs) are NO LONGER AVAILABLE.
 - * Help for patients to afford HFA inhalers is available.

[Transition Now Help](#)
[Proventil HFA](#)
[ProAir HFA](#)
[InhalerTransition.org](#)



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Emerging Therapies & the Drug Pipeline:

[Darusentan](#)
[CYT006-AngQb](#)

Hypertension—

An endothelin type A (Eta) receptor antagonist, **darusentan**, is currently making its way through Phase 3 trials. Endothelin-1 (ET-1) is an endogenous peptide released from the vascular epithelium. It is a potent vasoconstrictor with a long duration of action. It also modulates endothelial function and vascular remodeling. This drug represents a unique mechanism of action and has the potential to be a disease modifying drug. Tolerability (flushing and edema) and pregnancy category X are issues needing further assessment and/or safeguards. Phase 2 dose finding trial, HEAT-HTN, 100 mg reduced BP by 11.3/6.3 mmHg in pts w/untreated Stage 2 HTN.

A number of **vaccinations for hypertension** are under investigation. **CYT006-AngQb** is one such vaccine that facilitates titers of antibodies against angiotensin II. A lot of questions and uncertainties surround this very appealing method of treatment.

Pharm.D. Monthly O&A Review:

Incoming e-mail Question:

“What is the goal BP for patients with heart failure?”

[AHA \(Circulation\)](#)
[COPERNICUS](#)

Excerpt of Outgoing e-mail Answer:

- JNC VI = 130/85 → JNC VII = 140/90 (no specific mention of different goal for HF)
- 2007 AHA says 130/80 for most (Framingham score ≥ 10% Risk), if LV dysfunction (EF <40%) then 120/80
 - * Note: ALL of the following are contraindicated in LVD; verapamil, diltiazem, clonidine, and alpha blockers
- PER AHA 2007, “BP targets in HF have NOT been firmly established, but in most successful trials, SBP was lowered to the range of 110-130 mmHg. One trial, COPERNICUS, demonstrated benefits of carvedilol in patients with entry criteria that included an SBP as low as ≥85 mmHg and who had a mean BP of 123/76 mmHg, which suggests that lower BPs (SBP < 120 mmHg) may be desirable in some patients.”
 - * In patients with an elevated DBP who have CAD and HF with evidence of ischemia, the BP should be lowered slowly, and caution is advised in inducing falls of DBP below 60 mmHg if the patient has diabetes mellitus or is > 60 yrs of age.

Disease State Or Literature Update:

OPIOID TREATMENT GUIDELINES:

Clinical Guidelines for the Use of Chronic Opioid Therapy (COT) in Chronic Noncancer Pain (CNCP) [Pain.EDU Site](#)
[Journal of Pain Guidelines](#)

Recommendations (Part 1—3):

1. Patient Selection and Risk Stratification
2. Informed Consent and Opioid Management Plans
3. Initiation and Titration of COT
4. Methadone
5. Monitoring
6. High-risk Patients
7. Dose Escalations, High-Dose Opioid Therapy, Opioid Rotation, and Indications for Discontinuation of therapy
8. Opioid-related Adverse Effects
9. Use of Psychotherapeutic Cointerventions
10. Driving and Work Safety
11. Identifying a Medical Home and When to Obtain Consultation
12. Breakthrough Pain
13. Opioids in Pregnancy
14. Opioid Policies

Tools and Resources:

- Screener and Opioid Assessment for Patients in Pain (**SOAPP**)
- * Brief paper and pencil tool to facilitate assessment and planning for chronic pain patients being considered for long-term opioid treatment. [[Link](#)]
 - * Tutorial, Video Examples and FAQs also at above link.
- Current Opioid Misuse Measure (**COMM**)
- * Evaluate current opioid users, vs. predict with SOAPP [[Link](#)]
- Pain Assessment and Documentation Tool (**PADT**)
- * A progress note template [[Link](#)]
- Sample Medical Agreement from AAPM [[Link](#)]
- Informed Consent form for Chronic Opioid Therapy [[Link](#)]
- Part 2 of 3**—Aberrant Drug Behaviors [[Link](#)]
- Part 3 of 3**—Research Gaps on Use of Opioids for CNCP [[Link](#)]

Formulary Updates:

Tier changes:

Moved from Tier 2 to Tier 1: Asmanex Twisthaler, Flovent, Pulmicort Flexhaler, Alvesco

Moved to Tier 3 because of generic availability: Parcopa, Videx, Razadyne, Cosopt, Keppra
Generics for the following are Tier 3 despite new generic availability: Seroquel XR, Palgic, Camptostar, Trusopt
Non-formulary Tier 3 despite P+T review: Aplenzin, Stavzor, Sancuso, Aloxi, Keppra XR, Sanctura XR, Requip XL

Additions:

Hycamin added to Tier 2 w/ PAR

[Link to IHA Formulary](#)
[Tablet Splitting Program](#)

