Pharmacy Benefits Management-
Medical Advisory Panel-
VISN Pharmacist Executives
E_z - MINUTES

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May 2014 - July 2014

Watch for the next issue of Ez-Minutes November 4, 2014

See us at*:* **http://www.pbm.va.gov/ or https://vaww.cmopnational.va.gov/cmop/PBM/default.aspx.**

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The purpose of PBM-MAP-VPE Ez-Minutes Newsletter is to communicate with the field on items which will impact clinical practice in the VA

Inside This Issue

NEW: 3 Prior Authorization Categories on the VANF

Prior authorization-National (PA-N)
Refers to medications that are formulary but require prior approval at the national level before dispensing. (It is used to ensure that the medication is appropriate for each individual Veteran). *Example: Lomitapide*

Prior authorization-VISN (PA-V)
Refers to medications that are formulary but require prior approval at the VISN level before dispensing.

Prior authorization- Facility (PA-F)
Refers to medications that are formulary but require prior approval at the facility level before dispensing. *Example: Naltrexone Extended Release Iniection*

Posting of National PBM Documents May 2014 -July 2014

Formulary Decisions

Added to the VA National Formulary (VANF)	Not added to the National Formulary (VANF)	Removed from the National Formulary
• Atovaquone/proguanil-Restricted to CDC Guidelines for treatment and prophylaxis of malaria. • Dolutegravir • Lurasidone-Restricted to depressive episodes associated with bipolar disorder • Naloxone Auto-injector • Naltrexone Extended-release Injection- Prior authorization-Facility (PA-F). A National Prior Authorization template is being developed to be exported to the field as a future patch. In the interim, facilities should establish a process to ensure immediate dispensing to appropriate patients in concordance with national CFU.	• Bedaquiline - Restricted to ID or local designee • Flunisolide Inhaler • Glucarpidase • Polidocanol • Posaconazole delayed-release tablets and injection; restricted to ID providers or local designee • Luliconazole Topical Cream • Topiramate extended release • Unoprostone Ophthalmic Solution • Umeclidinium/vilanterol inhaler • Vigabatrin	None during this time period

Criteria for Use (CFU)

- Capecitabine
- Simeprevir [Updated, June 2014]
- Sofosbuvir [Updated June 2014]

Abbreviated Review

- Flunisolide Inhaler
- Naloxone Auto-injector
- Posaconazole delayed-release tablets and injection
- Topiramate Extended Release
- Naloxone Autoinjector- [Revised July 2014]

Patient and Provider Letters [InTRAnet only]

- Eszopiclone Provider Letter
- Eszopiclone Patient Letter
- Tramadol C-IV Patient Letter
- Tramadol C-IV Provider Letter

Clinical Recommendations

- Iron (Intravenous) in CKD, Clinical Recommendations [Updated to include ferric carboxymaltose; HMW iron dextran no longer available]
- Mineralocorticoid Receptor Antagonists (Eplerenone, Spironolactone) in Heart Failure, Recommendations for Use [Updated per 2013 ACCF/AHA Heart Failure Guideline]
- Naloxone Kits [Interim Recommendations June 2014]

Drug Monograph

- Aflibercept for Central Retinal Vein Occlusion [Addendum June 2014]
- Atovaquone/proguanil
- Bedaquiline
- Capecitabine Evidence Summary
- Collagenase Clostridium Histolyticum for Peyronie's Disease [Addendum April 2014]
- Collagenase Clostridium Histolyticum for Dupuytren's Contracture [Updated April 2014]
- Dolutegravir
- Glucarpidase (Monograph and Considerations for Use)
- Ibrutinib Drug Monograph
- Luliconazole Topical Cream
- Lurasidone [Updated, and Addendum June 2014]
- Polidocanol
- Unoprostone Ophthalmic Solution
- Umeclidinium/Vilanterol
- Vigabatrin

DID YOU KNOW?

- The following document(s) were archived:
  - Aflibercept CFU; Collagenase Clostridium Histolyticum CFU, and Eszopiclone CFU
- Tramadol is being rescheduled to a C-IV controlled substance, effective August 18, 2014. Besides patient/provider letters, other posted documents include:
  - Tramadol - PBM Guidance on Reclassification_07172014
  - Tramadol CMOPImplementationSchedule_Attachment B
  - Tramadol_DEAFederalRegisterNotice_Attachment A_07022014
- RSS Feed is available to subscribe to the Ez Minutes. Check it out!
  http://www.pbm.va.gov/PBM/linksotherresources/PBMMAPVPEEzMinutes.asp

Posting of VAMedSAFE Documents May 2014-July 2014

VA Center for Medication Safety

- Acetaminophen Safety [June 10, 2014]
- Adverse Neurologic Events and Epidural Corticosteriod Injections for Pain [May 1, 2014]
- Eszopiclone (Lunesta): Lowered Dose Recommendations Due to Next-Day Impairment [May 28, 2014]

Pharmacy-Prosthetics-Logistics (PPL)* Workgroup

The table below depicts the various products reviewed during **April-June 2014** meetings. The X marks which service(s) is responsible for managing the respective products. Please click HERE for previous recommendations and minutes 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+
Anticoagulant Citrate Dextrose	X		
Carbamide peroxide (Bly-oxide) otic solution	X		
Clarix Cord 1 K or 100 Regenerative Matrix			X
Epsom salts	X (outpatients)		X (inpatients or clinic use)
EZ Loc Femoral Fixation Device		X	
Fresnel-Prisms		X	X
Heavy mineral oil for use as a laxative	X (inpatient and outpatient)		
Light mineral oil, 100% sterile, topical, for use in the ears	X (inpatient and outpatient)		
Mineral oil enemas	X (outpatient)		X (outpatient)
Prokera			X
Renal calculi strainer			X (inpatients and clinic use)
Silver Nitrate Sticks			X
Surgimend			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.

DUSHOM Memorandum: Requesting Continuous Glucose Monitoring Devices through Prosthetic and Sensory Aids Service

VISN endocrinologists are responsible for approving the Veteran's appropriateness of need for continuous glucose monitoring. The review of continued need is done on a yearly basis but operationalization of these changes will be determined within each VISN.

Click to read the Criteria for Use of Continuous Glucose Monitoring (CGM)

Click to read the Memorandum on more details regarding the change in process of requesting CGM Devices through Prosthetic and Sensory Aids Service

PBM-EDUCATION
NATIONAL PHARMACY BENEFITS MANAGEMENT

NEXT PBM Webinar: August 19, 2014 @ 3 PM ET

Pharmacy Statistics 101: Demystifying Statistics for the Clinician

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Free Naloxone Kit and Autoinjector Initiative

VA is actively engaged in promoting safe and effective practices in the management of pain. Partnering with Veterans, VA is focused on exploring all options to manage chronic pain. In an effort to prevent fatal and non-fatal opioid overdoses, VA will begin to offer opioid overdose education and naloxone (kit) distribution (OEND) to at risk Veterans. To make these kits accessible to Veterans in need of them, the Pharmacy Benefits Management (PBM) has deployed the Free Naloxone Kit Initiative. The initiative will ultimately result in 28,000 kits being provided to VA patients. For additional information if needed, please contact your VISN Pharmacist Executive (VPE).

UPDATE: As of August 1, 2014, the VA Consolidated Mail Out Pharmacy (CMOP) currently has a total of 4,000 naloxone kits available and has obtained enough supplies to make an additional 5,000 kits. The maximum order quantity for medical centers placing orders with CMOP has been eliminated. Sites can now order as many kits as are needed to support local dispensing. Funding from PBM has been made available to cover the cost of CMOP prepared naloxone rescue kits. As such, the naloxone kits will now be provided at no cost starting August 4th.

Order naloxone rescue kits from CMOP for local use. **Naloxone Rescue Kits Ordering Page**

CLICK to Read the Informational Letter: **IMPLEMENTATION OF OPIOID OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION (OEND) TO REDUCE RISK OF OPIOID-RELATED DEATH**

SAVE THE DATE: October 21st, 2014 @ 3 PM ET: The PBM Webinar will be highlighting the OEND Program and other related updates to this initiative. Faculty: Drs. Elizabeth Oliva and Robert Sproul.

Five Opioid Overdose Reversals With Naloxone!

The VA Opioid Overdose Education and Naloxone Distribution (OEND) program would like to announce that VA naloxone kits have been used to reverse 5 opioid overdoses. Two reversals involved family member naloxone administration, one involved staff naloxone administration, and one involved patient naloxone administration for another individual. These reversals underscore the importance of training patients, family members, and staff on OEND. Brief details of cases include:

- Cleveland reported two successful reversals, with the first occurring within the first two months of pilot implementation of OEND.
- Cincinnati, one of the first VA sites to distribute national naloxone kits, reported a successful reversal within the second week of distributing kits.
- Dayton and San Francisco, respectively, reported the 4th and 5th successful reversals with a naloxone kit.

The VA OEND National Support & Development Workgroup is encouraged by these reports and will continue their efforts to support implementation of OEND. Provider and patient educational materials, posters to increase patient awareness of OEND, and videos demonstrating how providers can train patients on OEND as well as how patients can respond to an opioid overdose with VA naloxone kits will be available soon on the new VA National OEND SharePoint site: https://vaww.portal2.va.gov/sites/mentalhealth/OEND/default.aspx.

Questions about VA OEND implementation can be directed to elizabeth.oliva@va.gov. Naloxone kits for intramuscular and intranasal administration and the naloxone autoinjector for intramuscular/subcutaneous administration are on the VA National Formulary. To assist in identifying patients for OEND, National PBM Recommendations for Use of Naloxone Kits and an abbreviated review of the naloxone autoinjector (EVZIO) are available at www.pbm.va.gov and the PBM INTRAnet site.

Submitted by Elizabeth M. Oliva, Ph.D. VA National OEND Coordinator

Mineralocorticoid Receptor Antagonists in Heart Failure Safety Surveillance Focus on Appropriate Initial Follow-up of Potassium and Kidney Function

Current clinical practice guidelines recommend treatment with a mineralocorticoid receptor antagonist (MRA) in patients with heart failure (HF) with reduced ejection fraction (HF*r*EF) and in patients with mild to severe HF symptoms (i.e., New York Heart Association [NYHA] class II-IV HF). Treatment with a MRA in addition to standard therapy in patients has been shown to decrease all-cause and cardiovascular mortality, and reduce HF hospitalizations. Careful monitoring is recommended with treatment with a MRA as there is the potential for adverse outcomes related to hyperkalemia, and lack of appropriate follow-up.

Clinical recommendations* for the use of the MRAs in patients with HF*r*EF, to emphasize appropriate selection of patients as well as the need for close monitoring and follow-up were developed.

Recommended Frequency for Monitoring Potassium and Serum Creatinine with the VA National Formulary MRA (spironolactone)

- At baseline
- Again at or within 1 week
- Every 4 weeks for the first 3 months
- Every 3 months for 1 year
- Every 6 months thereafter

*The Clinical Recommendations were developed by the following groups: VA Pharmacy Benefits Management Services (PBM), Medical Advisory Panel (MAP), and VISN Pharmacist Executives (VPEs), in collaboration with members of the Chronic Heart Failure (CHF) Quality Enhancement Research Initiative (QUERI)

Editor's Note: Due to space constraint, the submission was abbreviated: Please click HERE to read the entire document.

OBSERVATIONS:

- Approximately 42% of patients being evaluated with HF*r*EF and an initial prescription for a MRA, received follow-up laboratory monitoring according to the recommendations of within 1 week (or within 2 weeks for patients who had their prescription mailed)
- Of the patients who exceeded the recommended timeframe for follow-up, approximately 78% had laboratory follow-up within 3 months of the initial MRA prescription
- The most frequent reason for the patient not having lab follow-up within the recommended timeframe was either that the lab was ordered for > 2 weeks (46%) or that a follow-up lab was not ordered (13%)
- When comparing potassium in patients with follow-up within the recommended timeframe vs. those outside the recommendations (but within 3 months of the initial prescription):
  - An elevated potassium (> 5.5 mEq/L) after the initial MRA prescription occurred in 0.96% of patients with follow-up within 1 week (within 2 weeks if prescription was mailed) vs. 1.6% who had lab follow-up within 3 months
  - A similar number of patients in each group who had potassium levels > 5.0 mEq/L upon follow-up, had risk factors for developing hyperkalemia (e.g., baseline potassium > 5.0 mEq/L or serum creatinine $\geq$ 2.5 mg/dl; prescribed potassium supplements)

There were no reports of potassium $\geq$ 6.0 mEq/L in either follow-up group.

CONCLUSIONS AND RECOMMENDATIONS

- Laboratory evaluation of potassium as recommended within 1 week after initial prescription of a MRA in patients with HF*r*EF is suboptimal.
- Provider education should emphasize the recommended timeframe for follow-up (refer to recommendations above or at Mineralocorticoid Receptor Antagonists (Eplerenone, Spironolactone) in Heart Failure, Recommendations for Use), and the potential factors that may increase the risk for hyperkalemia during treatment with a MRA (e.g., baseline elevated potassium and/or serum creatinine; concomitant medications that may contribute to increased potassium levels).
- Methods for national implementation of appropriate follow-up with a MRA (e.g., Medication Use Evaluation Tracker [MUET], Dashboard) are being explored.

Submitted by Elaine Furmaga, National Program Manager and Cedric L. Salone Pharm.D, MPH, National PBM and VA MedSAFE