Pharmacy Benefits Management-Medical Advisory Panel

E_z-Minutes

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Happy New Year! 2006

Please be sure to bookmark the PBM websites at: http://vaww.pbm.va.gov/ or www.pbm.va.gov

Editor's Note: New beginnings can happen anytime but with the start of a new year—it just seems appropriate to implement new changes, resolutions or even a new updated format for a newsletter. So it is with this edition of the PBM-MAP E_z-Minutes. An updated, snazzy look with a new and fresh format is being unveiled for 2006. However, some things will remain the same. This quarterly online newsletter is published specifically to help connect the PBM to VHA field-based providers. So, whether it is VHA National Drug Formulary updates/changes or new National Criteria for Use, Treatment Guidelines, patient medication safety issues or perhaps highlights implemented at the VISN level (see page 2)...all that won't change. The newsletter will still be quick and Ez to read! We hope you will enjoy the new look for the newsletter for the new year. Here's to a great year of serving our country's veterans!

Recent Postings of National PBM Reviews on Web Site

Criteria for Use/ Nonformulary Use

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

Azacitidine (Vidaza™)
Erlotinib (Tarceva™)
Ezetimibe (Zetia®)
High-dose Oral PPI
Leflunomide and Biologic DMARDs in the TX of Moderate & Severe RA
Levetiracetam (Keppra®)
Non-calcium, Non-Aluminum Phosphate Binders (Lanthanum Carbonate and Sevelamer HCl)
Preliminary Guidance of Pregabalin Lyrica™)
Pramlintide (Symlin®)

Drug Monographs

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

Mometasone (Asmanex® Twisthaler®)
Lanthanum Carbonate (Fosrenol®)

New Molecular Entity Reviews

Mometasone (Asmanex® Twisthaler®) -Added to the VA National Formulary and VISN Formularies
Lanthanum Carbonate-Not added to VA National Formulary and VIS Formularies restricted to Nephrology and to patients with ESRD on dialysis

Vardenafil to Replace Sildenafil on the VA National Formulary

In December 2005, a mandatory national contract was awarded to vardenafil (Levitra) effective January 15, 2006 until January 14, 2007. Vardenafil is one of three currently marketed phosphodiesterase type 5 (PDE5) inhibitors approved for the treatment of erectile dysfunction. As this is a mandatory national contract, it is anticipated that veterans currently prescribed sildenafil will be converted to vardenafil. Veterans prescribed sildenafil for pulmonary hypertension are not to be switched, but are to continue to receive sildenafil.

The PDE5 inhibitor's drug class review is posted at:
http://www.pbm.va.gov/reviews/PDE5InhibitorDrugClassReviewFinal12_27_05_2.pdf or
http://vaww.pbm.va.gov/reviews/PDE5InhibitorDrugClassReviewFinal12_27_05_2.pdf

ATTENTION: Mandatory National Contract: Effective January 15, 2006

Veterans prescribed sildenafil for pulmonary hypertension are not to be switched, and should continue to receive sildenafil.

Below are links to the letters to prescribers and patients posted on the PBM websites (under therapeutic guidance) explaining the conversion. Be sure to read!
http://vaww.pbm.va.gov/tig/VardenafilProviderMemo.pdf
http://vaww.pbm.va.gov/tig/VardenafilPatientLetter.pdf

Carvedilol Shortage

According to the manufacturer, GlaxoSmithKline, the availability of carvedilol may become unreliable for a period of up to eight weeks, potentially interrupting patient care. According to PBM utilization data, there were approximately 85,000 unique patients that received a Rx for carvedilol during the 3rd and 4th quarters of FY2005.

Carvedilol is available on the VA National Formulary, restricted to patients with a history of symptomatic chronic heart failure (HF). Therapeutic interchange guidance have been developed by the PBM-MAP and clinical cardiology experts for those veteran patients currently prescribed carvedilol for chronic HF who may be affected by the shortage. These recommendations (see next column) and a Patient Letter will be disseminated through the VISN Formulary Leaders and have been posted at http://www.pbm.va.gov/PBM/tig.htm and http://vaww.pbm.va.gov/PBM/tig.htm. These documents should be considered as guidance, and may be modified at the VISN and/or local level.

The process for identifying patients that should not be switched, and recommendations for follow-up monitoring and possible titration should be discussed with local cardiology experts.

THERAPEUTIC INTERCHANGE GUIDANCE FOR CHRONIC HEART FAILURE

» Until an adequate supply of carvedilol can be guaranteed, it would be prudent to consider alternative therapies rather than starting new patients on this medication.

» **For patients with HF who are currently considered unstable, it is recommended that a change from carvedilol not be made. The manufacturer will attempt to provide carvedilol for patients where it has been determined that they should not be switched based on their current health status.**

» In patients receiving carvedilol for the management of chronic HF and who are considered stable, the following dosage conversion to metoprolol XL[a] may be considered (note: recommendations are not based on head-to-head comparison trials; dosage conversions are derived from the initial, mean, and target doses reported in long-term, randomized, placebo-controlled morbidity and mortality outcome trials and from national clinical practice guideline recommendations). **The following may be modified based on clinical judgment and upward titration may be necessary:**

Carvedilol 3.25 mg twice daily → Metoprolol XL 12.5 mg (NYHA class III to IV) to 25 mg once daily (NYHA class II)

Carvedilol 6.25 mg twice daily → Metoprolol XL 25 to 50 mg once daily

Carvedilol 12.5 mg twice daily → Metoprolol XL 50 to 100 mg once daily

Carvedilol 25 mg twice daily → Metoprolol XL 100 mg to 200 mg once daily

Carvedilol 50 mg twice daily* → Metoprolol XL 200 mg once daily
***in patients weighing ≥ 85 kg**

» Other beta-adrenergic blockers that are listed on the VANF that have been studied in patients with HF include atenolol and metoprolol IR; however, data as to their long-term clinical outcome benefit and their optimal dose have not been determined. Bisoprolol is also available as a nonformulary agent and has been shown to reduce morbidity and mortality in a long-term, randomized, placebo-controlled morbidity and mortality outcome trial in patients with HF.

» **Recommendations for follow-up monitoring should be discussed with local cardiology experts.**

[a] Metoprolol XL (METOPROLOL SUCCINATE) is available as 25 mg, 50 mg, 100 mg, and 200 mg scored, film-coated extended- release tablets

For additional discussion, refer to:
Recommendations for the Use of Beta-Adrenergic Blockers in VA Patients with Chronic Heart Failure with Left Ventricular Systolic Dysfunction, available at http://www.pbm.va.gov/criteria/bblockerscriteria.pdf.
Hunt SA, Abraham WT, Chin MH, et al. ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure). American College of Cardiology Web site. Available at: http://www.acc.org/clinical/guidelines/failure/index.pdf.
The pharmacologic management of chronic heart failure. Washington, DC: Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel, Veterans Health Administration, Department of Veterans Affairs; April 2001; Updated August 2003. PBM-MAP Publication No. 00-0015. Available at http://www.pbm.va.gov/guidelines/28766Chronicheartfailure.pdf and http://www.oqp.med.va.gov/cpg/CHF/28766chronicheartfailure.pdf. (Update 2006 in progress).

VISN 9 Formulary Available on EPOCRATES®

Many healthcare professionals are familiar with EPOCRATES, a drug-information application which can be downloaded to their PDA. Now, users of EPOCRATES in VISN 9 have access to the VISN formulary on their PDA devices and online. Users of EPOCRATES outside of VISN 9 can still view the formulary on their PDA's by selecting the "VISN 9 Formulary" option. The formulary is updated to mirror the National Formulary, so users outside of VISN 9 may find this useful when attempting to determine if a drug is on the formulary. For information on how to use this feature, users can go to

http://vaww.visn9.med.va.gov/pharmacy/Epocrates%20Downloading%20Reference.pdf

Submitted by: Mark A. Slagle, PharmD, BCPS
VISN 9 Pharmacoeconomist
Midsouth Healthcare Network

Nicotine Lozenge Added to National Formulary

Nicotine lozenges (nicotine polacrilex- Commit®) was added to the national formulary. The lozenges are restricted to use according to the Clinical Practice Guideline for the Management of Tobacco Use found at:
http://vaww.oqp.med.va.gov/CPGintra/cpg/TUC3/TUC_Base.htm
http://www.oqp.med.va.gov/cpg/tuc3/tuc/base.htm.

In addition, the lozenges are restricted to patients who cannot tolerate nicotine gum—which includes, but not limited to patients with the following:

- partial or full dentures
- a significant number of missing teeth particularly in the back or side of the mouth,
- difficulty chewing because of dental or TMJ issues or
- status-post head and neck surgery

All of these conditions can all be assessed by a cursory exam and viewing of patients dentition by any clinician.

The lozenge is available in a 2mg and 4mg strength; 4mg should be used in patients with high nicotine dependence and the 2mg in patients with low nicotine dependence. When used alone, patients should dissolve one lozenge in the buccal cavity every 1-2 hours for the first six weeks of treatment; then one every 2-4 hours for 3 weeks; and finally one every 4-8 hours for 3 weeks. When used in combination with a patch, use the lowest dose that relieves breakthrough symptoms every 2-4 hours prn.

Submitted by Mark Geraci, PharmD., BCOP
on behalf of the Tobacco Use Cessation (TUC) Technical Advisory Group

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

Remember:
Patients should be strongly counseled to avoid any tobacco use when using nicotine replacement products.

Click here to read the complete article including more about quit rates and adverse effects for nicotine lozenge:
http://www.pbm.va.gov/ezminutes/Lozenge.pdf

VAMedSAFE: Patient Safety Issues

Several patient safety issues are currently being investigated including:

1. Benzocaine (Hurricane Spray)

Health professionals should be aware that potentially uncontrollable doses can be administered due to the design of the delivery device causing symptoms of benzocaine-induced methemoglobinemia.

The spray is not a metered dose product and as such each actuation does not deliver a specific dose per actuation. The dose per spray is dependent on the orientation of the canister prior to use, force of actuation, and canister content, thus, the amount of benzocaine that is administered is variable. The instructions provided by the manufacturer for safe application appear ONLY on the canister's cap and not on the canister's container label. If the canister cap is misplaced, then the instructions for appropriate administration will not be available.

Nationally, some VHA facilities are already aware of this potential problem and are using alternative treatment regimens to resolve this problem. Until alternatives to this treatment regimen are implemented VHA-wide facilities should proactively report to FDA's MedWatch reporting system any problems associated with Benzocaine (Hurricane Spray) use.

2. Amphotericin B Irrigation

Since 2001, 5 cases of bladder irrigation setups being attached to the IV catheter instead of the bladder catheter have been reported. This mix-up can induce serious complications (e.g. renal failure). The NCPS (National Center for Patient Safety) will be developing an action plan and issue a Patient Safety Alert to ensure the safe and correct route of administration. Please look for further recommendations in the near future.

WHAT DO I NEED TO KNOW AND TELL MY VA PATIENTS ABOUT MEDICARE PART D?

January 1, 2006 marked the beginning of Medicare's new prescription drug coverage (Medicare Part D). Enrollment in the program began November 15, 2005 and continues through May 15, 2006. Veterans who are enrolled in VA's health care program and who are eligible for Medicare may choose to participate in the Medicare prescription drug program in addition to their VA prescription drug coverage.

The prescription drug benefit provided as part of the medical benefits package for veterans enrolled in the VA health care system is "creditable coverage," meaning that it is at least as good as the Medicare drug coverage. Veterans who are enrolled with the VA healthcare system may choose to wait and join a Medicare prescription drug plan after May 15, 2006 without being subject to a higher monthly premium ("late enrollment penalty"). However, they may have to wait until the next annual enrollment period, from November 15 to December 31 each year. A veteran who loses VA enrollment status through no fault of his/her own (for example, if VA makes an enrollment decision that would further restrict access to certain Priority Groups) would be able to enroll in a Medicare Part D plan without the late penalty if he/she signs up within 62 days of loss of such enrollment status. VA will provide the necessary proof of creditable coverage in these instances.

Veterans will be receiving a Notice of Creditable Coverage in mail order prescriptions, revenue statements and enrollment letters. Veterans who do not receive a notice in one of those mailings may obtain the notice from the Internet or by asking at their local facility.

In addition to the Notice of Creditable Coverage, VA has created several documents about Part D with more information for veterans and staff. The documents can be found at **www.va.gov/healtheligibility**. More information on the Medicare Part D program may be obtained from the Centers for Medicare and Medicaid Services (CMS) at 1-800-MEDICARE (1-800-633-4227), or on the Internet at **www.medicare.gov**.

Submitted by: *Patricia Lynch Watts, J.D., Health Eligibility Center Liaison, Chief Business Office, Veteran Health Administration*

The following sites may be of further interest:
http://www.va.gov/healtheligibility/costs/MedicarePrescriptionDrugCoverage-PartD.asp
http://www.cms.hhs.gov/partnerships/downloads/VA.pdf

Effective January 1, 2006: Increase in VA's Outpatient Medication Copayment Rate from $7 to $8 for a 30-day or less supply for treatment of a nonservice-connected condition.

Click to read all about it at:
http://www.va.gov/healtheligibility/DOCS/CoPays.doc

"Frequently Asked Questions and Answers Document for VA Facility Staff"
http://www.pbm.va.gov/ezminutes/RXCopayFAQ.pdf

Additional informational tools for veterans and field staff are posted on the CBO website at
http://vaww1.va.gov/cbo/copays.asp

Future Topics for 2006 PBM-MAP Distance Learning Broadcasts:

Impact of Substance Abuse on the Course of Bipolar Disorder

ADR Program

Insulin Therapy for the Management of DM in the VHA

Check the PBM web site for more details in the near future

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