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

Volume 13, Issue 4

Aug 2015 – Dec 2015

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Due to travel restrictions and the need to reschedule the PBM-MAP-VPE Meetings where formulary decisions are made, this issue of the EZ Minutes combines two issues in one. Formulary Decisions from August 2015-December 11, 2015 are included in this issue.

Inside This Issue

Happy Holidays and a Safe New Year

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. Please send and feedback and/or comments to Janet.Dailey@VA.gov.

The recent issue of Ez Minutes can be read from your smart phone! Put the below link in your browser; hit search… and the current issue from the PBM INTERnet site will be ready to read. http://www.pbm.va.gov/PBM/ezminutes/current/currentEzMinutes.pdf

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Posting of National PBM Documents Aug – Dec 16, 2015

Formulary Decisions

ADDED to the VA National Formulary (VANF)

- 9-valent HPV vaccine
- Bupropion XL (24-hour formulation)
- Daclatasvir
- Idarucizumab
- Lacosamide IV
- Lidocaine cream/ointment
- Lidocaine 5% patch
- Melatonin (Certified Product Only)
- Paliperidone palmitate IM
- Phenylephrine (oral)
- Potassium Chloride oral solutionTechnivie
- Tiotropium/olodaterol Inhaler
- Ulipristal acetate

Criteria for Use (CFU)

- 9-valent HPV vaccine
- Acetylcholinesterase Inhibitors *[Updated Dec. 2015]*
- Alemtuzumab
- Alirocumab
- Brimonidine Topical Gel
- Carbidopa Levodopa ER
- Daclatasvir
- Ezetimibe/Ezetimibe+Simvastatin [*Updated Nov. 2015*]
- Ivabradine
- Methylnaltrexone Injection *[Updated Dec. 2015]*
- Paliperidone
- Pneumococcal 13 Valent Conjugate Vaccine [*Updated Oct. 2015*]
- Sacubitril Valsartan
- Sofosbuvir and Ledipasvir-Sofosbuvir *[Updated Oct. 2015; Dec 2015)*
- Tasimelteon
- Ticagrelor *[Updated Dec. 2015]*
- Varenicline *[Updated Dec. 2015]*
- Vedolizumab Injection
- *Viekira Pak and Technivie* *[Updated Dec. 2015]*

Abbreviated Review

- 9-valent HPV vaccine
- Hydrocodone bitartrate ER
- Oxycodone HCl Acetaminophen Extended-Release
- Pasireotide
- Technivie
- Tiotropium/olodaterol Inhaler

NOT ADDED to the National Formulary (VANF)

- Adapalene 0.3% and benzoyl peroxide 2.5% topical gel combination
- Afatinib
- Alemtuzumab
- Alirocumab
- Antihemophilic Factor (recombinant), Porcine Sequence
- Bosutinib
- Brimonidine Topical Gel
- Buprenorphine Transdermal System
- Carbidopa Levodopa ER
- Ceftazidime/avibactam
- Edoxaban
- Flucinolone acetonide 0.19 intraviteral implant
- Glucagon Injection [synthetic] –the VANF line item name will be changed to Glucagon Recombinant Injection to differentiate between synthetic glucagon (nonformulary) and recombinant glucagon (formulary)
- Hydrocodone bitartrate ER
- Insulin glargine 300U per mL
- Ivabradine
- Leuprolide acetate for depot injection and norethindrone acetate
- Lidocane 5% ointment
- Omacetaxine Mepesuccinate
- Osemifene
- Oxycodone HCl Acetaminophen Extended-Release
- Paclitaxel Protein-Bound
- Paroxetine mesylate 7.5 mg
- Pasireotide
- Ponatinib
- Sacubitril Valsartan
- Tasimelteon
- Vedolizumab Injection
- Von Willebrand Factor/Coagulation Factor VIII Complex (human)

Patient and Provider Letters

- Digoxin Patient Letter, Provider Letter (Digoxin has been removed from the VA Drug Standardization List due to a shortage of the active pharmaceutical ingredient
- Glatiramer Provider Letter and Patient Letter

Removed from the National Formulary (VANF)

- Antipyrine/benzocaine/glycerin Otic
- Chloral hydrate
- Ipecac Syrup
- 4-valent HPV vaccine

Drug Monograph

- Afatinib
- Alemtuzumab
- Alirocumab
- Bosutinib
- Buprenorphine Transdermal System
- Carbidopa Levodopa ER
- Ceftazidime/avibactam
- Edoxaban
- Empagliflozin (Pending: formulary status/update to the SGLT2 Inhibitor CFU)
- Fluocinolone acetonide 0.19 intravitreal implant
- Idarucizumab
- Insulin glargine 300U per mL
- Ivabradine
- Lacosamide Addendum
- Melatonin
- Omacetaxine Mepesuccinate
- Ospemifene
- Paclitaxel Protein-Bound
- Paliperidone palmitate IM
- Ponatinib
- Sacubitril Valsartan
- Tasimelteon
- Ticagrelor Addendum
- Vortioxetine

Clinical Recommendations

- Naloxone Kits and Autoinjector
- Ulipristal acetate

Additional Information

Methylnaltrexone Injection guidances - indication for opioid-induced constipation in chronic noncancer pain was added
Oxcarbazepine-Not restricted to neuro

Other Helpful Resources

Cost Comparison for HCV Genotype 3 Regimens *[InTRAnet only]*
Lidocaine 5% Patch Literature Review

Posting of VAMedSAFE Documents AUG-DEC 2015

- OmniPod Insulin Management System Recall: ADDENDUM [December 14, 2015]
- Auvi-Q (epinephrine injection, USP) Recall - Potential Inaccurate Dosage Delivery [October 30, 2015]
- BD Syringes and Loss of Drug Potency: FDA Expands Warning-UPDATE [September 23, 2015]
- OmniPod Insulin Management System Recall [September 5, 2015]
- Allergan Ophthalmic Product Recall Due to Particulate Matter: ADDENDUM [September 4, 2015]
- Allergan Ophthalmic Product Recall Due to Particulate Matter [September 2, 2015]
- BD Syringes and Loss of Drug Potency [August 31, 2015]

National Contract Awards for Calendar Year 2015

Click on this link to view the National Contract Awards CY 2015. [*InTRAnet only*]

Pharmacy-Prosthetics-Logistics (PPL)* Workgroup

The table below depicts the various products reviewed during July-October 2015 meetings. The X marks which service(s) is responsible for managing the respective products. Please click HERE for previous recommendation and minutes made from earlier meetings.

**The PPL 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+
Anchor Arthrex Suture (permanent)		X	
Bio-adhesive glue and remover for facial prosthesis [Initial supply provide by prosthetics, replacement refills by pharmacy]	X (outpatients)	X (Initial)	
Cefaly used for in migraines		X (outpatients)	
Blood pressure devices/cuffs for home use		X	
Endoscopic Bariatric Therapy (gastric balloon)			X
Enteral declogging system (non-drug, e.g., ClogZapper and other similar products) if alternative agents (e.g., pancreatic enzyme products) are deemed ineffective or contraindicated	X (outpatient use)		X (inpatient or clinic use)
Ful-Glo (fluorescein strips or drops)			X (inpatient or clinic use)
GEM 21s, Osteogen and other similar resorbable boney void fillers			X
Lancets for blood glucose testing	X (outpatients)		X (inpatients and clinics)
Oral care kit and suctioning system (e.g., Q-Care Kit containing chlorhexidine gluconate 0.12%)			X (inpatient or clinic use)
Ovulation Kits for female Veterans	X (outpatient use)		
Rocker cast boots/shoes or post-operative shoes		X (outpatients)	
Rose Bengal			X (inpatient or clinic use)
Sheepskin		X (outpatient use)	
SPACEOAR (used prior to radiation of the prostate)			X
Vinyl or plastic pants to wear over adult diapers	X (in properly selected outpatients)	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.

NEW NAME

DOAC

TSOAC RENAMED TO DOAC (DIRECT ORAL ANTICOAGULANTS)

The Scientific and Standardization Committee (SSC) of the International Society of Hemostasis and Thrombosis (ISTH) recently published recommendations on the use of consistent nomenclature for the newer class of oral anticoagulants that directly inhibit a single target and have similar clinical properties (e.g., dabigatran, rivaroxaban, apixaban, and edoxaban). After evaluation of several possibilities, the SCC of the ISTH recommends **DOAC for direct oral anticoagulants**. The nomenclature has been endorsed by several professional societies including the Anticoagulation Forum. (*J Thromb Haemost. 2015;13:1154-6*)

VA had widely adopted the target specific oral anticoagulants or TSOAC nomenclature (e.g., PBM documents, policy, CPRS ordering menus, MUET, etc.) as was originally endorsed by the Anticoagulation Forum and VA subject matter experts. Based on the new ISTH recommendations, the MAP and VPEs (National PBM) agreed that VA should transition from TSOAC to DOAC to be consistent with practices outside of VA.

The field will begin to see the new nomenclature of DOAC in PBM documents, communications, policy, MUET, etc. Facilities are encouraged to re-evaluate local and VISN level use of the TSOAC term and consider transitioning to the DOAC term. It may be helpful to include a reference to the former name of TSOAC (e.g., Direct Oral Anticoagulant [DOAC], formerly called TSOAC).

Reducing Polypharmacy in the Palliative Care Setting

Polypharmacy is a major risk factor for adverse medication reactions and interactions, particularly in the geriatric population. Despite this recognition, there is no uniform or consensus definition of polypharmacy although either "the use of 6 or more concomitant medications" or "use of a potentially inappropriate or unnecessary medication" has been frequently cited. Regardless of the definition employed, we know that there are many drivers of polypharmacy including:

1. Multiple disease specific guidelines in patients with multiple comorbidities
2. Treating acute problems in patients with multiple comorbidities (adding meds to meds)
3. Multiple providers involved in treating multiple comorbidities
4. Misinterpreting and mistreating adverse medication reactions (adding meds to meds)
5. **Patient and family perception of medication necessity**

The most challenging issue to address is often item five, the patient and family perception of need for a whole host of medications that no longer may be helpful and can even be harmful. The most important way to address this issue is for treating physicians, in conjunction with palliative care consultants as needed, to frequently and systematically assess the ***goals of care*** for individual patients with serious and/or life-limiting illness. In many instances, if patients are primarily seeking symptom relief and/or maximization of overall functional status, then medications designed to prevent long term complications from chronic disease may no longer be appropriate. In those situations, a process of ***"deprescribing"*** should ensue, which is *defined as an effort to taper, reduce dose or stop medications in an effort to reduce polypharmacy, minimize adverse medication effects and avoid ineffective or even potentially harmful medications*.

How the process of deprescribing is communicated to the patient and family is also critical. Relating it to the goals of care discussion is usually the first step. If symptom relief and/ or functional status improvement are the major goals then many medications that do not contribute to achieving those goals can often be discontinued. The language used in this process is also very important – terms like, "optimize, individualize, limit pill burden, maximize benefit and minimize harm" are much better received than terms such as, "stopping, quitting, decrease cost, no longer covered, etc." As with all issues in Palliative Care, this **must be** a process of shared decision making so patients and families do not feel like they are being abandoned or that their treating clinicians are "giving up."

In my experience, many patients who are taking six, eight or ten or more separate medications per day and often twice those numbers in terms of pills per day welcome the opportunity for this regimen to be streamlined. Furthermore, as most of us can attest to from experience, many patients do not feel worse as medications are withdrawn but may actually feel better, in which case it becomes much easier to convince them to reduce polypharmacy. The most common classes of medications where there is often great opportunity to "deprescribe" in the Palliative setting with a high likelihood that the benefit (including just reducing the pill "burden" and reducing cost of care) outweighs the harm include:

Dementia Meds
- Acetylcholinesterase Inhibitors (AChEI) may be efficacious in slowing disease progression for mild to moderate Alzheimer's Disease, less helpful and more harmful in advanced disease
- Memantine has small beneficial effect at six months only in moderate to advanced dementia and no clear added benefit in combo with AChEI
- Rivastigmine may help in Lewy Body disease but none of these agents are clearly helpful in vascular dementia and may be harmful in Frontotemporal dementia
- Potential side effects including nausea, diarrhea, insomnia, and others not usually well tolerated in Palliative Care population
- It is safest to wean these medications over two weeks when stopping

Statins
- Highly prevalent in Palliative Care population (including those with metastatic cancer) for prevention of cardiovascular morbidity which often is no longer relevant
- Recent study showed no difference in mortality at 60 days when statin is discontinued in Palliative Care setting (Kutner JS, etal. Safety and benefit of discontinuing statin therapy in the setting of advanced, life-limiting illness: a randomized clinical trial. (JAMA Intern Med. 2015; 175:691-700)
- Many Palliative Care patients have anorexia, weight loss or poor nutrition for which cholesterol lowering no longer makes sense

Anticoagulan & ASA
- Is it treatment or prophylaxis of VTE, AFib, ischemic or valvular heart disease?
  - The role of prophylactic anticoagulation is limited in this setting
- The use is highly dependent on goals of care and bleeding risk versus (usually) low short term risk of thrombosis or stroke
- Inconvenience and cost of monitoring (warfarin) must be factors in the decision
- Bleeding risk of warfarin in patients with liver disease or metastasis and/or poor nutrition and low albumin can increase significantly

Anti hyper-tensives
- The main purpose of these agents is long-term reduction of heart failure, myocardial infarction, stroke, and kidney disease incidence which often become moot in Palliative Care setting
- The agents have minimal role in preventing or avoiding symptoms
- The risks for orthostasis, dehydration, falls and other adverse events or side effects are often higher in Palliative Care population
- If continued, the dose or number of agents can often be reduced and goal blood pressure can be less aggressive

Insulin & oral hypoglycemic meds
- The main role for long-term prevention of micro and macrovascular disease often becomes moot in Palliative Care population
- The risk of hypoglycemia often increases with occurrence of anorexia, decreased food intake and weight loss in many Palliative Care patients
- Avoiding extremes of blood glucose is usually more sensible than "tight control" in Palliative Care setting

Vitamins, Iron, Supplements
- Vitamin D and calcium for osteoporosis prevention no longer is relevant in most Palliative Care patients
- Anemia of chronic disease is often misdiagnosed as iron deficiency leading to unnecessary supplementation and frequent GI side effects
- Added pill burden and cost for little benefit

Summary and Conclusion: Just as in the geriatric population, in the Palliative Care setting, a "less is more" approach to medication management is often the most sensible. While many patients and their clinicians tend to think of Palliative Care as akin to hospice and only dealing with patients illnesses. While prognostication is fraught with hazard and uncertainty, one of the simple questions Palliative Care clinicians often ask when evaluating a patient is the so called "surprise" question: "Would I be surprised if this patient were not alive one year from now?" If the answer to this question is, "no" (and clinicians' gut response to this question is surprisingly accurate) then reconsidering the goals of medication therapy in these patients is very appropriate. Does it really make sense to continue medications designed to reduce mortality and mortality over many years when life expectancy is likely far less than that? Do the benefits of continuing a medication outweigh the risks (side effects, adverse events) and/or disadvantages (inconvenience, cost)? Is a given medication providing any *symptomatic* relief, or is it actually causing side effects or harm? Frequently reviewing the goals of care for patients with serious illness and engaging in effective communication and shared decision making to guide medication therapy and help achieve those goals is the optimal way to reduce polypharmacy and improve outcomes for Veterans.

Submitted by: Paul E. Stander, MD, MBA, FACP Director, Outpatient Palliative Care Phoenix, VAMC

Editor's Note: The PBM welcomes Dr. Stander as one of the newest member to the Medical Advisory Panel. Thank you for your contribution to the Ez-Minutes. Due to space constraint, this article was abbreviated. Please click HERE to read the article in its entirety.

PBM-EDUCATION
NATIONAL PHARMACY BENEFITS MANAGEMENT

All PBM-MAP-VPE webinars are conducted using the same Adobe Connect meeting link and VANTs number.
http://va-eerc-ees.adobeconnect.com/pbm-monthly-webinars/
VANTS: 1-800-767-1750 Access Code 49792#
Third Tuesday of the month @ 3 PM ET

2015 PBM Webinars

2016

If you missed any of the PBM webinars this year…..Below are links to the taped 2015 PBM Webinars.

JANUARY: **Concomitant use of Benzodiazepines with Opioids**
http://va-eerc-ees.adobeconnect.com/p7ythol82cp/

FEBRUARY: **Hepatitis C Updates**
http://va-eerc-ees.adobeconnect.com/p5cvv93l1ai/

FEBRUARY: **Naloxone Kit Updates**
http://va-eerc-ees.adobeconnect.com/p2sq15b3ano/

MARCH: **VA/DOD Clinical Practice Guidelines (CPG) for the Management of Dyslipidemia for CV Risk Reduction**
http://va-eerc-ees.adobeconnect.com/p5z7u4n3nd2/

APRIL: **Naloxone Kit Updates**
http://va-eerc-ees.adobeconnect.com/p7h3jicoxqd/

MAY: **Demystifying Statistics for the Clinician** Part 1
http://va-eerc-ees.adobeconnect.com/p379bw4ocwr/

JUNE: **Demystifying Statistics for the Clinician** Part 2
http://va-eerc-ees.adobeconnect.com/p4maxlymnl8/

JULY: **Naloxone Kit Updates**
http://va-eerc-ees.adobeconnect.com/p6jfco9rj2o/

AUGUST: **Transforming Clinical Pharmacy Practice-Highlights from VHA Handbook 1108.01**
http://va-eerc-ees.adobeconnect.com/p8bl401up4v/

SEPTEMBER: **VA/DOD Clinical Practice Guidelines (CPG) for the Management of Dyslipidemia for CV Risk Reduction**

OCTOBER: **Anticoagulation Series Part 1: Anticoagulation Surveillance**
http://va-eerc-ees.adobeconnect.com/p9h281rm7mj/

NOVEMBER: **Anticoagulation Series Part 2:Anticoagulation Key Practices in VHA**
http://va-eerc-ees.adobeconnect.com/p6fj4rc39nk/

DECEMBER: **PBM EdAC Education and Training Programs in 2016**
http://va-eerc-ees.adobeconnect.com/p70stdfyari/
Board Certification Study Groups; DM Moodle Modules, How-To-Videos (Patient Education)

2016 PBM Webinars Schedule to Date

- January 19th, 2016

Final Program of the 3 part Anticoagulation Series: Anticoagulation in the Known and Unknown

- February 16th, 2016

Updates on HCV Genotype 2, 3, and 4

- March 15th, April 19th May 17th, 2016

A 3 part series begins on Demystifying Statistics for the Clinician

All webinars are ACPE, ACPE-T, ACCME, ACCME-NP accredited
Remember to register PRIOR to the program. Below are the registration links that will work for all the webinars listed above. Register for one or all webinars using the links below.
RSS: Pharmacy Benefits Management Virtual Series for Pharmacists and Clinicians

BELOW LINK IS FOR PHARMACY TECHNICIANS ONLY
RSS: Pharmacy Benefits Management Virtual SERIES - RSSTECHS

The PBM-MAP-VPE would like to thank and recognize the following members for their service to the VA and contributions to this committee:

Retired in 2015
Malcolm Weiss (VPE)
Carl Hensley (VPE)
Robert Rosenstein (MAP)

Resigned in 2015
Lori Highberger (MAP)

Welcome to the new members in 2015:
Allen Blaivas (MAP)
Shannon Kilgore (MAP)
Karla Mallo (VPE)
Paul Stander (MAP)
Mark Donahue (MAP)
Bruce Capehart (MAP)
Matthew Schreiber (MAP)

Attention Pharmacist & Pharmacy Technicians
Virtual VHA Board Certification Study Groups will start January 2016. Anyone can participate in the study group even if you are not interested in taking the exam. For additional information contact Janet.Dailey@va.gov and/or the POC for the following respective groups:
BCPS: Kimberly.Schnacky@va.gov
BCACP: Jonathan.Hoffman@va.gov
BCOP: Lindsay.Kaster@va.gov
BCCP: June.Griffith@va.gov
CGP: Martin.Cruz@va.gov
PTCB: Marta.Kane@va.gov/ and/or
Jennifer.Suther@va.gov

ON BEHALF OF THE PBM-VPE-MAP

HAPPY HOLIDAYS

HAPPY NEW YEAR!