



# Pharmacy Benefits Management- Medical Advisory Panel E<sub>Z</sub>-Minutes

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Please be sure to bookmark the PBM websites at:

[vaww.pbm.va.gov](http://vaww.pbm.va.gov) or [www.pbm.va.gov](http://www.pbm.va.gov)

PDA format --available for VA National Formulary-See Below



This issue of the Ez-Minutes is dedicated to the VA employees, their families and veterans affected by Hurricanes Katrina, Rita and Wilma. No words can adequately express what the residents in these affected areas have experienced from the impact of these powerful storms. The PBM-MAP acknowledges the support and assistance from you in extending hope and support to our colleagues and friends in these devastated areas. Please continue! Thanks.

### Recent National PBM Reviews Postings on Web Site Criteria for Use/Nonformulary Use

<http://www.pbm.va.gov/PBM/criteria.htm>

Azacitidine (Vidaza™)  
Drotrecogin Alpha (activated)-(Revised 6/05)  
Erlutinib (Tarceva®)  
Ezetimibe (Zetia®)  
Getitinib (Iressa®)  
Levetiracetam (Keppra®)  
Orlistat (Xenical®)  
Pegaptanib-(Macugen®)  
Sibutramine (Meridia®)  
Tipranavir (Aptivus™)

### Drug Monographs

<http://www.pbm.va.gov/PBM/drugmonograph.htm>

Acamprosate (Campral®)  
Eszopiclone (Lunesta™)  
Exenatide (Byetta™)  
Ezetimibe (Zetia®)  
Iloprost Inhalation Sol't-(Ventavis®)-Revised  
Nesiritide Addendum (Natrekor®)  
Levetiracetam (Keppra®)--Revised  
Orlistat (Xenical®)  
Sibutramine (Meridia®)  
Tipranavir (Aptivus®)

### New Molecular Entities Review

Acamprosate (Campral®)-Not added to VA National Formulary or VISN Formularies  
Iloprost (Ventavis®)-Not added to VA National Formulary or VISN Formularies  
Pentetate Calcium Trisodium Injection (Ca-DTPA®)-Not added to VA National Formulary or VISN Formularies  
Pentetate Zinc Trisodium Injection (Zn-DTPA®)-Not added to VA National Formulary or VISN Formularies  
Tegaserod (Zelnorm®)-Not added to VA National Formulary or VISN Formularies  
Eszopiclone (Lunesta™)-Not added to VA National Formulary or VISN Formularies  
Exenatide (Byetta™)-Not added to VA National Formulary or VISN Formularies  
Tipranavir (Aptivuse®)-Added to VA

PBM-MAP Nutriceutical Guidance.  
Click on

<http://vaww.pbm.va.gov/Wpapers/Nutriceuticals%20White%20Paper.pdf>

**Did you know?** The VA National Formulary 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/pdanatform.htm>. TELL EVERYONE!

## **VAMedSAFE: Guidance to Providers on the use of PDE-5 Inhibitors**

### **What is NAION?**

Nonarteritic Anterior Ischemic Optic Neuropathy—a sudden loss of eyesight due to blocked blood flow to the optic nerve

### **How many cases have been reported to the FDA since May, 2005? 43**

38 cases have been associated with sildenafil (approved March, 1998)  
1 case with vardenafil (approved August, 2003)

### **How many cases have reported visual loss?**

36/43 (26 reported continuing or permanent visual loss)

### **Is there new FDA approved labeling changes for all three PDE5 inhibitors? Yes**

### **What is the VA utilization of PDE-5 Inhibitors?**

During the third QTR of 2005, sildenafil, tadalafil and vardenafil (PDE5 Inhibitors) were dispensed to 281,369 unique patients.

### **WILL the PBM-MAP and VAMedSAFE continue to monitor the situation? Yes.**

In September 2005, the PBM-MAP and VAMedSAFE designed an evaluation where medication and administrative databases were merged to determine the prevalence of NAION in patients taking PDE V Inhibitors in the VA. Validation of NAION cases will be reported to the VA and FDA.

### **What does the VAMedSAFE recommend?**

- Prior to initiation of PDE5 inhibitor therapy in all patients, practitioners must inquire about any previous history of NAION or symptoms that resemble NAION. "Have you ever experienced a sudden loss or change in your vision?" with additional probing following a positive response.
- PDE5 inhibitors should not be prescribed in patients with a history of NAION.
- Health care providers should discontinue all PDE-5 inhibitors in any patient who develops NAION or who presents with similar visual complaints. In addition, caution should be used with other vasodilators in these patients.
- Health care providers should inform all patients prescribed PDE5 inhibitors of the potential for this optic neuropathy adverse event.
- Health care providers should inform patients to stop use of all PDE5 inhibitors and seek medical attention immediately in the event of visual changes, a sudden loss of vision in one or both eyes, dizziness, flushing, or headache.
- Ophthalmologists, optometrists and other eye care providers should ask all veterans with NAION about the use of PDE5 inhibitors since this information might not be readily volunteered without specific inquiry. These patients should also be advised never to take a PDE5 inhibitor.

Click to read the complete report. [www.pbm.va.gov/alerts/PDE5.pdf](http://www.pbm.va.gov/alerts/PDE5.pdf)

**PATIENT SAFETY: STOP USING TRYPAN BLUE® OPHTHALMIC SOLUTION IMMEDIATELY**

**CLICK TO READ MORE DETAILS ..TRYPAN BLUE RECALL.pdf**

**I GOT MY FLU SHOT**

**ARE YOU READY? GET SET... GO!**

**The flu season has started and so has the vaccine campaign!**

**Who really needs the shot? Read all about it on page 4**

## **OSTEONECROSIS FROM IV BISPHOSPHANATES**

**Where is osteonecrosis seen?** Jaw (maxilla or mandible)

**What is the incidence?** Unknown

**What type of patients?** Patients receiving IV bisphosphonates along with chemotherapy, steroids, radiation therapy, or chemoradiation concomitant therapy.

**What are the risk factors?** Patients with diagnosis of cancer, chemotherapy, steroids, radiation therapy, combination therapy, trauma from dental procedures, advanced age, and exposure of the jaw bone to the environment.

**What are the symptoms?** Symptoms include: (but are not limited to) Pain, swelling, or infection of the gums; loosening of teeth; poor healing of the gums; or numbness or the feeling of heaviness in the jaw

**What is the treatment?** Non-surgical treatment is preferred. Because of the high risk for osteomyelitis, treatment recommendations include systemic antibiotics, antifungal agents, or antiviral agents as needed along with oral chlorhexidine mouth rinse.

**Is there a need to discontinue biophosphanates?** Unclear. Prevention is the key to minimize exposure! Patients should be aware of symptoms to watch for, use good oral hygiene habits, and communicate with physicians and dentists if experiencing any pain in the mouth, teeth, or jaw or any other symptoms of possible dental problems.

**Want more details? Click on the attached PDF documents. Learn what the panel of medical experts and the PBM clinical pharmacist are recommending. [ONJ white paper.pdf](#) [Osteonecrosis of Jaw with Bisphosphates.pdf](#)**

**Click below for a patient education brochure available from Novartis on dental health and osteonecrosis of the jaw. [http://www.us.novartis oncology.com/info/coping/dental\\_health.jsp?checked=y](http://www.us.novartis oncology.com/info/coping/dental_health.jsp?checked=y)**

## PART II: WHAT ELSE DO I NEED TO KNOW ABOUT GOOD ADEs REPORTING?

*Editor's Note: In the last issue of Ez-Minutes, a brief overview of what type of information is required for good reporting of ADEs for the MedWatch Form 3500. See <http://www.pbm.va.gov/ezminutes/Ez-MinutesVol3Iss2Apr-Jun05.pdf>*

**Did you know that ~ 34% of drugs entered into the VHA database under the “Miscellaneous” category were contrast dye products such as iodinated, IV contrast, IV contrast dye, non ionic, radiocontrast dye?**

Information entered in the “Medication Name” field should include either the drug product’s “Validated Generic Name” or corresponding proprietary name. If the medication name is entered by its pharmacological category or classification, then the data is recorded under a “Miscellaneous” list instead. Example: The medication potentially causing an ADE being entered as a “statin” instead of specifying it as e.g., simvastatin, lovastatin or pravastatin, etc.

**What does a “miscellaneous” entry mean when compiling ADE reports?** Searching for specific drugs that may be contributing to ADEs is more difficult and/or renders the query inaccessible in obtaining accurate results of a possible causative relationship between the ADE and a specific medication. Good reporting practices will facilitate correct MedDRA (Medical Dictionary for Regulatory Activities) coding of ADE reports and searches in the database. So, be sure to enter specific names for drugs or products (including the correct spelling of the medication) when reporting the primary, secondary or concomitant drugs in the MedWatch Form (Section C).

Click here for more information. [Part II Medication Name Field.pdf](#)

**FOR PHYSICIANS:** A short PowerPoint on “How to Enter ADEs into CPRS” is available. Click on <http://www.pbm.va.gov/vamedsafe/How%20To%20Enter%20an%20Allergy%20or%20Adverse%20Drug%20.ppt>

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## RECENTLY PUBLISHED ARTICLE: Contributing authors from VISN 8, MAP and PBM.

**Effect of splitting simvastatin tablets for control of low-density lipoprotein cholesterol. Parra D, Beckey NP, Raval HS, Schnacky KR, Calabrese V, Coakley RW, Goodhope RC. Veterans Integrated Service Network 8 Pharmacy Benefits Management Utilization Committee. Am J Cardiol 2005; 95:1481-3.**

Abstract: The efficacy, safety, and economics of a voluntary conversion from whole simvastatin tablets to split tablets in six Veterans Affairs Medical Centers were retrospectively evaluated in 3,787 patients who received a consistent daily dose (5 to 40 mg) of simvastatin in 1999. Baseline and final low-density lipoprotein cholesterol levels and average change from baseline were not significantly different between groups ( $p > 0.05$ ), nor were the incidence of transaminase increases ( $p > 0.05$ ) or measurements of patient compliance ( $p = 0.07$ ). Widespread implementation of this initiative resulted in a cost avoidance of  $> \$1.2$  million in the six medical centers and  $\$10.3$  million across the Veterans Affairs Medical system in 1999, with  $> \$46$  million avoided in 2003.

**Congrats Everyone! BE SURE TO READ THE COMPLETE ARTICLE.**

*Hold on to your hat....there's more....Click to see read “VA Blazes Trail on Drug Prices.”*  
<http://www.theledger.com/apps/pbcs.dll/article?AID=/20051010/NEWS/510100405/1004/RSS&source=RSS>

### OTHER VA NEWS IN THE PRESS

[VAMedicareHMO.pdf](#)

### ARE YOU LOOKING FOR THE FLU VACCINE ATICLE?

YOUR'RE CLOSE....ONE MORE PAGE

I GOT MY  
FLU SHOT

## VA Influenza Vaccine Advisory #2: 2005-2006

Until October 24, 2005, VA health care facilities should provide inactivated (injected) flu vaccine to these individuals only:

- Veteran patients 65 years or older enrolled for VA health care
- Veteran patients of any age with comorbid conditions (pulmonary, cardiac, chronic metabolic, immunosuppression, compromised respiratory function--see VA Influenza directive or [www.cdc.gov/flu](http://www.cdc.gov/flu) for a detailed list) enrolled for VA Health Care
- Residents of VA's long-term-care facilities; veterans housed in group or shelter situations
- Pregnant women veterans enrolled for VA health care
- Personnel who work in VA health care facilities
- Household contacts and out-of-home caregivers of children aged <6 months

After October 24, 2005, any members of the VA community (enrolled veterans or staff) may be vaccinated as supplies allow. Note that this Tiered Timing approach only applies to inactivated (injected) influenza vaccine.

For information on this year's flu campaign see [www.publichealth.va.gov/flu](http://www.publichealth.va.gov/flu) or VA Intranet <http://vaww.vhaco.va.gov/phshcg/Flu/Default.htm>.

### FYI: USERS of ProClarity or VISTA

In MARCH 04, the National Drug File (NDF) updated the VA Class Listings. However, no patches have been released to the field since 12-04. If running reports in ProClarity or VISTA that rely on the VA class field ----be sure to review the reports for accuracy. Click below for more details.

### PBM-MAP DISTANCE LEARNING PROGRAMS

#### Clinical Update on the Management of BPH

There is still time to obtain CE for this program. The remaining dates and times this program can be viewed includes: November 4<sup>th</sup>, 11am (ET), November 8<sup>th</sup>, 8pm (ET), November 17<sup>th</sup>, 2am (ET) and November 25<sup>th</sup>, 12 pm (ET). The faculty for this program is the following: Justin Sherman, PharmD, Donald R. Bodner, MD, and Barry Cusack, MD.

Copies of the slides are available at <http://vaww.pbm.va.gov/PBM/dislearning.htm> or <http://www.pbm.va.gov/PBM/dislearning.htm>.

Registration on-line is available at <https://vaww.ees.aac.va.gov>. External users can register at <https://www.ees-learning-net>.

Be sure to click on [vaww.pbm.va.gov/PBM/dislearning.htm](http://vaww.pbm.va.gov/PBM/dislearning.htm) or [www.pbm.va.gov/PBM/dislearning.htm](http://www.pbm.va.gov/PBM/dislearning.htm) for information on future programs.

### LOOK FOR ANOTHER EXTREME MAKEOVER TO THE PBM WEB PAGE!

#### BY NOV 2005 –THESE CHANGES WILL HAPPEN

- Web links will be added and replace statements such as "refer to PBM Guidelines for....." These web links will allow easy access to the most current drug monographs and criteria for use on formulary and nonformulary items. This will provide consistent information across our network.
- Dosage forms on formulary items will be added. Previously, listing of generic products with a dosage form such as oral, topical, suppository, or injection was included. This revision includes a more concise and consistent dosage format for formulary items that each VISN will use to indicate which dosage form of a product should be listed as formulary.

#### Please Note: VA HIV and Hepatitis C Communities

The VA National Hepatitis C Program in conjunction with the VA Hepatitis C Resource Center Program is pleased to announce the release of:

*"Management and Treatment of Hepatitis C Virus Infection in HIV-Infected Adults: Recommendations from the Veterans Affairs Hepatitis C Resource Center Program and National Hepatitis C Program Office."*

These recommendations are now available on the VA Hepatitis C Web site at <http://www.hepatitis.va.gov/vahep?page=tp04-gd-01> and on the VA HIV Web site at <http://www.hiv.va.gov/vahiv?page=prtop06-gd-01>.

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