Pharmacy Benefits Management- Medical Advisory Panel
E_z-Minutes

Volume 1. Issue 3 *December 2003*

Inside this issue:

Happy Holidays!

Leaves have now ended their descent and snow has started to conceal the ground in many areas of the country which is a good indication that winter has arrived. Besides the change in seasons, other changes have occurred within the PBM family. It is our pleasure to announce that Mike Valentino, RPh MHSA has been appointed as the Chief Consultant for the PBM. Although we hate to see him leave the Windy City, we are delighted to have him at the helm in Washington DC. Congratulations Mike! Taking the helm at the PBM in Hines is Joe Canzolino, R. Ph., Acting Associate Chief Consultant. Congrats Joe! It is also our pleasure to announce 2 new members to the PBM staff- Todd Semla MS, Pharm.D., BCPS, FCCP and Janet Dailey, PharmD. Welcome aboard!

Change In Restrictions on Smoking Cessation Medications

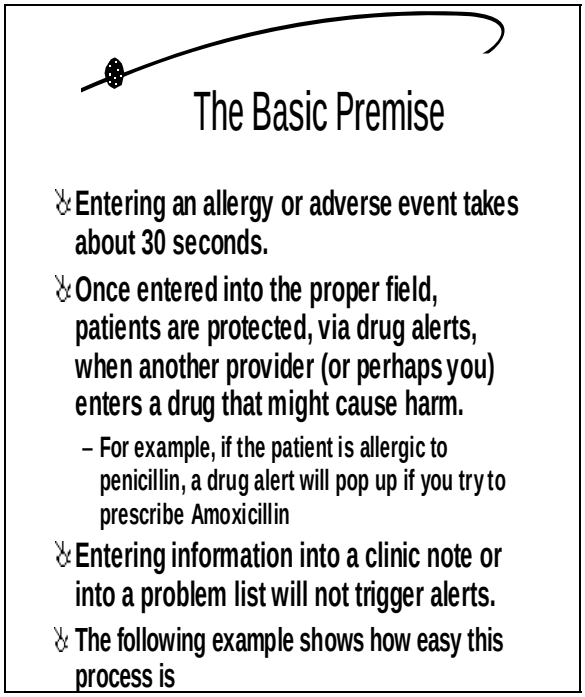
A VHA Directive on the National Smoking and Tobacco Use Cessation Program was signed in August 2003. Please note that smoking cessation aids should now or soon be available for primary care at your facility; please discuss with your local P&T committee on how this will be done. Updated guidelines will be forthcoming. The Department of Veterans Affairs and Department of Defense guidelines are available at http://www.oqp.med.va.gov/cpg/TUC/TUC_Base.htm.

NOW AVAILABLE- UPDATED CHRONIC HEART FAILURE GUIDELINES TOOLS AND ACPE/ACME CREDIT

The PBM-MAP Pharmacologic Management of Chronic Heart Failure (CHF) has been updated and approved (Aug. 2003). The document is available at www.vapbm.org (PBM internet) or http://vaww.pbm.med.va.gov (PBM intranet). Provider tools (e.g., Pocket Guide, Key Points Card) are available through the local Education Coordinators. CE credits (2 hours ACPE, ACME) are offered through a link to the University of Wisconsin CE Web site. Once linked to the PBM intranet, click on the link "Continuing Education Program at the University of Wisconsin." Here you can review the Pharmacologic Management of CHF document and then link to http://www.ce.pharmacy.wisc.edu/html/files/8/12833/12834/treatment_CE_CME.htm where instructions are available for obtaining ACPE or ACME credit.

VAMedSAFE

Funding was recently announced for the Center for Medication Safety, a joint venture of the PBM and NCPS. (See Vol 1. Issue 2 of PBM-MAP newsletter available at www.vapbm.org or vaww.pbm.med.va.gov). The Center's mission will be to research, implement, and monitor issues related to medication safety. This month, the process of documenting an adverse drug reaction in CPRS will be reviewed. Here is one of the slides from the presentation.



Click on the following link http://www.vapbm.org/vamedsafe/How%20To%20Enter%20an%20Allergy%20or%20Adverse%20Drug%20.ppt to review the short and informative presentation on "How to Enter an Allergy or Adverse Drug Event (ADE)." It is a great educational tool!

New Molecular Entities Review

- Gefitinib (Iressa®)-Not added to VANF or VISN Formulary
- Omalizumab (Xolair®)-Not added to VANF and VISN Formulary
- Pegvisomant (Somavert®)-Not added to VANF or VISN Formulary
- Agalsidase beta (Abrasive®) - Not added to VANF or VISN Formulary
- Caspofungin (Cancidas®)-Not added to VANF, VISNs may add
- Ethinyl estradiol/Drospirenon (Yasmin®) – Not added to VANF or VISN Formulary
- Treprostinil Sodium Injection Remodulin®-- Not added to VANF or VISN Formulary
- Nitazoxanide (Alinia®)-Not added to VANF or VISN Formulary
- Rosuvastatin (Crestor®) – not added to VANF or VISN Formulary

Contract Updates

NATIONAL CONTRACT ANNOUNCEMENT

Oral Fluoroquinolone: Gatifloxacin-Tequin® Tablets

Effective Period: **1/1/2004 – 12/31/2005**

Medication Safety

During the holidays, it seems only appropriate to focus on a food-drug interaction. A traditional food item served during the holiday season is cranberry sauce.

The London Committee on Safety of Medicines (CSM) recently reported a report regarding a possible interaction between warfarin and cranberry juice. CSM has received 5 separate case reports since 1999 suggesting a potential interaction. One case involved a patient who experienced a dramatic increase in INR (INR>50) 6 weeks after beginning cranberry juice consumption The pt. died of GI and pericardial hemorrhage. Two other cases indicated less drastic elevation in the INR level, one was managed with a decreased dose of warfarin and the other discontinued the consumption of cranberry juice. Cranberries contain little vitamin K (~ 1mcg/100g of cranberry sauce). Authors hypothesized the interaction is due to the flavonoid components of cranberry inhibiting CYP450 activity. Warfarin is metabolized via CYP 2C9. The proposed mechanism of cranberry/warfarin interaction differs with that of grapefruit juice which inhibits via CYP 3A4 pathway. Obviously, the variation in patient responses, volume consumed or type of "juice" is unknown so the clinical relevance of this possible interaction can not be determined. So, perhaps the best advice to tell your patients taking warfarin is to go easy on the sauce this holiday. ☺ [Evidence level D]

Shields KM. Possible Cranberry and Warfarin Interaction. Pharmacist's Letter/ Prescriber's Letter. November 2003.

Table 1: Comparison of Adverse Events between Alphagan P® and Brimonidine

	Alphagan P®	Brimonidine 0.2%
hyperemia	ocular	conjunctival
pruritus	10-20%	10-30%
abnormal vision	5-9%	3-9%
eyelid edema	X	X
blepharitis	X	X
conjunctival folliculosis	X	X
foreign body sensation	X	X
burning/stinging	X	X

Hebel SK, ed. Drug Facts and Comparisons. St. Louis, MO: Facts and Comparisons Inc; 2003; X= denotes occurrence

In March 2001, Alphagan P® was approved with the same indications as Alphagan®. The % of active ingredient and the preservative differ between the 2 agents (see Table 1). However, no statistically significant difference between brimonidine 0.15% purite and brimonidine 0.2% in regards to adverse events, (See Table 2) treatment withdrawals or intraocular pressure lowering was seen in studies 007 and 008 submitted to the FDA. (J Ocular Pharm and Thera 2003; 19(1): 37-44). Generic products similar to Alphagan® products are available and compared in Table 2.

Table 2. Comparison of Alphagan®, Alphagan-P®, and Brimonidine

	Alphagan® Allergan	Alphagan-P® Allergan	Brimonidine-Falcon	Brimonidine-Bausch and Lomb
Active ingredient	Brimonidine 0.2%	Brimonidine 0.15%	Brimonidine 0.2%	Brimonidine 0.2%
Preservative	Benzalkonium chloride (BAK)	Stabilized oxychloro complex (Purite)	Benzalkonium chloride (BAK)	Benzalkonium chloride (BAK)
pH	5.6-6.6	6.6-7.4	5.6-6.6	5.6-6.6
Inactive agents	Citric acid, polyvinyl alcohol, sodium chloride, sodium citrate, purified water	Boric acid, calcium chloride, magnesium chloride, potassium chloride, purified water, sodium borate, sodium carboxymethylcellulose	Citric acid, polyvinyl alcohol, sodium chloride, sodium citrate, purified water	Citric acid, polyvinyl alcohol, sodium chloride, sodium citrate, purified water
FSS price 5ml		$17.81	$5.03	$5.00
10ml		$35.24	$10.05	$10.00
15ml		$53.07	$15.08	$15.00

Recent National PBM Reviews Postings on Web site

Criteria for Use
http://www.vapbm.org/PBM/criteria.htm
Meperidine
Enfuvirtide (Fuzeon®)
Fluvastatin and Fluvastatin XL

Criteria for Nonformulary Use
http://www.vapbm.org/PBM/criteria.htm
Agalsidase beta (Fabrazyme®)
Aripiprazole (Abilify®)
Atorvastatin (Lipitor®)
Becaplermin (Regranex®) Gel
Gefitinib (Iressa®)
pantoprazole IV
Pravastatin (Pravachol®)

Treatment Guidelines
http://www.vapbm.org/PBM/treatment.htm
Pharmacologic Mgmt of Chronic Heart Failure

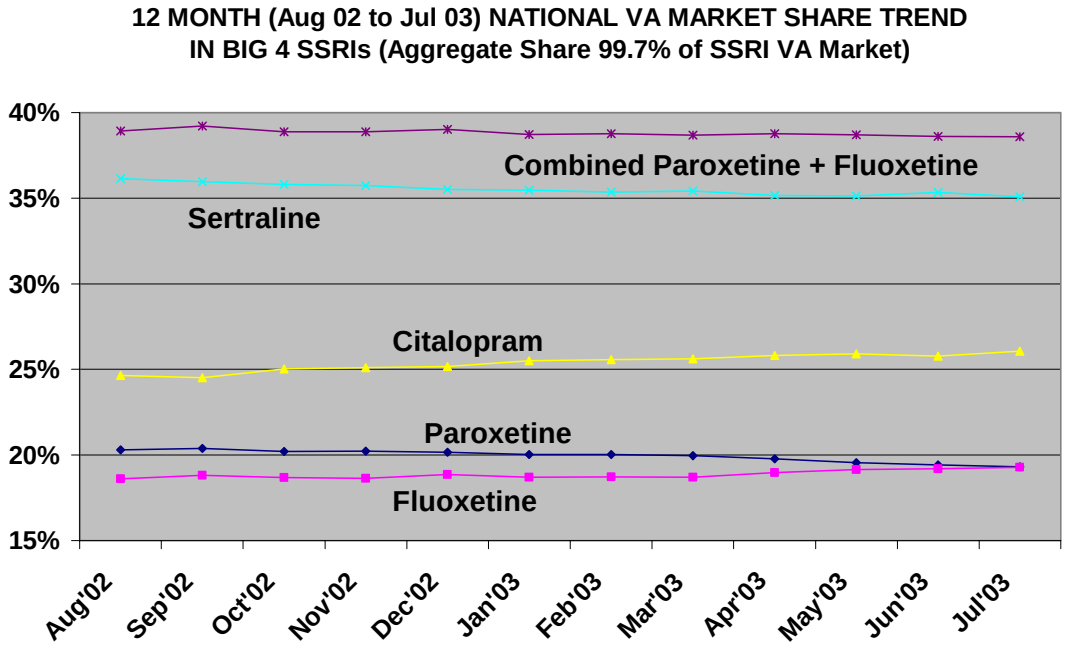
Drug Class Reviews
http://www.vapbm.org/PBM/reviews.htm
Combined Estrogen and Progestin Products for Hormone Therapy (Abbreviated Review)
Oral bisphosphonates for tx of osteoporosis
Proton Pump Inhibitors (Abbreviated Review)
Fluoroquinolones

Drug Monographs
http://www.vapbm.org/PBM/drugmonograph.htm
Agalsidase beta (Fabrazyme®)
Nitazosanide (Alinia®)
Omalizamab (Xolair®)
Tegaserod (Zelnorm®)
Pantoprazole IV
Pegvisomant for injection (Somavert®)

Patient and/or Provider Information Letters
http://www.vapbm.org/PBM/tig.htm
PPI Patient and Provider Letters

Major Depressive Disorder is a common condition among veterans, and the VA has developed guidelines and helpful tools for clinicians (available at http://vaww.oqp.med.va.gov/CPGintra/cpg/MDD/MDD_Base.htm or at http://www.oqp.med.va.gov/cpg/cpg.htm) The cornerstones are being alert to symptoms (e.g., engaging in screening), documenting the diagnosis (by DSM-IV criteria) and developing an appropriate treatment plan, often utilizing antidepressants and/or counseling.

The following figure shows utilization of the four SSRI in VA from July 2002 to July 2003. While all 4 medications are useful, and choice should generally be tailored to patients' presentation and comorbidities, costs vary dramatically, especially as these drugs become available generically.



The following list provides current VA pricing for each of the four medications at common doses.

Citalopram	20, 40 mgs	1.14, 1.14
Fluoxetine	20, 40 mgs	0.03, 3.66
Paroxetine	20, 30 mgs	0.83, 0.86
Sertraline	50, 100 mgs	1.21, 1.24

(Prices may change as of 1/1/04)

No matter which drug is used, though, providers should monitor adherence and side effects every 1-2 weeks initially and then assess response at 4 to 6 weeks, adjusting the dose of medication as required. Patients should be reassessed by 12 weeks. If the response remains incomplete, a consultation with or referral to a mental health specialist is strongly encouraged, if it has not already been done.

Comments and Feedback or Questions about PBM-MAP E_z-Minutes?

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Editor: Pete Glassman, MBBS, MSc at peter.glassman@med.va.gov. Remember to check the Web site at www.vapbm.org or vaww.pbm.med.va.gov on a routine basis for additional cool news for the holidays.