Volume 11, Issue 3
May-July 2013

Pharmacy Benefits Management- Medical Advisory Panel- VISN Pharmacist Executives

E_z - MINUTES

Watch for the next issue of Ez-Minutes November 5, 2013
We're on the Web! See us at: **http://www.pbm.va.gov/ or https://vaww.cmopnational.va.gov/cmop/PBM/default.aspx**

Editor's Note: The purpose of the PBM-MAP-VPE Ez-Minutes Newsletter is to communicate with the field on items that will impact clinical practice in the VA.

Please note: The KYOTO HEART STUDY reference was removed from the following documents due to retraction of the publication:

Angiotensin II Receptor Antagonists, Drug Class Review

Angiotensin II Receptor Antagonists, Clinical Recommendations

Also, the Ziprasidone CFU developed in 2002 has been removed from the PBM web site.

Inside This Issue

Posting of National PBM Documents May-July 2013

Formulary Decisions

Added to the VA National Formulary (VANF)

- Leflunomide
- Metformin ER

Clinical Recommendations

- Hydroxyethyl Starch (HES) Solutions in Critically Ill or Septic Patients (read article below for further details)
- Sodium Phosphate Sodium Biphosphate Enema Safety Considerations (read article below for further details)

Criteria for Use (CFU)

- Biologics in Psoriasis and Psoriatic Arthritis, Criteria for Use
- Enzalutamide
- Hyaluronic Acid or Hylan G-F 20 Criteria for Use (Updated July, 2013) with the following statement: *VA does not support use of compounded corticosteroids purchased from compounding pharmacies. VA providers should only use commercially available products for joint injection.*
- Lorcaserin
- Mirabegron
- Regorafenib (Updated, July, 2013U:
- Thrombopoietin agonist for Hepatitis C related Thrombocytopenia
- Teriflunomide
- Vemurafenib
- Zoster Vaccine (Updated June, 2013)

Not added to the National Formulary (VANF)

- Balsalazide disodium
- Dextromethorphan Hydrobromide and Quinidine Sulfate
- Eltrombopag for Hepatitis C related Thrombocytopenia
- Enzalutamide
- Glycerol Phenylbutyrate
- Golimumab
- Lorcaserin
- Mesalamine DR
- Ocriplasmin
- Picosulfate-Magnesium Oxide-Citric Acid
- Rabeprazole Sprinkle Delayed-release Capsules (pediatric formulation)
- Regorafenib
- Taliglucerase alfa
- Vemurafenib

What's NEW..... CFU?

A new disclaimer statement has been added to all CFU (See bolded text below) "The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. **Local adjudication should be used until updated guidance and/or CFU are developed by the National PBM.** The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient. Individual cases that are outside the recommendations should be adjudicated at the local facility according to the policy and procedures of its P&T Committee and Pharmacy Services."

Removed from the National Formulary

- None during this time period

Drug Monograph

- Apixaban
- Biologics in Psoriasis and Psoriatic Arthritis, Monograph and Literature Review
- Cross-Linked Hyaluronate (Gel-One)
- Dasatinib Addendum
- Dextromethrophan hydobromide and Quinidine Sulfate
- Eltrombopag Addendum for Hepatitis C related Thrombocytopenia
- Enzalutamide
- Lorcaserin
- Mirabegron
- Ocriplasmin
- Picosulfate - Magnesium Oxide - Citric Acid
- Regorafenib
- Rotigotine
- Vemurafenib

Abbreviated Review

- Taliglucerase alfa
- Emtricitabine-tenofovir for Pre-exposure HIV Prophylaxis
- Glycerol Phenylbutyrate

Posting of VAMedSAFE Documents May-July 2013

National PBM Bulletins	National PBM Communication
Hydoxethyl Starch Solutions and Mortality and Acute Kidney Injury [July, 2013]	Medtronic Recall of Reservoirs Used with Paradigm Insulin Pumps Due to Leaks [July, 2013]
	Aspirin Lot Recalled for Containing Acetaminophen Instead [July, 2013]

Pharmacy-Prosthetics-Logistics and Acquisitions (PPLA)* Workgroup

The table below depicts the various products reviewed during May and June, 2013 meetings. The X marks which service(s) is responsible for managing the respective products. Please click HERE for further details and decisions made from earlier meetings.

**The PPLA workgroup was created to help clarify the responsibility for management (e.g., ordering, storing, purchasing, and/or dispensing) of those products in which it is not clear which service should provide. The workgroup is not responsible for determining formulary status, clinical merit, or appropriate use of the products reviewed.*

Products	Pharmacy+	Prosthetics+	Logistics and Acquisitions+
Agile Patency System (used in GI lab)			X
Glucose solution for glucose tolerance testing			X
Insulin syringe magnifiers		X	
Kirschner wires (K-wires)			X
Large contact lenses placed after surgery (not used for vision correcting)			X
Lugol's solution (use in GYN clinic)			X
Monsel's solution and AstroGyn (use in GYN clinic)			X
MUGARD, GelClair, OraMagicRX	X (outpatients)		X (inpatient or clinic use)
Surgical sealants (e.g., Evicel, TachoSil, FloSeal, Tisseel, etc.)			X
Phenol EZ Swabs			X (inpatients or clinic use)
Prescription strength (aluminum chloride hexahydrate 15-20%) antiperspirants for residual limb hyperhydrosis	X (inpatients and outpatients)		
Propel-Steroid Dissolving Implant (used in sinus surgery)			X

+ Contingent upon approval from VISN or local Clinical Products Review Committee (CPRC). Implementation of these recommendations should be coordinated between services at local sites to ensure a smooth transition if recommendations lead to a change in responsible service. If you have any questions related to this announcement, please contact the responsible local service (Pharmacy, Prosthetics, or Logistics) for more detailed information.

Hydroxyethyl Starch (HES) Solutions for Fluid Resuscitation of Critically Ill or Septic Patients

Over the past two years, there have been a number of publications focusing on the use of hydroxyethyl starch (HES) solutions compared to other fluids (e.g., crystalloids or non-HES colloids such as albumin) for fluid resuscitation of critically ill or septic patients. The recent evidence supports no added benefit of HES solutions over other resuscitation fluids and a potential for harm in these patients. As a result, the VA Pharmacy Benefits Management Services, Medical Advisory Panel, VISN Pharmacist Executives have recommended avoidance of HES solutions for fluid resuscitation of critically ill or septic patients and recommend that crystalloid solutions be used instead. They acknowledge that in patients requiring large amounts of crystalloids (>30 ml/kg/d), use of albumin can also be considered. The VA Pulmonary/Critical Care Field Advisory Committee has concurred with the recommendations. Facilities are encouraged to review any local guidance for albumin and remove any requirement for HES solutions prior to albumin in critically ill or septic patients.

The Evidence summary and recommendations have been posted on the PBM websites. Click HERE to access the full evidence summary/recommendations.

Submitted by Cathy Kelley PharmD, National PBM Clincial Pharmacy Program Manager

Safety Considerations with the Use of Sodium Phosphate/Sodium Biphosphate Enemas

In the VA, sodium phosphate/sodium biphosphate enema is available for bowel preparation prior to a procedure or for intermittent management of constipation. On March 26, 2013, the PBM VA Center for Medication Safety issued a National PBM Bulletin in response to a fatality in a patient with severe constipation who had been prescribed, and who received, several sodium phosphate/sodium biphosphate enemas in less than 12 hours. Reports of severe adverse events resulting in severe electrolyte imbalance (hypernatremia, hyperphosphatemia, hypocalcemia, hypokalemia), dehydration and hypovolemia, tetany, QT prolongation, seizures, coma, and death are rare, but have been reported in the literature. An increased risk for severe adverse events or mortality may be associated with gastrointestinal disorders causing increased retention of enema contents in the gut; in addition, risks also include chronic renal failure, advanced age, and number of doses administered exceeding one within 24 hours.

In an effort to increase awareness of the potential safety concerns with the use of sodium phosphate/sodium biphosphate enemas, the Pharmacy Benefits Management Services (PBM), Medical Advisory Panel (MAP) and VISN Pharmacist Executives (VPEs) have developed the "Sodium Phosphate/Sodium Biphosphate, Enema: Safety Considerations", that identifies patients who may be at greatest risk for a severe adverse event (e.g., those with contraindications such as patients with significant kidney impairment with an eGFR < 30 ml/min; or in patients $\geq$ 70 years of age) and where a sodium phosphate/sodium biphosphate enema should be used with caution (e.g., in patients with an eGFR 30 to 60 ml/min; or more than 64 years of age). It is recommended that providers refer to this document for several additional contraindications and precautions that are listed (see Sodium Phosphate Sodium Biphosphate Enema, Safety Considerations).

In addition, the following safety consideration for dosage and administration are noted:

- Administration of more than one enema in 24 hours, particularly in patients with constipation, risk factors for electrolyte disturbances and comorbidities, can be harmful and has resulted in death.
- In those cases where complications have been reported, overdoses are often involved.
- No other sodium phosphates preparation including sodium phosphates oral solution or tablets should be given concomitantly.
- Use of sodium phosphate enemas for chronic management of constipation is not recommended. If an enema is indicated for management of severe constipation (after alternate treatment options have been attempted), consider using warm water enemas or mineral oil enemas (i.e., following disimpaction) before considering sodium phosphate enemas. These treatments may have the potential for toxicity if not used appropriately, with recommendations not to exceed more than one per 24 hours. If a sodium phosphate enema is used for severe constipation, it is recommended that no more than one dose be administered per 24 hour period, for no more than 3 days.

In order to assist with implementation of the safe use of sodium phosphate/sodium biphosphate enemas, the following measures will be undertaken:

- The VPEs will discuss the Sodium Phosphate/Sodium Biphosphate Enema Safety Considerations at the VISN/local level so that leadership at all VAMCS are alerted to the concerns in patients with chronic kidney disease as well as other safety considerations (including contraindications, warnings/precautions, and recommended dosing of sodium phosphate/sodium biphosphate enemas, especially for patients with constipation) and can implement methods to alert providers as deemed appropriate by the VISN/facilities.
- At the VISN/local level, leadership should engage local gastroenterologists (and other experts) to review the appropriate use of sodium phosphate/sodium biphosphate enemas for adequate, yet safe bowel cleansing prior to a procedure.

In an effort to evaluate whether sodium phosphate/sodium biphosphate enema is being used inappropriately on a chronic basis for constipation, the VA Center for Medication Safety will review outpatient utilization via a Medication Use Evaluation (MUE).

Submitted by Elaine Furmaga, PharmD, and Francine Goodman, PharmD, BCPS; National PBM Clinical Pharmacy Program Managers

SAVE-THE-DATE : August 20th PBM-MAP-VPE Webinar

The Pharmacy Benefits Management-Medical Advisory Panel-VISN Pharmacy Executives
And National PBM Education Advisory Committee (PBM-EdAC)
in conjunction with Employee Education System
and acknowledged by the
National Center for Health Promotion and Disease Prevention,
VHA Office of Patient Care Services
is pleased to present

MOVE! Weight Management Program for Veterans

Faculty:

Kenneth R. Jones, Ph.D.
Clinical Health Psychologist
National Program Director for Weight Management/MOVE!
National Center for Health Promotion and Disease Prevention (10P4N)
VHA Office of Patient Care Services (VACO)
and
Todd Semla, MS, PharmD, BCPS, FCCP, AGSF
National PBM Clinical Program Manager – Mental Health & Geriatrics
U.S. Department of Veterans Affairs
Pharmacy Benefits Management Services

WHEN: Tuesday, August 20th @ 3 PM to 4 PM EST

DIAL IN NUMBER: 1-800-767-1750 Access Code 49792#

Accreditation: ACCME, ACCME-NP, ACPE, APA

Registration Link:
https://www.tms.va.gov/learning/user/deeplink_redirect.jsp?linkId=ITEM_DETAILS&componentID=18744&componentTypeID=VA&revisionDate=1375709640000

Adobe Connect Meeting Link: http://va-eerc-ees.adobeconnect.com/r5grsrbq851/

Objectives:

At the conclusion of this educational webinar, active learners will be able to:
1) State the prevalence of overweight/obesity in VHA
2) Describe the six components of the VHA MOVE program
3) Apply the National PBM criteria-for-use for weight loss pharmacotherapy (i.e. phentermine/topiramate, and/or lorcaserin) to a patient-case.
4) Identify at least two ways in which health professionals can support Veterans in the MOVE program.

To become more familiar with the *MOVE!* program (i.e., design, effectiveness data) including pharmacotherapy, please read/review the following articles in advance of this webinar. This will help in your participation during the case discussion….not to mention the *MOVE!* Brain Teasers.

http://www.cdc.gov/pcd/issues/2009/jul/08_0150.htm Design and Dissemination of *MOVE!*
http://www.cdc.gov/pcd/issues/2013/12_0325.htm- Effectiveness of *MOVE!* in LA
http://vaww.move.med.va.gov- *MOVE!* Website

Lorcaserin CFU
Lorcaserin Monograph
Phentermine/Topiramate CFU
Phentermine/Topiramate Monograph

Please forward this announcement to all pharmacists, PACT pharmacists, and all interested disciplines including dietitians, psychologists, physicians etc. working in an area (e.g., lipid, diabetes, hypertension, smoking cessation, primary care clinics) that incorporates weight management therapy.

PBM-MAP-VPE webinars are held every third Tues. of the month @ 3 PM ET

All previous taped webinars are available via 0n-demand viewing in on PBM Education SharePoint site Click HERE .

Taped webinars are also available via On-demand viewing in TMS: https://www.tms.va.gov/learning/user/login.jsp. Type "PBM" in the search field to retrieve PBM-MAP-VPE programs.

Clinical Pharmacy Virtual BOOT CAMPS –PART II ARE HERE

Starting August 19th
thru September, 2013

This series will focus on disease state management training in the following:

Smoking Cessation
Hepatitis C
Pain Management
Diabetes
Hypertension
Lipids

Adobe Connect Link:
http://va-eerc-ees.adobeconnect.com/bootcamps/

VANTS: 1-800-767-1750
78567#

ACPE offered!
Program details are available on National PBM Education Site
For any questions or for more information regarding these Virtual Conferences, please contact Heather.Ourth@va.gov or Janet.Dailey@va.gov