## Posting of National PBM Documents August – October 2016

### Formulary Decisions

<table>
<thead>
<tr>
<th>ADDED to the VA National Formulary (VANF)</th>
<th>NOT ADDED to the National Formulary (VANF)</th>
<th>Removed from the National Formulary (VANF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Atezolizumab</td>
<td>• Azaelica Acid Topical Foam 15%</td>
<td>• Chlorpromazine Oral Solution (no longer on the market)</td>
</tr>
<tr>
<td>• Botulinum Toxin (one of the agents must be marked formulary, discretion is left to VISN or Facility to determine which agent is restricted to existing CFU)</td>
<td>• Beclohemasone nasal spray</td>
<td>• Darunavir/ritonavir (DHHS Guidelines)</td>
</tr>
<tr>
<td>• Edoxaban-Restricted to CFU</td>
<td>• Buprenorphine buccal film</td>
<td>• Entecavir/tenofovir tablet and capsules</td>
</tr>
<tr>
<td>• Filgrastim-sndz</td>
<td>• Carfilzomib</td>
<td>• Etravirine capsule</td>
</tr>
<tr>
<td>• Uridine Triacetate- [PA-F CFU] pending Rilpirivine/tenofovir</td>
<td>• Carfilzomib</td>
<td>• Fosamprenavir tablet</td>
</tr>
<tr>
<td>• Sacubitril Valsartan-Restricted to PA-F CFU</td>
<td>• Tenofovir alafenamide/emtricitabine</td>
<td>• Fosapenamicol capsule</td>
</tr>
<tr>
<td>• Sofosbuvir/velpatasvir- Restricted to PA-F CFU</td>
<td>• Tenofovir alafenamide/emtricitabine</td>
<td>• Fusidic acid capsule</td>
</tr>
<tr>
<td>• Sugammadex-Limited for use in high risk patients</td>
<td>• Tenofovir alafenamide/emtricitabine</td>
<td>• Fusidic acid ointment</td>
</tr>
<tr>
<td>• Tenofovir alafenamide/emtricitabine-Restricted to pre-exposure HIV prophylaxis (PREP) and Hepatitis B</td>
<td>• Tenofovir alafenamide/emtricitabine</td>
<td>• Fusidic acid ointment</td>
</tr>
</tbody>
</table>

### Abbreviated Review

- Buprenorphine buccal film
- Tenofovir alafenamide/emtricitabine
- Edoxaban

### Clinical Recommendations

- Cost Comparison of HCV Antiviral Regimens by GT (InTRANet only-Updated Aug 2016)
- Naloxone Rescue - Recommendations for Issuing for the VA OEND Program (Updated Aug 2016)
- Sodium Biphosphate/Sodium Phosphate Enemas Safety Considerations (Updated Sept 2016) – SEE Page 3 for more details

### Other Announcements

- Dabigatran remains the preferred DOAC for the nonvalvular atrial fibrillation indication, and rivaroxaban, apixaban, and edoxaban are all second-line alternatives to dabigatran.
- Ganciclovir ophthalmic gel 0.15% - Restriction was expanded to include ophthalmology as well as ophthalmology.
- Tenofovir disoproxil fumarate/emtricitabine—Restricted for PEP and Hepatitis B (i.e. new starts for treatment of HIV should be started on tenofovir alafenamide/emtricitabine unless clinically inappropriate)

### Criteria for Use (CFU)

- Atezolizumab [Updated Aug 2016]
- Alvimopran [Revised Oct 2016]
- Anticoagulants, Direct Oral (DOACs) - CFU and Algorithm for Nonvalvular Atrial Fibrillation - [incorporates edoxaban for AF - Updated Sept 2016]
- Daclatasvir and Sofosbuvir CFU - [Updated Sept 2016]
- Dronedarone Criteria for Use (Rev Aug 2016) - [Revised per 2014 AHA/ACC/HRS Atrial Fibrillation Guideline-Updated Aug 2016]
- Insulin Degludec
- Insulin Glargine 300 units per mL
- Ibrutinib - Revised per 2016 ACC/AHA/ESC Guideline-Updated Aug 2016
- Ledipasvir/Sofosbuvir and Sofosbuvir/velpatasvir - [Updated Aug 2016]
- Lipitor [Updated Aug 2016]
- PCSK9 Inhibitors [Updated Sep 2016]
- Perampanel
- Resluzumab
- Sacubitril Valsartan - [Updated Sept 2016]
- Tacrolimus Based Immune Modulator (IMM Uni) Tablets [Updated Sept 2016]
- Tapentadol Immediate Release (IR) Tablets [Updated Sept 2016]
- Tapentadol Sustained Action (SA) Tablets [Updated Sept 2016]
- Ticagrelor – (SOCRATES added-Updated Aug 2016)

### Archived Documents

- Abbreviated Drug Monograph
  - Fentanyl Transmucosal Immediate-release – added Fentanyl Sublingual Spray [Updated Aug 2016]
  - Filgrastim-sndz
  - Flibanserin
  - Halobetasol Propionate Lotion Cream 0.05%
  - Ixazomib
  - Lebetalol
  - Maraviroc, tipranavir, rilpivirine and etravirine
  - Mifepristone
  - Paliperidone ER
  - Pegvisomant
  - Potassium Chloride (no longer on the market)
  - Prednisone
  - Regorafenib
  - Rilpivirine/tenofovir
  - Ruxolitinib
  - Sibutramine
  - Staufenib
  - Tapentadol IR Tab [Sept 2010]
  - Ticagrelor (Dec. 2015)

- Misc. Documents
  - Naloxone Rescue Kits - Recommendations for Issuing for the VA OEND Program (April 2016)
Liquid Products Recall Due to Potential Risk of Product Contamination | 10/12/16 | National PBM Patient Level Recall Communication
GlucaGen® HypoKit® Recall Due to Needle Detachment from Syringe | 09/14/16 | National PBM Patient Level Recall Communication
Eye Wash/Eye Irrigating Solutions Recall Due to Microbial Contamination | 09/09/16 | National PBM Patient Level Recall Communication
Topical Skin Products Recall Due to Microbial Contamination | 08/29/16 | National PBM Patient Level Recall Communication
Amikacin Recall Due to Particulate Matter in Vials | 08/08/16 | National PBM Patient Level Recall Communication
Bactroban Recall Expansion | 08/04/16 | National PBM Patient Level Recall Communication

**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.

** Per Logistic Management Handbook 7002—absolute alcohol/ethanol will be sold only in original containers. Sales will be confined to the Chief, Pharmacy Service; Chief, Pathology and Laboratory Medicine service (PALMS); and Chief, Research and Development Service; thus absolute alcohol/ethanol will be provided to inpatient areas or clinics by either pharmacy or laboratory service.

+ 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 ever receive questions from Veterans/family members or from CHOICE/fee-basis providers regarding the VA nonformulary medications or the process? Read the FAQ Document for helpful information (Link below) VA Nonformulary Frequently Asked Questions-[InTRANet only]

Do you know the differences between the VA Non-Promotable List, VA Drug Standardization List, and the DoD VHA Transitional Continuity of Care Drug List-[InTRANet only]?

Reviews of these lists were included in previous Ez-Minutes Newsletter. Check it out. (Links below)
Follow-up on Safety Considerations for the Use of Sodium Biphosphate/Sodium Phosphate Enemas

**Background:** In 2013, a National PBM VA Center for Medication Safety (VA MedSAFE) Bulletin outlined safety considerations after a fatality was reported in a patient administered several doses of sodium biphosphate/sodium phosphate enemas in < 12 hours for severe constipation.

In the VA, sodium biphosphate/sodium phosphate enema is available for bowel preparation prior to a procedure or for intermittent management of constipation. However, use of sodium biphosphate/sodium phosphate enema is not without concern. Reports of severe adverse events (AE) resulting in severe electrolyte imbalance, dehydration and hypovolemia, tetany, QT prolongation, seizures, coma, and death have been reported. An increased risk for severe AEs or mortality may be associated with GI disorders causing increased retention of enema contents in the gut; in addition, risks also include chronic renal failure, advanced age, and number of doses administered exceeding one within 24 hours. Contraindications and Precautions for sodium biphosphate/sodium phosphate enema are noted below:

### Contraindications
- Do not use for constipation in patients aged ≥ 70 years
- Congestive heart failure
- With clinically significant impairment of renal function (eGFR < 30 ml/min)
- With known or suspected gastrointestinal obstruction
- With megacolon (congenital or acquired)
- Paralytic ileus
- Perforation
- Active inflammatory bowel disease
- Imperforate anus
- Dehydration
- Generally, in cases of increased absorption capacity or decreased elimination
- Hypersensitivity to any product ingredients

### Precautions
- Use with caution in patients:
  - With impaired renal function (eGFR 30 to 60 ml/min) or other comorbidities, such as gastrointestinal (including dysmotility, colonostomy), hepatic (including ascites), neurologic, cancer, pulmonary or cardiovascular disorders
  - Taking medications known to affect renal perfusion or function, or hydration status
  - With pre-existing electrolyte disturbances or who are taking diuretics or other medications which may affect electrolyte levels
  - Taking medications known to prolong the QT interval
  - 55 years of age or older
  - Who are pregnant or nursing a baby
  - With conditions that may predispose to dehydration or those taking medications that may decrease glomerular filtration rate, such as diuretics, angiotensin-converting enzyme inhibitors (ACEIs), angiotensin II receptor antagonists (ARBs), or nonsteroidal anti-inflammatory drugs (NSAIDs), should be assessed for hydration status prior to use and managed appropriately

### Data Evaluation
In FY2015, PBM VA MedSAFE performed a database inquiry on the use of sodium biphosphate/sodium phosphate enemas in patients believed to be at risk for a severe adverse event due to chronic kidney disease as well as other risk factors and a considerable number of patients prescribed sodium biphosphate/sodium phosphate enemas at high risk for safety concerns were noted. Of the ~30,000 patients prescribed a sodium biphosphate/sodium phosphate enema: > 8% had a diagnosis of chronic kidney disease; > 6% had chronic kidney disease and were 65 years of age or older; > 6% had chronic kidney disease and were prescribed an ACEI, ARB, or diuretic; and ~ 5% were noted to have all these risk factors.

### Safety Considerations for Dosage and Administration
- Administration of more than one enema in 24 hours, particularly in patients with constipation, risk factors for electrolyte disturbances and comorbidities, can be harmful and has resulted in death.
- Constipation: Use of sodium biphosphate/sodium phosphate enemas for chronic management of constipation is not recommended. Sodium biphosphate/sodium phosphate enemas should also not be used as first-line treatment of constipation. If a patient has contraindications or risk factors for electrolyte abnormalities or renal injury, avoid the use of sodium biphosphate/sodium phosphate enemas and use alternative laxatives (e.g., consider using warm water enemas or mineral oil enemas, following disimpaction). If a sodium biphosphate/sodium phosphate enema is used for severe constipation, it is recommended that no more than one dose be administered per 24 hour period, for no more than 3 consecutive days.
- Perioperative bowel cleansing: Not more than two sodium biphosphate/sodium phosphate enemas (one on the day prior and one the day of surgery) if no contraindications or risk factors for electrolyte abnormalities or renal injury. Sodium phosphate products (oral or enema) are not recommended in patients with eGFR < 60 ml/min (2014 guideline Optimizing Adequacy of Bowel Cleansing for Colonoscopy: Recommendations from the US Multi-society Task Force on Colorectal Cancer), in older patients, in patients with contraindications or risk factors for electrolyte abnormalities or renal injury, or in patients with known or suspected inflammatory bowel disease. Sodium phosphate is not a first-line bowel cleansing preparation. Use bowel cleansing regimens and practices concordant with evidence-based guidelines (2014 guideline Optimizing Adequacy of Bowel Cleansing for Colonoscopy: Recommendations from the US Multi-society Task Force on Colorectal Cancer and the 2015 guideline Bowel Preparation Before Colonoscopy by the American Society for Gastrointestinal Endoscopy).

**Recommended Follow-up and Intervention**
- VISNs/VAMCs are encouraged to review utilization of sodium biphosphate/sodium phosphate enemas to ensure appropriate number of doses and length of therapy (Refer to Dosage and Administration per above), and avoidance in patients at increased risk for a severe adverse event as per the Safety Considerations (Contraindications and Precautions noted above).
- Develop potential interventions at the point of prescribing to alert providers of patients at increased risk for an adverse outcome (e.g., "sodium biphosphate/sodium phosphate enema contraindicated when eGFR < 30 ml/min; reconsider if eGFR 30 to 60 ml/min, especially if additional risk factors for harm.")
- Safety Considerations updated to include precaution in patients ≥ 55 years of age as per the manufacturer’s prescribing information and the FDA Drug Safety Communication.
- Links added to the VA National Formulary to alert providers of the available safety documents for the sodium phosphate products.
- National utilization of sodium biphosphate/sodium phosphate enemas in patients with risk factors for adverse events to be re-evaluated in 6 to 12 months.

*Article Submitted by: Elaine Furmaga, PharmD National PBM Clinical Pharmacy Program Managers-PBM Formulary Management
Editor’s Note: Please note: The original article was abbreviated slightly due to space constraint.*
ON THE ROAD AGAIN…….

Goin' places that I've never been  
Seemin' things that I may never see again 
On the Road Again….  

It is difficult for the PBM Emergency Pharmacy Service (EPS) staff to sing Willie Nelson’s famous song, “On The Road Again” because in reality, what that means is that somewhere in the country a major disaster or emergency has happened……and this year, it was a hurricane named Matthew. Numerous states in the path of Hurricane Matthew were affected including Florida, South Carolina, Georgia, and North Carolina….and many Veterans and VA employees were impacted by the life-threatening storm surge, torrential rainfall, and power outages delivered by this devastating storm.

In response, the VA Emergency Pharmacy Services deployed two Mobile Pharmacy vehicles like the one pictured above. These vehicles function as an outpatient pharmacy on wheels and provide care to Veterans, VA staff, as well as civilians responding to, involved in, or otherwise affected by a disaster or emergency. These self-contained vehicles are capable of delivering life-saving pharmaceuticals and medical supplies for urgent and life threatening conditions until other resources are available in the immediate area. The unofficial count from the recent deployment includes the following: >200 Rxs were dispensed and >85 Veterans were served. After being deployed for almost 3 weeks, the EPS staff and numerous VA pharmacist and pharmacy technician volunteers while pulling away from the site were heard singing a different song……and that was John Denver’s song, “Take Me Home, Country Roads.” Oh, and one more thing….Rumor has it that the staff driving the Mobile Pharmacy Vehicle sighted on the road a little yellow convertible. (See picture below) Wonder who was driving? BEEP!!! BEEP!!!

Editor’s Note: Many areas affected by Hurricane Matthew are still recovering and will be for some time. No words can adequately express what residents in the affected areas have experienced from the impact of this powerful storm. The PBM-MAP-VPE acknowledges the support and assistance from you in extending hope and support to our colleagues and Veterans in these devastated areas. Please continue!

2016 Pharmacy Workforce Assessment-Now Available

In conjunction with the VHA Office of Quality, Safety and Value’s Product Effectiveness Program Office, the Pharmacy Benefits Management Office is conducting a following-up assessment to the 2014 baseline workforce study. This assessment (which includes a Needs Assessment) is only for VHA Pharmacy Services Staff and is available through November 30th, 2016. Thank you for your participation in the 2014 assessment. As a result of your responses in 2014, many interventions were done. (More details will be shared during the December 2016 PBM Webinar-see below). Be sure to ask your Chief of Pharmacy for more details and the link to this assessment. Your vote counts this month!!!

PBM-MAP-VPE Webinars: 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. 
VANTS: 1-800-767-1750 Access Code 49792#  
All webinars are ACPE, ACPE-T, ACCME, ACCME-NP accredited.

November 2016 Webinar: NO WEBINAR

December 20th, 2016 Webinar Topic: Review Outcomes from the FY16 PBM-EdAC Sponsored Programs AND FY17 PBM Webinar Schedule including the PBM Board Certification Study Groups and the PBM-PHS BCPS/BCACP/BCPP Webinar Schedule. Please note: Since December’s webinar content is informational in nature, no accreditation will be offered.