Objectives

• Describe the key functions of the VA Pharmacy Benefits Management Services (PBM)

• Describe the key objectives of the VA Formulary Management Process

• Understand how drugs are added to the VA National Formulary

• Discuss movement disorder medications and VA pharmacy resources for movement disorder management
Key PBM Functions

• HQ Washington, DC
  – Drug benefit design
  – Pharmacy policy development and deployment
    • Formulary management process handbook
  – Stakeholder relations
    • Congress, advocacy groups, etc.
  – Professional pharmacy practice development
    • Pharmacy residency program
Key PBM Functions

- **CMOP**
  - Centralized prescription processing

- **Hines, Illinois**
  - Emergency Pharmacy Services
    - Drug caches, mobile pharmacy

- **VAMedSAFE**
  - Patient safety
    - ADE reporting and analysis, post-marketing surveillance
  - Utilization management
    - Outcomes assessment, national drug use evaluations
Key PBM Functions

– PBM Office (Formulary Management)
  • Evidence-based medicine
    – Clinical reviews, clinical algorithm and guideline development, pharmaceutical contracting
  • DoD collaboration
    – clinical practice guideline development, pharmaceutical contracting
  • Education
    – Staff CE/CME programs
  • Data management
    – PPV purchases and prescription data
  • Administration of Public Law 102–585
    – Federal drug pricing
Formulary Management
Key Objectives of the Formulary Process

• Promote formulary decisions that are evidenced-based, not preference-based
• Promote appropriate drug therapy and discourage inappropriate drug therapy
• Reduce the geographic variability in utilization of pharmaceuticals across the VHA
• Promote portability and uniformity of the drug benefit
• Promote patient safety through safe prescribing
• Design and implement relevant outcomes assessment projects
Formulary Mgt Infrastructure

- Office of the Under Secretary for Health
- VA Medical Advisory Panel
- VISN Pharmacist Executives Committee
- VA Clinical Subject Matter Experts
- VA Pharmacy Benefits Management (PBM)
- Regional (VISN) P&T Committees
- Local (VAMC) P&T Committees
- Procurement / Acquisition Staff
VA National “P&T” Committee

• Medical Advisory Panel (MAP)
  – 14 physicians (1 DoD)
  – 10 PBM Clinical Pharmacists
  – 1 VPE member

• VISN Pharmacist Executives Committee (VPE)
  – 21 pharmacists
  – 1 MAP member

• Meetings
  – Monthly conference calls
  – Face-to-Face quarterly meetings
  – 2 Face-to-Face quarterly meetings are combined
How the National PBM Supports the VANF, Providers, and Patients

Clinical Document Development
1. New Molecular Entity Drug Monographs (NMEs)
2. Abbreviated NME Reviews
3. Drug Class Reviews
4. Criteria for Use (CFU)
5. Recommendations for Use
6. Guidance and White Papers
7. Clinical Practice Guidelines (CPGs)
New Molecular Entity (NME) Drug Monographs

• Reviews efficacy, safety, cost, and other data of NMEs
  – “A medication containing an active substance that has never before been approved for marketing in any form in the United States”
  – Includes drug and biologic products
  – Abbreviated review for new dosage form or VANF addition request

• Involves an extensive literature review and evidence-based medicine approach

• Assesses the evidence and clinical significance

• Evaluate NME’s place in therapy

• Supports criteria for use decisions
Criteria for Use

• Outlines appropriate place in therapy for most patients
• Uses clinical trial results (drug monograph) and expert / field opinions to determine appropriateness
• Consists of
  – Exclusion and inclusion criteria checklists
  – Issues for consideration [optional]
  – Dosage and administration [optional]
  – Renewal criteria [optional]
• Discourages inappropriate use
• Encourages safe and cost–effective use
• Aims to provide uniform pharmacy benefit
Drug Class Reviews

• Are similar to NME monographs
• Uses evidence-based evaluation to determine
  – Therapeutic interchangeability
  – Eligibility for competitive solicitation
• Compares data for efficacy, safety, tolerability, monitoring, drug interactions, drug administration, cost, and other pharmaceutical issues
Most scientists regarded the new streamlined peer-review process as ‘quite an improvement.’
Peer Review Process for Documents

• Review of document by multiple disciplines as deemed appropriate:
  – Medical Advisor and/or subject matter experts
  – MAP Committee
  – VISN Pharmacist Executives (VPEs) Committee
  – VPE Operational Advisors Group

• Presentation to both MAP and VPE Committees for approval of the document (Note: NME does not require initial approval prior to field review)

• Suggestions/comments/changes from the above individual(s) and/or groups are incorporated into the document
Peer Review Process for Documents

NME Monographs, Drug Class Reviews, and CFU
(Note: Abbreviated reviews are not disseminated to field for review)

- Sent to VPEs for dissemination
  - VISN and local P&T Committees
  - Pharmacy Chiefs
  - Chief Medical Officers
  - Local subject matter experts

- Field Advisory Committees (FACs) or Technical Advisory Groups (TAGs)

- VHA Chief Consultants
Peer Review Process for Documents

Disclosure of Financial or Other Relationship

– Requested with comments on Drug Class Reviews for national contracting
– Requested of field reviewers on NME and CFU documents
– Committee Chair determines if comments submitted without information on potential financial or other relevant relationships will be considered
National PBM Supports Implementation of Formulary Change

- Announcement of National Formulary changes in PBM–MAP E\textsubscript{2} Minutes
- Formulary Changes are posted on PBM Web site
- Letters to prescribers and patients
- Addition of drug–drug interactions to the NDF
- ADE reporting and monitoring
VAMedSAFE Pharmacovigilance
(Rapid Cycle Evaluations and Risk Reduction)

• Pharmacovigilance/Post-Marketing Surveillance
  – Evaluate known or suspected Adverse Drug Event (ADE) signals
  – Link results of safety event analyses to formulary activities and medication use within VA

• Risk Reduction/Mitigation
  – Intervene on known ADE risks to improve safe prescribing practices and medication use
VA Center for Medication Safety - A Patient Safety Center

BULLETINS AND NEWS ALERTS

<table>
<thead>
<tr>
<th>Safety Issue</th>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lo/Ovral-28 and Norgestrel/Ethyl Estradiol Tablets - Recall for Inexact Tablet Counts or Out of Sequence Tablets</td>
<td>02/03/2012</td>
<td>National</td>
</tr>
<tr>
<td>Aliskiren: Adverse Drug Events When Concomitantly Used with ACE Inhibitors or ARBs in Patients with Type II DM</td>
<td>01/13/2012</td>
<td>National</td>
</tr>
<tr>
<td>Dronedarone and Cardiovascular Events in Permanent Atrial Fibrillation</td>
<td>01/10/2012</td>
<td>National</td>
</tr>
<tr>
<td>Target Dose of Angiotensin II Receptor Antagonists in Patients with Heart Failure</td>
<td>10/31/2011</td>
<td>National</td>
</tr>
<tr>
<td>Citalopram Hydrobromide (Celexa®) and Dose-Dependent QT Interval Prolongation: UPDATE</td>
<td>09/29/2011</td>
<td>National</td>
</tr>
<tr>
<td>Oral Contraceptives and Packaging Error Recall</td>
<td>09/21/2011</td>
<td>National</td>
</tr>
<tr>
<td>Citalopram Hydrobromide (Celexa®) and Dose-Dependent QT Interval Prolongation</td>
<td>08/31/2011</td>
<td>National</td>
</tr>
</tbody>
</table>
Where do I find all these documents?

VAWW.PBM.VA.GOV
Welcome!

Notice to Beneficiaries of the Veterans Health Administration: For questions pertaining to Health Care Benefits, please visit http://www.va.gov/Health_Benefits/. For questions pertaining to prescription renewal, please visit http://www.myhealth.va.gov/. Questions pertaining to your drug therapy or other medical questions should be referred directly to your Health Care Providers located at the VA facilities where you receive care.

Mission: To improve the health status of veterans by encouraging the appropriate use of medications in a comprehensive medical care setting.

If you have a clinical question pertaining to the content on this website or about PBM activities, please contact Ask PBM Clinical.

If you have a question pertaining to this website and only things contained in this website, please contact the PBM Webmaster.

What's New At PBM?

<table>
<thead>
<tr>
<th>Modified</th>
<th>URL</th>
<th>Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/2/2012 7:57 AM</td>
<td>Transgender Care, FtM Cross-Sex Hormone Therapy Criteria for Use</td>
<td>Clinical Guidance, Criteria for Use</td>
</tr>
<tr>
<td>3/2/2012 7:54 AM</td>
<td>Transgender Care, MTF Cross-Sex Hormone Therapy Criteria for Use</td>
<td>Clinical Guidance, Criteria for Use</td>
</tr>
<tr>
<td>3/2/2012 7:50 AM</td>
<td>Transgender Care, Cross-Sex Hormone Therapy</td>
<td>Clinical Guidance, Clinical Recommendations</td>
</tr>
<tr>
<td>3/1/2012 8:02 AM</td>
<td>Vilazodone Monograph</td>
<td>Monograph</td>
</tr>
<tr>
<td>3/1/2012 7:38 AM</td>
<td>GLP-1 agonists, Criteria for Use</td>
<td>Criteria for Use</td>
</tr>
<tr>
<td>3/1/2012 7:03 AM</td>
<td>Metoclopramide ODT (Metozolv) Abbreviated Review</td>
<td>Clinical Guidance / Abbreviated Reviews</td>
</tr>
<tr>
<td>2/29/2012 11:38 AM</td>
<td>Statin Criteria for Use (Fluvia-Prava-Atorva-Rosuva-Pitava) (2-12)</td>
<td>Clinical Guidance, Criteria for Use</td>
</tr>
<tr>
<td>2/29/2012 11:35 AM</td>
<td>Pitavastatin (Livalo) Drug Monograph</td>
<td>Clinical Guidance, Drug Monograph</td>
</tr>
<tr>
<td>2/29/2012 11:32 AM</td>
<td>Centruroides (Scorpion) Immune F(ab')2 (Equine) Drug Monograph</td>
<td>Clinical Guidance, Drug Monograph</td>
</tr>
<tr>
<td>2/27/2012 11:39 AM</td>
<td>Fidaxomicin Monograph</td>
<td>Clinical Guidance, Drug Monograph</td>
</tr>
<tr>
<td>2/27/2012 11:37 AM</td>
<td>Fidaxomicin CFU</td>
<td>Clinical Guidance, Criteria for Use</td>
</tr>
<tr>
<td>2/27/2012 10:54 AM</td>
<td>Asparaginase Erwinia chrysanthemi, Abbreviated Drug Review</td>
<td>Clinical Guidance, Abbreviated Drug Review</td>
</tr>
<tr>
<td>2/27/2012 7:41 AM</td>
<td>Aliskiren, Criteria for Use</td>
<td>Clinical Guidance, Criteria for Use</td>
</tr>
<tr>
<td>2/27/2012 12:53 PM</td>
<td>Belimyam Drug Monograph</td>
<td>Clinical Guidance, Drug Monograph</td>
</tr>
</tbody>
</table>
Regadenoson, Drug Monograph
Rilipivirine and co-formulated rilipivirine with TDF-FTC monograph
Riluzole
Roflamilast monograph
Romiprost (Nplate) Drug Monograph
Rufinamide (Banzel) Drug Monograph
Saxagliptin monograph
Sertaconazole
Sinecatechins
Sipuleul-T Drug Monograph
Sitagliptin
Sorafenib in Hepatocellular Carcinoma, Addendum
Sorafenib, Monograph
Spinocad Monograph
Sunitinib
Tapentadol IR (Nucynta) Monograph
Telaprevir Monograph
Telavancin
Tesamorelin
Tetrapenazine
Thrombin, Topical (Thrombin JMI, Evithrom, Recothrom) Drug Monograph-Final (December 2008)
Tocilizumab Drug Monograph
Tolvaptan Drug Monograph
Treprostinil INHALATION Drug Monograph
Ustekinumab (Stelara) NMEM
Varenicline
Vilazodone Monograph
Treatment of Parkinson’s Disease

VHA Pharmacy Benefits Management Services, Medical Advisory Panel and VISN Pharmacist Executive
February 2012

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient. Individual cases that are outside the recommendations should be adjudicated at the local facility according to the policy and procedures of its P&T Committee and Pharmacy Services.

Parkinson’s Disease (PD) presents therapeutic challenges for providers. Several of the commonly used agents have significant adverse effect profiles and prove challenging for patients to be compliant with. Additionally, the area of neuroprotective agents is developing as a treatment focus and should be considered for newly diagnosed patients. As patients move thru the spectrum of impairment, other agents may be added to therapy to maintain an optimal levodopa response.

Guidelines from the American Academy of Neurology and the European Federation of neurological Societies along with recent clinical trials support the following points in regards to optimal PD therapy.

- Selection of initial therapy, management of dosing and use of adjunct therapies is necessary to provide optimal outcomes and minimize adverse event profiles.
- The initiation of pharmacotherapy can vary but is frequently reserved till functional impairment symptoms begin to interfere with daily life. Recent evidence concerning neuroprotection has demonstrated a benefit with early versus delayed start monotherapy in PD for some patients.
- Monotherapy with amantadine, monoamine oxidase type B (MAO-B) inhibitor or a dopamine agonist (DA) in the early stages of disease may result in less motor complications.
- Rasagline offers advantages over the first-generation MAO-B inhibitor selegiline in its lack of tyramine reactions and lack of amphetamine related adverse effects.
- Levodopa is the most effective therapy for treating PD symptoms. Its use is complicated by the development of motor dyskinesias after 3-5 years of therapy.
- MAO-B inhibitors and catechol-O-methyl-transferase inhibitors (COMT) are effective at decreasing the motor fluctuations seen in patients treated with levodopa/cARBIDopa.
- COMT inhibitors prolong the action of levodopa and allow for a dose reduction which can aid in reducing motor fluctuations.
- Neostigmine in combination with levodopa/carbidopa is the most effective DA agonist. DA agonists can be considered for treatment when levodopa/carbidopa is no longer effective.
Patient recently diagnosed with Parkinson's Disease

No functional disability

- Monitor for motor impairment
- Bradykinesia, rigidity (moderate/severe functional impairment)
  - Physiologic age < 75 yrs
    - Dopamine agonist
    - MAO-B inhibitor
  - Physiologic age > 75 yrs and presence of cognitive impairment
    - Levodopa/carbidopa

Functional Disability

- Tremor predominant (mild impairment)
  - Anticholinergics
    - Amantadine
    - Side effect profile of anticholinergics may limit therapy

Development of peak dose dyskinesias
- Reduce levodopa dose and add dopamine agonist
Process for VANF Addition/Removal

• Formal requests require completion of form by requesting person or committee
  – Form available on PBM website
  – Requests may be made by VISN P&T, VPE, MAP, Chief Consultant, CMO
  – Requires evidence for efficacy and safety in comparison to existing formulary alternatives

• Informal requests
  – VPEs may present a request or idea to the group before submitting a formal request form to get preliminary feedback, gauge interest, etc.
<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>National Drug File Support Group Guidelines</td>
</tr>
<tr>
<td></td>
<td>Request For Formulary Review</td>
</tr>
<tr>
<td></td>
<td>Request for Formulary Review (Local Use Only)</td>
</tr>
<tr>
<td></td>
<td>Request for removal of drug from VA National Formulary</td>
</tr>
<tr>
<td></td>
<td>VA National Formulary Frequently Asked Questions</td>
</tr>
</tbody>
</table>
Keeping up with changes
PBM–MAP–VPE Educational Programs

- Web-based LMS Anticoagulation Basic and Advanced Modules
- Osteoporosis in Male Veterans Broadcast Programs
- Live-Meeting VAADERs Program
Pharmacy Benefits Management - Medical Advisory Panel - VISN Pharmacist Executives Ez-Minutes


The purpose of the PBM-MAP-VPE Ez-Minutes Newsletter is to communicate with the field on items that will impact clinical practice in the VA. Whether it be changes to the National Formulary, availability of new Ontario for use, or recent medication safety issues. We want clinicians to be informed and be the first to know about all updates and changes because it will impact the end users... i.e., the Veterans who have the privilege of serving. Speaking of changes you may have noticed with the previous issue, that you never received an automatic notice informing you that the Ez-Minutes Newsletter was now available. Subscribing to the PBM-MAP-VPE Ez-Minutes and the electronic notification will no longer be offered. We believe our 15K+ "followers" of Ez-Minutes is sufficient to keep the lines open between the field and the PBM-MAP-VPE Committee. The Ez-Minutes Newsletter will continue to be posted on the PBM Internet and Intranet websites. Notification of the availability of Ez-Minutes Newsletter will be done electronically via multiple internal listserv owners. Of course, we are depending on you to continue to spread the word, forward the newsletter to your colleagues, P&T committee members, and CMOs etc. Each issue will include the date when the next issue will be released so you will know in advance when to expect the next issue of Ez-Minutes.

Editor's Note: This newsletter is in a HTML format. A printer-friendly version throughout the system is more likely to occur with a PDF format compared to a word document. Users should select print preview and review the document, then make any necessary changes to the document before printing to ensure the document will print fine for their hardware configuration. As further updates to the newsletter continue, we welcome any feedback and comments. Send comments directly to Janet.Dalley@va.gov with Ez-Minutes in the subject line.

INSIDE THIS ISSUE
- National PBM Documents Posted: Nov 11-Jan 12
- VAMedSAFE Documents posted: Nov 11-Jan 12
- Anticoagulation in Women Veterans
- Effect of Concomitant Use of Cloniprodigrel and PPI after PCI...again??
- PBM-D Formular
- National PBM Documents Posted: Nov 11-Jan 12
- VAMedSAFE Documents posted: Nov 11-Jan 12
- Anticoagulation in Women Veterans
- Effect of Concomitant Use of Cloniprodigrel and PPI after PCI...again??
- PBM-D Formular

Posting of National PBM Documents Nov 11- Jan 12

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>- Clindamycin Lotion</td>
<td>- Atraseron</td>
<td>- Nutrition Supl. Eunice</td>
</tr>
<tr>
<td>- Mesalamine Enema</td>
<td>- Azathioprine</td>
<td>- Nutrition Supl. Jevity (1.0 Cal)</td>
</tr>
<tr>
<td>- Nutrition Supl Boost Plus Vanilla (OTC)</td>
<td>- Donepezil</td>
<td>- Nutrition Supl. Osmolite (1.0 Cal)</td>
</tr>
<tr>
<td>- Nutrition Supl Jevity (1.2 Cal, 1.5 Cal)</td>
<td></td>
<td>- Thyroxine Soln, Cap, Tab, EC</td>
</tr>
<tr>
<td>- Nutrition Supl Osmolite (1.2 Cal)</td>
<td></td>
<td>(existing patients use &quot;grandfathered&quot;)</td>
</tr>
<tr>
<td>- Sildenafl</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Clinical Recommendations

- Anticoagulation, Special Considerations for Warfarin
- Beta-Blockers

Criteria For Use

- GI Ulcers
- Hypertension

Abbreviated Drug Monograph

- Aliskiren/Amlodipine
On-line quarterly Newsletter
To subscribe:
Send e-mail to stxcollage@va.gov
with “PBM subscribe” in the subject line.
National Formulary
**National Formulary**

- National Drug File Support Group Guidelines
- Request For Formulary Review
- Request for Formulary Review (Local Use Only)
- Request for removal of drug from VA National Formulary
- VA National Formulary Frequently Asked Questions
<table>
<thead>
<tr>
<th>VA Class</th>
<th>Generic</th>
<th>Dosage Form</th>
<th>Restriction</th>
<th>Special Handling</th>
</tr>
</thead>
<tbody>
<tr>
<td>CN500</td>
<td>APOMORPHINE</td>
<td>INJ,SOLN</td>
<td>Restricted to neurology for treatment of acute hypomobility episode of advanced Parkinson's disease.</td>
<td></td>
</tr>
<tr>
<td>CN500</td>
<td>CARBIDOPA /LEVODOPA</td>
<td>TAB,SA</td>
<td>criteria</td>
<td></td>
</tr>
<tr>
<td>CN500</td>
<td>CARBIDOPA/LEVODOPA</td>
<td>TAB</td>
<td>criteria</td>
<td></td>
</tr>
<tr>
<td>CN500</td>
<td>ENTACAPONE</td>
<td>TAB</td>
<td>Neurologist treating Parkinson</td>
<td></td>
</tr>
<tr>
<td>CN500</td>
<td>RASAGILINE</td>
<td>TAB</td>
<td>Restricted to neurology, movement disorder specialist</td>
<td>Monograph</td>
</tr>
<tr>
<td>CN500</td>
<td>ROPINIROLE</td>
<td>TAB</td>
<td>criteria</td>
<td></td>
</tr>
<tr>
<td>CN500</td>
<td>SELEGILINE HCL</td>
<td>CAP OR TAB</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## VANF agents for spasticity

<table>
<thead>
<tr>
<th>VA Class</th>
<th>Generic</th>
<th>Dosage Form</th>
<th>Restriction</th>
</tr>
</thead>
<tbody>
<tr>
<td>MS200</td>
<td>BACLOFEN</td>
<td>INJ</td>
<td></td>
</tr>
<tr>
<td>MS200</td>
<td>BACLOFEN</td>
<td>TAB</td>
<td></td>
</tr>
<tr>
<td>MS200</td>
<td>CYCLOBENZAPRINE</td>
<td>TAB</td>
<td></td>
</tr>
<tr>
<td>MS200</td>
<td>DANTROLENE</td>
<td>CAP,ORAL</td>
<td>Restricted to spinal cord injury, neurology, and rehabilitation</td>
</tr>
<tr>
<td>MS200</td>
<td>DANTROLENE</td>
<td>INJ,SOLN</td>
<td>Restricted to spinal cord injury, neurology, and rehabilitation</td>
</tr>
<tr>
<td>MS200</td>
<td>METHOCARBAMOL</td>
<td>TAB</td>
<td></td>
</tr>
<tr>
<td>MS200</td>
<td>TIZANIDINE</td>
<td>TAB</td>
<td>Restricted to spinal cord injury, neurology, rehabilitation, pain management specialists, and traumatic brain injury clinics</td>
</tr>
</tbody>
</table>
Questions

VHAPBH Ask PBM Clinical
AskPBMClinical@va.gov
Summary

• Formulary management
• Vetting of documents
• Announcement of decisions
• Where can I ask questions
• What type of documents are on the PBM website