

Volume 13, Issue 2
Feb 2015 – April 2015

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

Watch for the next issue of Ez-Minutes Tuesday, August 4, 2015

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

[Click Here to Subscribe to the Ez Minutes](#)

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.

Posting of National PBM Documents Feb. – April 2015 Formulary Decisions

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3 Prior Authorization Categories on the VANF

The Prior Authorization webinar originally planned for April 2015 needed to be rescheduled. The new date has not been determined. Please watch for details. In the meantime, if you have questions on the Prior Authorization Process, please send email to VHAPBH Prior Authorization National.



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. Try it!

<http://www.pbm.va.gov/PBM/ezminutes/current/currentEzMinutes.pdf>

Don't forget...you can also subscribe to Ez-Minutes and any documents posted to the What's New Section on the PBM INTERNET web site by subscribing to the RSS Feed. http://www.pbm.va.gov/PBM/rss/Whats_New_At_PBM_RSS_Feed.xml

ADDED to the VA National Formulary (VANF)	NOT ADDED to the National Formulary (VANF)	Removed from the National Formulary (VANF)
<ul style="list-style-type: none"> Alfuzosin Amphotericin B liposomal (Ambisome) Doxylamine tablets [Restricted to Women's Health] Duloxetine Delayed Release Capsules Olodaterol Respimat Pertuzumab- in last Ez Minutes Trastuzumab Prothrombin-Complex Concentrate, 4-Factor (Kcentra) [Restricted to Recommendations for Use] Ramipril 	<ul style="list-style-type: none"> Ado-Trastuzumab Emtansine Ceftolozane-tazobactam Doxylamine-Pyridoxine Delayed Release Dulaglutide Eliglustat Everolimus in Breast Cancer Ferric Citrate Loxapine inhaled Nintedanib Omega-3-Acid Ethyl Esters A Omega-3-Carboxylic Acids Peginterferon beta 1a NME Peramivir [Restricted to ID, ICU or locally designated provider(s) per CDC Guidance for Influenza in Hospitalized Patients] Pirfenidone Tedizolid phosphate [Restricted to ID or locally designated provider(s)] 	<ul style="list-style-type: none"> Amphotericin B lipid complex (Abelcet)
Criteria for Use (CFU)	Abbreviated Review	Drug Monograph
<ul style="list-style-type: none"> Ado-Trastuzumab Emtansine Aripiprazole Long-acting Injection [Updated April 2015] Anticoagulants, Target Specific Oral (TSOAC) for Prophylaxis of VTE in Ortho Surgery Anticoagulants, Target Specific Oral (TSOAC) w Algorithm for VTE Treatment DPP-4 inhibitor [Updated April 2015] Enzalutamide [Updated March 2015] Fluphenazine decanoate Haloperidol decanoate Modafinil for Fatigue [Updated March 2015] Nintedanib Ombitasvir, Paritaprevir/Ritonavir plus Dasabuvir [Updated Feb 2015] Omega-3-Fatty Acid Prescription Products [Updated Feb 2015] Orlistat [Updated Mar 2015] Paliperidone Long-acting Injection [Updated Apr 2015] Pirfenidone [Updated Mar 2015] Risperidone Long-acting Injection [Updated Apr 2015] Roflumilast [Updated Apr 2015] Trastuzumab Simeprevir plus Sofosbuvir [Updated Apr 2015] Sofosbuvir and Ledipasvir/Sofosbuvir [Updated Apr 2015] 	<ul style="list-style-type: none"> Acetaminophen Injection [Updated, Mar 2015] Cyclosporine in Chronic Idiopathic Urticaria [Addendum to Omalizumab] Doxylamine-Pyridoxine Delayed Release Eliglustat Omalizumab in Chronic Idiopathic Urticaria [CFU in progress] <p>DID YOU KNOW?</p> <p>The following document(s) were archived</p> <ul style="list-style-type: none"> Duloxetine Criteria for Use Influenza (oseltamivir and zanamivir), Clinical Recommendations Rivaroxaban VTE Prophylaxis CFU Rivaroxaban VTE Treatment CFU <p>Also, a clinical pathway for Rheumatoid Arthritis Therapies will be drafted in lieu of CFU of TOFAcitiNIB</p>	<ul style="list-style-type: none"> Budesonide ER Tablet Brimonidine Gel Ceftolozane-tazobactam Dulaglutide Enzalutamide [Addendum Updated March 2015] Everolimus in Breast Cancer Ferric Citrate Idelalisib Olodaterol Respimat Omega-3-Acid Ethyl Esters A Omega-3-Carboxylic Acids Loxapine inhaled Naloxegol Nintedanib Peginterferon beta 1a NME Peramivir Pirfenidone Prothrombin-Complex Concentrate, 4-Factor Ramucirumab Tedizolid phosphate Trastuzumab
		Clinical Recommendations
		<ul style="list-style-type: none"> Duloxetine for Chronic Pain Gram-Positive: Ceftaroline, daptomycin, linezolid, quin-dalf, tedizolid, telavancin, tigecycline [Updated Mar 2015] Naloxone Kit/Autoinjector [Available May 1st, 2015] Prothrombin-Complex Concentrate, 4-Factor (Kcentra)
		Other Helpful Resources:
		<ul style="list-style-type: none"> Use of Continuous Glucose Monitoring- developed by Diabetes-Endocrinology Field Advisory Committee, Specialty Care Services, and Patient Care Services VA Drug Standardization List -March 2015

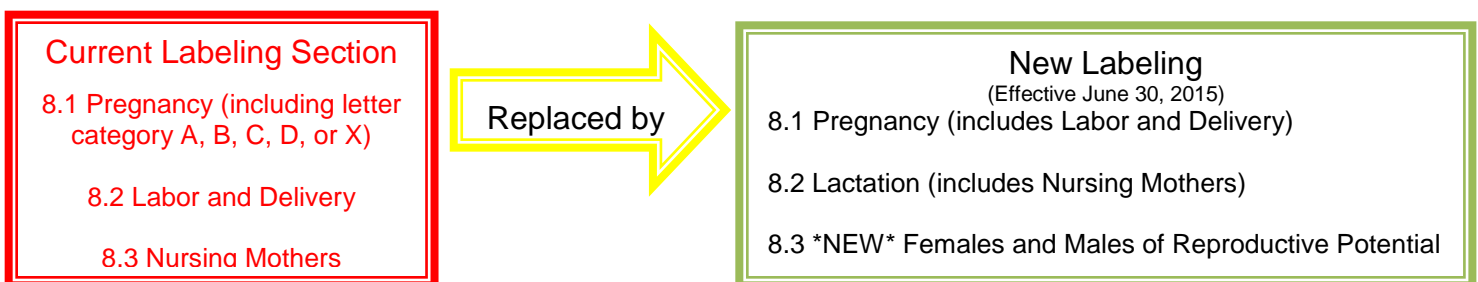


Posting of VAMedSAFE Documents FEB-APRIL 2015

- [Ferumoxytol and Risk of Serious Allergic Reactions](#) [April 28, 2015]
- [Amiodarone Use with Ledipasvir/Sofosbuvir \(Harvoni\) or Sofosbuvir \(Sovaldi\) Combined with Another Direct-Acting Antiviral and Bradycardia](#) [March 31, 2015]
- [UPDATE: Testosterone Products and Cardiovascular Safety](#) [March 26, 2015]

FDA Pregnancy Labeling Changes

FDA released new labeling rules referred to as the “Pregnancy and Lactation Labeling Rule” (or PLLR or final rule). Pregnancy categories of A, B, C, D, and X used to classify the risks of using prescription drugs during pregnancy are being removed and the label reorganized with three detailed subsections (pregnancy, lactation, and fertility) that describe risks within the real-world context of caring for pregnant women.



More details can be found at the following link:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Labeling/ucm093307.htm>

Below are answers to some of the most frequent questions being asked about PLLR.

Why are the pregnancy letter categories being removed from drug labeling?

They are often viewed as confusing and overly simplistic and don't effectively communicate the risk a drug may have during pregnancy and lactation and in females and males of reproductive potential. The new rule format will assist health care providers in assessing benefit vs. risk and in subsequent counseling of pregnant women and nursing mothers who need to take medication, thus allowing them to make informed and educated decisions for themselves and their children.

What will the new labeling offer?

The new labeling creates a consistent format for providing information about the risks and benefits of prescription drug and/or biological product use during pregnancy and lactation and by females and males of reproductive potential. Relevant information about pregnancy testing, contraception, and infertility for health care providers prescribing for females and males of reproductive potential will now be required which will assist health care providers in assessing benefit versus risk and in subsequent counseling of pregnant women and nursing mothers who need to take medication, thus allowing them to make informed and educated decisions for themselves and their children.

When will these changes go into effect?

The labeling changes in the package insert will go into effect on June 30, 2015 for all human prescription drug and biological products. Products approved on or after June 30, 2001 will be phased in gradually. For labeling of products approved prior to June 30, 2001, manufacturers are required to remove the pregnancy category within 3 years of the effective date of the final rule.

Does the PLLR affect all drugs?

All prescription drug and biological products approved since June 30, 2001 must revise the content and format of their pregnancy and lactation sections in labeling according to the implementation schedule published in the rule. Labeling for over-the-counter (OTC) medicines will not change. OTC drugs are not affected by the PLLR.

Pharmacy-Prosthetics-Logistics (PPL)* Workgroup

The table below depicts the various products reviewed during Feb. 2015 meeting. 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 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+
Olympic tracheostomy button		X (outpatients)	X (inpatients)
Spacer devices used with oral inhalers for outpatient and inpatient use	X (outpatients and inpatients)		
Spy Kits for use in the operating room or endoscopy suite			X
Tracheostomy masks (durable)		X (outpatients)	X (inpatients)

+ 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.

National Contract Awards for Calendar Year 2015

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



Next PBM-MAP-VPE Webinar

DEMYSTIFYING STATISTICS FOR THE CLINICIAN

2 PART SERIES
MAY 19TH AND JUNE 16TH 2015
@ 3 PM ET

Learning Objectives:

Statistics 101: Demystifying Statistics for the Clinician (part 1)

1. Describe the hierarchy of evidence formed by various study designs.
2. Differentiate between simple randomization, blocked randomization, stratification, and matching; compare and contrast the role of each in study design.
3. Identify different types of data (nominal, ordinal, continuous) to choose an appropriate type of statistical test.
4. Given a study design, select an appropriate biostatistical test to compare study groups.

Statistics 101: Demystifying Statistics for the Clinician (part 2)

1. Compare correlation and regression analysis; interpret the correlation coefficient and coefficient of determination, respectively.
2. Differentiate between type I and type II decision errors and identify conditions under which they may occur.
3. Describe p-values and confidence intervals and interpret these values to determine the statistical significance of study findings.
4. Calculate means of association (relative risk, absolute risk reduction, relative risk reduction, number needed to treat) and interpret the clinical significance of these results.

Registration Link is pending. Check TMS for registration links in the near future. Any questions, please contact Eric.Esplin@va.gov (EES) or Janet.Dailey@va.gov (PBM)

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#

Anticoagulation Revised TMS Programs

Basic Anticoagulation Program is available

Direct Registration Link:

https://www.tms.va.gov/learning/user/deeplink_redirect.jsp?linkId=ITEM_DETAILS&componentID=6720&componentTypeID=VA&revisionDate=127991670000

Accreditation: ACPE-T, ANCC, CDR, CA BRN for 3 years

Advanced Anticoagulation Program

This program is undergoing accreditation review.

Accreditation: ACPE and ACMME for 3 years (pending)

Watch for details for upcoming PBM Webinars on anticoagulation issues tentatively scheduled for the months of July and August 2015.

PACT TEAM TEASER QUESTIONS

What are the differences between the VA/DoD Lipid Guidelines compared to the other available guidelines?...

OR

How many documented saves has the VA had since the Naloxone Kit has been made available AND what tool in the Naloxone Kit is free to the facility starting May 1st to assist in training patients?

Learn the answers to those questions and more by viewing these taped webinars. (see links below)

[VA/DoD Clinical Practice Guidelines \(CPG\) for the Management of Dyslipidemia For CV Risk Reduction.](http://va-eerc-ees.adobeconnect.com/p5z7u4n3nd2/) (<http://va-eerc-ees.adobeconnect.com/p5z7u4n3nd2/>)

March 17th, 2015

Resources/slides are [available here](#) and at the VA/DoD Clinical Practice Guidelines site: <http://www.healthquality.va.gov/>

[Naloxone Kit Updates...](#) April 23rd, 2015

Resources/slides are [available here](#) and at the National Opioid Overdose Education and Naloxone Distribution (OEND) SharePoint Site: <https://vaww.portal2.va.gov/sites/mentalhealth/OEND/default.aspx>