Volume 13, Issue 1

Nov 2014 – Jan. 2015

Pharmacy Benefits Management- Medical Advisory Panel- VISN Pharmacist Executives

E_z - MINUTES

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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.

Inside This Issue

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). *Examples: lomitapide, ziv-aflibercept*

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 do require prior approval at the facility level before dispensing.

A detailed document describing the PA designation is forthcoming. Prior Authorization will be the topic on the PBM webinar scheduled for April 21st @ 3 PM ET. Please mark your calendar. In the meantime, if you have questions on the Prior Authorization Process, please send email to VHAPBH Prior Authorization National

Posting of National PBM Documents Nov. 2014 –Jan. 2015

Formulary Decisions

Added to the VA National Formulary (VANF)	Not added to the National Formulary (VANF)	Removed from the National Formulary (VANF)
• Apixaban • Ledipasvir/Sofosbuvir *[Restricted to CFU]* • Pertuzumab • Rilpivirine coformulated with TDF.*FTC [Restricted to CFU]* • Rilpivirine *[Restricted to CFU]* • Tiotropium (Respimat) • Tranexamic Acid in TKA or THA • Ombitasvir, Paritaprevir/Ritonavir plus Dasabuvir *[Restricted to CFU]* • Polyethylene Glycol 3350/Electrolytes/Sodium Ascorbate/Ascorbic Acid (i.e., MOVIPREP)	• Ado-Trastuzumab Emtansine • Albiglutide • Apremilast • Bupivacaine Liposome Injectable Suspension • Droxidopa • Esomeprazole Strontium Delayed-release capsules • Ezogabine • Hydrocodone Extended-release Capsules • Sulfate Salts and PEG-3350/Electrolytes	• None during this time

Abbreviated Review

- Anticoagulants, Target Specific Oral (TSOACs) Dabigatran, Rivaroxaban, Apixaban Drug Class Review *[Updated Dec. 2014]*
- Hydrocodone ER
- Tiotropium Respimat

Drug Class Review

- Anticoagulants, Target Specific Oral (TSOACs) Dabigatran, Rivaroxaban, Apixaban *[Updated Dec. 2014]*

Clinical Recommendations

- Tranexamic Acid in TKA or THA
- PDE5I BPH-LUTS Evidence & Penile Rehabilitation

Drug Monograph

- Ado-Trastuzumab Emtansine
- Albiglutide
- Apremilast
- Bupivacaine Liposome Injectable Suspension (*Updated Jan. 2015)*
- Droxidopa
- Ezogabine
- Ledipasvir/Sofosbuvir
- Ombitasvir, Paritaprevir/Ritonavir plus Dasabuvir
- Pertuzumab
- Simeprevir *[Updated Nov. 2014]*
- Sulfate Salts and PEG-E
- Vedolizumab

Criteria for Use (CFU)

- Aliskiren *[Updated Nov. 2014]*
- Anticoagulants, Target Specific Oral (TSOACs) CFU and Algorithm for Nonvalvular Atrial Fibrillation *[Updated Dec. 2014]*
- GLP-1 Agonist *[Updated Dec. 2014]*
- Omalizumab in Asthma *[Updated Dec. 2014]*
- Orally Disintegrating Tablets *[Updated Nov. 2015]*
- Ombitasvir, Paritaprevir/Ritonavir plus Dasabuvir
- Rilpivirine
- Rilpivirine coformulated with TDF.FTC
- Simprevir *[Updated Nov. 2014]*
- Sofosbuvir and Ledipasvir/Sofosbuvir
- Ticagrelor *[Updated with 2014 AHA/ACC Guidelines for NSTEMI]*
- Tocilizumab *[Updated Nov. 2014]*

DID YOU KNOW?

The following document(s) were archived:

- Ramipril, Criteria for Non-Formulary Use
- Dihydropyridine Calcium Channel Antagonists, Clinical Recommendations
- Thiazides in Hypertension, Review of Recent Evidence
- Sofosbuvir CFU

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 out! http://www.pbm.va.gov/PBM/ezminutes/current/currentEzMinutes.pdf

Posting of VAMedSAFE Documents Nov 2014-JAN 2015

- Dimethyl Fumarate (Tecfidera) and PML Resulting in Death- [November 7, 2014]
- DAPT Trial and Risk of Non-Cardiovascular Death-[December 17, 2014]—SEE ARTICLE BELOW

Dual Antiplatelet Therapy Trial (DAPT)-Is the Verdict In?

On November 17, 2014 the Food and Drug Administration (FDA) issued a MedWatch Safety Alert regarding The Dual Antiplatelet Therapy (DAPT) trial which was published in the New England Journal of Medicine on November 16, 2014. Click Here to Read the VAMedSAFE National PBM Bulletin

The DAPT Study originated as an international initiative that came in response to a FDA request following the recommendation of a December 2006 Advisory Panel for post-market studies of DES that would yield sufficient data to answer these important public health questions. As a result, unique public-private collaboration to design and conduct the DAPT Study formed amongst the U.S. FDA, stent and thienopyridine manufacturers and the Harvard Clinical Research Institute. The goal of the DAPT Study was to present data from real-world situations.

The DAPT Study

- The trial compared 30 months versus 12 months of treatment with DAPT consisting of ASA plus either clopidogrel or prasugrel, following implantation of drug-eluting coronary stents.
- Two powered co-primary effectiveness endpoints were: 1) definite or probable stent thrombosis (ST, defined by Academic Research Consortium (ARC) at 12-30 months post-procedure, and 2) MACCE (death, MI or stroke) at 12-30 months post-procedure.
- N=25,682 including a large number of diabetic patients, patients with myocardial infarction, and patients with both lower and higher risks of thrombosis.
- Relative reductions of 71% for ST, 29% for MACCE and 53% for MI
- Treatment benefit on ST and MI consistent across drugs, for newer and older stents, and across subjects with higher or lower risk of events
- The benefit of extended DAPT was tempered by an increase in bleeding events (relative increase, 61%). Severe and/or fatal bleeding was uncommon.
- Continued DAPT markedly reduces both stent-related and other ischemic events beyond the stent-treated region in patients who have tolerated one year of DAPT after drug-eluting coronary stent treatment.
- The DAPT trial demonstrated that treatment for 30 months with DAPT decreased the risk of heart attacks and clot formation in stents, but there was an increased overall risk of death compared to 12 months of treatment.
- Excess non-cardiovascular deaths in the 30 month DAPT group were related to bleeding, trauma, and cancer. The findings of increased non-cardiovascular mortality should be weighed with recent reports that non-cardiovascular mortality now contributes to up to 2/3 of patients in real life practice.

Should we be concerned about the findings?

A meta-analysis of all randomized, controlled trials of DAPT treatment duration in various cardiovascular disorders compared results from 14 trials (N= 69,644)

- Continued DAPT treatment, compared with aspirin alone or shorter duration DAPT (≤6 months), was not associated with a difference in all-cause mortality (hazard ratio [HR], 1.05; 95% credible interval [CrI], 0.96-1.19; p = 0.33), cardiovascular mortality (HR, 1.01; 95% CrI, 0.93-1.12; p = 0.81), and noncardiovascular mortality (HR, 1.04; 95% CrI, 0.9-1.26; p = 0.66). A post hoc analysis of patients with coronary artery disease (10 studies) was consistent with results from the full analysis.
- Additionally, there are two other trials conducted in Europe, which have included shorter durations of DAPT with successful results.

The ISAR-Safe trial randomized patients receiving a drug eluting stent (DES) to 6 months of open-label DAPT with ASA and clopidogrel. At 6 months, they were randomized in a 1:1 fashion to an additional 6 months of DAPT or ASA alone. The trial was terminated early due to a lower than anticipated event rate. The primary MACE endpoint was similar between the 6- and 12-month DAPT arms (1.5% vs. 1.6%, p for noninferiority < 0.001). The composite of death, MI, stroke, and stent thrombosis was also similar (1.3% vs. 1.5%, p = 0.59).

The ITALIC trial assessed 6 month versus 24 month DAPT after DES placement. The trial was prematurely terminated due to problems with recruitment but managed to enroll 2031 patients. A composite of death, MI, urgent target vessel revascularization, stroke, and major bleeding at 12 months poststenting showed no significant difference between treatment groups regarding the primary endpoint (1.5 vs. 1.6%, p=0.85). In the 792 (44%) high-risk patients with ACS, primary and secondary endpoints did not significantly differ from the total treatment population.

FDA Recommendations:

- Patients should continue to take these drugs as directed to prevent ischemic events.
- Health care providers should not change the way they prescribe these drugs at this time

Current VA guidance for use of clopidogrel or prasugrel is available at: http://www.pbm.va.gov/clinicalguidance/criteriaforuse.asp

References

Food and Drug Administration. Long-term antiplatelet therapy: Safety announcement. Preliminary trial data shows benefits but a higher risk of non-cardiovascular death. November 16, 2014.

Mauri L, Kereiakes DJ, Yeh RW, et al. Twelve or 30 months of dual antiplatelet therapy after drug-eluting stents. N Engl J Med. 2014 Nov 16. [Epub ahead of print]

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Moussa ID, Simari RD, Gulati R. Trends in cause of death after percutaneous
coronary intervention. Circulation. 2014 Mar 25;129(12):1286-94

Elmariah S, Mauri L, Doros,G; et al. Extended duration dual antiplatelet therapy and mortality: a systematic review and meta-analysis. Lancet 2014; 2014 Nov 16. [Epub ahead of print]

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Gilard G, Barragan P, Noryani AA, et al. ITALIC: 6 versus 24 month DAPT. J Am Coll Cardiol 2014; DOI:10.1016/j.jacc.2014.11.008. Abstract

Submitted by Kathryn Tortorice PharmD, BCPS-National PBM Clinical Pharmacy Program Manager-Neurology and Solid Organ Transplant.

Pharmacy-Prosthetics-Logistics (PPL)* Workgroup

The table below depicts the various products reviewed during **Oct.- Dec. 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+
Bone void fillers (e.g., Stimulant Bone Void Filler Kit, Osteoset Mini Resorbable Bead Kit, bone putty and other similar resorbable bone filler devices) for use in the OR			X
Custom Dental Abutment (dental implants)		X	
Disposable masks	X (outpatients)		X (inpatients or clinic use)
Embolization Interlock Occlusion System		X	
Peritoneal dialysis belt		X (outpatients)	X (inpatients)
Sklar wire cutter			X
Stimulant Bone Void Filler (Calcium sulfate) Kit			X
Therasphere			X
Washable Incontinence Briefs	X (outpatients)		X (inpatients or long term care facilities)

+ 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.

PBM-EDUCATION
NATIONAL PHARMACY BENEFITS MANAGEMENT

2015 Hepatitis C Update
February 17th @ 3 PM ET

Faculty:
Pam Belperio, PharmD, BCPS, AAHIV
Melinda Neuhauser, PharmD, MPH
Timothy R. Morgan, MD

Accredited for: ACPE, ACCME, ACCME-NP, ANCC
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VANTS: 1-800-767-1750 Access Code 49792#

MARK YOUR CALENDAR: PBM 2015 Webinar Schedule

March 17th: VA Stance on the Lipid Guidelines
April 21st: VA National Formulary Prior Authorization Process
May 19th & June 16th: STATS
July 21st & August 18th: Anticoagulation Updates (tentative)
Coming Soon: Updated TMS Basic/Advanced Anticoagulation Programs and Moodle DM Modules with accreditation….and more!

TWO
February Webinars
Just For You!

Back By Popular Demand!!!
Naloxone Kit: What, For Whom, How…(and Why Not?)
February 24, 2015 @ 2 PM ET

Faculty:
Elizabeth M. Oliva, PhD
Francine Goodman, PharmD, BCPS
Robert Sproul, PharmD

Please note: If you attended the webinar and obtained CEUs when it was originally presented in Oct 2014 and then repeated in Dec. 2014, obtaining CEUs will not be possible by attending the February 2015 webinar.

Accreditation: ACPE, ACPE-T, ACCME, ACCME-NP, ASWB, ANCC, APA

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