



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

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## REMEMBER TO SUPPORT

## OUR TROOPS

### SAFETY INITIATIVE TO REDUCE USE OF SHORT- ACTING NIFEDIPINE FOR HYPERTENSION

*Editor's Note:* The following is one example of a drug-utilization safety initiative performed by the PBM. The utilization of short-acting nifedipine will be evaluated again in one year. We thought you may enjoy reading what impact this study had in our veteran population. As always, thanks for your contribution to the success of this project!

#### Objective

Due to concerns of using short-acting nifedipine for hypertension (e.g., reports of increased myocardial infarction; potential for precipitating an acute ischemic event when used for rapid reduction of blood pressure during hypertensive urgencies and emergencies), the VA Pharmacy Benefits Management, Medical Advisory Panel, and VISN Formulary Leaders conducted a safety initiative to decrease the use of short-acting nifedipine for hypertension in VA.

#### Results

Four data evaluations were conducted using the PBM national pharmaceutical database to identify and track prescription data for short-acting nifedipine from 1999 to mid 2004. Each query was followed by an intervention that resulted in a decrease in utilization of short-acting nifedipine for hypertension (Table 1).

Table 1. Summary of Results of Data Evaluations and Interventions

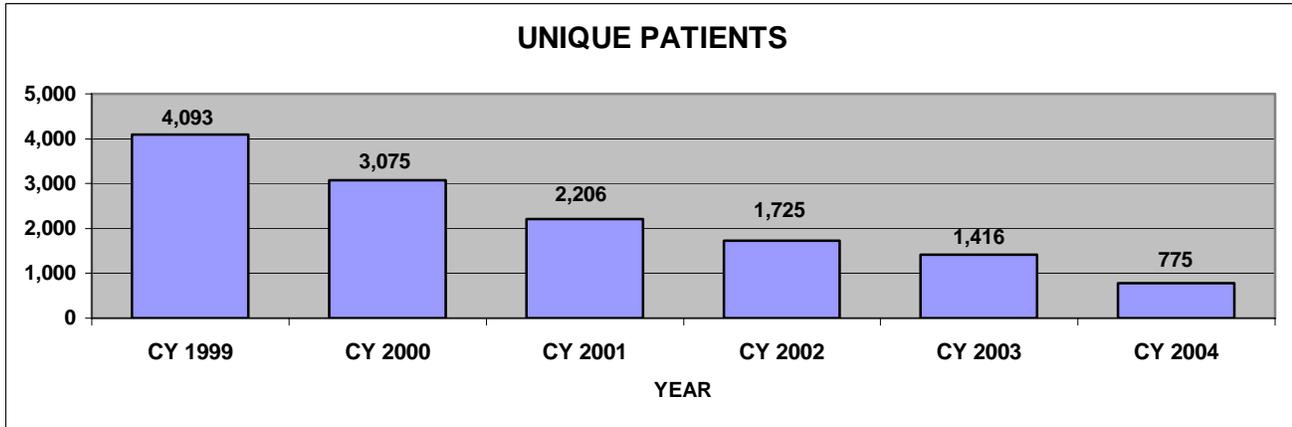
Evaluation	Date	Intervention
1	1/1/1999-12/31/2000	34% decrease in total quantity (from 2,069,694 to 1,369,691 units) (See Figure 1)
2	4/1/2002-3/31/2003	Overall: Intervention in 78% of 1648 prescriptions HTN (737 of 1648 Rxs): Intervention in 90% of 737 prescriptions
3	9/1/2003-12/31/2003	Overall: Intervention in 78% of 559 patients HTN (260 of 559 patients): Intervention in 96% of 260 patients
4	5/20004	Overall: Intervention in 99% of 75 patients HTN: only one patient in VA remains on short-acting nifedipine for HTN that was deemed appropriate after careful review

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## Overall Impact of Safety Initiative

From 1999 to 2004, the number of patients prescribed nifedipine fell 81%, from 4093 to 775 patients (Figure 1). By using the percent of prescriptions and patients on short-acting nifedipine for hypertension from the second and third evaluations, we estimate that at the start of the intervention, approximately 1,840 patients were on short-acting nifedipine for the treatment of hypertension. At the end of our intervention, only one patient in the VA remains on short-acting nifedipine for hypertension, and this use has been deemed appropriate after careful review. The number of patients on short-acting nifedipine will be monitored annually. The VISN Formulary Leaders are encouraged to continue educational efforts to avoid the use of short-acting nifedipine in the management of patients with hypertension.

Figure 1. Unique Patients Prescribed Short-Acting Nifedipine for Calendar Year (CY) 1999-2004



Publication of the complete results and discussion of this safety initiative can be found in: Furmaga EM, Glassman PA, Cunningham FE, Good CB. Reducing the use of short-acting nifedipine by hypertensives using a pharmaceutical database. In: Henriksen K, Battles JB, Marks ES, Lewin DI, editors. Advances in patient safety: from research to implementation. Vol. 3, Implementation issues. AHRQ Publication No. 05-0021-3. Rockville, MD: Agency for Healthcare Research and Quality; Feb. 2005:277-89.

### Recent National PBM Reviews Postings on Web Site

#### Criteria for Use

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

Duloxetine (Cymbalta®)

#### Drug Monographs

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

Pemetrexed (Alimta®)

Azacitidine (Vidaza®)

Erlotinib (Tarceva™)

Pegaptanib-(Macugen®)

Pramlintide (Symlin®)

### New Molecular Entities Review

Azacitidine (Vidaza®)-Added to VA national formulary with criteria for FDA indication only

Pegaptanib (Macugen®)-Not added to VA national formulary or VISN formularies

Erlotinib (Tarceva™)-Not added to VA national formulary or VISN formularies

Hyaluronidase for Injection (Vitrase®)-Added to VANF without restrictions

Pramlintide (Symlin®)-Not added to VA national formulary or VISN formularies

**Contract Review:** As noted in the last edition of E<sub>2</sub>-Minutes, <http://www.pbm.va.gov/ezminutes/Ez-MinutesVol31ss4Jan-Mar05.pdf>, the national award for the angiotensin II receptor antagonist was for losartan for patients with type 2 diabetic nephropathy. The award for the angiotensin II receptor for patients with systolic heart failure was pending. Since that time, the angiotensin II receptor antagonist for systolic heart failure is valsartan. As a reminder, Criteria for Use for the angiotensin II receptor antagonists are posted and are available at the following website. <http://www.pbm.va.gov/criteria/AIIRA.pdf> or <http://vawww.pbm.va.gov/criteria/AIIRA.pdf>.

### Galantamine and Risk of Stroke and/or MI in Veteran Patients

In January 2005, results of two randomized, placebo-controlled trials of 2 years duration in subjects with mild cognitive impairment (MCI) were released. A total of 13 subjects on galantamine (n=1026) and 1 subject on placebo (n=1022) died. The deaths were due to various causes which could be expected in an elderly population. About half of the galantamine deaths appeared to result from various vascular causes (myocardial infarction, stroke), and sudden death.

The PBM conducted a database review of patients on galantamine and the incidence of MI in the population. The results of the interim database analysis regarding the incidence of MI in veteran patients receiving galantamine were shared with the Medical Advisory Panel and the VISN Formulary Leaders. The review demonstrated that there was not an increase in MI risk for patients receiving galantamine. The review showed an incidence rate of 2/1000 patient years with age > 55 having a higher incidence.

## Questions from the Field

**What steps are involved for a national review of a New Molecular Entity (NME)? Can anyone from the field volunteer to develop a NME monograph?**

**What is a NME?** “A NME is a medication containing an active substance that has never before been approved for marketing in any form in the United States.” A NME will include drug and biologic products but not supplies or devices.

**Who monitors when a NME becomes available?** Monitoring of NME is done by the Pharmacy Benefits Management (PBM). The PBM will track new approvals from the FDA and will maintain a list of NMEs and their review status. The list is available at <http://vaww.pbm.va.gov> and will list the generic, trade names, the date of approval, FDA classification, name of the manufacture and indication. The status of the NME is color coded. (see below)

<b>YELLOW</b>	<b>= NEED VISN ASSISTANCE FOR REVIEW</b>
<b>GREEN</b>	<b>= REVIEW IN PROCESS. NO VISN ASSISTANCE NEEDED</b>
<b>BLUE</b>	<b>= REVIEW COMPLETED</b>
<b>RED</b>	<b>= IDENTIFIES CALENDARS AND NEW DIRECTIVE DATES</b>
<b>PINK</b>	<b>= IDENTIFIES REVISIT/FOLLOW-UP</b>

Of note, nonmarketed orphan drugs will NOT appear on the NME list and thus, not require a review. Once the orphan drug is marketed, it will be added to the NME list. At that time, an abbreviated review will be done by the PBM to determine the clinical usefulness of the drug within the VA and whether or not a more in-depth review will be required.

**Who is assigned a NME?**

- PBM clinicians
- Volunteers from the field or VISN may select an NME that is under the designation of “Volunteer Needed.”

**What is the time frame to complete a NME?**

Typically, completion date is 90 days from the assigned date.

**Who is responsible for updating the monograph?**

If possible, the original or designated author will be asked to prepare an addendum to the monograph if new data on safety or that will change formulary status becomes available.

**Is there peer-review of the monograph prior to posting?**

Yes, review of the document is performed by multiple disciplines including:

- the PBM clinician assigned to review that the information included and the format utilized for the monograph is appropriate
- Medical Advisory Panel (MAP) primary contact and/or subject matter experts
- MAP Committee
- VISN Formulary Leaders (VFLs) Committee
- VFLs (VISN Formulary Leader) will forward the document to subject matter experts within their respective VISN for comments. Suggestions/comments/changes from the above individual(s) and or groups should be reviewed and incorporated into the document if appropriate. The developer of the NME will present the monograph to the MAP and VFLs committees.

**What areas are included in a NME monograph?**

View the monograph template available at: <http://vaww.pbm.va.gov/pbm/drugmontemp.htm> for the required sections.

**Below, are some important contact names to assist the volunteer in preparing a NME monograph:**

- Send a request with the name of the clinician responsible for writing the monograph and the anticipated date of completion to: Bob Bulinski and Lisa Torphy at the PBM ([Bob.Bulinski@med.va.gov](mailto:Bob.Bulinski@med.va.gov); [Lisa.Torphy@med.va.gov](mailto:Lisa.Torphy@med.va.gov)). The requestor should await confirmation before proceeding to draft the monograph.
- Send trade and generic name, strength(s), dosage form, and route of administration for the look alike-sound alike analysis to Muriel Burk at PBM ([Muriel.Burk@med.va.gov](mailto:Muriel.Burk@med.va.gov)). (please include your contact information. Allow 3 to 4 weeks turnaround time).
- Send final NME monograph to Lisa Torphy at the PBM ([Lisa.Torphy@med.va.gov](mailto:Lisa.Torphy@med.va.gov)) to be placed on the agenda for

## A RECENT PUBLISHED PBM ARTICLE-Congrats!

The Department of Veterans Affairs (VA) National Pharmacy Benefits Management Strategic Healthcare Group (PBM SHG), established in 1995, manages pharmaceuticals and pharmaceutical-related policies for the VA via national formulary development, contracting efforts, and patient safety initiatives. The PBM promotes, optimizes, and assists VA practitioners with the safe and appropriate use of pharmaceuticals through routine formulary management, where scientific research and new data are translated into evidence-based practice using a number of methods including pharmacologic management algorithms, drug use criteria, and evidence-based drug monographs. Additionally, contracting endeavors by the PBM have allowed the VA to save approximately 1.5 billion dollars since 1996 in light of increasing drug expenditures, and has facilitated standardization and ease of access of pharmacy benefits nationwide across the VA. Moreover, the PBM Outcomes Research section coordinates data management efforts and undertakes patient safety initiatives through drug safety and efficacy evaluations. These evaluations have led to important interventions across a realm of activities ranging from changing formulary policy to developing new alerts in order to notify providers of medication safety concerns. But, don't take our word, read the article yourself!

**Sales MM, Cunningham FE, Glassman PA, Valentino MA, Good CB. Pharmacy Benefits Management in the Veterans Health Administration: 1995 to 2003. Am J Manag Care. 2005 Feb; 11(2):104-12.**

## Adverse Drug Event (ADE) per MedWatch Form 3500: Characteristics of Good Reporting

Did you know that the date of birth of the patient is reported only 59.5% of the time on the MedWatch Form 3500? On the same form, weight (including the unit) of the patient involved in the ADE is included less than 65% of the time.

*Editor's Note: Observing trends associated with drug-induced ADE is dependent on the quality of reporting i.e. good input = good output. In this case, completing the MedWatch Form with the recommended data is needed to better observe the existence of any trends with any suspected drug-induced ADE. The following is a brief overview of what type of information, at a minimum, is needed to complete MedWatch Form 3500. We hope that the readers of this newsletter will find the reminder helpful and useful.*

As you well know, the VHA ADE reporting database consists of serious observed reactions. The outcomes attributed to these observed reactions are categorized similarly to MedWatch Form 3500; Section B.2. (See <http://www.fda.gov/medwatch/SAFETY/3500.pdf>). Currently, the VA ADE database contains ~19,000 reports that have been collected on an on-going basis since 1998.

Approximately 1,000 ADEs reports are received quarterly. However, once the modernization of the ADE reporting system is completed, the volume is expected to markedly increase. (details regarding the modernization process will be a topic for a future Ez-Minutes edition)

At a minimum, when reporting ADEs on a MedWatch form, the following information must be included:

- 1) an identifiable patient
- 2) an identifiable reporter
- 3) a suspect medication
- 4) an adverse event.

**\*\*\*\*For VA's purposes, it is also important that each report contains the VA Medical Center identification and location.\*\*\*\***

### Description of Various Sections and Required Data for MedWatch Form 3500

Section	Description	Data Required and Comments
A	Patient demographic	age, date of birth, gender and weight
B1	Adverse Event and/or Product Problem	Check either or both boxes
B2	Outcome	Check off required Please note: If the option "Other" is checked, indicate the specific outcome on the line next to the "Other" box.
B5	Recording of Adverse Event	Be as specific as possible. A good report should contain detailed information on the observed signs, symptoms, supporting labs and if known, the diagnosis including time to onset of signs or symptoms.  Example: "GI bleed" or did a gastric ulcer bleed or gastric varices bleed actually occur? <i>Remember to include relevant therapeutic measures and laboratory data at baseline, during therapy, and subsequent to therapy, including blood levels, as appropriate.</i> Including a copy of the entire patient chart may not be necessary or helpful. Sometimes, too much information which is not related to the adverse event may be misleading. For example, a report of 'pain' may contain a long list of laboratory tests, some with abnormal results which may include high creatinine and BUN. On careful review of the patient's history, one can conclude that the high creatinine and BUN were not at all related with the onset of pain but were the expected lab results for the patient's "chronic renal failure." In this example, a description of the location of the pain, its frequency, severity, etc. in Section B5, would have been more useful than to have included the expected, chronically abnormal lab values.  <i>Any other relevant information (e.g., other details relating to the event or information on benefits received by the patient), if important to the assessment of the event can be recorded on another page, as needed.</i>
C	Recording of the Primary, Secondary Suspect and Concomitant Drugs	Dose strength, lot number, route, indication for use, dechallenge/ rechallenge information. Please note: It is essential that the actual product name (i.e. generic drug name) be provided.

For further information contact: Puri Subramaniam, Pharm.D. Chief, ADE Programs, at [puri.subra@va.gov](mailto:puri.subra@va.gov)

(Note: Additional Information on Characteristics of a Good Case Report can be found within the Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment Guidance at <http://www.fda.gov/cber/gdlms/pharmacovig.htm>).

# **PBM-MAP DISTANCE LEARNING BROADCAST PROGRAMS**

## **Challenges and Treatment Options for Metabolic Changes Seen in Patients with Mental Illness**

The faculty for this program included: Jannet M. Carmichael, PharmD, FCCP, BCPS, Lisa C. Holloman, PharmD, BCPP, and Donna Wirshing, MD. Many thanks to them for their time and sharing their expertise with the field regarding the issue of metabolic changes associated with antipsychotic medications. If you missed the initial airing of the program and all the rebroadcast programs, check your library for a VHS copy of the program. On-line CE is still available for this program until September 30<sup>th</sup>, 2005. Exception: Dietitians can obtain CE until May 31<sup>st</sup>, 2007. Please also note that for pharmacists, CE can only be obtained by viewing the broadcast (or rebroadcast programs) and by completing the post test. Post-test is available on-line (see the article below). All disciplines are required to complete a program evaluation for CE.

### **Clinical Update on the Management of Benign Prostatic Hyperplasia-NEW DATES!**

This program is scheduled to air on September 14<sup>th</sup> at 1 p.m. Eastern Time. A live Q/A period will follow the conclusion of the program. The rebroadcast dates and times are: September 20<sup>th</sup>, 2005, 8 p.m. (ET), September 29<sup>th</sup>, 2005, 2 a.m. (ET), October 7<sup>th</sup>, 2005, 11 a.m. (ET). There will be rebroadcast dates on November 4<sup>th</sup>, 11am (ET), November 8<sup>th</sup>, 8pm, 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. Don't miss it!

More details when available will be posted on the web site. Be sure to click on <http://www.pbm.va.gov/PBM/dislearning.htm>

Since on-line registration for CE is new for the PBM-MAP programs, below are "helpful" steps to follow to register for Continuing Education On-Line

Via InTRANet: Go to: <http://vaww.ees.aac.va.gov>

1. Create an account if you are a first time user. Enter your demographic information. If the information that appears is correct, click on yes.
2. Create a username/password (password must contain 3 of the 4 items: lower case letters, upper case letters, number or "special characters") and click submit. You will be congratulated that you have created an account. Close window.
3. Enter your username/password again onto the main page.
4. In the "Available Courses" option, click on the all content area down arrow and then choose "Diagnostic and Clinical Topics."
5. Click on the search button and then click on "Mental Illness and Metabolic Change, Challenges and Treatment."
6. Click on Sign me up. An option called "My Courses" will appear. Click on Mental Illness and Metabolic Change, Challenges and Treatment box again.
7. Click on Program Evaluation- and Enter Submit. Complete the evaluation of the program. Pharmacists must complete the post test.
8. Select the certificate appropriate for your profession and print off your statement of CE credit...You're done!

Via InTERNet: Go to: <https://www.ees-learning.net>

Similar steps apply as stated above when submitting for CE via InTERNet.

Hyperlinks to these EES sites for CE are available on the PBM web site. <http://www.pbm.va.gov/PBM/dislearning.htm>

### **OTHER SATELLITE BROADCAST PROGRAMS OF INTEREST FEATURING PBM-MAP MEMBERS:**

**MANAGEMENT of ACUTE CORONARY SYNDROME in the HIGH RISK PATIENTS:** Rebroadcast Dates and Times: July 27, 2005, 10 am (ET) Channel 1; July 29, 2005, 12pm (ET) Channel 1.

### **TREATMENT OF BEHAVIOR DISORDERS IN DEMENTIA: FDA ADVISORY on ATYPICAL ANTIPSYCHOTICS"**

Live Broadcast: August 9, 2005, 1:00-2:30 pm Eastern Time (ET) Channel 1.

Program Re-broadcast August 11, 2005, 5:00 pm (ET) Channel 1; August 17, 2005, 10:00 am (ET) Channel 1

August 25, 2005, 3:00 pm (ET) Channel 1, Sept. 9, 2005, 2:30 pm (ET) Channel 1, Sept. 14, 2005 8:00 pm (ET) Channel 1, Sept. 27, 2005 10:00 am (ET) Channel 1