



Volume 14, Issue 3  
May – July 2016

# Pharmacy Benefits Management- Medical Advisory Panel- VISN Pharmacist Executives E<sub>z</sub> - MINUTES

Watch for the next issue of Ez-Minutes Tuesday, November 1st, 2016  
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. Please send and feedback and/or comments to [Janet.Dailey@VA.gov](mailto:Janet.Dailey@VA.gov).

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## Posting of National PBM Documents May – July 2016 Formulary Decisions

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"> <li>• <a href="#">DoD VHA Transitional Continuity of Care Drug List</a> (see Page 3 for details)</li> <li>• Dofetilide</li> <li>• Fosaprepitant injection, lyophilized</li> <li>• Obinutuzumab-PA-F restricted to oncology</li> <li>• Pioglitazone</li> <li>• Siltuximab (restricted to oncology)</li> <li>• Uridine Triacetate- PA-F [CFU pending]</li> </ul>	<ul style="list-style-type: none"> <li>• Aspirin, Extended release</li> <li>• Calcipotriene-Betamethasone Dipropionate Topical Foam</li> <li>• Dichlorphenamide</li> <li>• Eluxadoline</li> <li>• Insulin Degludec</li> <li>• Lanthanum carbonate powder (refer to Recommendations for Use document)</li> <li>• Levetiracetam ZipDose</li> <li>• Liraglutide</li> <li>• Mepolizumab</li> <li>• Nitroglycerin lingual spray</li> <li>• Perampanel</li> <li>• Recombinant Human Parathyroid Hormone 1-84</li> <li>• Short Ragweed Pollen Allergen Extract</li> <li>• Trifluridine-tipiracil</li> <li>• Tacrolimus XR</li> </ul>	<ul style="list-style-type: none"> <li>• Ethinyl estradiol 20mcg tab</li> </ul>
<b>Criteria for Use (CFU)</b>	<b>Clinical Recommendations</b>	<b>Drug Monograph</b>
<ul style="list-style-type: none"> <li>• Buprenorphine TDS</li> <li>• Dipeptidyl Peptidase-4 (DDP-4) Inhibitors [Updated May 2016]</li> <li>• Dofetilide</li> <li>• Eszopiclone</li> <li>• Glucagon-Like Peptide-1 (GLP-1) Agonists [Updated May 2016]</li> <li>• Liraglutide for Weight Management</li> <li>• Lorcaserin [Updated July 2016]</li> <li>• Mepolizumab</li> <li>• Obinutuzumab</li> <li>• Orlistat [Updated July 2016]</li> <li>• OxyCODONE Tablet Sustained Action</li> <li>• OxyMORPHONE Tablet Immediate Release</li> <li>• OxyMORPHONE Tablet Sustained Action</li> <li>• Phentermine Topiramate [Updated July 2016]</li> <li>• Pregabalin [Updated June 2016]</li> <li>• Recombinant Human Parathyroid Hormone 1-84</li> <li>• Siltuximab</li> <li>• Trifluridine-tipiracil</li> </ul>	<ul style="list-style-type: none"> <li>• Oral Methadone Dosing Recommendations for Treatment of Chronic Pain [Updated July 2016]</li> <li>• Phosphate Binder (lanthanum, sevelamer, ferric citrate, sucroferri oxyhydroxide)</li> </ul>	<ul style="list-style-type: none"> <li>• Calcipotriene - Betamethasone Dipropionate Topical Foam</li> <li>• Eluxadoline</li> <li>• Insulin Degludec</li> <li>• Liraglutide for Weight Management</li> <li>• Mepolizumab</li> <li>• Obinutuzumab [Updated June 2016]</li> <li>• Perampanel</li> <li>• Secukinumab-[remains nonformulary while final decision on formulary status is pending]</li> <li>• Short Ragweed Pollen Allergen Extract</li> <li>• Recombinant Human Parathyroid Hormone 1-84</li> <li>• Uridine Triacetate</li> </ul>
<b>Abbreviated Review</b>	<b>Other Announcements</b>	<b>Archived Documents</b>
<ul style="list-style-type: none"> <li>• Dichlorphenamide</li> </ul>	<p>NEW! Prescribing authority for entecavir and tenofovir were extended to include oncology, rheumatology, and providers who care for patients with Hepatitis B.</p> <p><b>HELPFUL FAQ DOCUMENT</b> Do you ever receive questions from Veterans/family members or from CHOICE/fee-basis providers regarding the VA nonformulary medications or the process? Read on.</p> <ul style="list-style-type: none"> <li>• <a href="#">VA Nonformulary Frequently Asked Questions-[InTRANet only]</a></li> </ul>	<p><b>Abbreviated Drug Monograph</b></p> <ul style="list-style-type: none"> <li>• Aliskiren Amlodipine</li> <li>• Aliskiren Valsartan</li> <li>• Amlodipine Valsartan HCTZ</li> <li>• Olmesartan Amlodipine HCTZ</li> <li>• Telmisartan Amlodipine</li> </ul> <p><b>Criteria for Use</b></p> <ul style="list-style-type: none"> <li>• Aprepitant</li> <li>• Eszopiclone</li> <li>• Lorcaserin</li> <li>• Orlistat</li> <li>• Phentermine</li> <li>• Pioglitazone</li> <li>• Phosphate Binder CFU</li> <li>• Pregabalin</li> </ul> <p><b>Misc. Documents</b></p> <ul style="list-style-type: none"> <li>• Methadone, Dosing Recommendations</li> </ul>



VA Center for Medication Safety

**Posting of Center for Medication Safety VAMedSAFE Documents: May-June 2016**

Contaminated Oral Liquid Docusate	06/29/2016	<a href="#">National PBM Patient Level Recall Communication</a>
Fluoroquinolone Safety	06/03/2016	<a href="#">National PBM Bulletin</a>
Ketoconazole Safety	05/31/2016	<a href="#">National PBM Bulletin</a>
Canagliflozin and Risk of Amputations	05/31/2016	<a href="#">National PBM Bulletin</a>
Antipsychotic Agents and Safety Issues	05/13/2016	<a href="#">National PBM Bulletin</a>

**National Contract Awards for Calendar Year 2016**

Click on [this link](#) to view the National Contract Awards CY 2016. [InTRAnet only]

**Pharmacy-Prosthetics-Logistics (PPL)\* Workgroup**

The table below depicts the various products reviewed during April–May 2016 meetings. The X marks which service(s) is responsible for managing the respective products. Click [HERE](#) for 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+
Breast milk storage bags	X (outpatients)		
Closed system transfer devices (e.g., Onguard, Equishield, Phaseal)			X (inpatients or clinic use)
EnFit supplies for enteral feeding	X (outpatients) <u>Disposable</u> Supplies	X (outpatients) <u>Durable Supplies</u> (lasting for > 30 days) (e.g., feeding pumps)	X (inpatients) <u>Durable and Disposable Supplies</u> (e.g., feeding tubes placed in the operating room or changed in the clinic)
Gelfilm Sterile Film/Gelfilm Sterile Ophthalmic Film			X (clinic use)
Hi/Low Blood Glucose Control Solution	X (outpatients)		X (inpatients)
Tubigrip tubular bandages			X (inpatient or clinic use)

+ 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.

**DO YOU KNOW???**

**What are the differences between these three lists?**

Editor's Note: The VA Non-Promotable and Drug Standardization Lists were included in the March-April 2016 E<sub>z</sub> Minutes issue. Due to addition of new staff/residents, it is believed that it would be helpful to repeat the information again in this issue AND also add a NEW list that recently became available and one that may impact your clinical practice. Please be sure to READ.

The [VA Non-Promotable List](#) is a list of drug or supply items that are not to be promoted or detailed by pharmaceutical sales representatives.

The product Exparel (liposomal bupivacaine) has been removed from the list. Please note that this product remains non-formulary, so any promotion must be approved by the local Chief of Pharmacy as per Formulary Management Handbook.

**Questions to test your knowledge:**

What drug is on the VA Non-Promotable List?

What are the criteria used to determine whether a product is added to the list?  
Click [HERE](#) to learn more!

The [VA Drug Standardization List](#) is a list of pharmaceutical products for which substitution is not permitted under normal circumstances. The decisions to place products on this list are based on reviews of therapeutic equivalency and/or patient safety data.

Prograf was removed and replaced by generic tacrolimus (Golden State Medical Supply/Mylan). The contract is a mandatory source for generic tacrolimus, but there is no mandatory conversion of brand Prograf to generic tacrolimus. Whether or not to switch to the generic is left to the discretion of the provider/local medical center.

**Questions to test your knowledge:**

Which agents are on the VA Drug Standardization List?

Under what circumstance is substitution permitted?  
Click [HERE](#) to learn more!

The [DoD VHA Transitional Continuity of Care Drug List](#) is a list that creates a "uniform formulary" of pharmaceutical agents relating to the control of pain, sleep disorders, and psychiatric conditions including posttraumatic stress disorder for Veterans transitioning their care from the DoD to VHA. This list was mandated by the Defense Authorization Act and went into effect on July 1, 2016. The creation of the *DoD VHA Transitional Continuity of Care Drug List* necessitated the addition of nearly 50 drugs and dosage forms to the VANF.

ALL medications on the *DoD VHA Transitional Continuity of Care Drug List* that have criteria for use (CFU) will include the following criterion specific to the transitioning Veteran:

**TRANSITIONING VETERAN** (*This medication is on the DoD VHA Transitional Continuity of Care Drug List. If the criterion is met, then the remainder of the CFU is not applicable*)

- Veteran is transitioning care from the Department of Defense to VHA. A VA prescriber, after assessing and consulting with the Veteran, has determined that continuing the medication is safe and clinically appropriate.

Decisions on the approval of medications prescribed for mental health conditions that are **not** on the *DoD VHA Transitional Continuity of Care Drug List* should continue to be made in accordance with VHA DIRECTIVE 2014-02, "CONTINUATION OF MENTAL HEALTH MEDICATIONS INITIATED BY DEPARTMENT OF DEFENSE AUTHORIZED PROVIDERS."

[http://vaww.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=3075](http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=3075)

Please consult your VPE or Chief of Pharmacy on operational matters.

## Prevention of Hepatitis B Reactivation with Anti-CD20 Antibody Use in VA

Anti-CD20 antibody therapy has historically been limited to rituximab, as this was the first in-class therapy of its type. Currently, there are three anti-CD20 antibodies approved by the FDA: rituximab, ofatumumab and obinutuzumab. These drugs have indications in Non-Hodgkin lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis and other autoimmune conditions (e.g. granulomatosis with polyangiitis, macroscopic polyangiitis). Anti-CD20 antibody therapy causes immunosuppression. Immunosuppression can reactivate Hepatitis B virus (HBV). HBV reactivation may cause interruptions in chemotherapy and may increase mortality due to hepatitis, liver failure, and death. HBV reactivation is preventable through use of hepatitis B antiviral therapy.

A VHA quality improvement analysis (2002-2014) of 19,304 patients receiving anti-CD20 antibody therapy revealed that more than 60% of patients were tested prior to anti-CD20 antibody therapy for hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (HbCAb). Of those pretested, approximately 2% had chronic hepatitis B (HBsAg+) and 9% had prior hepatitis B (HBsAg- and HbCAb+). To prevent hepatitis B reactivation, hepatitis B antiviral therapy is recommended in these patients during their course of anti-CD20 antibody and 12 months beyond. Yet,  $\leq 37\%$  received the appropriate antiviral therapy. This resulted in significantly higher rates of hepatitis ( $\chi^2=27.8$   $p=0.001$ ; NS) and higher mortality in comparison to hepatitis B negative patients during this same time frame.

**Hepatitis B antiviral treatment (entecavir, tenofovir or continuation of current hepatitis B antivirals) is necessary for all patients that are HBsAg+ OR HbCAb+ throughout their course of anti-CD20 antibody treatment and 12 months thereafter.**

This analysis also showed that 16 patients developed acute hepatitis B, with 33% overall mortality. Acute hepatitis B is preventable with hepatitis B vaccine. Among those patients who were hepatitis B negative or unknown, only 4% received the hepatitis B vaccine. Prior to immunosuppression, hepatitis B vaccine should be administered to patients with pretreatment test indicating HBsAg-, HbCAb- and HBsAb-.

In summary, when anti-CD20 antibody therapy (e.g. rituximab, ofatumumab, obinutuzumab) are considered as part of a patient's treatment plan, ensure the following:

1. Pretreatment hepatitis B testing in all patients prior to anti-CD20 therapy including HBsAg, HbCAb, and HBsAb
2. If HBsAg+ or HbCAb+, hepatitis B antiviral therapy (entecavir or tenofovir, or continuation of lamivudine, adefovir or telbivudine) should be started before or contemporaneously with anti-CD20 antibody therapy and continued for at least 12 months following therapy, as agreed upon by hepatitis and hematology providers. All HBsAg+ or HbCAb+ patients should be screened for HIV prior to starting antiviral therapy to prevent HIV resistance with monotherapy.
3. HBV vaccination should be given in high risk patients (HBsAg-, HbCAb-, HBsAb-) if completed more than 30 days prior to chemotherapy initiation

To share best practices and prevent hepatitis B reactivation, a team of VA practitioners have developed:

- a Medication Use Evaluation Tracker (MUET) to retrospectively evaluate hepatitis B testing and initiation of antiviral treatment with anti-CD20 antibody therapy by site and nationally
- prescribing of entecavir and tenofovir has been expanded to include Oncology, Rheumatology, Infectious Diseases and Gastrointestinal Specialty Services
- Criteria for Use documents of anti-CD20 antibody therapies now include exclusion criterion that specifically pertains to hepatitis B testing, antiviral treatment, and reactivation information.
- an educational webinar on the prevention of hepatitis B reactivation with anti-CD20 antibody at: [http://va-eerc-ees.adobeconnect.com/p92j9sds7ov/?OWASP\\_CSRFTOKEN=084015fafed36586942c1254ee27139ea497f57074a313a06aea0b1b58e3151d](http://va-eerc-ees.adobeconnect.com/p92j9sds7ov/?OWASP_CSRFTOKEN=084015fafed36586942c1254ee27139ea497f57074a313a06aea0b1b58e3151d)
- VHA Oncology SharePoint site for hepatitis B reactivation at: <http://vawww.infoshare.va.gov/sites/MedicalSurgical/oncology/Shared%20Documents/Forms/AllItems.aspx?RootFolder=%2Fsites%2FMedicalSurgical%2Foncology%2FShared%20Documents%2FHepatitis%20Reactivation&FolderCTID=0x01200027D225AC89B63F4AB92E69554D64DF9A&View=%7bEA090F4B-4E26-483C-8222-30438D0B2600%7d>
- a National Clinical Reminder is in progress

### References

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- Arzerra (ofatumumab) Prescribing Information. East Hanover, New Jersey. Novartis Pharmaceuticals. 1/2016.

Article Submitted by: Berni Heron, Pharm.D., BCOP, Mark Geraci, Pharm.D., BCOP, National PBM Clinical Pharmacy Program Managers-PBM Formulary Management and Christine M. Hunt, MD, MPH, Durham VA Medical Center

## 2016 PBM-MAP-VPE Webinar Schedule: Third Tuesday of the month @ 3 PM ET

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#

All webinars are ACPE, ACPE-T, ACCME, ACCME-NP accredited, however for August and September 2016 webinars, accreditation will not be offered. August 16<sup>th</sup>, 2016 @ 3 PM ET: Academic Detailing OEND Tools and Reports