# Pharmacy Benefits Management-Medical Advisory Panel

# Ez-Minutes

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## Inside this Issue:




TRICK or TREAT? While constructing this newsletter, the PBM INTRAnet website magically changed. While the old links are still functional, and the content of the website has not changed very much, the organization is different. Don't be frightened by the new look. (See page 4 for more details) Another new look or rather a **treat** to watch for is the construction to the PBM INTERnet site in the near future. In an effort to improve navigation to this site, documents may be moved. So, no tricks for now. We appreciate your patience during this transition. Editor, PBM-MAP EZ- Minutes

## Tale of Two Thiazolidinediones (TZDs)

Many are well aware of the issues and controversies surrounding the TZDs. As a reminder to all, an A1C target of less than 7% may not be necessary for all patients. Please refer to the VA-DoD Diabetes Guidelines that recommend individualization of target A1c levels based upon factors such as life expectancy, co-morbid conditions, side effects, and patient preferences.
http://www.oqp.med.va.gov/cpg/DM/DM_base.htm
The PBM-MAP Criteria for Use and a recent AHRQ Report (Bolen et al. Ann Intern Med 2007) both confirm that TZDs should be used as third line agents (or earlier only if there are contraindications to sulfonylureas and metformin). Read the summary of key meta-analyses and a retrospective new users cohort study recently conducted in the VA in the FAQ document that show pioglitazone has a slight but consistently lower risk of myocardial infarction compared to rosiglitazone.
For these reasons, it was decided that rosiglitazone be removed from the VA National Formulary. Pioglitazone will remain non-formulary and is now the TZD of choice for new starts. For patients in whom use of a TZD remains appropriate, pioglitizone may be substituted at the discretion of providers and patients. If the decision to continue rosiglitazone made in light of the available data and only after a discussion of the risks and benefits of this and alternate therapies with the patient. In al cases, TZDs should be prescribed according to the criteria for non-formulary use.
Submitted by Debbie Khachikian, PharmD-VACO Pharmacy Benefits Management-Hines, IL.

## Recent Postings of National PBM Documents

**Criteria for Use / Nonformulary Use**
http://www.pbm.va.gov/CriteriaForUse.aspx

- Dihydropyridine (Long-Acting)Updated
- Ranolazine (Ranexa®)

**Therapeutic Interchange Guidance**
http://www.pbm.va.gov/TherapeuticInterchangeGuidance.aspx

- Alfuzosin to Tamsulosin Provider Letter
- Alfuzosin to Tamsulosin Patient Letter
- Felodipine
- Felodipine Patient Letter
- Fluvastatin to Pravastatin Provider Letter
- Fluvastatin to Pravastatin Patient Letter
- Dilantin Provider Letter:
- Digoxin Patient Letter:

**Directives, Policies,& Information Letters**
(InTRAnet only)

Guidance for Issuing Prescriptions to Veterans for Filling at Non-VA Pharmacies

**Drug Monographs**
http://www.pbm.va.gov/DrugMonograph.aspx

- Dasatinib (Sprycel™)
- Ranolazine (Ranexa®)
- Retapamulin (Altabax™)

**Formulary Decisions**

- Fluvastatin-Removed from the VA National Formulary (VANF)
- Dasatinib (Sprycel™)-Not added to VANF
- Retapamulin (Altabax®)-Not added to the VANF
- Pravastatin-Added to the VANF
- Ranolazine (Ranexa®)-Not added to the VANF
- Rosiglitazone (Avandia®)-Removed from VANF

**Recommendations for Use**
(InTRAnet only)

- Recommendations for Use Daptomycin, Linezolid, Quinupristin-Dalfopristin and Tigecycline

**Drug Class Reviews**
http://www.pbm.va.gov/DrugClassReviews.aspx

- Dopamine Agonists
- Ophthalmic Antihistamine/Mast Cell stabilizing agents

**Frequently Asked Questions (FAQ) Sheets**
(InTRAnet only)

- Thiazolidinedione (TZD): Questions and Answers for Providers & Patients
- Zoster Vaccine Provider and Patient Information

# NEW DILANTIN LOOK

The FDA recently approved a supplemental abbreviated new drug application (sANDA) for Dilantin® Extended Oral Capsules 100mg. This will result in the discontinuation of the current Pfizer product, DILANTIN® Kapseals® 100 mg capsules. It will be replaced with DILANTIN® (phenytoin sodium) 100 mg Extended Oral Capsules. This new formulation contains the same active ingredient, phenytoin sodium 100 mg and utilizes a gelatin capsule with additional dyes. The new capsule is half white and half orange. Please refer to the picture below. (Colored pictures are posted on the National PBM website.) Currently, no changes have been made to the 30 mg DILANTIN® Kapseal® or any other DILANTIN® products. Additional Information regarding bioequivalence studies is included in the provider's letter. (link below)

When the current supplies of Dilantin® Kapseals® provided by Pfizer are depleted, the VA CMOP and facility pharmacies will convert to Dilantin®, Extended Oral Capsule. No dosage adjustments are recommended. There are no recommendations regarding need for levels or monitoring. Patient and provider information letters are posted on the National PBM IntRAnet website.

Provider Letter: Patient Letter:

The VA MedSafe program will design a prospective database MUE that will track patients who were hospitalized, had an emergency room visit, or elevated phenytoin levels which may be related to the conversion. If you receive any reports of patients who experience an adverse event/hospitalization as a result of the conversion to the new phenytoin formulation, please enter the report into the VA Adverse Drug Event Reporting System (VA ADERS). The intranet site for VA ADERS is https://medora.va.gov/adr .


If you have any questions or concerns regarding the use of Dilantin® (phenytoin sodium) 100mg extended oral capsules, please contact the pharmacy at your facility.

Submitted by Kathryn Tortorice, PharmD, BCPS-VACO Pharmacy Benefits Management-Hines, IL

# FDA Alert and Health Advisory: Codeine Use in Breastfeeding Women

The use of codeine in certain breastfeeding mothers who are ultra-rapid metabolizers of the drug may increase the risk of serious side effects due to morphine overdose in nursing infants. Although reports of serious adverse events in nursing infants are rare, a recently published report described the death of an otherwise healthy nursing 13-day old infant to morphine overdose. It was later determined that the the infant's mother was an ultra-rapid metabolizer. Although there is a genetic test available to identify individuals carrying the specific genotype CYP2D6 that results in more rapid and complete conversion of codeine to morphine, the test is not routinely used at this time.

At the request of the FDA, manufacturers of codeine-containing products are expected to update their labels to include information on differences in metabolism and concerns in breastfeeding.

FDA Medwatch recommends that breastfeeding women using codeine be counseled on the potential for opioid overdose in their infants, since it is generally unknown whether individuals are ultra-rapid metabolizers. Nursing mothers should monitor for signs and symptoms of opioid overdose in their infants (i.e., increased sleepiness, difficulty breastfeeding, breathing difficulties, or limpness). If codeine is prescribed, the lowest effective dose for the shortest duration of time should be used.

FDA Information for Healthcare Professionals: http://www.fda.gov/cder/drug/InfoSheets/HCP/codeineHCP.htm

Submitted by Lisa Longo, PharmD, BCPS-VACO Pharmacy Benefits Management-Hines, IL.

## *Where do I find the posting of drug safety alerts?*

VA Center for Medication Safety features all the drug safety alerts including the National PBM Bulletins that have been sent to the field. Recent alerts include the following:

Sept 10, 2007: Viracept (nelfinavir mesylate) and presence of ethyl methanesulofonate, a process-related impurity
August 9, 2007: Omeprazole (Prilosec®) and Esomeprazole (Nexium®) and Cardiovascular Events
July 5, 2007: Ceftrizxone (Rocephin®) and Incompatibility with Calcium Products

Link to these alerts and more: http://www.pbm.va.gov/VACenterForMedicationSafety-DrugSafetyFeatures.aspx#DRUG%20SAFETY%20ALERTS
Future alerts will be posted on the PBM INTRAnet web site from present time onward.

**Did you know?** The New VA National Formulary (VANF) is now posted on the PBM website. Facilities should review the formulary and make any changes necessary to accommodate the new formulary drugs. Please remember that the VISN Formularies will remain in effect until the hand-book, with the new formulary policy in it is signed.

Adult Immunization Recommendations Quick Guide: http://www.cdc.gov/mmwr/pdf/wk/mm5641-Immunization.pdf

Prescription Update: Guidance for Issuing Prescriptions to Veterans to be filled at Outside Pharmacies:

## National Pharmacy Week October 21-27, 2007

Another year has passed, and as I reflect on the achievements that Pharmacy Service has seen this past year, I am reminded of the all the hard work that I witnessed from each of you. I would like to thank you for your invaluable contributions and dedication to veteran's care each and every day. It is a privilege to work with you and know that you will continue to serve veterans with passion and excellence.

Happy National Pharmacy Week!

Michael A. Valentino, R.Ph. MHSA
Chief Consultant, Pharmacy Benefits Management
Strategic Health Care Group (119)
Department of Veterans Affairs
Washington, DC

### New VA National Formulary Disclaimer

The following disclaimer will be included on the National Formulary lists on the PBM website(s).

The VANF is dosage form specific. If a specific dosage form is not listed, the specific product in question should be considered non-formulary (although other dosage forms of that molecular entity may be included as formulary). Dosage forms such as TAB and CAP, ORAL are considered immediate release. Sustained release products are listed individually. Formulary products may also be available in many dosage forms and strengths. In the case of products with multiple dosage forms and strengths, not all forms and strengths need to be stocked. Facilities should make those dosages available that are necessary to meet their patient needs.

**Don't forget** that 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 click here.

### IMPORTANT CONTRACT IMPLEMENTATION NOTES FOR PRAMIPEXOLE TO ROPINIROLE

1. There is no National Contract mandate to switch patients from existing pramipexole therapy (Mirapex®) to ropinirole (Requip®). Patients who were receiving pramipexole before September 18, 2007 will be permitted to continue to use those agents without having to complete a non-formulary drug request.

2. Patients who are naïve to therapy with any agent in the non-ergotamine dopamine agonist class for Parkinson's Disease (i.e., have not received a prescription for pramipexole within 6 months prior to September 18, 2007 and have a clinical need for a dopamine agonist, must be given an adequate therapeutic trial (30-60 days trial to allow sufficient time to assess the effect on movement disorder and/or restless leg syndrome) on ropinirole (Requip®), unless based on medical necessity, the prescriber receives approval to use pramipexole (Mirapex®). Medical necessity guidance is described in VHA Directive 2001-044 (http://vaww.pbm.va.gov/directive/vhadirective.pdf).

3. In order to maximize the opportunities for patients to achieve the desired therapeutic outcomes of dopamine agonist therapy, and as is recommended for all newly prescribed medications, VA physicians and pharmacists are urged to assure that comprehensive patient education is provided to each patient receiving a new prescription for a dopamine agonist. Such education should include at a minimum 1) appropriate medication administration techniques, 2) a description of common side effects that could be experienced, 3) the relative seriousness of the common side effects, and 4) under which circumstances side effects should be reported to the prescriber.

4. For patients who receive an adequate trial of the contracted agent after the effective date of this contract (September 18, 2007) but who cannot achieve the desired therapeutic outcomes, the non-formulary drug request process must be used to gain access to one of the non-contracted agents.

Submitted by Vincent Calabrese, PharmD, VACO Pharmacy Benefits Management-Hines, IL

**VA Negative Formulary Abolishment**:

The VA Negative Formulary has been abolished. There is now one list termed the VA Do Not Substitute List.

**Definition of the VA Do Not Substitute List:**

The Do Not Substitute List is a list of pharmaceutical products for which substitution is not permitted. Products are added to this list by vote of the VISN Formulary Leaders and the Medical Advisory Panel. Decisions are based on reviews of therapeutic equivalency and/or patient safety data as well as product cost. Products on this list should not be substituted with any other generic except in accordance to guidelines given by the before mentioned committees. Substitution is allowed in rare circumstances when the Do Not Substitute item is on back order or the patient has a documented allergy to the formulary product.

## PBM-MAP Broadcast Programs

### *"When HIV Treatment Fails-Optimizing Therapy"*

This program received acknowledgment from the VHA Public Health Strategic Healthcare Group. The video of the program is available to be viewed on-demand from desktop via CDN (Content Distribution Network). The links to view program on CDN are the following:

Part 1- http://vaww.vakncdn.lrn.va.gov/cl_popup.asp?mode=popup&Media_ID=1859&M_Cat_ID=24

Part 2- http://vaww.vakncdn.lrn.va.gov/cl_popup.asp?mode=popup&Media_ID=1860&M_Cat_ID=24

***NEW:*** ACPE accreditation for viewing the program via CDN is pending. Please check the PBM web site in the near future for the posting of additional details.

Please note: If CDN is not functional at your institution; please contact EESCDNSUPPORT@lrn.va.gov .

and

### *"Management of Chronic Hepatitis B"*

This program received acknowledgment from the VA Hepatitis C Resource Centers (HCRC). This program offers accreditation for ACCME, ANCC, CA BRN, ACPE, and targets VHA physicians, nurses, clinical pharmacy staff, and all staff involved in diagnosing and treating patients with Hepatitis B.

| Remaining Rebroadcasts | | Time (ET) | Channel |
|---|---|---|---|
| Tuesday | October 30, 2007 | 11:00 AM | 1 |
| Monday | November 5, 2007 | 3:00 PM | 1 |
| Thursday | November 8, 2007 | 8:00 PM | 1 |
| Thursday | November 15, 2007 | 8:00 AM | 1 |
| Tuesday | November 20, 2007 | 3:00 PM | 1 |
| Wednesday | November 28, 2007 PLUS VANTS CALL | 3:00 PM | 1 |

***NEW:*** The rebroadcast program on November 29, 2007 will be followed by a VANTs conference call to provide another opportunity for pharmacists to receive CE credits. Dial-in number is: 1-800-767-1750 Access Code: 90166#. Pharmacists may view the program on any of the remaining rebroadcast dates but must call in during the VANTs call to qualify for CE.

This program will be made available as an on-demand video on desktop via CDN.

Part 1: http://vaww.vakncdn.lrn.va.gov/cl_popup.asp?mode=popup&Media_ID=1896&M_Cat_ID=24

Part 2: http://vaww.vakncdn.lrn.va.gov/cl_popup.asp?mode=popup&Media_ID=1897&M_Cat_ID=24

***NEW:*** ACPE accreditation for viewing the program via CDN is pending. Please check the PBM web site in the near future for the posting of additional details.

Please note: If CDN is not functional at your institution; please contact EESCDNSUPPORT@lrn.va.gov .

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To access previous issues of the newsletter, click here

Past Issues are also available on InTERnet http://www.pbm.va.gov/PBM-MAPEzMinutes.aspx

CBOC Pharmacists: Network with your colleagues: Click Here: (InTRAnet only)

**PBM Guidance for VHA Facilities Pharmacy Automated Telephone Refill Service**

This document lists the minimum requirements for a VHA Pharmacy Automated Telephone Refill Service.

**PBM Advisory on Non VA Meds**

Click this link to read tips for improving your facility's data and compliance with performance monitors that use PBM's Non-VA Medications Data:

http://www.pbm.va.gov/ezminutes/AdvisoryOnNonVAMeds.pdf

**LOCAL MUE "CLEARING HOUSE"**

If you have suggestions for future MUE to be conducted at a national level or would like to share results of local MUE, please send them to Burk.Muriel@va.gov.

**NAME CHANGE: Omacor® to Lovaza®**

Due to Look Alike/Sound Alike issues with Amicar®, the name of Omacor® was changed. Instead of searching for Omacor® monograph or criteria for use on the PBM websites, search for its new name instead……. Lovaza®.

**VA National Formulary Contraceptive Agents**

(VA IntRAnet only)

**NEW! Check out the PBM InTRAnet SharePoint Website**

**The search function is now operational!** Please keep the following in mind when searching:

- Searches titles and text of most file types (Word documents, Excel Workbooks, etc.)
- Searches only titles of PDF files
- Going forward we will be moving away from PDF files to improve the search capability
- You need to be on the Home page to search the entire Website
- In most cases you should search using generic drug names, not brand names

If you are prompted with a dialog box requesting login credentials: Enter your VA email address in the "User Name" field (FirstName.LastName@va.gov) and your VA network password in the "Password" field.