



# Pharmacy Benefits Management- Medical Advisory Panel Ez-Minutes

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## Inside this Issue:

### Page 1

- Recent Posting-National PBM Reviews
  - Criteria for Use
  - Drug Monographs
  - Guidance for Clinicians
  - New Molecular Entity Reviews
- Other Formulary Decisions
- Welcome New Residents/Staff

### Page 2

- ACEI in Pregnancy
- Evaluation of Enfuvirtide (T20) in VA Patients
- NEW FDA Black Box warning for tipranavir

### Page 3

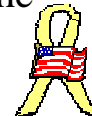
- VHA Directive: Mgmt of Pts. with Swallowing or Feeding Disorders
- Tobacco Use Cessation Guidelines
- "1" VA National Formulary

### Page 4

- Opioid/Fentanyl Patch ADE
- PBM-MAP Programs-CE!
- Allergy/ADR in CPRS PP program—Updated!
- Subscribe to Ez-Minutes

IntRAnet PBM website is currently being redesigned. The web address will remain the same. Be sure to bookmark these PBM websites:

<http://vaww.pbm.va.gov> or <http://www.pbm.va.gov>



## Recent Postings of National PBM Reviews on Web Site

### Criteria for Use/Nonformulary Use

<http://vaww.pbm.va.gov/pbm/criteria.htm>

- Highly Teratogenic Retinoids and High-dose Vitamin A (Pregnancy Category D or X)
- Enfuvirtide (Fuzeon™)
- Clinically Uroselective alpha blockers-(minor revision)
- Quinine Sulfate in the Management of Nocturnal Leg Cramps

Refer to the Quinine white paper at:

<http://vaww.pbm.va.gov/criteria/quinine.pdf>

### Drug Monographs

<http://vaww.pbm.va.gov/pbm/drugmonograph.htm>

- Tetanus-Diphtheria-Pertussis Vaccine (Adacel™ or Tdap)
- Combination Isosorbide Dinitrate/Hydralazine (BiDil®)
- Sorafenib (Nexavor®)
- Insulin detemir (Levemir®)
- Lenalidomide (Revlimid®)

### Guidance for Clinicians

<http://vaww.pbm.va.gov/pbm/guidclinicians.htm>

Guidance for Medication Assessment in Pts with Swallowing/Feeding Disorders (Refer to Page 3)

## New Molecular Entity Reviews

- Tetanus-Diphtheria-Pertussis Vaccine (Adacel™ or Tdap)-Added to the VA National Formulary for appropriate patients-Read the monograph for details.
- Lenalidomide (Revlimid®)-Not added to the VA National Formulary
- Bromfenac sodium (Xibrom®)-Not added to VA National Formulary

## Other Formulary Decisions:

- Calcium acetate capsule-Added to National Formulary-(tablet was removed from National Formulary due to change in manufacturing dosage form)
- Thickening agent (powder) -Added to VA National Formulary—restricted to Criteria for Use
- Formoterol (Foradil Aerolizer®)-Added to National Formulary
- Combination Isosorbide Dinitrate/Hydralazine (BiDil®)-Not added to National Formulary
- All pseudoephedrine containing products- same restriction as pseudoephedrine alone
- Placebo cap/tab-Change to Nonformulary status—(the use of placebo is prohibited outside of approved research protocols)

**WELCOME NEW RESIDENTS/STAFF!** The PBM-MAP would like to take this opportunity to welcome new residents/staff/providers. This quarterly online newsletter is designed to help connect the PBM-MAP to VA field-based providers on issues such as changes with the VHA National Drug Formulary, Criteria for Use or VHA Treatment Guidelines and more. The newsletter will also include important drug related topics including medication safety issues from the VAMedSafe group. Information included will no doubt be helpful to you during your tour of duty of serving and providing care to our nation's veterans. The best part is...the information can literally be read in minutes. It's easy, or rather Ez! To access previous issues of the newsletter, click on this link:

<http://vaww.pbm.med.va.gov/pbm/ezminutes.htm>

Interested in joining the already 6500+ subscribers to Ez-Minutes Newsletter? → check page 3 for more details.

## FDA Alert: Angiotensin-Converting Enzyme Inhibitors in Pregnancy

Angiotensin-converting enzyme inhibitors (ACEIs) are currently listed as pregnancy Category C for the first trimester, and Category D for the second and third trimesters. Product labeling recommends discontinuation of therapy with an ACEI as soon as a woman becomes pregnant. Recent data from an observational study of pregnant women receiving ACEIs in the first trimester were published in the June 8, 2006 edition of the *New England Journal of Medicine* and reported an increase in the rate of fetal abnormalities compared to infants not exposed to ACEIs or other antihypertensive agents throughout pregnancy (refer to summary of data below).

### Summary of Data from Cooper et al.<sup>1</sup>

**Data Source:** Tennessee Medicaid Data

**Inclusion Criteria:** Infants born between 1985 and 2000 with enrollment for the first 90 days after birth or through death (with required birth certificate information for study) and enrollment of mother throughout pregnancy

**Exclusion Criteria:** Evidence of maternal diabetes during or prior to pregnancy; prescription for an angiotensin II receptor antagonist; exposure to ACEIs or other antihypertensive agents past the first trimester; exposure to other potentially teratogenic agents

#### Results:

Congenital Malformations	ACEI <sup>a</sup> (N=209) Risk Ratio (95% CI) <sup>b</sup>	Other Antihypertensives <sup>a</sup> (N=202) Risk Ratio (95% CI) <sup>b</sup>
Any Major	2.71 (1.72-4.27)	0.66 (0.25-1.75)
Cardiovascular	3.72 (1.89-7.30)	0.89 (0.22-3.59)
Central Nervous System	4.39 (1.37-14.02)	(none reported)
Other	1.75 (0.79-3.89)	0.62 (0.15-2.45)

<sup>a</sup> First trimester alone

<sup>b</sup> vs. no antihypertensive agents throughout pregnancy (N=29,096)

**Study Conclusions:** The results suggest an increased risk for major congenital fetal malformations in patients exposed to an ACEI during the first trimester of pregnancy compared to infants whose mothers did not receive any antihypertensive medications during pregnancy. The authors recommend that ACEIs be avoided in the first trimester of pregnancy.

<sup>1</sup>Cooper WO, Hernandez-Diaz S, Arbogast PG, et al. Major congenital malformations after first-trimester exposure to ACE inhibitors. *N Engl J Med* 2006;354:2443-51.

Click here to learn more details of the study including what the FDA recommends: <http://www.pbm.va.gov/alerts/ACEIPregnancy.pdf>

Submitted by: Elaine Furmaga, PharmD-PBM

## VA MedSAFE: Evaluation of Enfuvirtide (T20) in VA Patients...Are providers following the Criteria for Use?- Study conducted by Pam Belperio, Pharm.D., BCPS Office of Public Health Strategic Healthcare Group

PBM Criteria: <http://vaww.pbm.va.gov/criteria/EnfuvirtideCriteriaForUse.pdf>

Total evaluable subjects (received at least one dose): 275

Method: Full CAPRI chart Review/data extraction (8/05-12/05)

### Percentage of Cases CFU were met:

Documented virological failure (VL>5000)	87%
Intolerance of at least 2 prior HAART regimens	91%
Previous exposure to 2 classes of ARVs	97%
Ability to construct a regimen with at least 1 other active agent (resistance testing)	52-86%
Hx of medication adherence and clinic attendance	52%
Assess for response	71%-79%

**SUMMARY:** Adherence to CFU: Providers did well overall. The SIG information was noted to be inconsistent and is an area that needs improvement. Providers are encouraged to document adherence in the medical record Click on this link in the near future to learn more findings from this study: <http://vaww.pbm.va.gov/pbm/vamedsafe.htm>

## New black box warning for AIDS drug Aptivus® (tipranavir)

Aptivus co-administered with 200mg ritonavir has been associated with reports of both fatal and non-fatal intracranial hemorrhage. Aptivus® co-administered with 200mg ritonavir has been associated with reports of clinical hepatitis and hepatic decompensation including some fatalities. Extra vigilance is warranted in patients with chronic hepatitis C co-infection, as these patients have an increased risk of hepatotoxicity.

Dear Healthcare Provider letter available at:

[http://www.fda.gov/medwatch/safety/2006/Aptivustipranavir\\_DHCP.pdf](http://www.fda.gov/medwatch/safety/2006/Aptivustipranavir_DHCP.pdf)

The revised product labeling available at:

[http://www.fda.gov/medwatch/safety/2006/Aptivus\\_PL.pdf](http://www.fda.gov/medwatch/safety/2006/Aptivus_PL.pdf)

## New PBM Clinical Guidance on Pharmacist's Assessment of Dysphagia Posted

The PBM, in compliance with of VHA Directive 2006-032 "(Management of Patients with Swallowing (Dysphagia) or Feeding Disorders)," has developed a clinical guidance on dysphagia. The purpose of this clinical guidance is to provide pharmacists in the VA with the information needed to conduct a medication regimen assessment for a patient with dysphagia. This unique patient population requires special review of the medications prescribed, dispensed and administered, to minimize the difficulty of swallowing medication, increase the adherence to medication regimens, and minimize the risk of adverse outcomes. This guidance also brings attention to the types of medications that should not be crushed. The guidance is available at the PBM's intranet site:

<http://vaww.pbm.va.gov/clinicians/ClinicalGuidanceForMedicationAssessmentInDysphagia.pdf>

Submitted by Todd Semla MS, Pharm.D., BCPS, FCCP-PBM

### Overview of VHA Directive 2006-032: Management of Patients with Swallowing (Dysphagia) or Feeding Disorders and Responsibilities of VHA Pharmacy Service and PBM SHG" Policy

The development of the Directive was the result of the VA OIG's Office of Healthcare Inspection's report evaluating the management of VHA patients with dysphagia. The PBM SHG was tasked with two items:

1. Developing and updating guidelines in coordination with Nutrition and Food Services and Rehabilitation Services;
2. Ensuring that thickening agents are added to the VA National Formulary

Inpatient and residents may be identified with dysphagia in one of two ways:

- Routine outpatient clinic visit: If VA primary care provider/physician observes symptoms of dysphagia during the clinical evaluation or examination, the patient will be referred to the speech and language pathologist for diagnostic evaluation.
- Within 24 hours of admission: If swallowing problems are noted during the initial nursing assessment the nursing staff will immediately notify the physician or provider responsible for the care of the patient. The physician or provider will then refer the patient to the speech-language pathologist for diagnostic evaluation. The evaluation must occur within 72 hours of identification. During the 72-hour period between identification and evaluation, the physician will use clinical judgment related to the safe and effective administration of medications. The physician or provider will request a consultation from the Chief of Pharmacy Service or designee for a pharmacist to provide a review of the patient's medication regimen including the most appropriate method of administering the medication(s).

Click to learn more details: <http://www.pbm.va.gov/alerts/DysphagiaDirective.pdf>

For more explanation, contact: Vaiyapuri Subramaniam, Pharm.D., M.S.; Associate Chief Consultant, PBM SHG, VACO  
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### Tobacco Use Cessation Guidelines

REMINDER: updated guidelines available at [http://www.oqp.med.va.gov/cpg/TUC3/TUC\\_Base.htm](http://www.oqp.med.va.gov/cpg/TUC3/TUC_Base.htm)

**Did you know?** One VA National Formulary will be implemented across all VISNs in the near future. As you know, a substantial amount of details related to this project of this magnitude are still being finalized. Keep reading future issues of the Ez-Minutes for more details. Speaking of the VA National Formulary, did you know it is available in a PDA format? A small program called "List" is required to view it. The formulary can be sorted by drug or by class. Both the program and the formulary can be downloaded from the PBM Internet and Intranet Websites, either from the "PDA National Formulary" link on the "National Formulary" page or directly at <http://www.pbm.va.gov/pdanatform/>

### Can't wait to read breaking news in the next issue of the PBM-MAP Ez-Minutes?

Then, subscribe to receive free reminders when the new edition of Ez-Minutes is hot off the press. Send an email to [subscribe@verdict.uthscsa.edu](mailto:subscribe@verdict.uthscsa.edu) with "subscribe to Ez-Minutes" in the subject field. If you have problems with these instructions, send an email to [stxcollage@med.va.gov](mailto:stxcollage@med.va.gov) with "subscribe to Ez-Minutes" in the subject line. We hope to make Ez-Minutes available via PDA format in the near future.

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## Opioid / Fentanyl Patch ADEs

Transdermal fentanyl has been involved in numerous serious adverse events and fatalities across the nation. In the past 2 years, the Food and Drug Administration, Institute for Safe Medication Practices, the manufacturer (Janssen Pharmaceuticals), and the Department of Defense Patient Safety Program have issued warnings and recommendations to improve the safe use of transdermal fentanyl. The PBM-MAP reviewed its VAMedSafe Serious Adverse Events (SAE) database to evaluate the safety of fentanyl relative to other opioids in the VA. Formulation-specific data are not available at this time. In 2004 and 2005, fentanyl did not seem to be worse than morphine or methadone in terms of rates of reactions per SAE per number of patients (Uniques) prescribed the respective drug (see Table 1). Oxycodone and short-acting opioid formulations seemed to have lower rates of reactions per patient. It was believed that the data were sufficient evidence to suggest that there is no safety signal with fentanyl patches relative to other strong opioids in the VHA.

**Table 1: Number of Reactions by Year**

Drug	Rxn Ct 2004	Rxn Ct 2005	Ttl Uniques FY04	Ttl Uniques FY05	Rxn Ct / Unique (x 1000) 2004	Rxn Ct / Unique (x 1000) 2005
Fentanyl	113	94	25,243	24,829	4.5	3.8
Morphine	247	270	64,717	71,380	3.8	3.8
Methadone	82	63	27,100	32,981	3.0	1.9
Oxycodone	103	76	235,852	238,095	0.4	0.3
APAP/Oxycodone	74	95	179,999	177,096	0.4	0.5
APAP/Propoxyphene	33	13	102,214	99,499	0.3	0.1
Propoxyphene	4	8	126,105	120,111	0.0	0.1

## Would you like to improve care today?

**Take advantage of this excellent opportunity to learn the right way: "How to Enter Allergies and Adverse Reactions into CPRS"**

**Available NOW at the Nearest VHA by You**

**NEW AND UPDATED PowerPoint PROGRAM!**

Just in time for new residents coming on board. Great teaching tool for staff and all providers! It's FREE and Ez to watch. See below for the link to view the program Brought to you by:

James Drozd-VA Connecticut Healthcare System and Peter A. Glassman-VA Greater LA Healthcare System

**Click on:**

<http://vaww.pbm.va.gov/vamedsafe/How%20To%20Enter%20an%20Allergy%20or%20Adverse%20Drug%20.pdf>

### Webcast program Available: "Case Management of Acute and Chronic Ischemic Heart Disease"

VA panelists include Robert Jesse, MD, PhD; Kathryn Tortorice, PharmD, BCPS; Bernadette Speiser, MSN, CCRN; and David Parra, PharmD, BCPS.

Access more program information here:

[http://vaww.sites.lrn.va.gov/vacatalog/cu\\_detail.asp?id=22211](http://vaww.sites.lrn.va.gov/vacatalog/cu_detail.asp?id=22211)

## Next PBM-MAP Distance Learning Broadcast Program

THE **A B C S** Of **A D E S**

(Adverse Drug Events...How To "Ask, Document and Enter")

**FIRST BROADCAST DATE:**

**Sept. 6th\*, 2006 @ 1PM ET, Channel 1**

\*VANTS conference call at 2PM on September 6th, 2006—opportunity to discuss the issues with the faculty, ask questions and exchange info.

Rebroadcast Dates: (ALL ET, CH 1)

9/8, 6P; 9/11, 9P; 9/12, 4P; 9/14, 8A, 9/20, 3A; 9/26, 3P; 9/28, 10A

Check the PBM websites for additional information. Please note that these programs can be viewed as an ON Demand Video to the Desktop via Content Distribution Network (if available at your site) two weeks after the initial broadcast. Click on this link in the near future for viewing information via CDN. <http://vaww.vakncdn.lrn.va.gov/>

### VA Faculty

**C. Bernie Good, MD, MPH, FACP, Pittsburgh, PA  
Jonathan R. Nebeker, MS, MD, Salt Lake City, UT  
Francesca Cunningham, Pharm.D., Hines, IL  
Jim Drozd, RPh, West Haven, CT**

### ATTENTION

Interventional radiologists, pharmacists, nurses, MDs, & dietitians. Mark your calendar NOW and plan to view this program. Learn what VHA does with all the ADR information that you enter...and much.. much more. Don't miss it! ACCME, ACPE, ANNC CE credits available.