#### **Pharmacy Benefits Management Services**

# National VHA Pharmacy Considerations and Medications for Movement Disorders

PADRECC EES Presentation May 10, 2012

Kathryn Tortorice Pharm D, BCPS



## 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 evidencedbased, 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

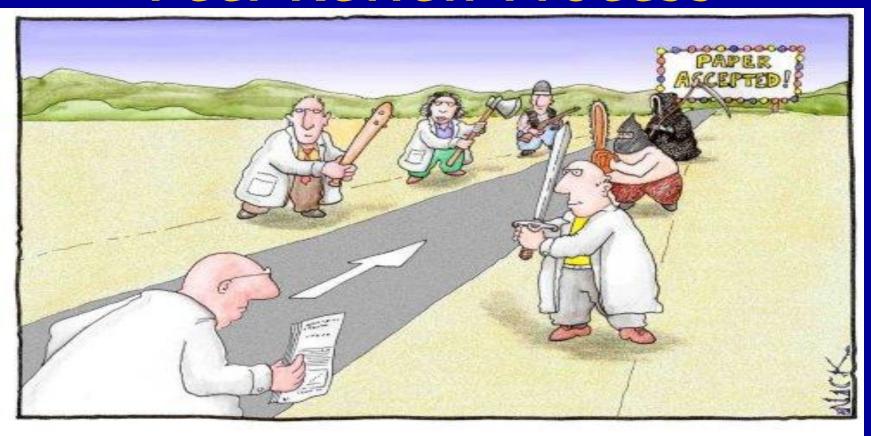
#### Criteria for Use

- 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

## Peer Review Process



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<sub>z</sub> 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

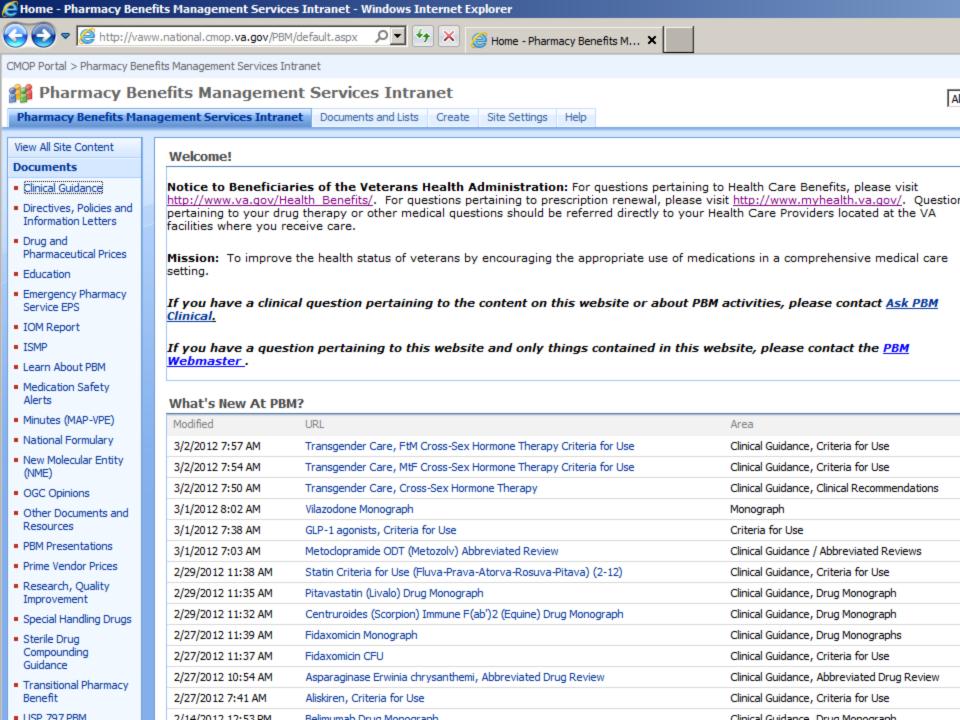
(Rapid Cycle Evaluations and Risk Reduction)

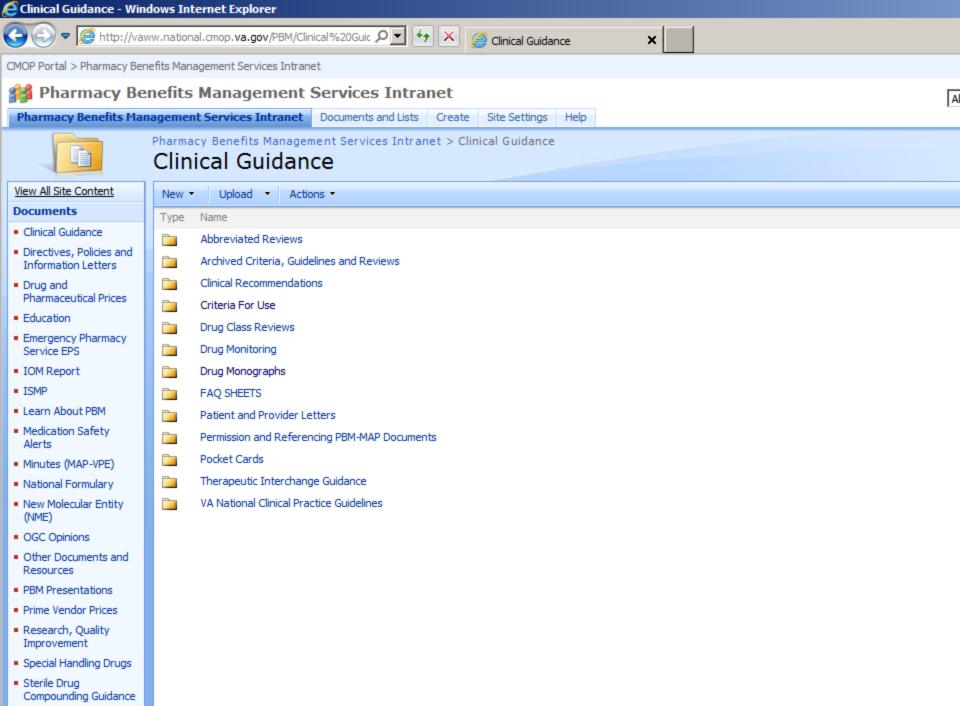
- Pharmacovigilance/Post-Marketing Surveillance
  - Evaluate known or suspected Adverse Drug Event (ADE) signals
  - Link results of safety event analyses to formulary activities and medication use within VA
- Risk Reduction/Mitigation
  - Intervene on known ADE risks to improve safe prescribing practices and medication use



# Where do I find all these documents?

VAWW.PBM.VA.GOV





Transitional Pharmacy

#### 🌈 Clinical Guidance - Windows Internet Explorer 🧧 http://vaww.national.cmop.va.gov/PBM/Clinical%20Guidance/Forms/AllItems.aspx?Paged=TRUE&p\_FSObjType=0&p\_FileLeafRef=Nelarabine%2epdf&p\_ID=736&View=%7b78 Edit View Favorites Tools Help Sor Professionals - PADRECC... M Pharmacists - Medscape Clinical Guidance Х CT Thrombocyte Activity Reasse... Compounding Guidance W Regadenoson, Drug Monograph Transitional Pharmacy Rilpivirine and co-formulated rilpivirine with TDF-FTC monograph Benefit W Riluzole USP 797 PBM Compounded Sterile e) Roflumilast monograph Preparations W Workgroup Romiplostim (Nplate) Drug Monograph VA Center for W Rufinamide(Banzel) Drug Monograph Medication Safety **(19)** Saxagliptin monograph VAMedSAFE Project Results (Select) Sertaconazole Workload and Billing Sinecatechins Process Sipuleucel-T Drug Monograph Publications by VA **Pharmacists** 人 Sitagliptin Chief of Pharmacy W Sorafenib in Hepatocellular Carcinoma, Addendum Meeting Minutes w Sorafenib, Monograph **Pictures (19)** Spinosad Monograph 2009 USH National 人 Sunitinib Pharmacy Award Photo Gallery Tapentadol IR (Nucynta) Monograph 2010 USH National W Telaprevir Monograph Pharmacy Award Photo Gallery W Telavancin Lists Tesamorelin Links Tetrabenazine W VA Pharmacy Phone Thrombin, Topical (Thrombin JMI, Evithrom, Recothrom) Drug Monograph-Final (December 2008) Directory Tocilizumab Drug Monograph Pharmacy Recruitment W and Retention Office Tolvaptan Drug Monograph (PRRO) Treprostinil INHALATION Drug Monograph Albumin Survey 2011 P) Ustekinumab (Stelara) NMEM

C IIs Stock

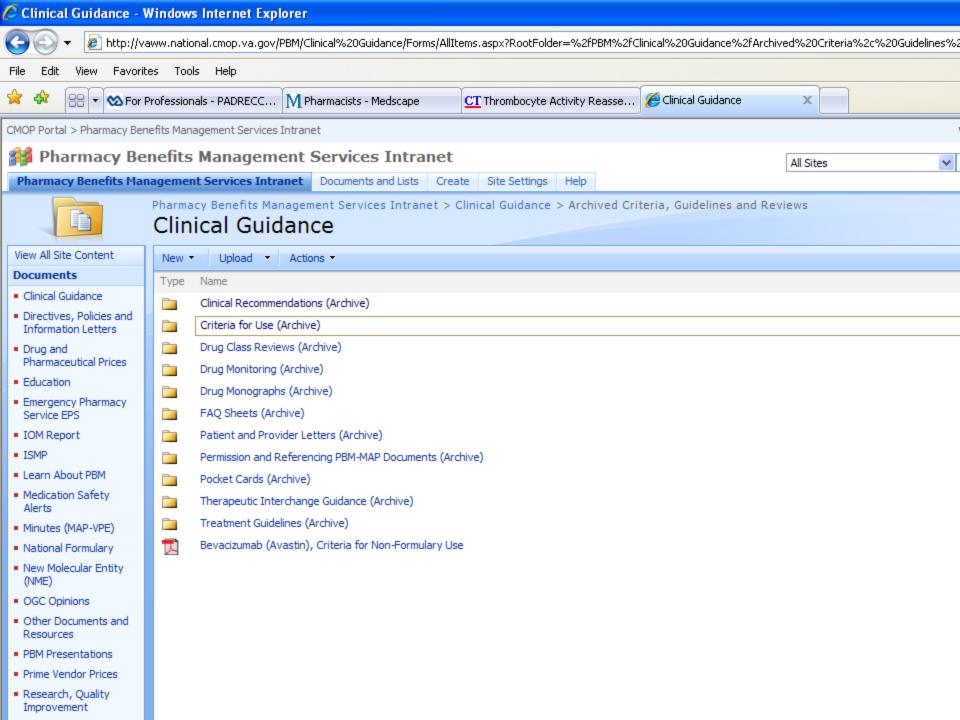
Discussions

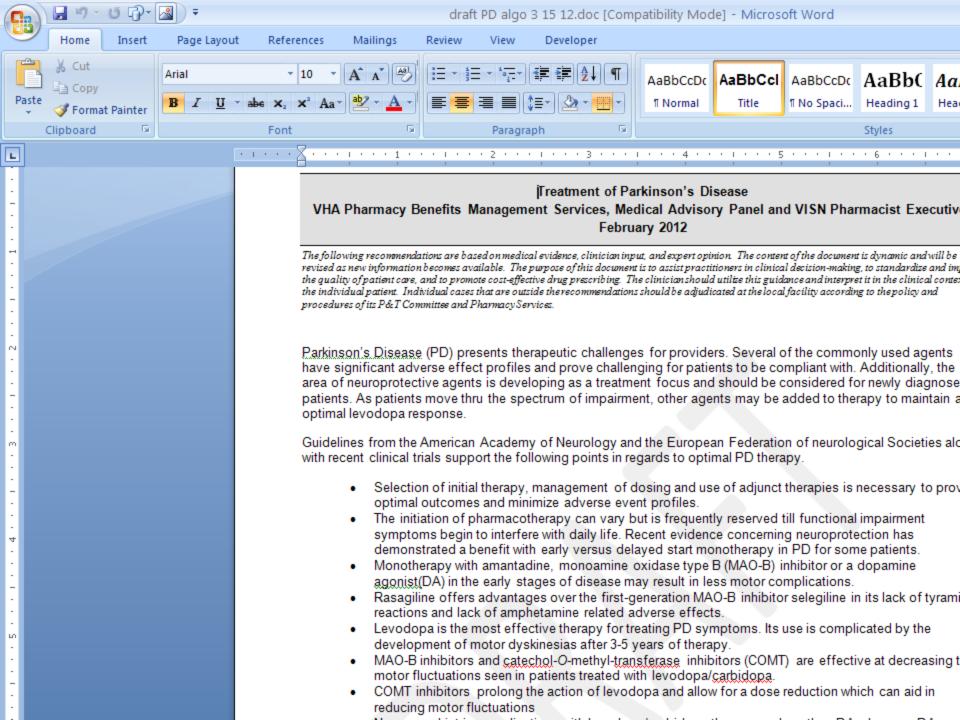
General Discussion

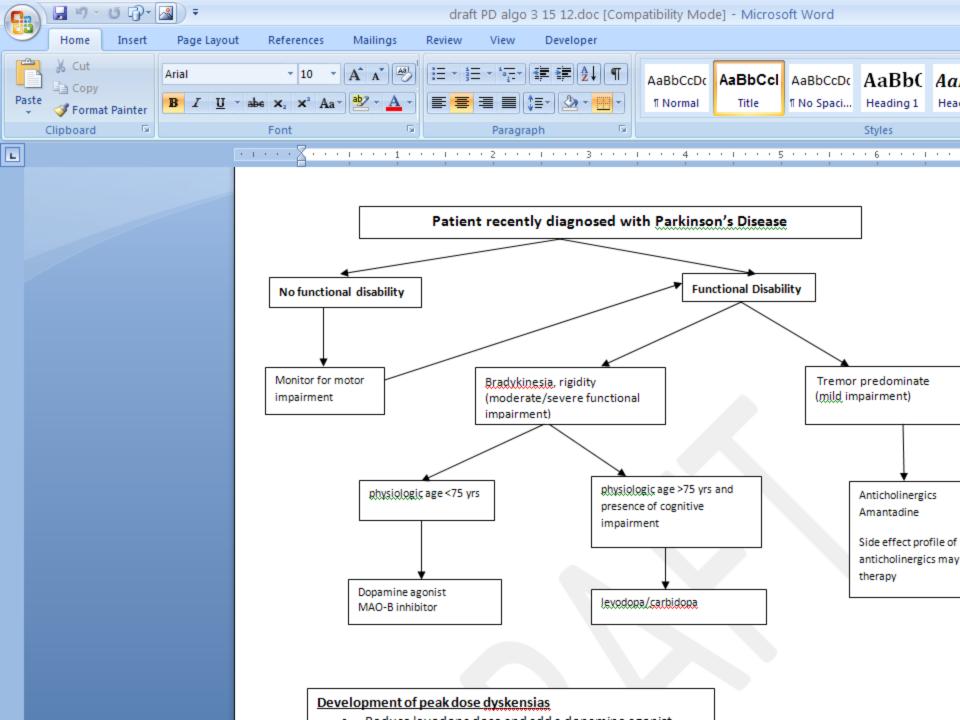
Varenicline

Vilazodone Monograph

W

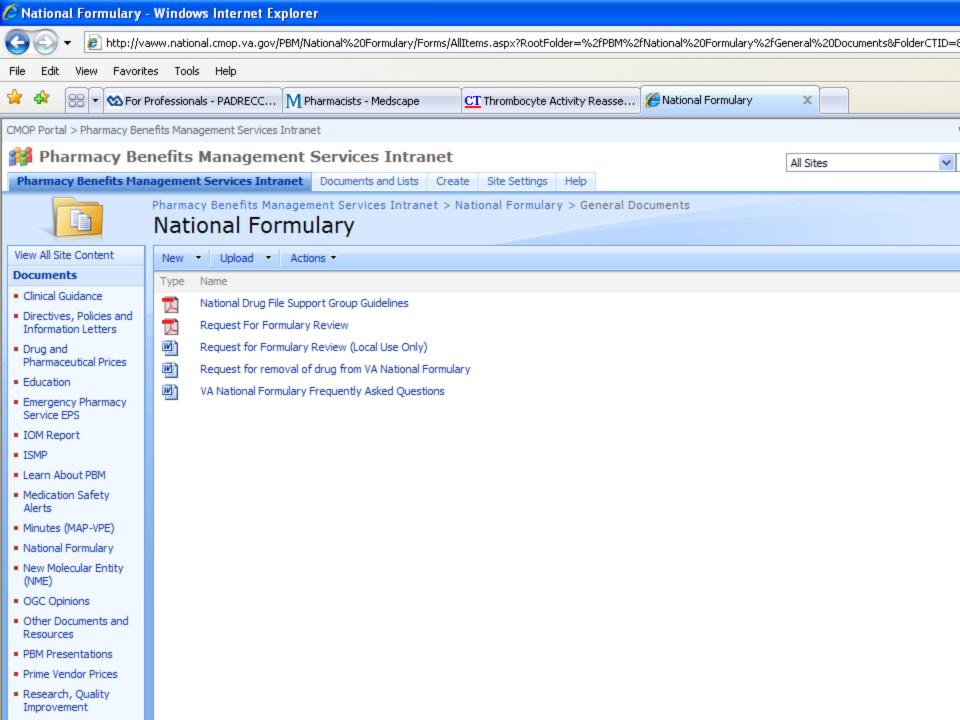




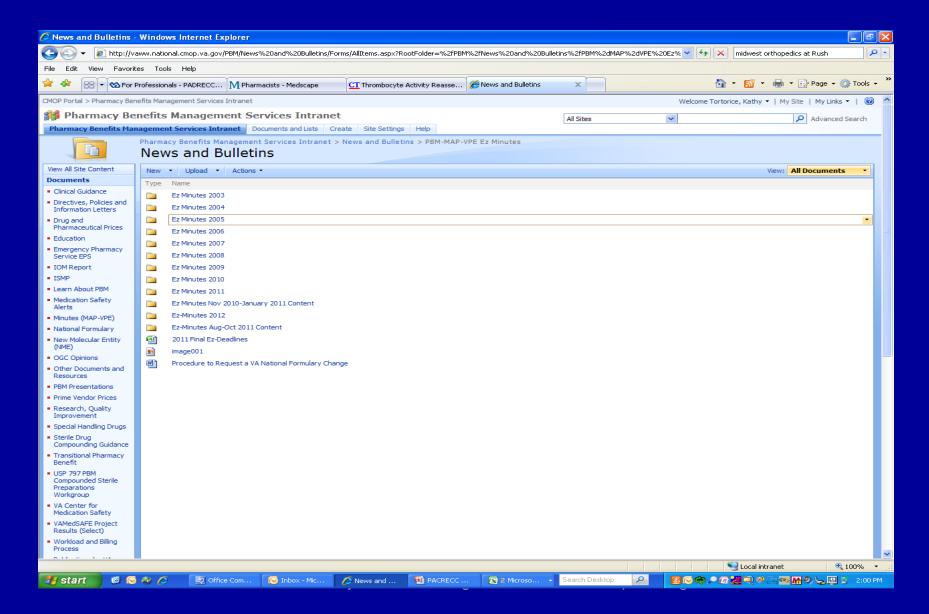


#### Process for VANF Addition/Removal

- 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.

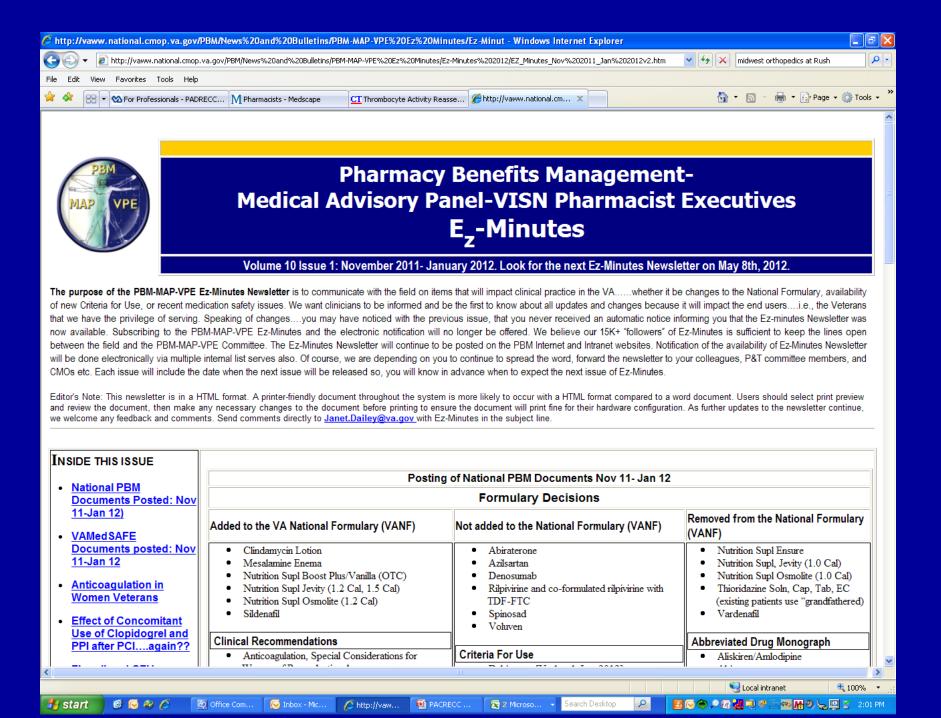


#### Keeping up with changes



# PBM-MAP-VPE Educational Programs

- Web-based LMS Anticoagulation Basic and Advanced Modules
- Osteoporosis in Male Veterans Broadcast Programs
- Live–Meeting VAADERs Program

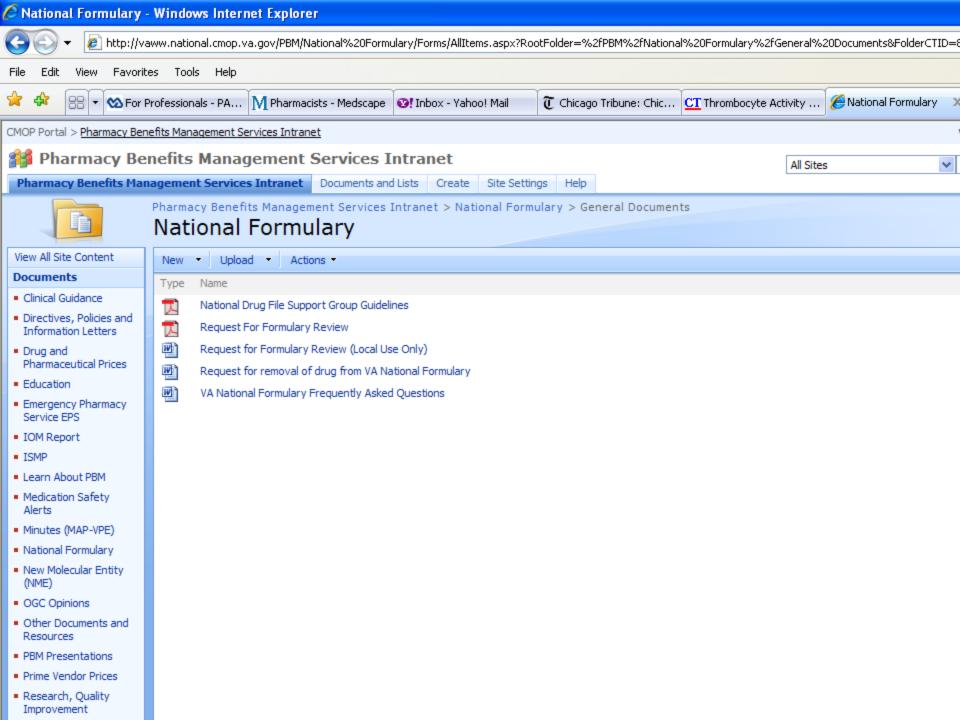


# Pharmacy Benefits Management Medical Advisory PanelVISN Pharmacist Executive Ez-Minutes Newsletter

On-line quarterly Newsletter To subscribe:

Send e-mail to **stxcollage@va.gov** with "PBM subscribe" in the subject line.

## National Formulary



## VANF agents for Parkinson's

VA Class	Generic	Dosage Form	Restriction			
CN500	APOMORPHINE	INJ,SOLN	Restricted to neurology for treatment of acute hypomobility episode of advanced Parkinson's disease.			<u>Special</u> <u>Handling</u>
CN500	CARBIDOPA /LEVODOPA	TAB,SA		<u>criteria</u>		
CN500	CARBIDOPA/LE VODOPA	TAB	-	<u>criteria</u>		
CN500	ENTACAPONE	TAB	Neurologist treating Parkinson			
CN500	RASAGILINE	TAB	Restricted to neurology, movement disorder specialist		Monograph	
CN500	ROPINIROLE	TAB	-	<u>criteria</u>		
CN500	SELEGILINE HCL	CAP OR TAB				

## VANF agents for spastcity

VA Class	Generic	Dosage Form	Restriction
MS200	BACLOFEN	INJ	
MS200	BACLOFEN	TAB	
MS200	CYCLOBENZAPRINE	TAB	
MS200	DANTROLENE	CAP,ORAL	Restricted to spinal cord injury, neurology, and rehabilitation
MS200	DANTROLENE	INJ,SOLN	Restricted to spinal cord injury, neurology, and rehabilitation
MS200	METHOCARBAMOL	TAB	
MS200	TIZANIDINE	TAB	Restricted to spinal cord injury, neurology, rehabilitation, pain management specialists, and traumatic brain injury clinics

## 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