



Pharmacy Benefits Management- Medical Advisory Panel E_z-Minutes

Volume 4, Issue 1
Jan-March 2006

Inside this Issue:

Page 1

Recent Posting of
National PBM Reviews
on Web

Criteria for Use
Drug Monographs
New Molecular Entity
Reviews
Therapeutic Interchange
Guidance
Termination of
Gatifloxacin National
Contract

Page 2

Sublingual
Buprenorphine/
Naloxone and
Buprenorphine on VA
National Formulary
With Criteria for Use
Look Alike/Sound Alike:
Omacor® and
Amicar®
National Contract News
Macugen® Labeling
Change

Page 3

Good ADE Reporting
ADE PP Presentation
CE Programs Available
Subscribe to PBM-MAP
E_z-Minutes Newsletter

PBM websites are currently being redesigned. Web addresses will remain the same. Be sure to bookmark the websites:

vaww.pbm.va.gov or 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>

- Acamprosate (Campral®)
- Buprenorphine/Naloxone and Buprenorphine Sublingual Tablets— See page 2
- Clopidogrel (Plavix®)
- Eszopiclone (Lunesta®)
- Fluoroquinolone
- Granulocyte Colony Stimulating Factor (GCSF) Criteria for Use for Hepatitis C Treatment-Related Neutropenia
- Recombinant Erythropoietin Criteria for Use for Hepatitis C Treatment-Related Anemia
- Guidance on the Use of Topical Anesthesia for Surfaces of the Nasopharynx, Oropharynx, Laryngotracheal Region and Airway
- Omega-3 acid ethyl esters (Omacor®)

Drug Monographs

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

- Acamprosate Addendum (Campral®)
- Buprenorphine, and Buprenorphine/Naloxone Sublingual Tablets Pharmacist Information included
- Omega-3-acid ethyl esters (Omacor®)
- Paricalcitol (Zemlar®)
- Ramelteon (Rozerem™)

New Molecular Entity Reviews

- Ertapenem (Invanz®)-Added to the VA National Formulary. VISNs/ facilities may apply local restrictions
- Levalbuterol-HFA (Xopenex®-HFA)- Added to the VA National Formulary
- Micafungin (Mycamine®)-not added to the VA National Formulary but VISNs should ensure that at least one echinocandin is available via the nonformulary process

Therapeutic Interchange Guidance

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

- Depakote EC versus Depakote ER
Depakote Provider Letter

Termination of the Gatifloxacin National Contract and Formulary Status of Moxifloxacin

Due to the increased risk of dysglycemias, new warnings added to the package insert for gatifloxacin, and a mutual termination of the workhorse contract effective 3/1/06, gatifloxacin was removed from the VA National Formulary (VANF). Please note moxifloxacin IV and PO has been added to the VANF.

SUBLINGUAL BUPRENORPHINE/NALOXONE AND BUPRENORPHINE PLACED ON VA NATIONAL FORMULARY WITH CRITERIA FOR USE

Sublingual buprenorphine / naloxone and buprenorphine, previously nonformulary with criteria for use, are now listed on the VA national formulary with criteria for use. Only qualified physicians who have waivers to use Schedule III to V opioids for opioid dependence under the Drug Addiction Treatment Act 2000 may prescribe sublingual buprenorphine formulations. VA Employee Education System training workshops to qualify for the required waiver are scheduled and further information is provided at :

<http://vaww.pbm.va.gov/ezminutes/BupSaveTheDate.doc>

The monograph and criteria for use of buprenorphine/naloxone and buprenorphine sublingual tablets have been updated and are available at:

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

and

<http://vaww.pbm.va.gov/drugmonograph/BuprenorphineDrugMonograph.pdf>

(Note: If you go to these links and the criteria are still labeled for "nonformulary" use, refresh your browser by holding down the Shift and Control keys and clicking on Refresh.)

National Contract News

Question: What happens when a National Contract expires?

Case in point: The generic version of simvastatin should become available on June 22, 2006; however, the National Contract option year will expire April 30th. The options available to the VA are...

- A. sign the next option year through May 2007 OR
- B. terminate the contract

If VA terminates the National Contract (option B), VA will pay substantial higher prices for Zocor until the generic product becomes available in sufficient quantities to meet VA needs (i.e. ~ \$63M loss for VA). If VA chose option A, VA would pay contract prices after the generic product becomes available at presumably at lower prices. Neither option is good for VA.

What is being done? The PBM has suggested to Merck that a 6 month extension of the National Contract with an immediate 24% reduction in price would be the best option for both VA and Merck. VA would enjoy the voluntary price reduction amounting to ~\$22M and Merck would profit from continued sales. The \$22M would offset some of the difference between the costs of Zocor and the price for the generic product, when the generic prices fall below the contract price.

LOOK ALIKE/SOUND ALIKE NAME CONFUSION: Omacor® and Amicar®

The Institute for Safe Medication Practices (ISMP) in November of 2005 reported confusion occurring between the drugs Omacor® (omega-3 ethyl esters) and Amicar® (aminocaproic acid).¹ Omacor® is used in the treatment of hypertriglyceridemia whereas Amicar® is useful in enhancing hemostasis.

Confusion between these agents occurred with a telephone order in which a pharmacist misunderstood an order for Omacor® as Amicar®. The FDA has stated that they have received several other reports of mix-ups between these two agents and are working with both manufacturers to identify ways to reduce confusion.² In the meantime, ISMP has recommended matching the patient's medication to their diagnosis; placing an alert in the computer order entry systems and; using TALL man letters to distinguish between products when they are both available in the inventory.

The PBM/MAP are aware of this potential name confusion and have included information in the Omacor® monograph under the look alike/sound alike (LA/SA) section. In the monograph, it is stated that the severity of receiving one dose of Amicar® instead of Omacor® is moderate and recommend matching the medication to the patient's diagnosis in order to limit this potential error from occurring. VA pharmacies seldom accept telephone orders for new prescriptions and generally use generic names instead of trade names in their written prescriptions and in their computerized prescription entry systems.

Recommendations for VA Health Professionals:

1. Utilize the electronic order menu and avoid phone or verbal orders, unless absolutely necessary
2. When it is necessary to use a verbal or telephone order, use the generic name of a drug and then (if there is any question) spell it out; and
3. If on the receiving end of the verbal or a telephone request, ask the provider to repeat the order, ask for the generic name (if not used or not sure), and, if there is any question, ask him/her to spell the name of the drug; and
4. Ensure that the verbal order makes sense in the context of the patient's condition

References: (accessed 3-15-06)

1. http://www.ismp.org/Newsletters/acutecare/articles/20051103_2.asp
2. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=49>

Click here for more safe practice recommendations for verbal orders from the ISMP

<http://www.ismp.org/Newsletters/acutecare/articles/20010124.asp>

FDA MedWatch - Macugen® (Labeling Change)

Pegaptanib (Macugen®) is indicated for the treatment of wet form age-related macular degeneration. It is administered once every 6 weeks by intravitreal injection. Rare reports of anaphylaxis/anaphylactoid reactions, including angioedema following the administration of it along with various medications administered as part of the injection preparation changes in the product labeling have been noted. Healthcare professionals should evaluate the patient's medical history for hypersensitivity reactions to Macugen® prior to using this product.

Read the complete MedWatch 2006 Safety Summary, including links to the Dear Healthcare Professional Letter and the updated Approved Product at:

<http://internet-dev.fda.gov/medwatch/safety/2006/safety06.htm#Macugen>

The PBM Adverse Drug Event (ADE) Reporting Database: Observations to Promote Good Reporting Practices

The Adverse Drug Event (ADE) Program database is a repository for all adverse drug event data originated at VHA centers. As in any other data collection system, the quantity and quality of the information provided by reporters determine the value of the data and the extent of its use. Useful ADE case reports contain a comprehensive list of patient characteristics, drug exposure information, and a detailed description of the adverse event. Below is a reminder of a few elements observed in ADE reporting where improvements are needed in the quantity and quality of data entered to support data mining, report validation and analysis, and in the long run.....improve patient care!

1. **Patient Characteristics:** Only 8% of the cases report medical history (family history, risk factors, and co-morbidities)
2. **Drug Information:** Suspect/concomitant product therapy details are missing, cryptic, or entered into the wrong data field.
3. **Adverse Event Information:** The description of the adverse events often includes only a word or a single phrase (i.e., bradycardia, death). Supporting laboratories are frequently missing, even in cases of drug toxicity and drug interaction.

(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/gdlns/pharmacovig.htm>) and previous issues of the Ez-Minutes. See <http://www.pbm.va.gov/ezminutes/Ez-MinutesVol3Iss2Apr-Jun05.pdf> and <http://vaww.pbm.va.gov/ezminutes/Ez-MinutesVol3Iss3July-September05.pdf>

(For further information contact: V. Subramaniam, Pharm.D., M.S., Assoc. Chief Consultant, PBM SHG)
vaiyapuri.subramaniam@va.gov

Next PBM-MAP Distance Learning Broadcast Program

The PBM-MAP in partnership with VHA EES and with the acknowledgment of the VHA Center for Excellence in Substance Abuse Treatment and Education (CESATE), and the Department of Veterans Affairs Office of Mental Health Services Presents: **"Impact of Substance Abuse on the Course of Bipolar Disorder"**

Part I: Recognizing Substance Abuse in Bipolar Disorder

*May 23, 2006, 1-2 PM Eastern Time (ET) Channel 1
 May 24, 2006, 3-4 PM Eastern Time (ET) Channel 1

Part 2: Integrated Treatment for Veterans with Bipolar Disorder and Substance Abuse

*May 30th, 1-2PM Eastern Time (ET) Channel 1
 May 31st, 3-4PM Eastern Time (ET), Channel 1

*VANTS conference call with the faculty at the conclusion of the program (2:00 PM ET) on these dates only.

ACPE, ANCC, ACCME, APA, ASWB continuing education credits will be available. Check the PBM websites for further details for rebroadcast dates and times. 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 <http://vaww.vakncdn.lrn.va.gov/> for viewing information. in the near future for more details!

REMINDER....

FOR PHYSICIANS:

A short PowerPoint presentation on **"How to Enter ADEs into CPRS"** is available.

Click on:

<http://www.pbm.va.gov/vamedsafe/HTEAAOD.pdf>

Want to Subscribe to Ez-Minutes?

Send an email to subscribe@verdict.uthscsa.edu with "subscribe to Ez-Minutes" in the subject field. If you have problems with these instructions, send an email to cara.goff@med.va.gov with "subscribe to Ez-Minutes" in the subject line.

To access previous issues of the newsletter, click here: <http://vaww.pbm.va.gov/pbm/ezminutes.htm>

Any questions, comments or would you like to submit an article to Ez-Minutes? Please e-mail: Janet H. Dailey, Pharm.D. at janet.dailey@med.va.gov OR Co-Editor: Pete Glassman, at peter.glassman@med.va.gov.