Department of Defense
Pharmacoeconomic Center

1750 Greeley Rd., Bldg. 4011, Rm. 217
Fort Sam Houston, TX 78234-6190

MCCS-GPE **16 NOV 00**

MEMORANDUM FOR: Executive Director of Tricare Management Activity (TMA)

SUBJECT: Minutes of the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee Meeting

1. A meeting of the DoD P&T committee convened at 0800 hours on 16 November 2000, at Ft Sam Houston, TX.

2. **MEMBERS PRESENT:**

CDR Terrance Egland, MC	Co-chair
COL Daniel D. Remund, MS	Co-chair
LTC Judith O'Connor, MC	Army
MAJ Brett Kelly, MS	Army
CDR Matt Nutaitis, MC	Navy
CDR Kevin Cook, MSC	Navy
COL (select) John R. Downs, MC	Air Force
MAJ George Jones, BSC	Air Force
CDR Robert Rist	Coast Guard
LTC Greg Russie	Joint Readiness Clinical Advisory Board
MAJ Mickey Bellemin, BSC	Defense Supply Center Philadelphia (DSCP)
Ron Mosier	Department of Veterans Affairs
Trevor Rabie	Uniformed Services Family Health Plans (USFHP)
Ray Nan Berry	Foundation Health
Kirby Davis	Anthem Alliance
William Hudson	Humana, Inc
Gene Lakey	TriWest
Ron McDonald	Sierra Military Health Services

MEMBERS ABSENT:

COL Rosa Stith, MC	Army

OTHERS PRESENT:

CAPT Joe Torkildson	DoD Pharmacoeconomic Center
COL Mike Heath, MS	Army Pharmacy Consultant, DoD Pharmacy Board of Directors
CDR Mark Brouker, MSC	DoD Pharmacoeconomic Center
LTC (P) William Davies	DoD Pharmacy Program Director, Tricare Management Activity (TMA)
LTC Don De Groff, MS	DoD Pharmacoeconomic Center
LTC Steven Humburg	Health Affairs
MAJ Cheryl Filby, MS	Defense Supply Center Philadelphia
LCDR Mark Richerson	DoD Pharmacoeconomic Center
MAJ Barbara Roach, MS	DoD Pharmacoeconomic Center
MAJ Ed Zastawny	DoD Pharmacoeconomic Center
HM3 Cory Beckner	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
Howard Altschwager	Deputy General Counsel, TMA
David Chicoine	Uniformed Services Family Health Plan
Eugene Moore	DoD Pharmacoeconomic Center
Jeremy Johnson	Family Practice Pharmacy Resident, University of Texas Pharmacy Program
Mark Petruzzi	Merck-Medco
Elizabeth Scaturro	Merck-Medco
Carol Scott	DoD Pharmacoeconomic Center
David Spiler	Merck-Medco
Shana Trice	DoD Pharmacoeconomic Center
Vincent Valinotti	Defense Supply Center Philadelphia
Paul Vasquez	Defense Supply Center Philadelphia
Eric Vetter	Pharm.D. Student, Ferris State University

ADMINISTRATIVE ISSUES

The minutes from the last meeting were corrected as below:

- The heading for Paragraph 11G was changed to "General Accounting Office (GAO) Report—Review of Drug Classes for Contracting Potential."

- Paragraph 16 (Formulary Controls in the Retail Pharmacy Network) was revised to delete the sentence "MCSCs can not currently impose prior authorizations beyond those approved by the DoD P&T committee."

3. **REVIEW OF INTERIM DECISIONS –** The co-chairs reported on the following interim decisions, which were confirmed by the committee:

- Quantity limit for testosterone gel (Androgel) – The normal quantity limit for a Schedule III drug would be a 30-day supply. An exception was made to allow prescriptions for Androgel to be filled for up to a 90-day supply, based on its chronic use and the lower potential for overuse compared to other testosterone formulations.

- Coverage of perindopril (Aceon; Solvay) through the National Mail Order Pharmacy (NMOP) program – Perindopril was approved in 1993, but only recently marketed. Perindopril was added to the NMOP Formulary.

- The co-chairs decided to establish and have the first meeting of the DoD Executive Council as a separate committee composed solely of federal employees. The DoD P&T Executive Council is responsible for performing certain inherently governmental functions relevant to a pharmacy benefits program and providing other direction and assistance to the P&T committee. The first meeting of the DoD Executive Council was held 15 Nov 00. Minutes of the meeting will be posted on the PEC website.

4. **PROCEDURE FOR REQUESTING BCF CHANGES** – At the last meeting, the committee appointed a subcommittee to develop standard procedures for MTFs to request changes to the Basic Core Formulary (BCF) and to propose agenda items for the DoD P&T Committee. MAJ George Jones presented findings of the subcommittee, including a proposed form to be placed on the PEC website to facilitate requests from MTF providers and other DoD personnel for additions, deletions, or changes to the BCF.

   Some committee members said that requests for BCF changes should be routed through the MTF or regional P&T committee rather than being submitted directly to the DoD P&T committee by an individual provider. Other committee members said that providers would view that as a "roadblock" to submitting requests. The committee voted not to require submission through the MTF or regional P&T committees. The committee asked the PEC to revise the draft form as necessary and place it on the PEC website. Use of the form will be reviewed in 3 to 6 months.

5. **IMPLEMENTATION OF FY00 AND FY01 NATIONAL DEFENSE AUTHORIZATION ACTS** – LTC Davies briefed the committee on the ongoing efforts to implement the provisions of the FY00 and FY01 National Defense Authorization Acts pertaining to the Uniform Formulary and the DoD P&T Committee.

6. **LINEZOLID USAGE IN THE RETAIL NETWORK** – The managed care support contractors (MCSCs) reported that linezolid usage had been minimal and appears appropriate. The committee agreed that a prior authorization is not necessary and closed the issue.

7. BCF AND NMOP FORMULARY ISSUES

A. The committee considered the eighteen newly approved drugs listed in Appendix A. For each drug, the committee determined status on the NMOP Formulary; the necessity for NMOP or retail network formulary restrictions (NMOP Preferred Drug Program, quantity limits, or prior authorization); and status on the BCF.

B. *Mifepristone (Mifeprex, RU-486; Danco Labs)*, approved 28 Sep 00 for medical termination of intrauterine pregnancy, through day 49 of pregnancy. Because the drug will only be available via direct shipment to qualified providers and because of existing DoD policies regarding termination of pregnancy, mifepristone was excluded from the NMOP and will not be a covered benefit through network providers. COL Davies addressed the issue of how mifepristone will be incorporated into existing medical care directives in the MTFs. He stated that TMA and Health Affairs is working on a policy to clarify the distribution of mifepristone and the processes that will need to be followed to obtain the drug. He stated that although there are potential uses for mifepristone other than termination of pregnancy, availability of the drug is likely to be limited by the FDA-approved indication and distribution process.

8. **NON-PREFERRED/PREFERRED DRUG PAIRS IN THE NMOP** – CDR Mark Brouker reported that the report could not be prepared because the data were not available.

9. PRIOR AUTHORIZATIONS

A. *Cost analysis of NMOP prior authorizations (PAs)* – Shana Trice (PEC) reported on the cost analysis of prior authorizations in the NMOP, using the same model presented at the Aug 00 meeting. For each drug, the costs that would be incurred for 1000 new prescriptions submitted to the NMOP that are subject to the PA process were compared to the costs that would be incurred if the prescriptions were not subject to the PA process. The analysis takes into account the cost of drug therapy, the charge from Merck-Medco for performing the PA, the estimated number of refills associated with each new prescription and the estimated cost of alternative therapy for prescriptions not filled as a result of the PA process. The analysis does not quantify the "sentinel effect" of PAs (i.e., the possibility that providers prescribe the drug less frequently because they know the drug is subject to prior authorization).

The analysis showed that total costs for each drug would be higher without PA than they are with PA. The cost avoidance resulting from the PA process is shown in the following table:

Drug	Cost avoidance per new Rx submitted
Etanercept (Enbrel)	$111.86
Sildenafil (Viagra)	$26.46
COX-2 inhibitors	$18.56

Although preliminary information on the PA for antifungals for onychomycosis (terbinafine and itraconazole) was presented, the committee agreed that it is too soon to draw any meaningful conclusions.

B. *Status of changes in prior authorization criteria for etanercept and COX-2s* – The changes in criteria for etanercept and COX-2s discussed at the February and August meetings have been completed, with the exception of the revision of the COX-2 PA to reflect approval of celecoxib for familial adenomatous polyposis (FAP). This change is in progress.

C. *Revision of prior authorization forms to reflect the rationale for the prior authorization* – The PA forms on the PEC website, which are mailed in by beneficiaries with their prescriptions after being completed by prescribers, have been changed to include the clinical rationale for the prior authorization. Merck-Medco is in the process of adding the clinical rationale language to the forms it faxes to prescribers.

D. *Proposal to increase the length of time for which etanercept is approved* – The committee considered a proposal to increase the length of time for which etanercept PAs are approved from one year to five years, which is Merck-Medco's current standard for etanercept in other health plans. Reports of rare cases of demyelinating disorders and pancytopenia in patients receiving etanercept engendered concern on the part of committee members about lengthening the approval period. The committee decided not to make any changes to the etanercept PA at this time.

E. *Proposal to change the COX-2 PA to reflect findings of the Celecoxib Long-term Arthritis Safety Study (CLASS)* – For patients taking aspirin in the CLASS study, the annualized incidence rates of upper GI ulcer complications alone and combined with symptomatic ulcers were not significantly different for celecoxib versus NSAIDS. These results indicate that celecoxib confers no GI safety benefit over NSAIDs for patients who take aspirin for cardioprotection. The PA criteria for COX-2 inhibitors may need to be revised so that usage of COX-2 inhibitors is not approved for patients who take aspirin for cardioprotection. The committee asked the PEC to further evaluate the consequences and costs of making such a change in the COX-2 PA criteria.

10. NMOP AND RETAIL NETWORK QUANTITY LIMITS

A. *Report of the subcommittee on quantity limits for proton pump inhibitors (PPIs)* – Bill Hudson (Humana) reported that the subcommittee considered two clinical questions 1) is there undetected disease that is being masked by chronic PPI therapy, and 2) do people really need long-term therapy with these drugs? With the assistance of expert opinion, the subcommittee concluded that there is probably very little undetected disease masked by PPI use. They also concluded that a substantial number of patients do need some type of long-term therapy, although many of these patients could be managed with a H2 blocker such as ranitidine instead of a PPI. The committee decided not to institute specific quantity limits for the PPIs in the NMOP and retail network.

B. *Quantity limits for isometheptene 65 / dichloralphenazone 100 / acetaminophen 325 mg oral (Midrin, generics)* – Because the status of this combination drug is being changed to

Schedule IV and because it is used for migraine treatment, the question arose as to whether quantity limits for the NMOP and retail network should be specified. However, the drug has different limits for different indications—5 capsules per day for migraines and 8 capsules per day for tension headaches—and it is difficult to determine how many capsules patients are likely to use on a monthly basis. The committee concluded that there is no need to have a specific quantity limit for this drug, since no specific limits are set for other scheduled medications. A clinical maximum for all drugs set by First Data Bank will apply across the MHS as the Prescription Data Transaction Service (PDTS) is implemented. Like other Schedule III - V drugs, isometheptene/dichloralphenazone/acetaminophen will be limited to a 30-day supply with 5 refills in the NMOP.

C. *Quantity limits for sumatriptan (Imitrex) 100 mg* – This is a newly approved dosage form of sumatriptan. The committee agreed with the proposed quantity limits of 27 tablets per 90 days in the NMOP and 9 tablets per 30 days in the retail network, which are consistent with quantity limits for other strengths of sumatriptan. Sumatriptan 100 mg tablets are packaged in 9's.

11. **CONTROLLED DISTRIBUTION OF ALENDRONATE (FOSAMAX) 40 MG (FOR PAGET'S DISEASE)** – Nationally, this dosage strength of alendronate will only be available from one specialty pharmacy (CVS ProCare). LTC Don De Groff reported on efforts to work out distribution within DoD. He reported that the manufacturer (Merck), DSCP, Merck-Medco, and the NMOP wholesaler have worked out the payment issues to allow DoD beneficiaries to go through the NMOP to process their prescriptions rather than dealing with CVS ProCare. DoD patients will receive a business reply card for Merck's Paget's Patient Support Program, giving them access to this program if they wish to participate. The PDTS Customer Service Support Center (CCSC) will assist in redirecting DoD beneficiaries receiving prescriptions through the retail pharmacy network to the NMOP in order to centralize the program. LTC De Groff emphasized that it is important that all MTF prescriptions for alendronate 40 mg, including new prescriptions, be filled at the NMOP because alendronate 40 mg will no longer be available to MTFs as of 15 Dec 00. More information will be supplied by DSCP and/or the PEC as soon as possible, and will be posted on the DSCP website. This program is expected to affect approximately 300 patients DoD-wide.

    The committee agreed that the BCF requirement for alendronate should be clarified to exclude the 40-mg tablet, since it will not be available at MTFs. The 40-mg tablet will remain on the NMOP Formulary, since the NMOP will be providing the drug.

12. **CONTROLLED DISTRIBUTION OF DOFETILIDE (TIKOSYN)** – Because of specialized educational requirements mandated by the FDA, this drug is only available for outpatient use through a single specialty pharmacy in the U.S. (Statlander's Pharmacy/CVS Procare). LTC Don De Groff reported that while the issue of payment for the medication is not yet entirely worked out, the communication procedures to support clinical monitoring have been defined. All prescriptions for dofetilide for DoD beneficiaries received by CVS Procare will be reported to the PDTS Customer Service Support Center (CCSC) (using a flat file in NCPDP compliant format) on a daily basis and a paper claim will be entered by the CSSC so that any positive prospective DURs (e.g., drug interactions) can be reported to CVS Procare. More information

concerning distribution and payment will be supplied by DSCP as soon as the issues are resolved.

13. **CONTROLLED DISTRIBUTION OF ETANERCEPT (ENBREL) –** The manufacturer of etanercept (Immunex) very recently reported that production of etanercept is at maximum capacity and that demand will likely exceed supply until new production facilities are constructed. In order to ensure that patients currently receiving etanercept are able to continue therapy, Immunex is setting up an process requiring existing patients to enroll by 1 Jan 01. Further details are available from Immunex at *www.enbrelenrollment.com*.

    The etanercept enrollment and distribution process is likely to be very difficult in DoD facilities because of the multiple chains of distribution through which MTF pharmacies obtain products. LTC Don De Groff reported on discussions with Immunex and Wyeth-Ayerst (co-marketer of Enbrel) to attempt to establish a process for DoD patients to use the NMOP only to obtain supplies of etanercept. The program start of 1 Jan 00 will not be enforced for DoD beneficiaries obtaining etanercept through the NMOP or MTFs, pending resolution of this issue.

14. **PUBLIC HEALTH ADVISORY FROM THE FDA REGARDING PHENYLPROPANOLAMINE (PPA) –** The committee discussed the recent advisory from the FDA stating that the agency is taking steps to remove PPA from all drug products and requesting that drug companies discontinue marketing products containing PPA, based on the evidence of an association between PPA and hemorrhagic stroke. Although the risk of hemorrhagic stroke is very low, the FDA is advising patients to stop taking products containing PPA. USAMMA has sent out two medical material quality control messages informing MTFs of the FDA advisory and advising pharmacies to stop dispensing the drug.

    The committee removed guaifenesin /PPA (e.g., Entex LA) from the BCF. The committee did not select an alternative agent for the BCF at this meeting because of anticipated reformulation of products by manufacturers and because the selection will be addressed as part of the BCF review to be addressed at the Feb 01 meeting.

15. **ADJOURNMENT –** The meeting adjourned at 1415 hours. The next meeting will be held in February 01 at a date and location to be determined. All agenda items should be submitted to the co-chairs no later than 15 Jan 01.

<signed>	<signed>
DANIEL D. REMUND	TERRANCE EGLAND
COL, MS, USA	CDR, MC, USN
Co-chair	Co-chair

List of Appendices

APPENDIX A: CONSIDERATION OF NEWLY APPROVED DRUGS FOR THE NMOP FORMULARY AND BCF

Generic name (Trade name; manufacturer)	**Indication, approval date**	**NMOP Formulary Status**	**NMOP or retail network formulary restrictions**	**BCF Status**
Metformin/ glyburide tablets (Glucovance; Bristol-Myers Squibb)	Approved 31 July 00 for initial therapy, as an adjunct to diet and exercise, to improve glycemic control in patients with type 2 diabetes whose hyperglycemia can not be satisfactorily managed with diet and exercise alone; and second-line therapy when diet, exercise and initial treatment with a sulfonylurea or metformin do not result in adequate glycemic control in patients with type 2 diabetes	Added	**NMOP Preferred Drug Program** No **Quantity Limits** General rule applies **Prior Authorization** No	Not added. While Glucovance is slightly less costly than Glucophage at the moment, generic metformin is expected to become available sometime around July 2001, presumably at a greatly decreased cost. The committee agreed that the combination therapy did not appear to offer enough additional benefit to offset the potential for higher costs compared to generic metformin and generic glyburide, as well as the loss of dosing and titration flexibility compared to the individual components.
Metformin extended release tablets (Glucophage XR; Bristol-Myers Squibb)	Approved 13 Oct 00 as monotherapy as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes; may be used concomitantly with a sulfonylurea or insulin to improve glycemic control (same indication as immediate release metformin).	Added	**NMOP Preferred Drug Program** No **Quantity Limits** General rule applies **Prior Authorization** No	Excluded from the BCF listing for metformin. MTFs are not required to have Glucophage XR on their formularies, but may add it if they so desire. While Glucophage XR 500 mg is slightly less costly than Glucophage 500 mg at the moment, generic metformin is expected to become available sometime around July 2001, presumably at a greatly decreased cost. The committee agreed that extended release preparation did not appear to offer enough additional benefit to offset the potential for higher costs compared to generic metformin, when available.
Alendronate 35- and 70-mg (once weekly) tablets (Fosamax; Merck)	Approved 20 Oct 00 for prevention (35-mg tablet) or treatment (70-mg tablet) of osteoporosis in postmenopausal women	Added	**NMOP Preferred Drug Program** No **Quantity Limits** General rule applies **Prior Authorization** No	Listing for alendronate on the BCF will include the once-weekly formulations. Once weekly administration appears to be as effective as once daily and may have tolerability/safety advantages. The cost per week for the once-weekly and once-daily tablets is the same. The earliest patent expiration listed in the FDA Orange Book for alendronate is 2007.

Generic name (Trade name; manufacturer)	**Indication, approval date**	**NMOP Formulary Status**	**NMOP or retail network formulary restrictions**	**BCF Status**
Divalproex sodium ER tablets (Depakote ER; Abbott)	Approved 13 Oct 00 for prophylaxis of migraines in adults	Added	**NMOP Preferred Drug Program** No	Listing for divalproex sodium on the BCF will include Depakote ER. Depakote ER is only indicated for prophylaxis of migraine headaches, while delayed release divalproex sodium (Depakote) is indicated for seizure disorder, bipolar disorder, and prophylaxis of migraine headaches. Depakote ER may have some convenience advantages (two 500-mg tablets once daily as opposed to one 500-mg Depakote tablet twice daily) and is cost-neutral. The earliest patent expiration listed in the FDA Orange Book for Depakote is 2008.
			Quantity Limits General rule applies	
			Prior Authorization No	
Methyl-phenidate HCl extended release tablet (Concerta; Alza)	Approved 1 Aug 00 for the treatment of attention deficit disorder	Added	**NMOP Preferred Drug Program** No	The BCF listing for methylphenidate will include Concerta. Concerta is given once daily. It consists of an immediate release component and an extended release component, which provides for initial morning efficacy followed by extended release of medication over an approximately 12-hour period. At $1.30 - $1.38 per day, Concerta is approximately 57% more costly than a typical regimen of extended-release plus immediate release methylphenidate. However, once daily dosing of Concerta has the potential to obviate the need for children to take doses during the school day. The committee pointed out that this is a quality of life issue that has a direct impact on active duty dependents and active duty personnel.
			Quantity Limits NMOP: 90 day supply Retail: 30 day supply or 90 day supply with 3 co-pays	
			Prior Authorization No	

Generic name (Trade name; manufacturer)	**Indication, approval date**	**NMOP Formulary Status**	**NMOP or retail network formulary restrictions**	**BCF Status**
Tinzaparin injection (Innohep; Dupont)	Approved 18 Jul 00 for treatment of acute symptomatic deep vein thrombosis with or without pulmonary embolism when administered in conjunction with warfarin sodium. Safety and effectiveness were established in hospitalized patients.	Not added. The low molecular weight heparins (LMWHs) are not currently available through the NMOP.	Non-applicable	The BCF listing for LMWHs specifies that "all MTFs must have at least one of the following products on the MTF formulary: ardeparin (Normiflo®); dalteparin (Fragmin®); danaparoid (Orgaran®); or enoxaparin (Lovenox®). MTFs will select the specific brand." The listing was amended to include tinzaparin as an option and to remove ardeparin, which is no longer available. The committee agreed that the class should be reviewed to assess the need for having the LMWHs available through the NMOP, the need for a prior authorization process at the NMOP/retail network to control inappropriately extended use, and the potential for contracting/incentive price agreements to reduce the unit cost of LMWH therapy. The VA is currently completing a LMWH clinical review, with a target date of Dec 00. The committee agreed that such an action could be done in conjunction with the VA.
Cande-sartan/ HCTZ tablets (Atacand HCT; AstraZeneca)	Approved 5 Sep 00 for treatment of hypertension	Added	**NMOP Preferred Drug Program** No **Quantity Limits** General rule applies **Prior Authorization** No	Not added. The committee noted that there are currently no angiotensin receptor blockers (ARBs) on the BCF. While the clinical usefulness of the ARBs appears to be limited to patients who cannot tolerate ACE inhibitors due to cough, the comment was made that in light of increasing utilization it might be reasonable to review this class. The VA does not have a clinical review scheduled in the near future.

Generic name (Trade name; manufacturer)	**Indication, approval date**	**NMOP Formulary Status**	**NMOP or retail network formulary restrictions**	**BCF Status**
Cole-sevelam HCl (Welchol; GelTex Pharma/ Sankyo Parke Davis)	Approved 30 May 00 as adjunctive therapy to diet and exercise for the reduction of elevated LDL cholesterol in patients with primary hypercholesterolemia, administered alone or in combination with an HMG-CoA reductase inhibitor (non-absorbed agent)	Added	**NMOP Preferred Drug Program** No **Quantity Limits** General rule applies **Prior Authorization** No	Not added. Colestipol, a bile acid sequestrant, is on the BCF. The committee asked the PEC to obtain more information to establish if a bile acid sequestrant continues to be required on the BCF and if colesevelam's apparent advantages of reduced constipation and fewer drug interactions make it a better choice for the BCF. The committee agreed that the PEC should wait until the Adult Treatment Panel III Guidelines are out and bring the issue back to the committee for consideration.
Beclo-methasone dipro-pionate HFA inhalation aerosol (QVar; 3M Pharma)	Approved 15 Sep 00 for the maintenance treatment of asthma as prophylactic therapy; and for asthma patients who require systemic corticosteroid administration, where adding QVar may reduce or eliminate the need for the systemic corticosteroids	Added	**NMOP Preferred Drug Program** No **Quantity Limits** **40-mcg strength:** 4 inhalers per 30 days, 12 inhalers per 90 days **80-mcg strength:** 2 inhalers per 30 days, 6 inhalers per 90 days. **Prior Authorization** No	Not added

Generic name (Trade name; manufacturer)	**Indication, approval date**	**NMOP Formulary Status**	**NMOP or retail network formulary restrictions**	**BCF Status**
Budesonide inhalation suspension (Pulmicort Respules; AstraZeneca)	Approved 8 Aug 00 for the maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age	Added	**NMOP Preferred Drug Program** No **Quantity Limits 0.25-mg strength:** 4 boxes of 30 per 30 days, 12 boxes of 30 per 90 days **0.5mg strength:** 2 boxes of 30 per 30 days, 6 boxes of 30 per 90 days **Prior Authorization** No	Not added
Unoprostone isopropyl ophthalmic solution, 0.15% (Rescula; Ciba Vision/ Novartis)	Approved 3 Aug 00 for lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are intolerant of other intraocular pressure lowering medications or insufficiently responsive (failed to achieve target IOP determined after multiple measurements over time) to another intraocular pressure lowering medication	Added	**NMOP Preferred Drug Program** No **Quantity Limits** General rule applies **Prior Authorization** No	Not added
Azelastine HCl ophthalmic solution, 0.05% (Optivar; ASTA Medica)	Approved 22 May 00 for treatment of itching of the eye associated with allergic conjunctivitis	Added	**NMOP Preferred Drug Program** No **Quantity Limits** General rule applies **Prior Authorization** No	Not added

Generic name (Trade name; manufacturer)	**Indication, approval date**	**NMOP Formulary Status**	**NMOP or retail network formulary restrictions**	**BCF Status**
Levo-floxacin ophthalmic solution, 0.5%, (Quixin; Santen)	Approved 21 Aug 00 for the treatment of bacterial conjunctivitis	Added The committee noted that although there is little reason for prescriptions for the 7-day regimen of Quixin to be filled through the NMOP, other acute use antibiotics are available through the NMOP.	**NMOP Preferred Drug Program** No **Quantity Limits** General rule applies **Prior Authorization** No	Not added
Estradiol/ norethin-drone acetate tablets (Activella; Pharmacia & Upjohn)	Approved 11 Apr 00 for women with an intact uterus for the prevention of postmenopausal osteoporosis	Added	**NMOP Preferred Drug Program** No **Quantity Limits** General rule applies **Prior Authorization** No	Not added
Atova-quone/ proguanil (Malarone; Glaxo Wellcome)	Approved 14 July 00 for the prevention and treatment of acute, uncomplicated Plasmodium falciparum malaria. Dosing recommendations in labeling for pediatric patients > 11 kg.	Added	**NMOP Preferred Drug Program** No **Quantity Limits** General rule applies **Prior Authorization** No	Not added The committee noted that this drug has more application for readiness applications than for managed care. Special note was made of the pediatric indications for Malarone. LTC Greg Russie from the Joint Readiness Clinical Advisory Board commented that it is likely that facilities that need the agent for deployment purposes will have it, while active duty dependents traveling overseas will have access to the drug through the NMOP.

Generic name (Trade name; manufacturer)	**Indication, approval date**	**NMOP Formulary Status**	**NMOP or retail network formulary restrictions**	**BCF Status**
Lopinavir/ ritonavir solution (Kaletra; Abbott)	Approved 15 Sep 00 for the treatment of HIV-1 infection in adults and pediatric patients age six months and older	Added	**NMOP Preferred Drug Program** No **Quantity Limits** General rule applies **Prior Authorization** No	Not added
Eflornithine HCl 13.9% cream (Vaniqa; Bristol-Myers Squibb)	Approved 28 Jul 00 for the reduction of unwanted facial hair in women	Excluded Drugs intended for purely cosmetic purposes are not covered under the TRICARE benefit.	Non-applicable	Not added
Bexarotene gel (Targretin gel; Ligand)	Approved 29 Jun 00 for the topical treatment of cutaneous lesions in patients with early-stage (TNM Stage IA and IB) cutaneous T-cell lymphoma (CTCL) who have refractory or persistent disease after other therapies or who have not tolerated other therapies	Excluded It does not appear feasible to meet strict requirements for avoiding pregnancy (including limiting to a one month supply, monthly pregnancy tests, and frequent counseling) in a mail-order program. Oral bexarotene was excluded from the NMOP Formulary in Feb 00.	Non-applicable	Not added

APPENDIX B: ITEMS TO BE ADDRESSED AT THE NEXT MEETING

1. Report of the subcommittee to develop standard procedures for MTFs to request BCF changes and propose agenda items for the DoD P&T Committee and follow-up on placement of a form on the PEC website for MTF providers and other DoD personnel involved in the prescribing process to propose additions, deletions, or changes to the BCF. Subcommittee members include: MAJ George Jones (chair), MAJ Barbara Roach (PEC), MAJ Brett Kelly, CDR Matt Nutaitis, MAJ Mickey Bellemin, LTC Judith O'Connor.

2. NMOP preferred drug program standing report – CDR Mark Brouker (PEC)

3. NMOP prior authorization program standing report – MAJ Mickey Bellemin, Shana Trice (PEC)

4. Controlled distribution of alendronate (Fosamax) 40 mg (for Paget's Disease)

5. Controlled distribution of dofetilide (Tikosyn)

6. Controlled distribution of etanercept (Enbrel)

Department of Defense
Pharmacoeconomic Center

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Fort Sam Houston, TX 78234-6190

MCCS-GPE **15 Nov 00**

MEMORANDUM FOR: Executive Director, TRICARE Management Activity (TMA)

SUBJECT: Minutes of the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Executive Council Meeting

1. The inaugural meeting of the DoD P&T Executive Council convened at 0800 hours on 15 November 2000, at Ft Sam Houston, TX. The DoD P&T Executive Council is responsible for performing certain inherently governmental functions relevant to the DoD pharmacy benefits program. The council focuses primarily on issues related to the Basic Core Formulary (BCF), national pharmaceutical contracts, and blanket purchase agreements. The DoD P&T Executive Council is comprised of federal employees who are members of the DoD P&T Committee.

2. **MEMBERS PRESENT:**

CDR Terrance Egland, MC	P& T Committee Co-chair
COL Daniel D. Remund, MS	P& T Committee Co-chair
MAJ Brett Kelly, MS	Army
LTC Judith O'Connor, MC	Army
CDR Matt Nutaitis, MC	Navy
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COL Bill Sykora, MC	Air Force
MAJ George Jones, BSC	Air Force
CDR Robert Rist	Coast Guard
Ronald L. Mosier	Department of Veterans Affairs
LTC Greg Russie, BSC	Joint Readiness Clinical Advisory Board
LTC Steven Humburg, MC	Health Affairs
MAJ Mickey Bellemin, BSC	Defense Supply Center Philadelphia

MEMBERS ABSENT:

COL Rosa Stith, MC	Army

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COL Mike Heath, MS	Army Pharmacy Consultant; Chair, DoD Pharmacy Board of Directors
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Shana Trice	DoD Pharmacoeconomic Center
Vincent Valinotti	Defense Supply Center Philadelphia
Paul Vasquez	Defense Supply Center Philadelphia

3. **IMPLICATIONS OF THE FY00 AND FY01 DEFENSE AUTHORIZATION ACTS** – COL Remund and LTC (P) Davies briefed the committee on implications of the FY00 and FY01 Defense Authorization Acts for the BCF. The BCF should be expanded to ensure uniform availability of cost-effective pharmaceuticals that will satisfy the primary care needs of the vast majority of patients served by MTF pharmacies. The DoD Pharmacoeconomic Center (PEC) will analyze drug usage data from MTF pharmacies, the NMOP and retail pharmacy networks to assist the committee in selecting additional pharmaceuticals for inclusion on the BCF at the next P&T meeting.

4. **NATIONAL PHARMACEUTICAL CONTRACTS**

A *Contract awards and renewals*

- The proton pump inhibitor (PPI) contract for omeprazole (Prilosec; Zeneca) was renewed. The price decreased from $1.40 to $1.10 per capsule.

- The FDA approved the marketing of the 0.8 mg dosage of cerivastatin (Baycol; Bayer). The 0.8 mg tablet is not being added to the statin contract, but is available at a DAPA price of $0.50 per tablet. According to package labeling, 0.8 mg/day of cerivastatin reduces LDL cholesterol by 42% and raises HDL cholesterol by 9% after 8 weeks of therapy. A 0.8 mg daily dose of cerivastatin costs $183 per year and provides approximately the same percent reduction in LDL-C as simvastatin 40 mg/day, which costs $361 per year.

- Joint VA/DoD single source contracts were awarded for acetaminophen, acyclovir, azathioprine, hydroxyurea, pentoxifylline, rifampin, sucralfate, and terazosin.

- Joint VA/DoD single source contracts were renewed for ranitidine, insulin, prazosin, and cimetidine.

- Prices and effective dates for contracts are available on the DSCP website.

B. *Financial impact of contracts* – Incomplete prime vendor data impaired the accuracy of previous estimates of the financial impact of national pharmaceutical contracts. The Defense Supply Center Philadelphia (DSCP) recently provided more complete prime vendor data to the PEC. Analysis of the more complete data revealed that MTFs spent approximately $1.03 billion on pharmaceuticals through the prime vendor system in FY 00. MTF cost avoidance from national pharmaceutical contracts was approximately $62.8 million in FY 00. A summary of MTF cost avoidance from national pharmaceutical contracts is provided in Appendix A. Market share and cost avoidance data associated with national pharmaceutical contracts are also available on the PEC website.

C. *Status of joint VA/DoD solicitation for non-sedating antihistamine contract* – Pharmaceutical companies have submitted multiple GAO protests to the solicitation. The PEC is working with the VA Pharmacy Benefit Management (PBM) Strategic Healthcare Group, the VA National Acquisition Center (NAC), and DSCP to resolve the protests.

D. *Status of contracting initiatives for oral contraceptives* – LCDR Beale reported that DSCP received no bids by the closing date of the solicitation for a joint VA/DoD single source contract for 35 mcg ethinyl estradiol (EE) / 1 mg norethindrone. DSCP plans to reissue the solicitation. DSCP also plans to issue solicitations for joint VA/DoD single source contracts for 35 mcg EE / 1 mg ethynodiol diacetate; EE 30/40/30 mcg / levonorgestrel 0.05/0.075/0.125 mcg; and 0.35 mg norethindrone.

E. *Returned goods contract* – LCDR Beale reported on DSCP's efforts to establish a returned goods contract.

F. *Potential future contract initiatives* – Potential candidates for future joint VA/DoD single source contracts include spironolactone, ticlopidine, isosorbide, diclofenac, ketoconazole cream, capsaicin cream, valproic acid, and hydrochlorothiazide.

5. **FLUOROQUINOLONES** – The committee considered safety, tolerability, efficacy and other pertinent factors and concluded that fluoroquinolones are not sufficiently interchangeable for a closed class contract. Fluoroquinolones differ significantly in adverse event profiles, spectrum of activity, and FDA-approved indications. The committee was also concerned that a closed class contract would preclude the use of new fluoroquinolones that may be approved by the FDA in the near future. The new fluoroquinolones may offer significant clinical advantages over existing agents.

   The committee selected levofloxacin for the BCF. The safety, tolerability and efficacy of levofloxacin are equivalent to or better than other fluoroquinolones. MTF fluoroquinolone usage has shifted away from ciprofloxacin in favor of levofloxacin over the past two years. Levofloxacin now accounts for nearly 70% of all fluoroquinolone prescriptions dispensed at

MTFs. The shift in market share was likely spurred by a blanket purchase agreement (BPA) that offered levofloxacin at a price of $2.00 per daily dose if levofloxacin attained a 60% market share at an MTF. Levofloxacin cost $2.50 per daily dose if the 60% market share was not achieved. A recent modification of the levofloxacin BPA lowers the market share requirement to 50%, but MTFs that do not meet the market share requirement will now pay the federal ceiling price of $3.25 per day for levofloxacin.

Some MTFs report that they are unable to obtain levofloxacin at the BPA price because purchases of ciprofloxacin for readiness requirements have artificially depressed the levofloxacin market share at their facilities. This problem is more prevalent at Air Force and Coast Guard pharmacies. The committee encouraged DSCP to modify the terms of the BPA so that MTFs can more easily obtain levofloxacin at the BPA price.

The fluoroquinolone class remains open on the BCF, so MTFs may have fluoroquinolones on their formulary in addition to levofloxacin. The committee is aware that ciprofloxacin is the only fluoroquinolone approved for the treatment of anthrax. The committee stressed that the selection of levofloxacin for the BCF has no bearing on the purchase of ciprofloxacin for readiness requirements.

6. **LEUTINIZING HORMONE RELEASING HORMONE (LHRH) AGONISTS** – The committee considered the PEC clinical review (available on the PEC website) and concluded that it is not possible to establish a closed class contract for a single agent to cover all nine clinical conditions that are treated with LHRH agonists. Seven of the clinical conditions affect only woman or children and two conditions affect only men. None of the four LHRH agonists is indicated for all the clinical conditions. The PEC estimates that 58% of MTF prescriptions for LHRH agonists are for prostate cancer and this usage is fairly evenly split between goserelin and leuprolide. Leuprolide accounts for nearly all the MTF usage for conditions other than prostate cancer.

   The committee concluded that goserelin and leuprolide are equivalent in regard to safety, tolerability, efficacy and other pertinent factors in the treatment of prostate cancer, so it is theoretically possible to establish a closed class contract for the specific indication of prostate cancer. The committee decided not to seek a closed class contract at this time. Since the VA already has a closed class contract for goserelin for treatment of prostate cancer, a joint VA/DoD contract should not be pursued until the VA is ready to rebid the contract. If DoD were to establish its own closed class contract now, it would likely hinder the ability to solicit for a joint VA/DoD contract in the future. The committee also has concerns about the potential complexity of administering a closed class contract for a specific indication within the military health system.

   The committee was informed of a recent voluntary price reduction for leuprolide and an offer of a blanket purchase agreement (BPA) for goserelin (see Appendix B for price information and BPA terms). The BPA prices for goserelin are equal to the VA national contract prices and are substantially lower than the prices for equivalent doses of leuprolide for prostate cancer. The committee advised DSCP to accept the BPA for goserelin. The committee asked DSCP and the PEC to initiate an education/marketing campaign to ensure that goserelin

achieves at least an 80% overall share of the MTF prescriptions for LHRH agonists for prostate cancer as required by the BPA. The PEC will use the Uniformed Services Prescription Database (USPD) to track the market shares for LHRH agonists for prostate cancer.

7. **NASAL INHALED CORTICOSTEROIDS** – The committee reviewed a draft of the VA clinical review and MTF usage and cost data for intranasal corticosteroids. The committee made the following observations and conclusions:

   - Nasal corticosteroids are widely used as first line agents in treating nasal symptoms of seasonal and perennial allergic rhinitis.

   - Nasal corticosteroids do not differ significantly in their safety profiles. All nasal corticosteroids carry the same warning regarding potential suppression of growth in children.

   - Patients generally tolerate the aqueous formulations better than the non-aqueous formulations.

   - All nasal corticosteroids can be considered equally effective for seasonal and perennial allergic rhinitis when used in equipotent doses. Agents that are normally dosed once or twice daily are commonly classified as "high potency" agents. These agents are budesonide 32mcg/spray, fluticasone 50mcg/spray, triamcinolone 55mcg/spray, mometasone 50mcg/spray, and beclomethasone 84mcg/spray.

   - Annual MTF usage of nasal corticosteroids has remained relatively constant, but annual expenditures have nearly doubled over the past three years due to large price increases for some of the agents. Significant shifts in market share have occurred over the past two years—probably in response to the large price increases. Two years ago, beclomethasone inhalers accounted for 80% of all nasal corticosteroid prescriptions filled at MTFs—now they account for only 20% of the prescriptions. Fluticasone 50mcg/spray (the only nasal corticosteroid inhaler currently on the BCF) and mometasone 50mcg/spray now account for 60% and 20% respectively of all nasal steroid prescriptions filled at MTF pharmacies.

   The committee agreed that the nasal corticosteroid inhaler class can be divided into two categories: aqueous and non-aqueous formulations. The aqueous formulations can be further subdivided into high potency and low potency categories. The committee concluded that the BCF must contain, at a minimum, a high potency aqueous nasal corticosteroid. The committee agreed that a closed class contract could be established for a high potency aqueous corticosteroid inhaler. The committee recommended that this should be a joint VA/DoD contract if the requirements of the two agencies are conducive to such a contract. The committee also supports a closed class contract for a non-aqueous corticosteroid inhaler if those involved in the contracting process conclude that it would be beneficial to seek such a contract.

8. **ORAL INHALED CORTICOSTEROIDS** – The committee considered the PEC clinical review (available on the PEC website) and made the following observations and conclusions.

   - High potency agents (budesonide and fluticasone) are not interchangeable with low potency agents (beclomethasone, triamcinolone, and flunisolide). Patients with moderate to severe asthma often prefer a high potency agent because they can obtain the necessary dosage with fewer puffs per day than with low potency agents.

   - Budesonide and fluticasone are not sufficiently interchangeable because fluticasone is available as a metered dose inhaler (MDI) and a dry powder inhaler (DPI) and budesonide is available only as a DPI. Some patients do not like using the breath-actuated DPI because it lacks the tactile feedback associated with an MDI that uses a propellant to deliver the drug. Breath actuation may be particularly difficult for pediatric patients. Patients who need to use a spacer with a face mask cannot use a budesonide DPI.

   - The bitter taste of flunisolide limits its interchangeability with other low potency agents.

   - The triamcinolone inhaler comes with a built-in spacer. While this ensures the use of a spacer, the spacer is relatively low volume and does not work well with a face mask.

   The committee concluded that oral corticosteroid inhalers are not sufficiently interchangeable for a closed class contract for the overall class or the high potency or low potency categories. The committee discussed the possibility of adding a high potency oral corticosteroid inhaler to the BCF, but concluded that the issue should be addressed in the process of selecting additional agents for the BCF at the next P&T meeting.

9. **POTENTIAL ADDITION OF A THIAZOLIDINEDIONE ("GLITAZONE") TO THE BCF**
   The thiazolidinediones currently on the market are rosiglitazone and pioglitazone. Troglitazone was withdrawn in March 2000 due to cases of hepatotoxicity and liver failure, some fatal. The committee agreed that post marketing surveillance has not yet proven conclusively that rosiglitazone and pioglitazone are free from similar safety problems. The committee also discussed the side effect of edema and weight gain known to occur with the glitazones and the related contraindication in patients with New York Heart Association Class III and IV heart failure. Although the glitazones are approved for monotherapy, clinical practice guidelines (including the DoD/VA Clinical Practice Guideline for diabetes) and expert opinion currently support use of glitazones only as add-on medications following sulfonylureas, metformin, and possibly other antidiabetic agents. The committee concluded that a thiazolidinedione should not be added to the BCF at this time.

10. **SELECTION OF A TRIPTAN FOR THE BCF (EVALUATION OF BPA PRICE QUOTES)**

    The committee considered the PEC class review (available on the PEC website) of oral 5-HT_1 receptor agonists (triptans) and concluded the following:

    - There are no clinically significant differences in the overall safety profiles of the individual triptans.

- Patients probably tolerate naratriptan better than the other triptans (the incidence of adverse events experienced by patients in phase III trials was similar to placebo). No significant differences in tolerability can be discerned between the other agents

- The efficacy of triptans can be measured by how fast they relieve headaches, to what degree they relieve headaches, and how frequently the headaches reoccur. Some studies suggest that rizatriptan may be slightly more efficacious than sumatriptan and zolmitriptan, but the available evidence is insufficient to conclude that there is any clinically significant difference in efficacy between rizatriptan, sumatriptan and zolmitriptan. Naratriptan should not be considered a first line agent because of its slower onset of action.

    - Head-to-head trials suggest that rizatriptan may provide earlier and/or more complete headache relief than either sumatriptan or zolmitriptan.

    - Two published meta-analyses of several studies found no significant differences in the "number needed to treat (NNT)" for sumatriptan, rizatriptan, and zolmitriptan. The NNT for naratriptan was significantly higher.

    - The PEC tried to compare the data from various clinical trials that measured efficacy in terms of the percentage of patients who obtained headache relief at two hours after the first dose of a triptan. In an effort to control for factors that may have varied between the trials, the PEC calculated the incremental efficacy of the triptan compared to placebo by subtracting the percentage of patients who obtained relief on placebo from the percentage of people who obtained relief on the triptan. This analysis showed a slightly higher incremental efficacy for rizatriptan. A formal statistical analysis was not performed, but it is likely that the difference between rizatriptan and the other triptans was not statistically significant.

The committee then considered the weighted average cost per prescribed dose for each triptan, which was derived from a frequency distribution of the prescribed doses and the price per tablet for each strength of each triptan. The frequency distributions of prescribed doses were obtained from the USPD. The price per tablet reflected the prices offered by pharmaceutical companies in response to a Blanket Purchase Agreement (BPA) request for price quotes issued by DSCP. The DAPA price was used if a company did not submit a price quote.

The committee concluded that sumatriptan offered the greatest value to DoD. Sumatriptan is similar in safety, tolerability and efficacy to rizatriptan and zolmitriptan. The price quote of $6.95 for sumatriptan 50 mg and 100 mg tablets reflects a 5% price reduction from the existing DAPA prices. Given the fact the sumatriptan accounts for 93% of the triptan usage at MTFs, acceptance of the sumatriptan price quote will yield the greatest cost avoidance for DoD.

The committee voted to add sumatriptan to the BCF. The triptan class remains open on the BCF. The committee emphasized that the addition of sumatriptan to the BCF is not intended to cause MTFs to delete other triptans from their formularies or to switch patients who are already using other triptans to sumatriptan.

11. **UPDATE AND REVISION OF THE ADVANCES IN MEDICAL PRACTICE (AMP) PROGRAM** – Total MTF expenditures and reimbursements in FY 00 for drugs covered by the AMP Program are given in the table below. Total expenditures were just slightly more than the $48.8 million that was programmed for pharmacy in the FY 00 AMP program.

	MTF Expenditures	AMP Reimbursement
All AMP drugs other than COX-2 inhibitors	$43,377,976	$43,377,976
COX-2 inhibitors*	$13,862,741	$6,931,370
Total	**$57,240,717**	**$50,309,346**

* reimbursed at 50%

Only $50.7 million in AMP funds are projected to be available for pharmacy in FY 01, which will be insufficient to cover the drugs currently included in the AMP program. During the last 3 months of FY 00, MTFs spent an average of $4 million per month on AMP drugs other than COX-2 inhibitors. It would be reasonable to project that expenditures for AMP drugs other than COX-2 inhibitors could easily exceed the $50.7 million in AMP funds programmed for pharmacy in FY 01. Expenditures for COX-2 inhibitors averaged nearly $2 million per month during the last 3 months of FY 00. Even if expenditures for COX-2 inhibitors in FY 01 leveled off at the expenditure rate observed in the last three months of FY 00, pharmacy would still require $12 million above the projected AMP program to reimburse MTFs for COX-2 inhibitors in FY 01. The committee concluded that COX-2 inhibitors should be removed from coverage under the AMP program because funds available to pharmacy are insufficient to support their reimbursement under the AMP program.

12. **CONSIDERATION OF COMBINATION DRUGS FOR THE BCF** – The committee discussed pros and cons of having combination drugs on the BCF. Combination drugs might offer the advantages of greater convenience and improved compliance for patients. They also could possibly reduce workload for pharmacies if a prescription for one combination product actually replaces two prescriptions for individual products. Combination products pose the disadvantages of fixed dosages that preclude adjustment in the dosage of the component drugs and the potential for unnecessary exposure to drugs if a combination product is used when a single drug would have sufficed.

The committee considered Glucovance, a newly-approved combination of metformin and glyburide. Even though Glucovance is priced slightly lower than the combined cost of the individual drugs, the committee decided not to add Glucovance to the BCF. Generic versions of metformin are expected to be available in less than a year, so the cost advantage offered by Glucovance will likely be a short-term phenomenon. The committee expects that cost of

generic versions of the individual drugs will likely be significantly less than the cost of Glucovance.

The committee considered Combivent inhaler, a combination of ipratropium and albuterol. While patients may find Combivent more convenient to use than separate inhalers, there is no conclusive evidence that patient compliance is improved significantly. Combivent costs slightly more than individual ipratropium and albuterol inhalers. The higher cost might be offset by reduced usage of albuterol inhalers, but conclusive data are not available. The committee decided not to add Combivent to the BCF.

<signed>
DANIEL D. REMUND
COL, MS, USA
Co-chair

<signed>
TERRANCE EGLAND
CDR, MC, USN
Co-chair

Appendix A: Estimated Cost Avoidance in DoD MTFs Due to National Pharmaceutical Contracts, Fiscal Year 2000

Total FY00 prime vendor purchases in DoD MTFs were $1,024,591,068. The total cost avoidance of $62,804,712 for FY00 was equal to 6.13% of the total FY00 prime vendor purchases.

Drug/Drug Class	Cost Avoidance
Statins	$22,340,377
PPIs	$19,297,055
Lisinopril	$10,072,755
Diltiazem	$6,967,368
Ranitidine	$1,862,449
Albuterol	$923,293
Timolol Gel	$540,882
Verapamil	$413,898
Cimetidine	$292,913
Captopril	$135,558
Nortriptyline	$83,643
Amoxicillin	$60,492
Timolol Drops	$31,473
Fluocinonide	$14,749
Prazosin	$14,153
Amantadine	$5,796
Insulin	($252,142)
TOTAL FY00	**$62,804,712**

Appendix B: Cost Considerations – Goserelin and Leuprolide Depot for Prostate Cancer

MAGNITUDE OF DOD EXPENDITURE: DoD can expect to spend approximately $5 million for 17,500 LHRH agonist prescriptions in FY01. Approximately 58% of these, or 10,000 prescriptions, will be for strengths used for prostate cancer. These 10,000 prescriptions are currently split almost evenly between goserelin and leuprolide. Over 97% of the remaining LHRH agonist prescriptions are for leuprolide.

DOD PRICING FOR GOSERELIN AND LEUPROLIDE DEPOT FORMULATIONS

	Goserelin			**Leuprolide**		
	Dosage Form	**Nov 00 DAPA price**	**BPA Price*** (equals VA contract price)	**Dosage Form**	**Oct 00 DAPA Price**	**Nov 00 DAPA Price** (resulting from voluntary price reduction)
1-month depot	3.6 mg implant	$213.80	$140.67	7.5 mg depot	$257.00	$227.21
3-month depot	10.8 mg implant	$611.62	$418.70	22.5 mg depot	$770.99	$681.63
4-month depot	Not available			30 mg depot	$976.58	$908.84

*The BPA for goserelin provides for a direct, immediate modification of the prime vendor price, not a rebate. The requirement is that goserelin achieve >80% market share of the prostate cancer market within 9 months (by August 2001).

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MCCS-GPE 17 Aug 2000

MEMORANDUM FOR: Assistant Secretary of Defense (Health Affairs)

SUBJECT: Minutes of the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee Meeting

1. In accordance with Health Affairs policy 98-025, a meeting of the DoD P&T committee convened at 0800 hours on 17 August 2000, at the Uniformed Services School of the Health Science, Bethesda, MD.

2. MEMBERS PRESENT:

CDR Terrance Egland, MC	Co-chair
COL Daniel D. Remund, MS	Co-chair
COL Mike Heath, MS	Army
LTC Judith O'Connor, MC	Army
CDR Matt Nutaitis, MC	Navy
CDR Kevin Cook, MSC	Navy
COL (select) John R. Downs, MC	Air Force
LTC Deborah Bostock	Air Force (alternate)
MAJ George Jones, BSC	Air Force
LCDR Pam Stewart-Kuhn	Coast Guard
MAJ Mickey Bellemin, BSC	Defense Supply Center Philadelphia (DSCP)
Trevor Rabie	Uniformed Services Family Health Plans (USFHP)
Ray Nan Berry	Foundation Health
Kirby Davis	Anthem Alliance
William Hudson	Humana, Inc
Gene Lakey	TriWest
Ron McDonald	Sierra Military Health Services

MEMBERS ABSENT:

COL Rosa Stith, MC	Army

Joint Readiness Clinical Advisory Board representative
Department of Veterans Affairs representative

OTHERS PRESENT

LTC (P) William Davies	DoD Pharmacy Program Director, Tricare Management Activity (TMA)
CDR Mark Brouker, MSC	DoD Pharmacoeconomic Center
LTC Don De Groff, MS	DoD Pharmacoeconomic Center
MAJ Cheryl Filby, MS	Defense Supply Center Philadelphia
MAJ Brett Kelly, MS	TRICARE Lead Agent Office (Region 1)
Howard Altschwager	Deputy General Counsel, TMA
David Chicoine	Uniformed Services Family Health Plan
Linda Magazu	Defense Supply Center Philadelphia
Mark Petruzzi	Merck-Medco
Elizabeth Scaturro	Merck-Medco
Shana Trice	DoD Pharmacoeconomic Center
Paul Vasquez	Defense Supply Center Philadelphia

3. ADMINISTRATIVE ISSUES

   The minutes from the last meeting were accepted as written. COL Mike Heath replaced Danielle Doyle as the Army pharmacy representative.

4. REVIEW OF INTERIM DECISIONS – The co-chairs made an interim decision to institute the same quantity limits in the National Mail Order Pharmacy (NMOP) program and the retail network for ondansetron oral dissolving tablets (Zofran ODT) as those currently in place for ondansetron tablets (Zofran). The committee agreed with the interim decision.

5. UPDATE ON THE ADVANCES IN MEDICAL PRACTICE (AMP) PROGRAM – COL Remund presented military treatment facility (MTF) prime vendor expenditure data through May 00 for drugs covered under the AMP program. Accurate prediction of the total AMP expenditures for FY 00 is impossible because prime vendor data are missing for numerous military treatment facilities (MTFs). The "best guess" is that total MTF expenditures for AMP drugs will be around $47 million in FY 00, which will use up all the AMP funds available for pharmacy. The committee decided to make no changes in the drugs covered by the AMP program until we are more certain about expenditures for AMP drugs in FY 00 and we know how much AMP funding will be available for pharmacy for FY 01.

6. UPDATE ON BCF ADDITIONS RESULTING FROM PROGRAM BUDGET DECISION (PBD) 041 – COL Remund presented prescription data from the Uniformed Services Prescription Database (USPD) for the drugs added to the Basic Core Formulary (BCF) in Jan 00 as a result of PBD 041. A marked increase in the number of prescriptions filled for these drugs indicates that MTFs have generally complied with BCF policy by adding these drugs to their formularies.

7. SELECTION OF AN ADDITIONAL ACE INHIBITOR FOR THE BCF

The primary purpose of adding another long-acting ACE inhibitor to the BCF is to ensure uniform availability at all MTFs of an additional agent within a class of drugs that is known to provide significant clinical benefits at a reasonable cost. The ACE inhibitor clinical review prepared by the PEC will be posted on the PEC website. The committee first considered the relative safety, tolerability, efficacy, and other factors pertaining to ACE inhibitors and agreed that:

- Fosinopril may offer a slight safety/convenience advantage in patients with renal or hepatic failure due to its lack of dose adjustment requirements.
- There is insufficient evidence to conclude that ACE inhibitors differ significantly in their propensity to cause cough.
- All long-acting ACE inhibitors appear to be similar in efficacy for hypertension.
- Benazepril, enalapril and ramipril have the most evidence of a beneficial effect on renal disease/diabetic nephropathy.
- Enalapril and ramipril have the most extensive evidence of reduction in morbidity and mortality in patients with congestive heart failure (CHF), post-myocardial infarction (MI), or asymptomatic left ventricular (LV) dysfunction. Trandolapril has evidence of reduction in morbidity and mortality in a subset of these patients (LV dysfunction post MI). Fosinopril, quinapril, and perindopril have evidence of a beneficial effect on signs and symptoms of CHF and on disease progression, but lack mortality data. Moexipril and benazepril have little or no evidence supporting use in these patient populations.
- Ramipril appears to be the only ACE inhibitor with evidence of a reduction in the risk of stroke in patients at high cardiovascular risk.

The committee then considered the weighted average daily cost per patient for each ACE inhibitor, which was derived from the frequency distribution of prescribed daily doses and the price per tablet for each strength of each ACE inhibitor. The frequency distributions of prescribed daily doses were obtained from the USPD. The price per tablet reflected the prices offered by pharmaceutical companies in response to a Blanket Purchase Agreement (BPA) request for price quotes issued by Defense Supply Center Philadelphia. The DAPA price was used if a company did not submit a price quote.

Ramipril had the second lowest weighted average daily cost per patient, which was only $0.008 more than the lowest cost ACE inhibitor (a difference of $2.92 per patient per year). The committee concluded that ramipril offered the greatest value to DoD because its extensive evidence of proven clinical benefits for a variety of conditions outweighed its slightly higher cost. The committee decided (by a vote of 8 to 1) to add ramipril to the BCF.

The ACE inhibitor class remains open on the BCF. The committee emphasized that the addition of ramipril to the BCF is not intended to cause MTFs to delete other ACE inhibitors from their formularies or to switch patients who are already using other ACE inhibitors to ramipril.

8. STATUS OF ORTHO NOVUM 7/7/7 ON THE BCF – Ethinyl estradiol 35 mcg/norethindrone 0.5/0.75/1 mg (Ortho-Novum 7/7/7) is one of two oral contraceptive products still available

through the DSCP Centrally Managed Inventory Program (the depot). The price of Ortho-Novum 7/7/7 through the depot is approximately $5.56 per cycle, including surcharge, compared to $15.78 per cycle through the prime vendor program (DAPA price as of May 00). The Ortho-Novum 7/7/7 packages stocked in the depot are clinic packs, which cannot be included under the prime vendor program. About 64% of the estimated 274,000 cycles of Ortho-Novum 7/7/7 purchased by MTFs from Apr 99 to Mar 00 were obtained from the depot. The DSCP product manager expects that the product will continue to be available through the depot until at least 2002. The committee agreed that Ortho-Novum 7/7/7 should remain on the BCF, but strongly encouraged MTFs to order the product through the depot.

9. STATUS OF OXYCODONE/ACETAMINOPHEN ON THE BCF – The BCF currently requires MTFs to have both the 5/325 and 5/500 mg strengths of oxycodone/acetaminophen on their formularies. MTF pharmacists contend that both strength combinations are not needed at all MTFs. The committee agreed to change the BCF to state: "oxycodone/acetaminophen 5/325 mg *and/or* 5/500mg." MTFs may decide to have one or both combinations on their formularies.

10. PROCEDURE FOR REQUESTING BCF CHANGES – The committee appointed a subcommittee to develop standard procedures for MTFs to request changes to the BCF and to propose agenda items for the DoD P&T Committee. The subcommittee will present its recommendations at the next meeting. Subcommittee members include: MAJ George Jones (chair), MAJ Barbara Roach (PEC), MAJ Brett Kelly, CDR Matt Nutaitis, MAJ Mickey Bellemin, LTC Judith O'Connor.

11. NATIONAL PHARMACEUTICAL CONTRACTS, BLANKET PURCHASE AGREEMENTS, AND INCENTIVE PRICE AGREEMENTS

    A. *Contracts Awarded Since Last Meeting* – LTC De Groff reported that a joint DoD/VA single source contract for terazosin tablets and capsules was awarded with a start date of 5 Sep 00. Contract prices are approximately 70% less than the pre-contract prices. DoD MTFs purchased at least $6.1 million of terazosin tablets and capsules through the prime vendor program during FY99.

    B. *Financial Impact of Contracts* – COL Remund reported cumulative cost avoidance for national pharmaceutical contracts based on prime vendor data through May 00. Cost avoidance information is maintained on the PEC website. Accurate calculation of cost avoidance is impossible because prime vendor data are missing for numerous MTFs. The "best guess" is that cost avoidance from national pharmaceutical contracts will total approximately $52 million for MTFs in FY 00. To put this in context, total expenditures at MTF pharmacies in FY99 were $878 million.

    COL Remund also reported that efforts by the PEC and DSCP to monitor the financial impact of national pharmaceutical contracts have yielded additional benefits. SFC (P) Tom Bolinger, NCOIC at the PEC, discovered that a prime vendor had charged an MTF the wrong price for three drugs. Correction of the pricing errors resulted in a $236,500 credit for that MTF.

C. *Potential contract for Extended Release Morphine* – The committee considered the possibility of competing MS Contin, "A-rated" generic equivalents to MS Contin, Oramorph SR, and Kadian against each other for a closed class contract. MTF providers contend that MS Contin has a longer duration of action than Oramorph SR, and two published studies support that contention. Kadian is dosed once daily, while the other products typically require multiple daily doses. The committee concluded that these drugs are not sufficiently interchangeable for a closed class contract.

D. *Potential Contracts for Oral Contraceptives* – The committee reiterated that single source contracts should be sought for each of the following oral contraceptive agents:

1) ethinyl estradiol (EE) 35 mcg / norethindrone 1 mg
2) EE 35 mcg / ethynodiol diacetate 1 mg
3) EE 30/40/30 mcg / levonorgestrel 0.05/0.075/0.125 mcg
4) norethindrone 0.35 mcg

E. *Returned Goods Contract* – Linda Magazu updated the committee on the status of the returned goods contract.

F. *Generic 2000 and 2000B packages (VA lead)* – LTC De Groff reported on the progress of joint DoD/VA single source contracts for multi-source drugs included in the Generic 2000 and 2000B packages. The Generic 2000 package includes acyclovir, azathioprine, etodolac, furosemide, glipizide, hydroxyurea, pentoxifylline, rifampin, selegiline, and sucralfate. The Generic 2000B package includes albuterol immediate release, amitriptyline, bupropion, buspirone, carbidopa/levodopa sustained action, carisoprodol, capsicum, diclofenac, hydrochlorothiazide, imipramine, isosorbide, ketoconazole cream, meclizine, methocarbamol, prednisone, sotalol, spironolactone 50- and 100-mg, sulindac, ticlopidine, verapamil immediate release, and valproic acid. An extensive 2000C package may be developed as drugs come off VA contracts in the next six months.

The committee reiterated that contracts for single sources of "A-rated" multi-source products do not normally require prior review by the DoD P&T Committee.

G. *General Accounting Office (GAO) Report – Review of Drug Classes for Contracting Potential* – The committee reviewed the GAO recommendations regarding drug classes that may be suitable for joint DoD/VA committed use contracts. The committee supports developing joint DoD/VA contracts whenever possible. The committee came to the following conclusions regarding the potential for contracts in seven drug classes as described below:

1) *$5HT_1$ receptor agonists for migraine ("triptans")* – The committee concluded that the oral triptans are not sufficiently interchangeable for a closed class contract because of variability in patient response to these agents. The committee decided that an oral triptan should be selected for the BCF in an open class to ensure uniform availability of one oral triptan while allowing MTFs to have additional oral triptans on their formularies. The PEC will do a clinical review and DSCP will obtain pricing

information by issuing a BPA request for price quotes to companies that market oral triptans. The committee is hopeful that its evaluation of the clinical and pricing information will lead to the selection of an oral triptan for the BCF at the next meeting.

2) *Thiazolidinediones ("glitazones")* – This drug class cannot be closed because the class is too new to accurately assess the interchangeability of the drugs. The PEC will do a clinical review to assess the need for adding one of these agents to the BCF. If an agent should be added to the BCF, the committee will likely advise DSCP to issue a BPA request for price quote.

3) *Oral inhaled corticosteroids* – The PEC will do a clinical review to assess the interchangeability of these agents for a closed class contract. Members commented that separate contracts might be needed for low-potency and high-potency agents.

4) *Nasal inhaled corticosteroids* – The PEC will do a clinical review to assess the interchangeability of these agents for a closed class contract.

5) *Fluoroquinolones* – The committee discussed a number of factors that could complicate contracting efforts in this drug class, including readiness requirements for ciprofloxacin (approved for anthrax) and regional variations in antibiotic resistance. The committee decided not to rule out the possibility of a closed class contract until the PEC completes a clinical review.

6) *Leutinizing hormone releasing hormones (LHRHs; leuprolide (Lupron) and goserelin (Zoladex))* – The VA has a closed class contract for goserelin (Zoladex) for prostate cancer, but a closed class contract may not be appropriate for DoD because these drugs are less interchangeable in a patient population that includes more women and children. Lupron is indicated for prostate cancer, endometriosis, uterine fibroids and precocious puberty. Zoladex is indicated for prostate cancer, endometriosis and breast cancer. The PEC will do a clinical review to assess the interchangeability of these agents for a closed class contract.

7) *Non-sedating antihistamines* – LTC De Groff reported that the market share requirements in the current incentive price agreements for the non-sedating antihistamines are difficult for MTFs to achieve. The committee concluded that the incentive price agreements probably would not yield substantial cost savings for MTFs. In light of the large increase in MHS expenditures for these agents, the committee reconsidered the possibility of a closed class contract for a non-sedating antihistamine. The committee decided that its previous objections to a closed class contract for a non-sedating antihistamine would be obviated under the following conditions:

    - Loratadine and fexofenadine are classified as non-sedating antihistamines and cetirizine is classified as a low-sedating antihistamine. Loratadine and fexofenadine are the only two drugs that compete for the contract.

- The contracted drug is the only non-sedating antihistamine on the BCF. The non-sedating antihistamine class would be closed on the BCF, so the contracted drug would be the only non-sedating antihistamine permitted on MTF formularies.
- The contract does not affect the current status or future status of loratadine or fexofenadine in regard to the NMOP formulary.
- The contract does not affect the current status or future status of cetirizine in regard to the BCF, MTF formularies, or NMOP formulary (cetirizine is not a non-sedating antihistamine).
- The contract does NOT require DoD beneficiaries who are currently taking the non-contracted drug to switch to the contracted drug.

The committee recommended that a joint DoD/VA closed class contract should be pursued if the VA is willing to amend its contract solicitation to include the DoD requirements.

12. AVAILABILITY OF INFORMATION ON INCENTIVE PRICE AGREEMENTS AND NATIONAL PHARMACEUTICAL CONTRACTS – MAJ Cheryl Filby (DSCP) reminded the committee that the DSCP website contains information on all national contracts and a list of all incentive agreements that have come through DSCP for review. Copies of the incentive agreements are available from DSCP. She also noted that MTFs were encouraged to submit incentive price agreements to DSCP for review by DSCP legal staff and posting on the DSCP website in order to expand availability to other MTFs. In addition, the website contains a tool that may assist MTFs in verifying that they are complying with (and realizing the cost avoidance associated with) all the national contracts.

13. IMPLEMENTATION OF FY00 NATIONAL DEFENSE AUTHORIZATION ACT – LTC Davies briefed the committee on the ongoing efforts to implement the provisions of the FY00 National Defense Authorization Act pertaining to the Uniform Formulary and the DoD P&T Committee.

14. BCF AND NMOP FORMULARY ISSUES

A. The following recently approved drugs were added to the NMOP formulary. None of these drugs were added to the BCF.

1. *Triamcinolone acetonide nasal spray (Tri-Nasal; Muro Pharma)*, approved 4 Feb 00 for treatment of nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 12 years and older. Tri-Nasal will have a quantity limit of 6 bottles (45 gm) per 90 days in the NMOP and 2 bottles (15 gm) per 30 days in the retail network, which is consistent with the established quantity limits for other nasal corticosteroids.

2. *Zonisamide capsules (Zonegran; Elan)*, approved 31 Mar 00 for adjunctive treatment of partial seizures in adults 16 years and older with epilepsy.

3. *Meloxicam tablets (Mobic; Boehringer-Ingelheim/Abbott)*, approved 13 Apr 00 for relief of the signs and symptoms of osteoarthritis. Meloxicam is a nonsteroidal anti-inflammatory drug (NSAID) that is preferential but not completely selective for

cyclooxygenase-2 (COX-2). If COX enzyme selectivity is conceptualized as a spectrum, meloxicam, like nabumetone and etodolac, tends to bind more to COX-2 than cyclooxygenase-1 (COX-1), while drugs such as naproxen tend to bind more to COX-1 than COX-2. Unlike celecoxib and rofecoxib, meloxicam retains some activity at COX-1 receptors. Bill Hudson noted that Humana had opted to require prior authorization of meloxicam on the same terms as rofecoxib for its commercial (non-DoD) clients. The committee noted that managed care support contractors (MCSCs) can not currently impose prior authorizations for DoD beneficiaries beyond those approved by the DoD P&T Committee (see paragraph 16 below). The committee decided that meloxicam will be identified as a non-preferred drug (like other brand name NSAIDs) on the NMOP formulary.

4. *Pemirolast potassium ophthalmic solution (Alamast; Santen)*, approved 24 Sept 99 for prevention of itching of the eye due to allergic conjunctivitis.

5. *Testosterone 1% gel (Androgel; Unimed Pharma)*, approved 28 Feb 00 for primary hypogonadism secondary to testicular failure and hypogonadotropic hypogonadism secondary to gonadotropin deficiency.

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B. *Linezolid injection, tablets, and oral suspension (Zyvox; Pharmacia & Upjohn)* were excluded from the NMOP and were not added to the BCF. Linezolid was approved 24 Apr 00 for nosocomial and community acquired pneumonia and complicated/uncomplicated skin/skin structure infections caused by susceptible organisms, primarily aerobic gram-positive organisms, including *Enterococcus faecium* (vancomycin-resistant only), *Staphylococcus aureus* (including methicillin-resistant strains), *Streptococcus pneumoniae* (penicillin sensitive strains only), *Streptococcus galactiae*, and *Streptococcus pyogenes*. Because of the potential that bacterial resistance will develop if this drug is used indiscriminately, as well as the need for dispensing the drug on a more timely basis than is possible in a mail order program, the committee excluded linezolid from the NMOP formulary.

The committee discussed the possibility of instituting a prior authorization program in the retail network to ensure that linezolid is used only when truly indicated, thus minimizing the potential for development of bacterial resistance. The committee decided not to establish a prior authorization process because a delay in therapy due to the prior authorization process would pose a greater threat than the inappropriate use that might occur in the absence of a prior authorization process. The committee requested that the MCSCs monitor usage of linezolid in their systems and report back to the committee at the next meeting.

C. *Fluoxetine (Sarafem; Lilly*) – Sarafem is supplied with special packaging/labeling for Premenstrual Dysphoric Disorder (PMDD). The committee added Sarafem to the NMOP formulary. The committee decided that the BCF listing for fluoxetine should specify that MTFs are not required to have the Sarafem brand of fluoxetine on their formularies because:

- There are no chemical or formulation differences between Sarafem and Prozac. Prozac is on the BCF.
- While Sarafem and Prozac may be the same price now, a generic form of fluoxetine may be available as soon as 2001 and will probably be much less expensive than Prozac. The generic form will probably not be substitutable for Sarafem.
- The committee is skeptical that the specialized labeling for Sarafem offers any significant incremental value over the Prozac brand of fluoxetine.

15. NON-PREFERRED/PREFERRED DRUG PAIRS IN THE NMOP – CDR Mark Brouker reported the switch rates and estimated cost avoidance for the preferred drug program in the NMOP (see Appendix C). The NMOP preferred drug program yields approximately $1.8 million in annual cost avoidance for DoD.

    The committee removed cilostazol (Pletal) from the list of non-preferred drugs due to a low switch rate (see Appendix A). No report was made on the herpes antivirals, since the new strategy of calling only on prescriptions for valacyclovir and famciclovir written for chronic use (> 30-day supply) was not implemented until 1 Jul 00.

    The committee asked the PEC to instruct Merck-Medco to remove enalapril (Vasotec) from the list of non-preferred drugs as soon as generic enalapril is available at a price that is competitive with other ACE inhibitors.

16. FORMULARY CONTROLS IN THE RETAIL PHARMACY NETWORK – LTC Bill Davies and Howard Altschwager informed the committee that clarifications have been issued to the MCSCs concerning formulary controls in the retail pharmacy networks.

- The NMOP formulary does not apply to the retail pharmacy network.
- The federal regulations that implement the law governing TRICARE currently allow prior authorizations to be applied in the retail pharmacy networks only for clinical considerations (appropriateness of therapy). Terbinafine, itraconazole, sildenafil, and etanercept will continue to be subject to prior authorization in the retail network. The prior authorization for COX-2 inhibitors will be withdrawn in the retail pharmacy networks because it is based primarily on cost-effectiveness considerations rather than clinical appropriateness. The PEC will make all required changes to its website. ~~MCSCs can not currently impose prior authorizations beyond those approved by the DoD P&T committee.~~ *(This sentence was deleted as a correction to the minutes at the Nov 00 meeting of the DoD P&T Committee.)*
- Quantity limits continue to apply both to the NMOP and the retail pharmacy network.

- Active duty personnel may fill prescriptions at retail network pharmacies—including prescriptions for controlled substances.

- DoD closed class pharmaceutical contracts (i.e. contracts for statins and proton pump inhibitors) do not apply to the retail network pharmacies. Closed class contracts that apply only to MTF pharmacies and the NMOP cannot serve as the basis for denying prescriptions in the retail pharmacy networks.

17. PRIOR AUTHORIZATIONS

A. *Cost analysis of NMOP prior authorizations* – Shana Trice (PEC) presented the subcommittee's extensive cost analysis of prior authorizations (PAs) in the NMOP. Subcommittee members included MAJ Mickey Bellemin (DPSC), MAJ Brett Kelly (TRICARE Region 1 Lead Agent Office), Shana Trice (PEC), and Dave Beshara (Merck-Medco).

For each drug, the costs that would be incurred for 1000 new prescriptions submitted to the NMOP that are subject to the PA process were compared to the costs that would be incurred if the prescriptions were not subject to the PA process. The analysis takes into account the cost of drug therapy, the charge from Merck-Medco for performing the PA, the estimated number of refills associated with each new prescription and the estimated cost of alternative therapy for prescriptions not filled as a result of the PA process. The analysis does not quantify the "sentinel effect" of PAs (i.e., the possibility that providers prescribe the drug less frequently because they know the drug is subject to prior authorization).

The analysis showed that total costs for each drug would be higher without PA than they are with PA. The cost avoidance resulting from the PA process is shown in the following table:

Drug	Cost avoidance per new Rx submitted
Etanercept (Enbrel)	$327.20
Sildenafil (Viagra)	$13.60
COX-2 inhibitors	$11.66

B. *COX-2 inhibitors* – As addressed previously, the clarification of TRICARE policy caused discontinuation of the COX-2 inhibitor PA in the retail pharmacy networks. The committee decided to continue the PA for COX-2 inhibitors in the NMOP because TRICARE policy allows prior authorizations to be based on cost-effectiveness considerations in the NMOP and because the cost analysis showed that prior authorization yielded cost avoidance in the NMOP. The committee is also concerned that usage of COX-2 inhibitors would increase even more rapidly if they were not subject to the PA process. Much of the incremental COX-2 inhibitor usage would occur among patients who are at relatively low risk for gastrointestinal problems and therefore would offer negligible incremental benefit compared to using the much less expensive generic NSAIDs.

Celecoxib is indicated for familial adenomatous polyposis (FAP), which is not addressed in the current PA criteria for COX-2 inhibitors. Patients with FAP have obtained celecoxib from the NMOP through the PA appeal process. The committee agreed that the PA criteria should be revised to address FAP. The PEC will collaborate with DSCP and Merck-Medco to revise the PA criteria.

C. *Etanercept* – As a result of the "ERA" study, etanercept is now indicated for reducing signs and symptoms and delaying structural damage in adult patients with moderately to severely active rheumatoid arthritis (RA). The PEC will collaborate with DSCP and Merck-Medco to revise the PA criteria for etanercept to properly address the expanded indication.

D. *Antifungals for onychomycosis (terbinafine, itraconazole)* – The PA for terbinafine and itraconazole for onychomycosis started 1 Jul 00 in the NMOP.

E. *Prior authorization portability process* – LTC Don De Groff reported that when the Prescription Data Transaction Service (PDTS) service is completely implemented, it will provide the capability to communicate prior authorization approvals across drug distribution channels (MTF pharmacies, NMOP, and retail pharmacies).

18. BENEFIT DETERMINATION FOR FERTILITY AGENTS – According to the Code of Federal Regulations and TRICARE policy, fertility drugs are not a covered benefit when used to assist in non-coital reproduction methods. The committee agreed with CDR Terry Egland's recommendation that prescriptions for the injectable gonadotropins (follitropin alfa, follitropin beta, urofollitropin, and menotropins) should be reviewed to determine benefit coverage.

19. PROTON PUMP INHIBITORS – Bill Hudson (Humana) initially proposed that a 90-day quantity limit be established for proton pump inhibitors (PPIs) to curb inappropriate long-term use. Committee members pointed out that extended use of PPIs does not necessarily indicate inappropriate care, so a 90-day quantity limit might impede access to appropriate care. The committee agreed with Mr. Hudson's suggestion to appoint a subcommittee to study this issue and offer recommendations at the next meeting. Subcommittee members are Bill Hudson, MAJ George Jones, LTC Judith O'Connor, MAJ Mickey Bellemin, and MAJ Ed Zastawny (PEC).

20. REPORT OF THE SUBCOMMITTEE ON QUANTITY LIMITS FOR TOPICALS – Bill Hudson reported frequency distributions of quantities dispensed per prescription for the topicals and a number of other high-volume drugs that are subject to quantity limits. Committee found that the current quantity limits appear to be appropriate.

21. CONTROLLED DISTRIBUTION OF ALENDRONATE (FOSAMAX) 40 MG (FOR PAGET'S DISEASE) – The committee was informed that Merck intends to implement a Paget's Disease Patient Support Program that includes enrollment of patients and exclusive distribution of alendronate (Fosamax) 40 mg through the specialty services pharmacy, CVS ProCare. Numerous issues regarding payment for prescriptions, patient enrollment, privacy concerns, etc., will have to be worked out in order for this program to be implemented for DoD patients.

22. CONTROLLED DISTRIBUTION OF DOFETILIDE (TIKOSYN) – Because of specialized educational requirements mandated by the FDA, this drug is only available for outpatient use through a single specialty pharmacy in the U.S. (Statlander's Pharmacy in Pittsburgh). LTC Bill Davies agreed to work with TMA contracting and policy officials and the MCSCs to address the issue of payment for dofetilide for patients in the retail network. Establishment of procedures for supplying and paying for dofetilide for MTF patients will likely require coordination between the pharmacy consultants/specialty leaders and resource management officials for each service. Dofetilide was excluded from the NMOP formulary at the last meeting.

23. CONSIDERATION OF COMBINATION DRUGS FOR THE NMOP – The committee agreed that newly marketed combination products should not be automatically added to the NMOP formulary, but should go through the normal evaluation process for addition to the formulary. If an acute need requires immediate attention, the issue should be referred to the co-chairs for an interim decision. COL Remund commented that the committee should evaluate the status of combination products with regard to the BCF at the next meeting.

24. ADJOURNMENT – The meeting adjourned at 1630 hours. The next meeting will be held 15 Nov 00 at a location to be determined. All agenda items should be submitted to the co-chairs no later than 15 Oct 00.

<signed>
DANIEL D. REMUND
COL, MS, USA
Co-chair

<signed>
TERRANCE EGLAND
CDR, MC, USN
Co-chair

List Of Appendices

Appendix A: Formulary Changes

1. BCF Changes
   A. Additions to the BCF
      1) Ramipril (Altace; Monarch) (See Paragraph 7.)
   B. Changes and Clarifications to the BCF
      1) The BCF listing for "oxycodone 5 mg /acetaminophen 325 and 500 mg" was changed to "oxycodone/acetaminophen 5/325 mg ***and/or*** 5/500 mg." MTFs may decide to have one or both combinations on their formularies. (See Paragraph 9.)
      2) The BCF listing for fluoxetine was changed to specify that MTFs are not required to have the Sarafem brand of fluoxetine on their formularies. (See Paragraph 14C.)

2. NMOP Formulary Changes
   A. *Additions to the NMOP Formulary* (See Paragraph 14A.)
      1) Triamcinolone acetonide nasal spray (Tri-Nasal; Muro Pharma)
      2) Zonisamide capsules (Zonegran; Elan)
      3) Meloxicam tablets (Mobic; Boehringer-Ingelheim/Abbott).
      4) Pemirolast potassium ophthalmic solution (Alamast; Santen)
      5) Testosterone gel (Androgel; Unimed Pharma)
   B. *Exclusions from the NMOP Formulary* (See Paragraph 14B.)
      1) Linezolid injection, tablets, and oral suspension (Zyvox; Pharmacia & Upjohn),
   C. *Changes to the NMOP Preferred Drug Program*
      1) Deletion of non-preferred/preferred pair for cilostazol/pentoxifylline (See Paragraph 15.)
      2) Addition of meloxicam to NMOP Preferred Drug Program as a brand name NSAID (See Paragraph 14A3.)
      3) Discontinuation of the non-preferred/preferred drug pair for enalapril/lisinopril as soon as generic enalapril is available at a price that is competitive with other ACE inhibitors. (See Paragraph 15.)

3. Quantity Limit Changes (NMOP and retail network)
   A. Quantity limits for triamcinolone acetonide nasal spray (Tri-Nasal; Muro Pharma) were established: 6 bottles (45 gm) per 90 days in the NMOP and 2 bottles (15 gm) per 30 days in the retail network. (See Paragraph 14A1.)
   B. Quantity limits for ondansetron oral dissolving tablets (Zofran ODT) were clarified to be the same as quantity limits for ondansetron tablets (Zofran): 45 tablets per 90 days in the NMOP and 15 tablets per 30 days in the retail network for both the 4- and 8-mg tablets. (See Paragraph 4.)

Appendix A continued: Formulary Changes

4. Changes to the Prior Authorization Program (NMOP and retail network)
   A. Clarification of TRICARE policy caused discontinuation of the PA for COX-2 inhibitors in the retail pharmacy network. The COX-2 inhibitor PA will continue in the NMOP. (See Paragraphs 16 and 17B.)
   B. The COX-2 inhibitor PA in the NMOP will be revised to address the use of celecoxib for familial adenomatous polyposis. (See Paragraph 17B.)
   C. The etanercept PA in the NMOP and retail network will be revised to address the newly expanded indication of etanercept for reducing signs and symptoms and delaying structural damage in adult patients with moderately to severely active rheumatoid arthritis (RA). (See Paragraph 17C.)

Appendix B: Items to Be Addressed at the Next Meeting

1. Report of the subcommittee to develop standard procedures for MTFs to request BCF changes and propose agenda items for the DoD P&T Committee. Subcommittee members include: MAJ George Jones (chair), MAJ Barbara Roach (PEC), MAJ Brett Kelly, CDR Matt Nutaitis, MAJ Mickey Bellemin, LTC Judith O'Connor.

2. Clinical review for $5HT_1$ receptor agonists for migraine ("triptans") – PEC

3. Price quotes for oral triptans obtained through a blanket purchase agreement request for quote – DSCP

4. Clinical review for thiazolidinediones ("glitazones") – PEC

5. Clinical review for oral inhaled corticosteroids – PEC

6. Clinical review for nasal inhaled corticosteroids – PEC

7. Clinical review for leutinizing hormone releasing hormones (LHRHs) - PEC

8. Report from the managed care support contractors regarding usage of linezolid in the retail network

9. Report of the subcommittee to study quantity limits for proton pump inhibitors. Subcommittee members include: Bill Hudson, MAJ George Jones, LTC Judith O'Connor, MAJ Mickey Bellemin, MAJ Ed Zastawny (PEC).

10. Controlled distribution of alendronate (Fosamax) 40 mg (for Paget's Disease)

11. Controlled distribution of dofetilide (Tikosyn)

12. Combination drugs on the BCF and NMOP Formulary

13. NMOP preferred drug program standing report – CDR Mark Brouker (PEC)

14. NMOP prior authorization program standing report – MAJ Mickey Bellemin, Shana Trice (PEC)

Appendix C: National Mail Order Pharmacy (NMOP) Preferred Drug Program Summary

Summary of Switch Rates and Estimated Cost Avoidance, Jun 99 – Jun 00*

Non-Preferred Drug	Preferred Drug	Switch Rate	Estimated Cost Avoidance	Total Number of Attempted Provider Contacts	Estimated Cost Avoidance per Attempted Provider Contact	Annualized Estimated Cost Avoidance
Cardizem CD Dilacor XR Diltia XT Diltiazem XR	**Tiazac**	68%	$466,128	4751	$98	$430,272
Procardia XL	**Adalat CC**	53%	$358,233	1963	$182	$330,722
Lodine XL Relafen Voltaren XR Daypro Naprelan	**Generic NSAIDs**	33%	$461,867	5502	$84	$426,338
H2 Blockers	**Generic ranitidine**	38%	$164,996**	1740	$95	$282,679
Enalapril	**Zestril**	45%	$92,854**	1704	$54	$222,850
Pletal	**Generic pentoxifylline**	11%	$1682	169	$10	$4036
Ditropan XL Detrol	**Generic oxybutynin**	29%	$112,269	3912	$30	$103,633
	Total	**$1,658,031**	**19741**	**$87**	**$1,800,530**	

* The anti-herpes data are not presented because the new anti-herpes strategy of calling only on prescriptions for valacyclovir and famciclovir for chronic use (>30-day supply) was not implemented until 1 July 00.

** H2 blockers and enalapril→lisinopril implemented Dec 99 and Feb 00, respectively. Data and cost avoidance estimate in table is from date of implementation through Jun 00.

Appendix C continued: National Mail Order Pharmacy (NMOP) Preferred Drug Program Summary

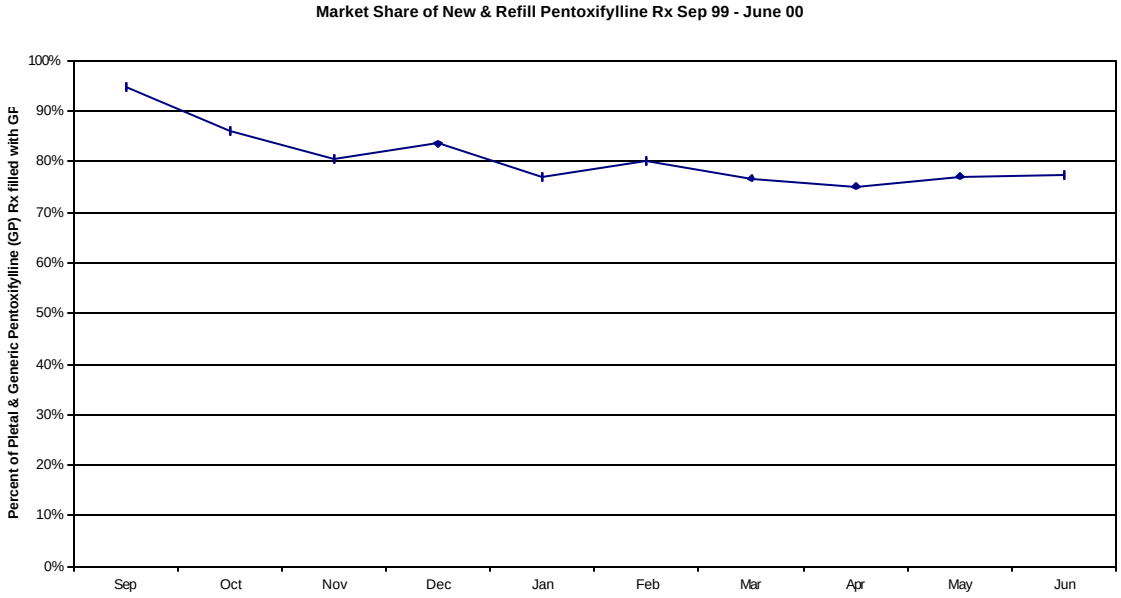
Summary of Switch Rates & Estimated Cost Avoidance for Pentoxifylline/Cilostazol, Feb 00 – Jun 00

Generic pentoxifylline was designated as a preferred drug in NMOP in August 99. Pletal (cilostazol) was designated as a non-preferred drug. Implementation began in February 2000.

Prescriptions for Non-Preferred Anti-Claudication Drugs in NMOP, Feb 00 – June 00[1]						
Month	**Feb 00**	**Mar 00**	**Apr 00**	**May 00**	**Jun 00**	**Feb 00- Jun 00**
New Rxs Received	23	33	32	41	40	169
Prescriber Contacts	21	28	26	37	38	150
Switches	5	0	3	4	6	18
Switch rate[2]	21%	0%	9%	10%	15%	11%

1 From Merck-Medco reports "NMOP Switch Report," "DoD Target Drug Report," and "DoD Prescription Volume Report" covering February through 30 June 00.
2. Percentage of new prescriptions received for non-preferred drugs that were switched to generic pentoxifylline.

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



Monthly Cost Avoidance*

Month	Feb 00	Mar 00	Apr 00	May 00	Jun 00	**Feb 00 – Jun 00**
Monthly Cost avoidance	$466	$0	$280	$457	$679	$1682

***** Monthly cost avoidance calculated by subtracting current expenditures from expenditures that would have occurred if the stated prescriptions had not been switched. Derived by multiplying the number of reported prescriptions switched for each target drug times the difference in average cost per prescription (target drug – pentoxifylline). [Note: this is a different methodology than used for other drugs and is due to difficulties in establishing a baseline percentage of market share for each of these drugs and uncertainty as to the validity of carrying percentages through to subsequent months.]

Department of Defense
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MCCS-GPE 11 May 2000

MEMORANDUM FOR Assistant Secretary of Defense (Health Affairs)

SUBJECT: Minutes of the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee Meeting

1. In accordance with Health Affairs policy 98-025, a meeting of the DoD P&T committee convened at 0800 hours on 11 May 2000, at Fort Sam Houston, TX.

2. MEMBERS PRESENT:

CDR Terrance Egland, MC	Co-chair
COL Daniel D. Remund, MS	Co-chair
COL Rosa Stith, MC	Army
LTC Judith O'Connor, MC	Army
Daniele Doyle, DAC	Army
CDR Matt Nutaitis, MC	Navy
LCDR Kevin Cook, MSC	Navy
COL (select) Bill Sykora, MC	Air Force
COL (select) John R. Downs, MC	Air Force
MAJ George Jones, BSC	Air Force
CDR Robert W. Rist	Coast Guard
Ronald L. Mosier	Department of Veterans Affairs (alternate)
LTC Greg Russie, BSC	Joint Readiness Clinical Advisory Board (alternate)
LTC Steven Humburg, MC	Health Affairs
MAJ Mickey Bellemin, BSC	Defense Supply Center Philadelphia (DSCP)
Trevor Rabie	Uniformed Services Family Health Plans (USFHP)
Ray Nan Berry	Foundation Health
Kirby Davis	Anthem Alliance
William Hudson	Humana, Inc
Gene Lakey	TriWest

OTHERS PRESENT:

CAPT Charlie Hostettler, MSC	DoD Pharmacy Program Director, TMA
COL Mike Heath, MS	Army Pharmacy Consultant; Chair, DoD Pharmacy Board of Directors
LTC Gary Blamire, BSC	TRICARE Lead Agent Office (Region 6)
CDR Mark Brouker, MSC	DoD Pharmacoeconomic Center (PEC)
MAJ Barbara Roach, MS	DoD Pharmacoeconomic Center (PEC)
MAJ Jennifer Styles, MS	Pharmacy Practice Resident, BAMC
MAJ Brett Kelly, MS	TRICARE Lead Agent Office (Region 1)
LCDR Mark Richerson, MSC	DoD Pharmacoeconomic Center (PEC)
SFC Tom Bolinger	DoD Pharmacoeconomic Center (PEC)
Paul Vasquez	Defense Supply Center Philadelphia (DSCP)
Vinny Valinotti	Defense Supply Center Philadelphia (DSCP)
Shana Trice, DAC	DoD Pharmacoeconomic Center (PEC)
Eugene Moore, DAC	DoD Pharmacoeconomic Center (PEC)
Mark Petruzzi	Merck-Medco
Liz Scaturro	Merck-Medco

3. ADMINISTRATIVE ISSUES:

The minutes from the last meeting were accepted as written.

4. OLD BUSINESS

A. Review of Interim Decisions

1) The committee co-chairs revised the National Mail Order Pharmacy (NMOP) and retail pharmacy network quantity limits on an interim basis to meet timelines for the alpha test of the Pharmacy Data Transaction Service (PDTS). The committee agreed with the revised quantity limits. The revised quantity limits will be posted on the PEC website. Although the quantity limits do not currently apply to military treatment facility (MTF) pharmacies, it is likely that the NMOP quantity limits will apply to MTF pharmacies sometime in the future.

2) The committee co-chairs made an interim decision to suspend the designation of Nitro-Dur as the preferred brand of nitroglycerin patch in the NMOP when it was discovered that the Nitro-Dur patches do not cost less than other brands of nitroglycerin patches. Nitro-Dur packages designated for institutional use have low DAPA prices, but Merck-Medco cannot legally dispense these patches through the NMOP. The committee agreed with the co-chairs' interim decision. A preferred brand of nitroglycerin patch is no longer designated in the NMOP.

B. *Update on the Pharmacy Data Transaction Service (PDTS)*—COL Remund updated the committee on deployment and progress of the PDTS project. The alpha deployment at Wright-Patterson AFB successfully tested the PDTS process. Enhancements are required to the CHCS software prior to additional deployments of PDTS within the direct care system.

CAPT Hostettler commented that PDTS represents a major DoD initiative for medication error prevention and patient safety.

C. National Mail Order Pharmacy (NMOP) Preferred Drug Program

1) CDR Brouker reported the switch rates and estimated cost avoidance for the preferred drug program in the NMOP (see Appendix A). The NMOP Preferred Drug Program is estimated to result in $1.56 million in annual cost avoidance for DoD.

2) *Antiviral Drugs for Herpes (acyclovir, valacyclovir, famciclovir)*—The preferred drug program for this class currently has an estimated cost avoidance per attempted provider contact of only $8, compared to an average of $76 for the entire NMOP preferred drug program. However, if the switch program for this drug class were to be targeted to chronic suppression of herpes, the estimated cost avoidance per attempted provider contact would increase to approximately $86. The cost to DoD for a 90-day regimen of acyclovir is approximately $7, compared to $403 for famciclovir and $183 for valacyclovir. Acyclovir is given twice daily for chronic suppression, compared to once daily for valacyclovir and twice daily for famciclovir. The committee approved the proposal to request switches to acyclovir only on famciclovir and valacyclovir prescriptions that are written for more than a 30-day supply (chronic therapy).

The committee discussed the following additional proposal: *When prescriptions for chronic therapy with famciclovir or valacyclovir are received by the NMOP, Merck-Medco would call the prescriber to offer a switch to acyclovir. If the prescriber declined to switch from famciclovir to acyclovir, Merck-Medco would then suggest the famciclovir be switched to valacyclovir.* Mark Petruzzi (Merck-Medco) will report to the co-chairs by July 17th regarding the feasibility of the additional proposal. In the interim, Merck-Medco will ask prescribers to switch prescriptions for chronic therapy with famciclovir or valacyclovir to acyclovir.

D. *Report of the Subcommittee on Quantity Limits for Topicals*—The committee approved the quantity limits presented by the subcommittee for the five high-cost topicals identified at the last meeting: imiquimod (Aldara); calcipotriene (Dovonex); altitretinoin (Panretin); becaplermin (Regranex); and tazarotene (Tazorac) (See Appendix B). The subcommittee will report on the frequency distribution of quantities dispensed per prescription for these drugs at the next meeting. An interim report is due to the co-chairs by 17 Jul 00.

E. *Report of the Growth Hormone Subcommittee*—The committee reviewed the data presented by Bill Hudson (Humana) to justify a prior authorization program for growth hormone in the NMOP and the retail network. Mr. Hudson estimated a 1% denial rate for growth hormone prescriptions. The committee decided not to institute a prior authorization program because the inconvenience to prescribers and patients outweighs the relatively small potential for cost avoidance.

F. *Update on the Advances in Medical Practice (AMP) Program*—COL Remund reported that AMP funds have been distributed to the service level. The pharmacy consultants/specialty

leaders are working with the service resource management officers to devise procedures for reimbursing MTFs for expenditures on drugs covered by the AMP program.

G. *Update on Program Budget Decision 041*—The DOD P&T Committee added several drugs to the BCF at the Jan 00 interim meeting. Per DoD Health Affairs Policy 98-034 (Policy for Basic Core Formulary and Committed Use Requirements Contracts), all BCF drugs must be included on all MTF formularies.

H. *Cost-efficiency of prior authorizations in the NMOP*—MAJ Bellemin provided a verbal report to the committee. The committee directed the co-chairs to appoint a subcommittee to 1) develop a standard written report for prior authorization data, and 2) explore methods to quantify the clinical, economic, and humanistic outcomes associated with the prior authorization program. The subcommittee will include members from DSCP, PEC, Merck-Medco, and the Managed Care Support Contractors. A report is due to the co-chairs by 17 Jul 00.

I. *Prior authorization for oral antifungals for onychomycosis*—The co-chairs presented prior authorization criteria for terbinafine for the treatment of onychomycosis. The criteria require the confirmation of an active fungal infection to ensure the clinical appropriateness of therapy for onychomycosis.

Bill Hudson reported that the vast majority of use of itraconazole in Region 3 and 5 is for onychomycosis and proposed that the prior authorization also apply to itraconazole for the treatment of onychomycosis. The committee agreed that the prior authorization program should apply to itraconazole as well as terbinafine in the treatment of onychomycosis.

J. *Determining benefit coverage of fertility agents*—According to the Code of Federal Regulations and TRICARE policy, fertility drugs are not a covered benefit when used to assist in non-coital reproduction methods. Paul Vasquez (DSCP) reported that a recent contract modification to the NMOP Statement of Work (SOW) reiterated the original SOW requirement for the contractor to fill prescriptions in accordance with TRICARE policy. Merck-Medco will develop a process to ensure that prescriptions for fertility agents are dispensed to DoD beneficiaries in accordance with TRICARE policy. Since this was an original requirement of the contract, there will be no additional payment by DoD for this process.

K. *Revising prior authorization forms to include education for providers*—The committee endorsed the recommendation by LTC Judith O'Connor that the prior authorization program should include an educational component. The committee decided that the prior authorization request forms should briefly explain why the drug requires prior authorization. The PEC will revise the prior authorization request forms accordingly.

L. *Portability of Prior Authorizations*—MAJ Mickey Bellemin reported that portability of prior authorization approvals across the retail network and NMOP will eventually be accomplished through PDTS. CAPT Hostettler commented that the managed care support contractors are still exploring other options to achieve portability of prior authorization approvals.

5. NEW BUSINESS

A. National Pharmaceutical Contracts

1) *Contracts awarded since last meeting*:

a. The VA National Acquisition Center (NAC) awarded DoD/VA joint contracts to Able Laboratories for salsalate 500 and 750 mg tablets (effective date 15 Mar 00) and to Becton Dickinson for insulin syringes with needles (effective date 1 May 00). All DoD MTFs and all VA facilities that use these products are required to purchase the contract brands. The contract for insulin syringes with needles also applies to the NMOP.

b. Defense Supply Center Philadelphia (DSCP) awarded a DoD/VA contract to Novartis Consumer Health for nicotine patches (effective date 1 Jun 00). All DoD MTFs and VA facilities that use a 3-step nicotine patch are required to purchase the contract brand of this product. **Please note:** The contract does not mandate inclusion of nicotine patches on the BCF. MTFs are not required to add nicotine patches to their formularies.

2) *Financial Impact of National Pharmaceutical Contracts*— The PEC uses prime vendor purchase data to quantify the financial impact of national pharmaceutical contracts. COL Remund presented slides showing the cost avoidance associated with major DoD and DoD/VA contracts for FY99 and the first 5 months of FY00. These slides will be published on the PEC website at **www.pec.osd.ha.mil**.

COL Remund also reported on recent voluntary price reductions by Merck for simvastatin (decrease from $0.66 to 0.62 for the 10 mg tablet, $1.07 to $0.75 for the 20 mg tablet, and from $1.07 to $1.00 for the 40 mg tablet). The price reduction will yield approximately $10 million annually in additional cost avoidance for MTFs.

3) *Returned Goods Contract* – DSCP has the lead on developing the solicitation for a joint DoD/VA contract for processing returned goods.

4) *Second Generation Antihistamines*—The committee (on a vote of ten in favor with two abstentions) decided that DoD should not seek a joint DoD/VA closed class contract for a single once-daily, non-sedating antihistamine because:

a. The provisions of a closed class contract are not compatible with clinical practice regarding this drug class. A relatively large percentage of patients will not respond adequately to a given antihistamine. If a patient does not respond adequately to an antihistamine, it is common clinical practice to try a different antihistamine. Under a closed class contract, non-contracted drugs can be used only after a prior authorization or non-formulary request process is completed. Implementation of a

closed class contract for a single agent in this class would place an unacceptably large administrative burden on DoD beneficiaries, prescribers, and pharmacies.

b. A closed class contract requires patients to be switched from non-contracted drugs to the contracted drug. Converting patients from non-contracted drugs to contracted drugs is much more difficult to accomplish in the Military Health Care System than in the VA because of major differences in pharmacy benefit designs and drug distribution systems.

B. *FY00 National Defense Authorization Act*—CAPT Hostettler briefed the committee on the ongoing efforts to implement the provisions pertaining to the Uniform Formulary and the DoD P&T Committee.

C. *BCF and NMOP formulary issues:*

1) *Added to the NMOP Formulary*—The following drugs were added to the NMOP Formulary. None of these drugs were added to the BCF.

a. Levetiracetam tablets (Keppra; UCB Pharma) approved 30 Nov 99 as adjunctive therapy for partial onset seizures in adults

b. Ciclopirox topical solution (Penlac Nail Lacquer; Dermik/Aventis) approved 17 Dec 99 for mild to moderate onychomycosis

c. Nedocromil sodium ophthalmic solution, 2% (Alocril; Allergan) approved 8 Dec 99 for itch associated with allergic conjunctivitis

d. Cevimeline HCl capsules (Evoxac; Snowbrand Pharma) approved 11 Jan 00 for dry mouth in Sjögrens Syndrome

e. Alosetron tablets (Lotronex; Glaxo) approved 9 Feb 00 for women with diarrhea-predominant irritable bowel syndrome (IBS). Alosetron has been tested largely in women, who make up the majority of patients complaining of IBS in the U.S. In addition, plasma concentrations of alosetron appear to be influenced by gender (27% lower in men). Because there is currently no evidence of efficacy in male patients, coverage of this drug in the NMOP will be limited to female patients. Alosetron will be excluded from the NMOP formulary when prescribed for male patients.

f. Rivastigmine capsules (Exelon; Novartis) approved 24 Apr 00 for mild to moderate Alzheimers disease

g. Sotalol (BetapaceAF; Berlex) approved 22 Feb 00 for maintenance of normal sinus rhythm [delay in time to recurrence of atrial fibrillation/atrial flutter (AFIB/AFL)] in patients with symptomatic AFIB/AFL who are currently in sinus rhythm. Sotalol was previously marketed (as Betapace) for ventricular arrhythmias only. Betapace AF is chemically identical to Betapace but is supplied in unit-of-use packages containing specialized labeling for patients with atrial fibrillation (analogous to dual packaging of bupropion as Zyban and Wellbutrin). The FDA recommends that patients

currently receiving Betapace for atrial arrhythmias be converted to BetapaceAF in order to receive appropriate patient information. The NMOP will fill prescriptions for these products as written, e.g., BetapaceAF for "BetapaceAF" and Betapace (or the soon-to-be-available AB-rated generic) for "Betapace."

2) *Excluded from the NMOP Formulary*—Dofetilide (Tikosyn; Pfizer), approved 1 Oct 99 for maintenance of normal sinus rhythm in atrial fibrillation/flutter, was excluded from the NMOP formulary and will not be available through the NMOP. Dofetilide was NOT added to the BCF. Because of the potential for dofetilide to cause torsade de pointes, a serious and potentially lethal ventricular arrhythmia, the drug is subject to a restricted distribution process. The FDA requires documentation that prescribers and inpatient pharmacies have received education concerning the algorithm for initiating the drug, which must be started in a monitored inpatient setting. Maintenance supplies for outpatient use are currently dispensed only through Statlander's Pharmacy in Pittsburgh. The NMOP has no mechanism to refer prescriptions to Statlander's and turnaround time is a major concern. Mark Petruzzi (Merck-Medco) stated that a joint venture might occur between Merck-Medco and a specialty pharmacy company, which may be able to provide this type of medication in the future. Merck-Medco will report back to the committee if it becomes possible to provide dofetilide through the NMOP.

3) *Clarification of Antihemophilic Factors on the NMOP Formulary Covered Injectables List*—The committee intends that all antihemophilic factors be available through the NMOP. The committee clarified the current listing on the NMOP Covered Injectables List to read " *Antihemophilic Factors (including Factor VII, Factor VIII, Factor IX, Factor IX Complex, and Anti-Inhibitor Factor Complex).*"

4) *Catastrophic Drug Accounts*—The preceding discussion of antihemophilic factors led to a discussion of catastrophic drug accounts for MTFs. Extremely high cost specialty medications, such as the antihemophilic factors, cause extreme strain on the budgets of smaller MTFs. The issue of catastrophic drug accounts is beyond the purview of the committee, so it was referred to COL Mike Heath as chairman of the Pharmacy Board of Directors.

5) *Nasal Corticosteroids (BCF)*—LCDR Mark Richerson (PEC) presented an analysis of MTF prescription data that showed weighted averages of 3.57 sprays per day for fluticasone nasal spray and 3.95 sprays per day for mometasone nasal spray. Based on DAPA prices of $11.12 per fluticasone inhaler and $10.49 per mometasone inhaler, fluticasone is slightly more cost-effective than mometasone. Since mometasone does not offer any advantage in cost-effectiveness, the committee decided that fluticasone should remain as the only nasal corticosteroid inhaler on the BCF.

6) *Consideration of Niaspan (niacin extended release; Kos Pharma) for the BCF*—The committee decided not to add Niaspan to the BCF because it does not offer sufficient clinical advantage over immediate release niacin to justify the large increase in cost.

The committee made its decision based on the following comparison of Niaspan and immediate release niacin.

a. Niaspan and immediate release niacin have similar safety profiles. During clinical trials, increases in liver enzymes with Niaspan were comparable to those occurring with immediate release niacin. Required monitoring of liver function tests is the same for Niaspan and immediate release niacin.

b. It is unclear whether Niaspan offers a clinically meaningful advantage in patient tolerability over immediate release niacin. In a comparative study, 42% of patients on Niaspan and 39% of patients on immediate release niacin experienced flushing. However, the Niaspan group averaged only 1.9 episodes per month compared to 8.6 episodes per month for the immediate release niacin group. In a study comparing Niaspan to placebo, 88% of patients taking Niaspan 1000 mg per day and 83% of patients taking Niaspan 2000 mg per day experienced flushing, compared to 20% of placebo patients. In a 96-week open label study, 75% of Niaspan patients experienced flushing and 47% of Niaspan patients dropped out of the study for reasons related to the drug (although the specific reasons were not identified in the study).

c. At equivalent doses, Niaspan and immediate release niacin have a similar effect on lipid levels.

d. Depending on dosage, Niaspan costs about 20 to 30 times more than immediate release niacin.

7) Review of ophthalmic glaucoma agents for the BCF—CDR Matt Nutaitis, an ophthalmologist and glaucoma specialist, presented recommendations based on his own experience; input from glaucoma specialists from all three services; current usage in DoD; and the relative safety, tolerability, efficacy, and cost of available ophthalmic agents for the treatment of glaucoma. (See Appendix C.) The committee adopted the following recommendations:

Remove the following agents from the BCF:

- Betaxolol Ophthalmic Suspension
- Dorzolamide Ophthalmic Solution
- Pilocarpine Ophthalmic Gel

Add the following agent to the BCF:

- Brimonidine Ophthalmic Solution (Alphagan; Allergan)

8) *Consideration of metronidazole vaginal gel for the BCF*—The committee added metronidazole vaginal gel to the BCF to provide an alternative to clindamycin vaginal cream in pregnant women with symptomatic bacterial vaginosis who are at low risk for premature birth. The Centers for Disease Control and Prevention (CDC) 1998

Guidelines for Treatment of Sexually Transmitted Diseases state that for treatment of pregnant women, "the use of clindamycin vaginal cream during pregnancy is not recommended, because two randomized trials indicated an increase in the number of preterm deliveries among pregnant women who were treated with this medication." Clindamycin vaginal cream and metronidazole vaginal gel are similar in cost. Clindamycin vaginal cream remains on the BCF.

9) *Clarification of oxycodone/acetaminophen listing on BCF*— The approval in mid-99 of three new strengths for oxycodone/acetaminophen (Percocet 2.5/325, 7.5/500, 10/650; Endo) has led to questions by MTFs about which strengths of Percocet they are required to carry. The committee decided that the incremental clinical value of the new strengths was likely to be minimal. Because including the new strengths on the BCF would increase accounting and storage requirements for these controlled drugs, the committee did not opt to add them to the BCF. The committee decided that the BCF should specify that MTFs must have oxycodone/acetaminophen in the 5/325 and 5/500 mg strengths on their formularies but are not required to have the 2.5/325, 7.5/500, and 10/650 mg strengths on their formularies.

10) *Status of angiotensin-converting enzyme inhibitors (ACEIs) on the BCF*—The committee discussed at length a proposal to add ramipril (Altace; Monarch) to the BCF as a second long-acting ACEI. ACEIs already on the BCF are the short-acting agent captopril and the long-acting agent lisinopril.

Arguments in favor of the proposal to add ramipril to the BCF included:

- ACEIs tend to be underutilized. Addition of another ACEI to the BCF would ensure uniform availability of another agent within a class of drugs that is known to provide significant clinical benefits at a reasonable cost.
- Significant clinical benefits were demonstrated in a recent study where patients at high risk of cardiovascular events but without existing heart failure were treated with ramipril. The Heart Outcomes Prevention Evaluation (HOPE) study (*NEJM* 342(3):145-53; 20 Jan 00) and the MICRO-HOPE diabetic substudy (*Lancet* 355(9200):253-9; 22 Jan 00)] demonstrated significant decreases in the rate of death, myocardial infarction, and stroke in patients receiving ramipril; as well as significant decreases in the risk of overt nephropathy in diabetic patients.
- The addition of ramipril might encourage price competition within the ACEI drug class because the DAPA price of $.12 per tablet for all strengths of ramipril is $.02 less than the $.14 price per tablet for all strengths of lisinopril.

Arguments against the proposal to add ramipril to the BCF included:

- Many MTFs already have more than one long-acting ACEI on their formularies, so the addition of ramipril to the BCF might not have any effect on the overall utilization of ACEIs. Ramipril currently has very little market share in DoD MTFs.
- It is not known if other ACEIs would achieve the same clinical benefits as ramipril achieved in the HOPE study. These results could possibly represent a class effect of ACEIs.

- Greater price competition could probably be achieved by selecting a second long-acting ACEI through a contracting initiative or incentive price agreement.

COL Remund informed the committee that contracting officials have not yet delineated a method for contracting for a BCF selection among different chemical entities in an open drug class. All the open class contracts established to date have involved the selection of a specific brand of a single chemical entity that is marketed by more than one company. The selection of a second long-acting ACEI for the BCF would involve competition between different chemical entities. The committee does not want to close the ACEI drug class on the BCF, so a closed class contract is not a suitable method for selecting a second long-acting ACEI.

A motion to table the proposal to add ramipril to the BCF was defeated by a vote of 5 in favor, 6 against, and one abstention. The committee subsequently approved the addition of ramipril to the BCF by a vote of 7 in favor and 5 against.

Following the meeting and prior to the preparation of the meeting minutes, committee members contacted the co-chairs to express their concerns about the committee's decision to add ramipril to the BCF:

- A committee member pointed out that the $.02 per tablet price advantage for ramipril over lisinopril might be at least partially negated if twice a day dosing is more common for ramipril than for lisinopril. A subsequent analysis of the frequency distributions of dosages observed by a large national PBM revealed that twice a day dosing is more common for ramipril than for lisinopril. Based on the dosage distribution, the DAPA price for ramipril, and the contract price for lisinopril; the average weighted daily costs differ by only $.009 ($0.147 for ramipril and $0.156 for lisinopril).
- A committee member expressed concern that the committee did not consider the possibility that the incidence of cough as an adverse effect may be higher for ramipril than for other ACEIs. The table of adverse effects for ACEIs in *Facts and Comparisons* shows a higher incidence of cough for ramipril than for all but one other ACEI. However, the data are pooled from separate studies and are not necessarily comparable.

In light of these concerns, the P&T Committee members approved a motion to rescind the addition of ramipril to the BCF by a vote of 9 in favor and 0 against (three committee members were on leave or temporary duty and could not be contacted).

11) *Status of oral contraceptive products (OCPs) on the BCF* (see Appendix D for a list of OCPs)—(Note: costs quoted in the following discussion are based on DAPA prices as of May 00; prices are for the 28-day packs if both 21- and 28-day packs are available)

a. Monophasic OCPs with 20 mcg ethinyl estradiol (EE): There is no BCF agent in this category. The committee made no selection or recommendation in this category.

b. *Monophasic OCPs with 30 mcg EE:* EE 30 mcg/0.3 mg norgestrel (e.g., Lo/Ovral, Low-Orgestrel) remains on the BCF. The current cost per cycle for both Lo/Ovral and Low-Ogestrel is $8.00. The committee added EE 30 mcg/1.5 mg norethindrone (Loestrin FE 1.5/30) to the BCF as an alternative that offers a significant economic advantage. The current cost per cycle for Loestrin FE 1.5/30 is $2.00.

c. *Monophasic OCPs with 35 mcg EE:* The 35 mcg EE/1 mg norethindrone combination (e.g., Necon, Norinyl, Ortho-Novum) remains on the BCF. Any brand containing this combination of ingredients may be used by MTFs to fulfill the BCF requirement. The committee recommended selection of a specific brand of 35 mcg EE/1 mg norethindrone for the BCF as a potential item for a contract or incentive price agreement.

The committee added EE 35 mcg/1 mg ethynodiol diacetate (e.g., Demulen, Zovia) to the BCF. Any brand containing this combination of ingredients may be used by MTFs to fulfill the BCF requirement. This agent was added because military providers said that the combination was clinically useful for patients with acne, and because it is less expensive than other oral contraceptives touted for use in patients with acne. The committee recommended selection of a specific brand of EE 35 mcg/1 mg ethynodiol diacetate for the BCF as a potential item for a contract or incentive price agreement.

d. *Biphasic OCPs*–There is no BCF agent in this category. There is very little use of biphasic products in DoD. The committee made no selection or recommendation in this category.

e. *Triphasic OCPs*—EE 30/40/30mcg/levonorgestrel 0.05/0.075/0.125 mcg remains on the BCF. Any brand containing this combination of ingredients may be used by MTFs to fulfill the BCF requirement (e.g., Tri-levlen, Triphasil, Trivora). The committee recommended selection of a specific brand of EE 30/40/30mcg / levonorgestrel 0.05/0.075/0.125 mcg for the BCF as a potential item for a contract or incentive price agreement.

The committee initially decided to remove EE 35 mcg/norethindrone 0.5/0.75/1 mg (Ortho-Novum 7/7/7) from the BCF based on a comparison of the DAPA price for Ortho-Novum 7/7/7 to the DAPA prices of other triphasic OCPs. Subsequent to the meeting, additional information concerning the availability and pricing of Ortho-Novum 7/7/7 through the DSCP Centrally Managed Inventory Program (Depot) was brought to the attention of the co-chairs. The co-chairs made an interim decision to leave Ortho-Novum 7/7/7 on the BCF. The BCF status of Ortho-Novum 7/7/7 will be reconsidered when more definitive information is available concerning the pricing, usage volume, and prospective status of Ortho-Novum 7/7/7 as a depot stock item.

f. *Progestin-only OCPs ("mini-pills"):* The committee added 0.35 mg norethindrone (e.g., Micronor, Nor-Q.D) to the BCF to meet the needs of women who require a

progestin-only product. There were previously no progestin-only products on the BCF. The committee recommended selection of a specific brand of 0.35 mg norethindrone for the BCF as a potential item for a contract or incentive price agreement.

g. Other OCPs: Due to their infrequent use, OCPs with 50 mcg EE or mestranol as the estrogen component were not considered.

The committee requested that the PEC amend BCF listings on the PEC website to make it clear that the BCF does not currently specify any drug by trade name in this class. For example, the listing for 35 mcg EE/1 mg norethindrone means that any product containing this combination of ingredients is acceptable. The committee agreed that 28-day packages of oral contraceptives are preferable to 21-day packages because patients are more likely to remember to take the tablets on a daily basis.

12) *Status of narcotic pain medications on the BCF*—The committee was asked by an MTF to consider the addition of a long-acting oral narcotic analgesic to the BCF. The committee added extended release morphine tablets (MS Contin or its AB-rated generic equivalent) in the following strengths: 15-, 30-, and 60-mg. MS Contin is also currently available in 100- and 200-mg tablets, which are not included in the BCF listing. MTFs may add the 100- and 200-mg strengths to their local formularies if they so desire. The BCF listing does not include Oramorph SR, Kadian, or any other extended release morphine product other than MS Contin or AB-rated generic equivalents.

13) *Withdrawal of troglitazone and cisapride:* The committee discussed the withdrawal of troglitazone (Rezulin) and cisapride (Propulsid) from the market. Troglitazone is no longer available. Cisapride will continue to be available only through an investigational drug/limited access program once the manufacturer discontinues marketing (Jul 00) and existing stocks are exhausted. MTFs should be in the process of switching patients to alternative medications and identifying patients whose need for treatment with cisapride justifies pursuing approval through the limited access program.

7. ADJOURNMENT: The meeting adjourned at 1530 hours. The next meeting will be held on Thursday, 17 Aug 00 at a site to be determined. All agenda items should be submitted to the co-chairs no later than 17 Jul 00.

<signed>
DANIEL D. REMUND
COL, MS, USA
Co-chair

<signed>
TERRANCE EGLAND
CDR, MC, USN
Co-chair

List Of Appendices

APPENDIX A: NMOP Preferred Drug Program Report

May 00 NMOP Preferred Drug Program Report

1. Extended Release Diltiazem

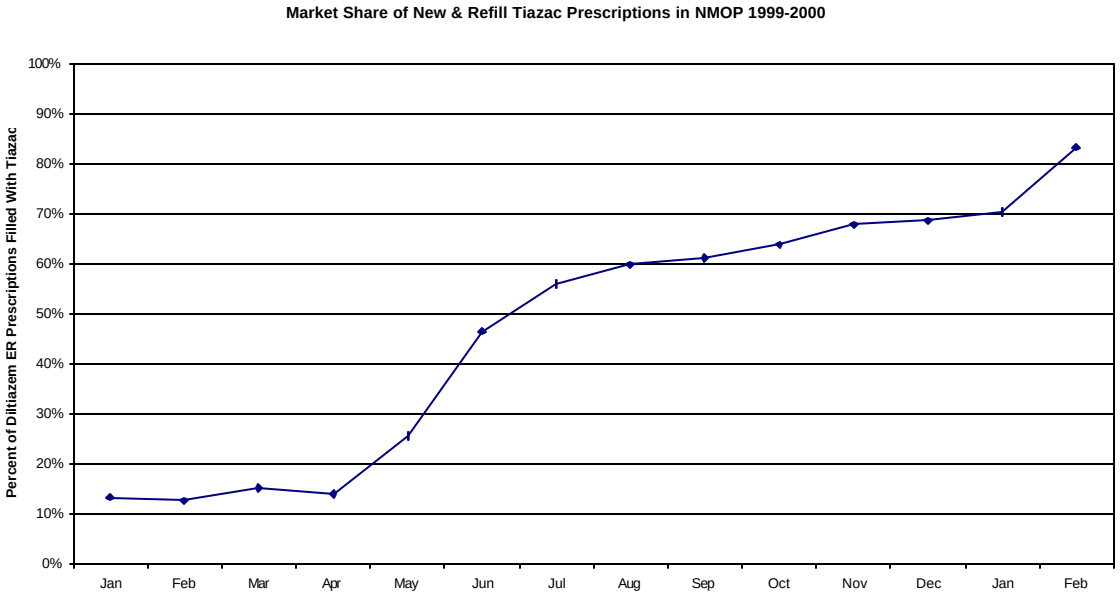
Tiazac was designated as the preferred diltiazem ER product in NMOP in May 99. Non-preferred diltiazems include Cardizem CD, Diltia XT, Dilacor XR, and generic diltiazem ER.

Table 1: Prescriptions for Non-Preferred Diltiazem ER products in NMOP, Jun 99 – Feb 00[1]

Month	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	**Jun 99-Feb 00**
New Rxs Received	720	661	573	395	328	291	346	155	178	**3647**
Prescriber Contacts	653	616	540	352	301	263	311	134	156	**3326**
Switches	514	495	434	255	215	189	217	97	116	**2532**
Switch rate[2]	71%	75%	76%	65%	66%	65%	63%	63%	65%	**69%**

1 From Merck-Medco reports "NMOP Switch Report", "DoD Target Drug Report", and "DoD Prescription Volume Report" covering period from 29 May 1999 through 29 February 2000.
2. Percentage of new prescriptions received for non-preferred drugs that were switched to Tiazac

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



Monthly Cost Avoidance*

Month	Jun 99	Jul 99	Aug 99	Sep 99	Oct 99	Nov 99	Dec 99	Jan 00	Feb 00	**Jun 99-Feb 00**
Monthly Cost avoidance	$21,796	$27,287	$31,098	$29,017	$28,112	$34,592	$30,123	$33,877	$37,697	**$273,599**

*Monthly cost avoidance calculated by subtracting current expenditures from expenditures that would have occurred if the prescriptions had not been switched. The figure for "would-have-been" expenditures is derived by multiplying the mean percentage of market share (by prescription; both new and refill) during Jan-Apr 99 for each drug by the total number of new and refill prescriptions in each month for all non-preferred and preferred drugs, and then multiplying this figure by the average cost per prescription for each drug, and summing for all non-preferred and preferred drugs.

2. Extended Release Nifedipine

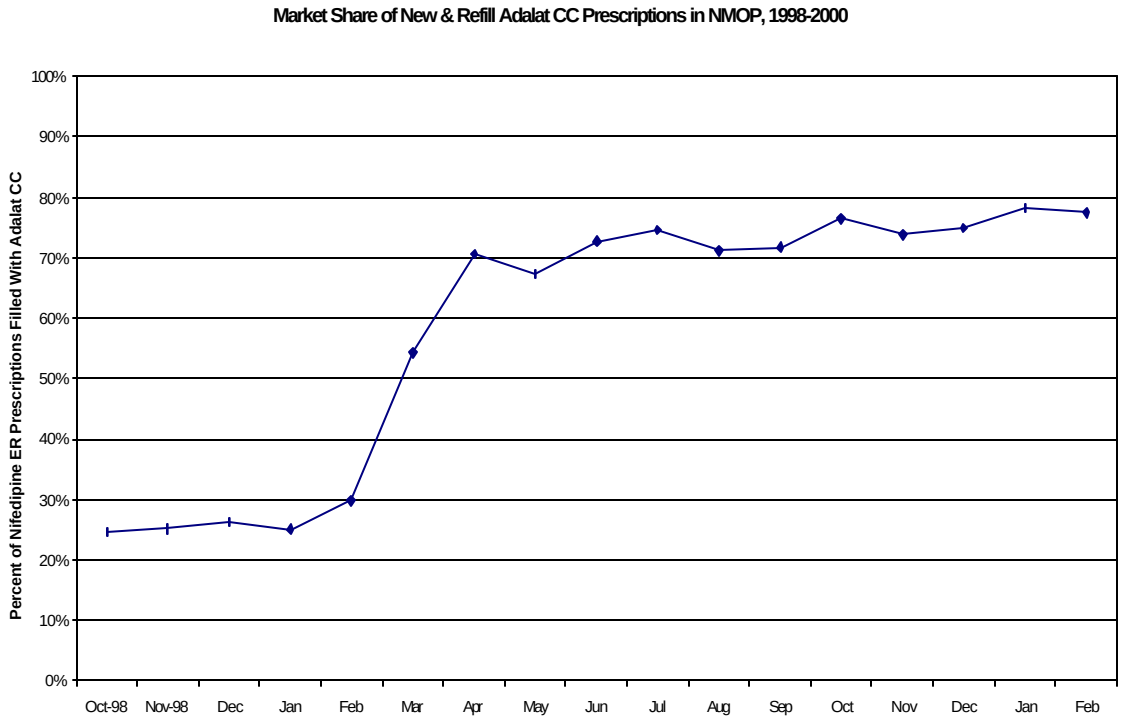
In Nov 98 the DOD P & T Committee selected Adalat CC as the preferred nifedipine ER product. Procardia XL is non-preferred.

Table 2: Prescriptions for Non-Preferred Nifedipine ER in NMOP, Jun 99 – Feb 2000[1]

Month	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Jun 99 – Feb 00
New Rxs Received	379	142	125	139	124	127	153	111	115	**1415**
Prescriber Contacts	345	132	102	120	114	101	129	99	105	**1247**
Switches	254	91	66	63	61	58	90	62	53	**798**
Switch rate[2]	67%	64%	53%	45%	49%	46%	59%	56%	46%	**56%**

1. From Merck-Medco reports "NMOP Switch Report", "DoD Target Drug Report", and "DoD Prescription Volume Report" covering period from 29 May 1999 through 29 February.
2. Percentage of new prescriptions received for non-preferred drugs that were switched to Adalat CC.

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



Monthly Cost Avoidance*

Month	Jun 99	Jul 99	Aug 99	Sep 99	Oct 99	Nov 99	Dec 99	Jan 00	Feb 00	Jun 99 – Feb 00
Cost Avoidance	$27,494	$26,624	$24,962	$24,510	$27,938	$26,122	$24,173	$32,785	$27,030	**$241,638**

*Monthly cost avoidance calculated by subtracting current expenditures from expenditures that would have occurred if the prescriptions had not been switched. The figure for "would-have-been" expenditures is derived by multiplying the mean percentage of market share (by prescription; both new and refill) during Oct – Nov 98 for each drug by the total number of new and refill prescriptions in each month for all non-preferred and preferred drugs, and then multiplying this figure by the average cost per prescription for each drug, and summing for all non-preferred and preferred drugs.

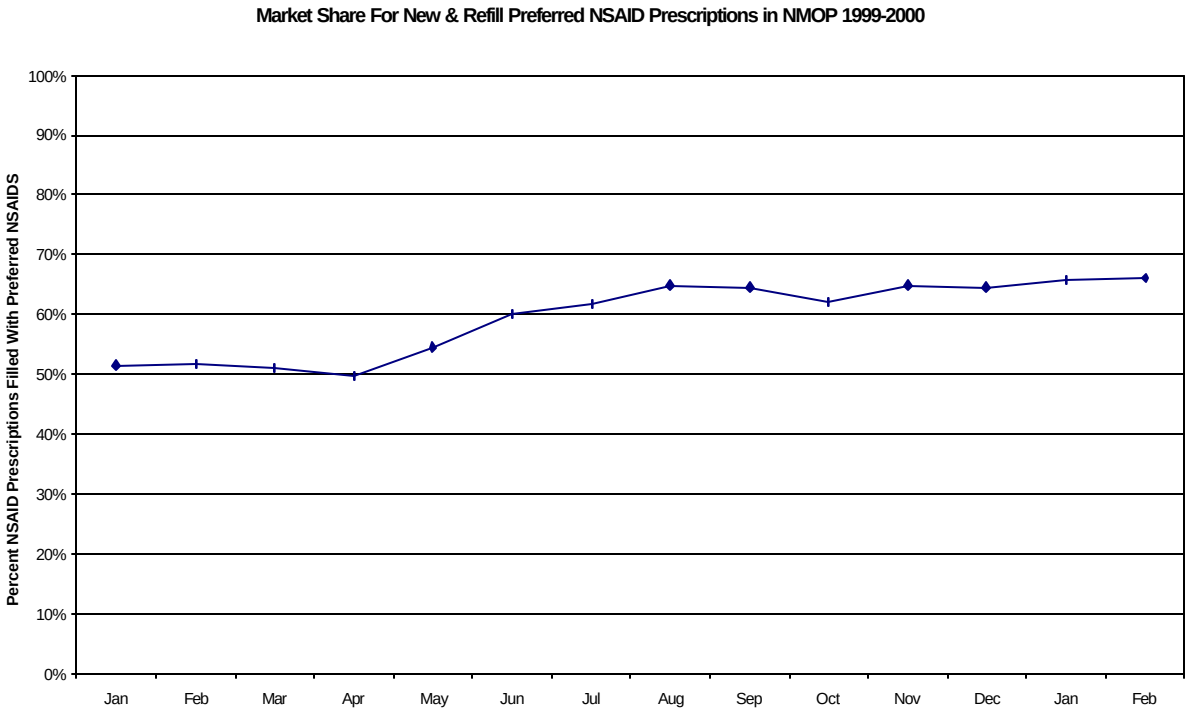
3. NSAIDS

Generic NSAIDs are preferred. Daypro, Relafen, Voltaren XR, Lodine XL, and Naprelan are non-preferred. Program started mid-May, 99

Table 3: Prescriptions For Non-Preferred NSAIDs in NMOP, Jun 99 – Feb 00[1]										
Month	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	**Jun 99 – Feb 00**
New Rxs Received	617	596	549	456	432	361	434	336	347	**4128**
Prescriber Contacts	525	504	492	385	367	304	384	309	314	**3574**
Switches	244	220	248	153	150	140	136	114	115	**1420**
Switch rate[2]	40%	37%	45%	34%	35%	39%	31%	34%	33%	**34%**

1 From Merck-Medco reports "NMOP Switch Report", "DoD Target Drug Report", and "DoD Prescription Volume Report" covering period from 29 May 1999 through 29 February 2000.
2. Percentage of new prescriptions received for non-preferred drugs that were switched to generic NSAIDs.

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



Monthly Cost Avoidance*

Month	Jun 99	Jul 99	Aug 99	Sep 99	Oct 99	Nov 99	Dec 99	Jan 00	Feb 00	**Jun 99 – Feb 00**
Cost Avoidance	$21,771	$19,929	$27,670	$29,294	$25,052	$36,465	$29,364	$41,151	$35,260	**$342,206**

*Monthly cost avoidance calculated by subtracting current expenditures from expenditures that would have occurred if the prescriptions had not been switched. The figure for "would-have-been" expenditures is derived by multiplying the mean percentage of market share (by prescription; both new and refill) during Jan – Apr 99 for each drug by the total number of new and refill prescriptions in each month for all non-preferred and preferred drugs, and then multiplying this figure by the average cost per prescription for each drug, and summing for all non-preferred and preferred drugs.

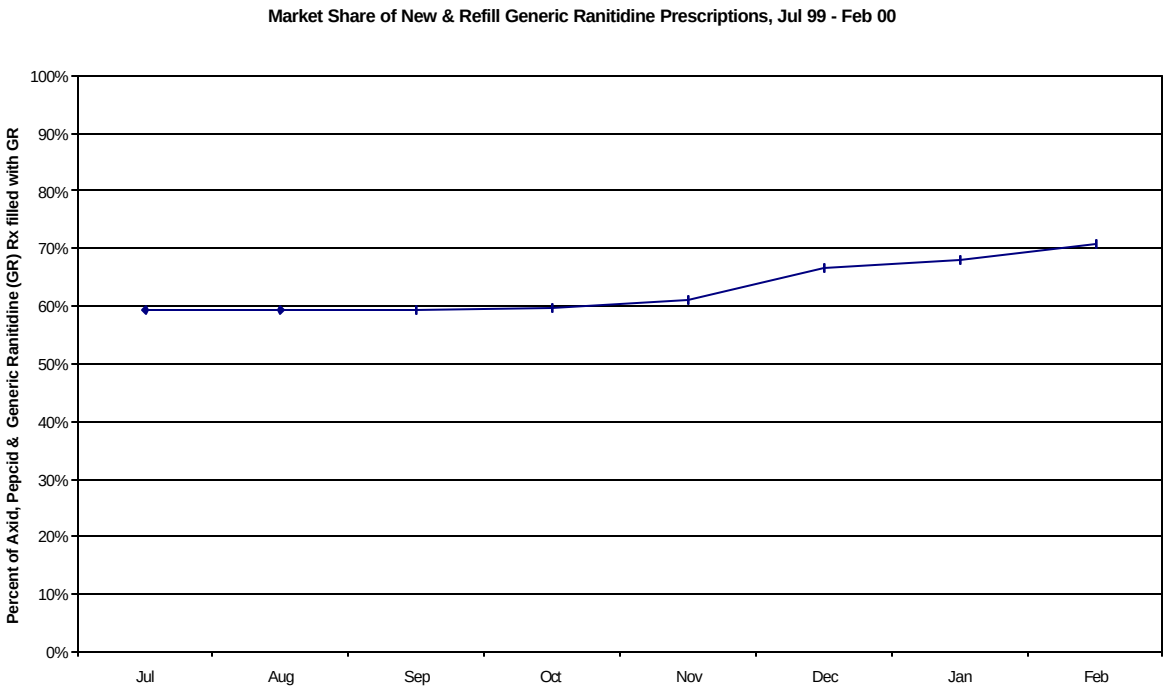
4. H2 Blockers

Generic ranitidine was designated as preferred in NMOP in August 99. Axid (nizatidine) and Pepcid (famotidine) are non-preferred. Implementation began in December, 1999.

Table 4: Prescriptions for Non-Preferred H2 Blockers in NMOP, Dec 99 – Feb 00[1]				
Month	Dec	Jan	Feb	**Dec 99-Feb 00**
New Rxs Received	213	240	234	**687**
Prescriber Contacts	182	228	210	**620**
Switches	117	169	117	**403**
Switch rate[2]	55%	70%	50%	**59%**

1 From Merck-Medco reports "NMOP Switch Report", "DoD Target Drug Report", and "DoD Prescription Volume Report" covering period from 01 December 1999 through 29 February 2000.
2. Percentage of new prescriptions received for non-preferred drugs that were switched to generic ranitidine.

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



Monthly Cost Avoidance*

Month	Dec 99	Jan 00	Feb 00	**Dec 99-Feb 00**
Monthly Cost avoidance	$10,167	$15,285	$16,907	**$42,359**

*Monthly cost avoidance calculated by subtracting current expenditures from expenditures that would have occurred if the prescriptions had not been switched. The figure for "would-have-been" expenditures is derived by multiplying the mean percentage of market share (by prescription; both new and refill) during Jul 99-Nov 99 for each drug by the total number of new and refill prescriptions in each month for all non-preferred and preferred drugs, and then multiplying this figure by the average cost per prescription for each drug, and summing for all non-preferred and preferred drugs.

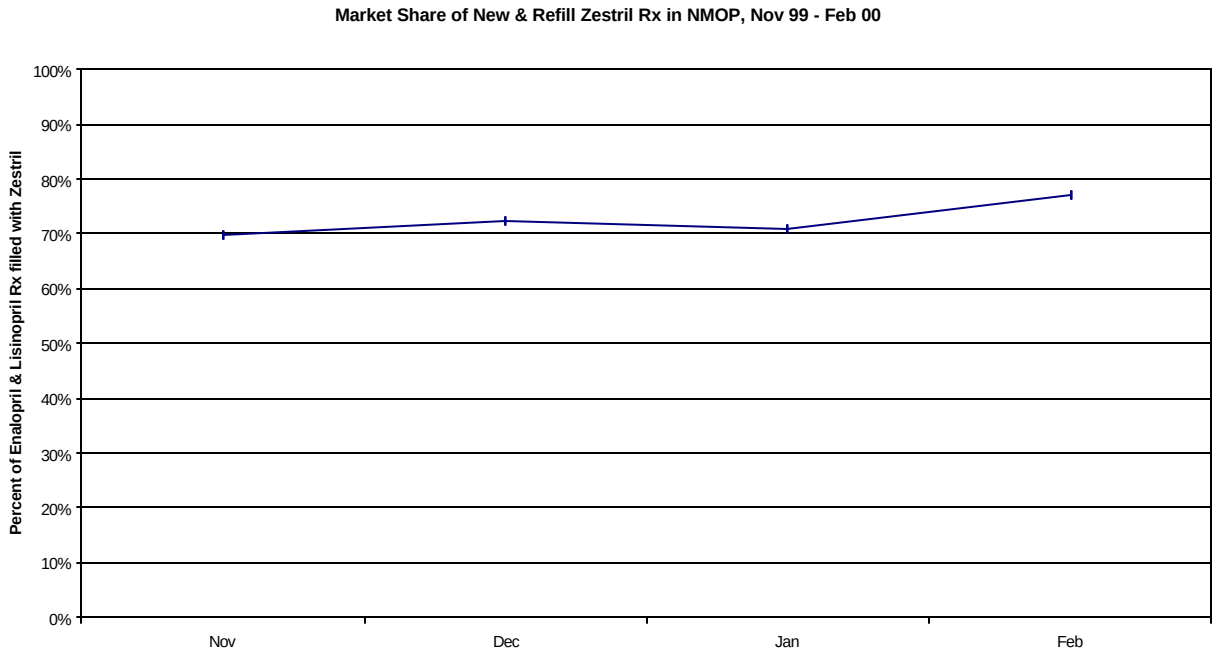
5. Enalapril

Zestril (lisinopril) generic was designated as preferred in NMOP in August 99. Vasotec (enalopril) was designated non-preferred. Implementation began in February 2000.

Table 5: Prescriptions for enalapril in NMOP, Feb 00[1]	
Month	Feb 00
New Rxs Received	265
Prescriber Contacts	239
Switches	146
Switch rate[2]	55%

1 From Merck-Medco reports "NMOP Switch Report", "DoD Target Drug Report", and "DoD Prescription Volume Report" covering February 2000.
2. Percentage of new prescriptions received for non-preferred drugs that were switched to Zestril

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



Monthly Cost Avoidance*

Month	Feb 00
Monthly Cost avoidance	$12,069

*Monthly cost avoidance calculated by subtracting current expenditures from expenditures that would have occurred if the prescriptions had not been switched. The figure for "would-have-been" expenditures is derived by multiplying the mean percentage of market share (by prescription; both new and refill) during Nov 99 – Jan 00 for each drug by the total number of new and refill prescriptions in each month for all non-preferred and preferred drugs, and then multiplying this figure by the average cost per prescription for each drug, and summing for all non-preferred and preferred drugs.

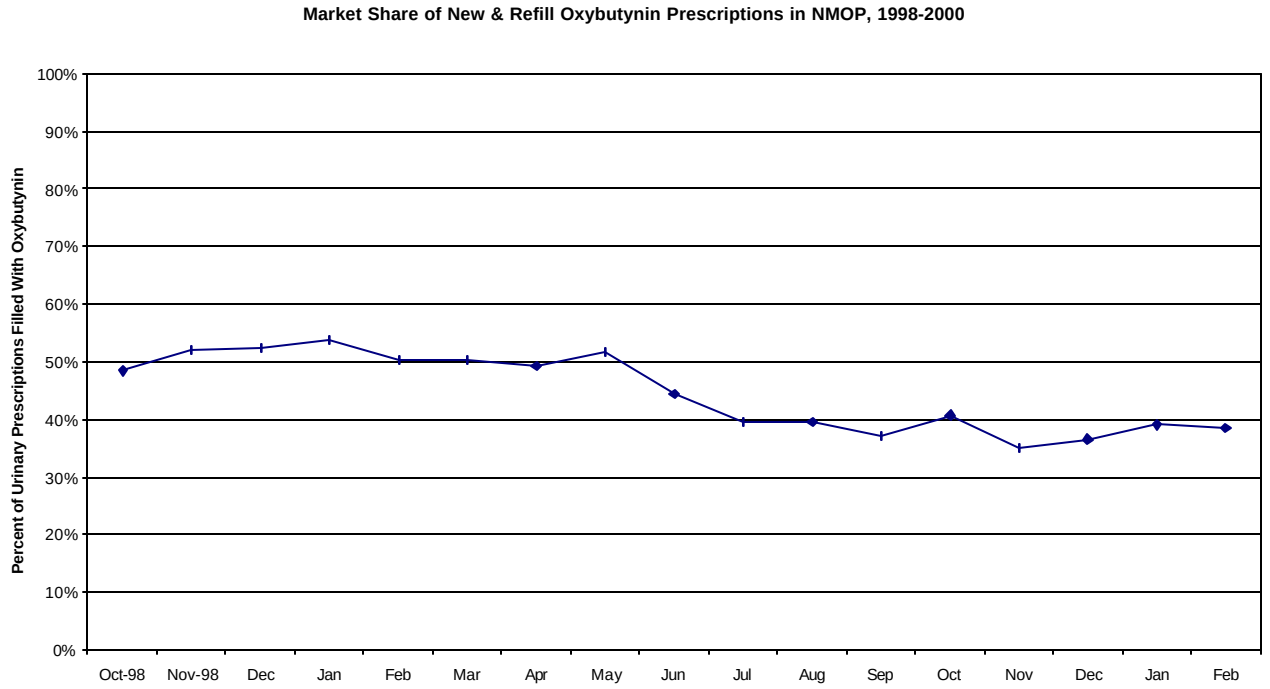
6. Urinary Agents

In November 1998, the DOD P & T Committee selected oxybutynin generic as the preferred urinary agent. Detrol and Ditropan XL are non-preferred.

Table 6: Prescriptions for Non-Preferred Urinary Drugs in NMOP, Jun 99 – Feb 00[1]										
Month	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	**Jun 99 – Feb 00**
New Rxs Received	224	183	270	271	308	325	363	270	272	**2486**
Prescriber Contacts	195	158	233	236	270	256	331	248	247	**2174**
Switches	80	40	76	69	95	88	105	83	100	**736**
Switch rate[2]	36%	22%	28%	25%	31%	27%	29%	31%	37%	**30%**

1. From Merck-Medco reports "NMOP Switch Report", "DoD Target Drug Report", and "DoD Prescription Volume Report" covering period from 29 May 1999 through 29 February 2000.
2. Percentage of new prescriptions received for non-preferred drugs that were switched to generic oxybutynin

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



Monthly Cost Avoidance*

Month	Jun 99	Jul 99	Aug 99	Sep 99	Oct 99	Nov 99	Dec 99	Jan 00	Feb 00	**Jun 99 – Feb 00**
Monthly Cost Avoidance	$7,735	$4,355	$6,823	$6,575	$8,769	$8,414	$10,271	$7,953	$10,075	**$70,970**

Monthly cost avoidance calculated by subtracting current expenditures from expenditures that would have occurred if the stated prescriptions had not been switched. Derived by multiplying the number of reported prescriptions switched for each target drug times the difference in average cost per prescription (target drug – oxybutynin). [Note: this is a different methodology than used for other drugs and is due to difficulties in establishing a baseline percentage of market share for each of these drugs and uncertainty as to the validity of carrying percentages through to subsequent months.]

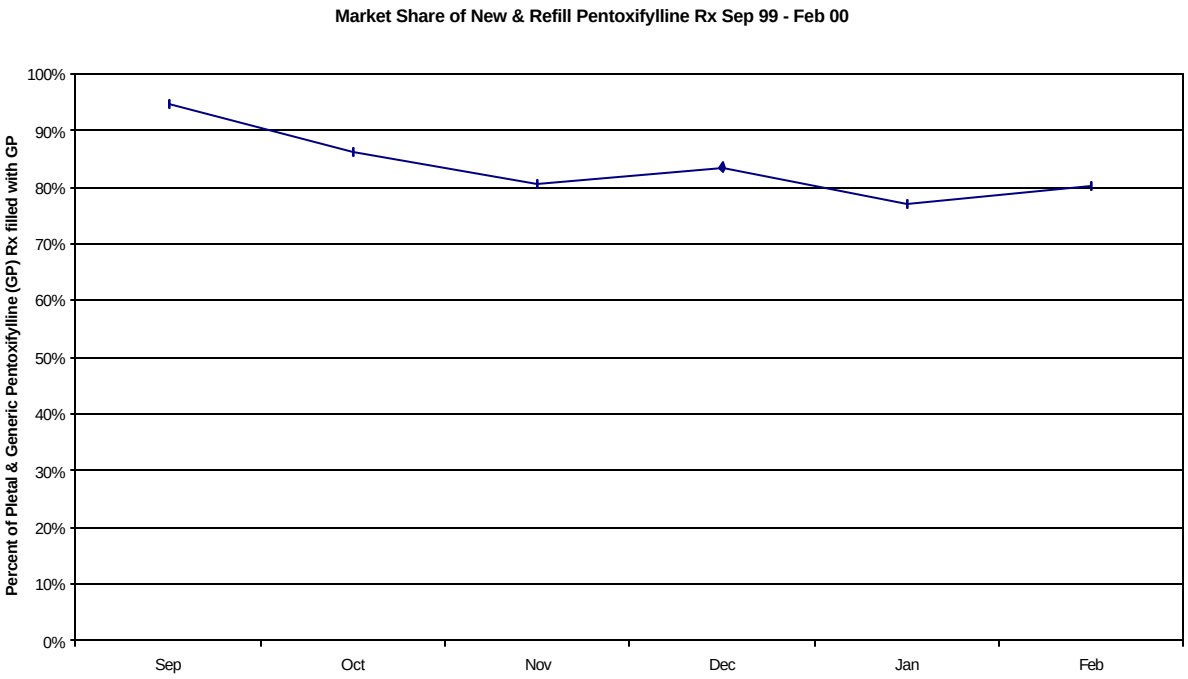
7. Cilostazol

Pentoxifylline generic was designated as preferred in NMOP in August 99. Pletal (cilostazol) was designated non-preferred. Implementation began in February 2000.

Table 7: Prescriptions for Non-Preferred Claudication Agents in NMOP, Feb 00[1]	
Month	Feb 00
New Rxs Received	23
Prescriber Contacts	21
Switches	5
Switch rate[2]	21%

1 From Merck-Medco reports "NMOP Switch Report", "DoD Target Drug Report", and "DoD Prescription Volume Report" covering February 2000.
2. Percentage of new prescriptions received for non-preferred drugs that were switched to generic pentoxifylline

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



Monthly Cost Avoidance*

Month	**Sep 99-Feb 00**
Monthly Cost avoidance	$466

***** Monthly cost avoidance calculated by subtracting current expenditures from expenditures that would have occurred if the stated prescriptions had not been switched. Derived by multiplying the number of reported prescriptions switched for each target drug times the difference in average cost per prescription (target drug – pentoxifylline). [Note: this is a different methodology than used for other drugs and is due to difficulties in establishing a baseline percentage of market share for each of these drugs and uncertainty as to the validity of carrying percentages through to subsequent months.]

8. Herpes Antivirals

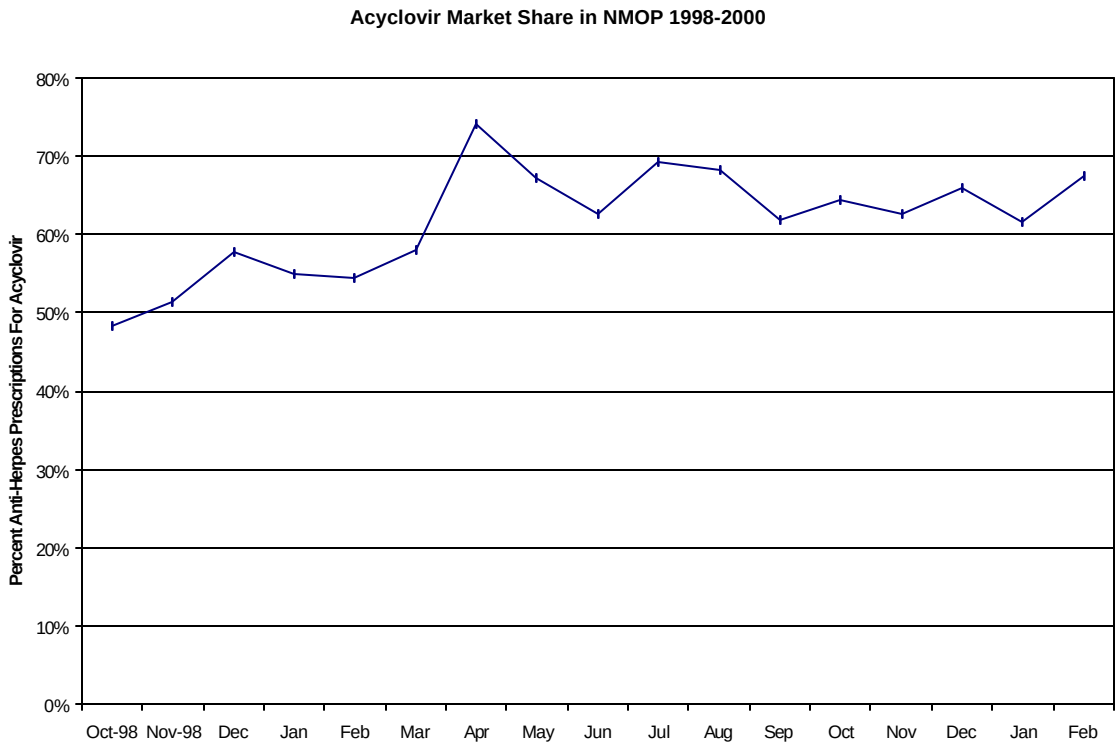
Generic acyclovir is the preferred herpes antiviral. Famciclovir (Famvir; SmithKline Beecham) and valacyclovir (Valtrex; Glaxo) are non-preferred agents. Famciclovir was selected as a non-preferred agent in Nov 98 and valacyclovir in Feb 99.

Table 5: Prescriptions For Non-Preferred Herpes Antivirals in NMOP, Jun 99 – Feb 00[1]

Month	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Jun 99 –Feb 00
New Rxs Received	77	52	51	44	60	62	70	70	76	**562**
Prescriber Contacts	68	44	39	30	41	46	57	59	50	**434**
Switches	28	14	21	21	15	17	17	29	25	**187**
Switch rate[2]	36%	27%	54%	41%	25%	27%	24%	41%	33%	**33%**

1. From Merck-Medco reports "NMOP Switch Report", "DoD Target Drug Report", and "DoD Prescription Volume Report" covering period from 29 May 1999 through 29 February 2000.
2. Percentage of new prescriptions received for non-preferred drugs that were switched to generic acyclovir.

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



Monthly Cost Avoidance*

Month	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Jun99 –Feb00
Monthly Cost Avoidance	$666	$302	$635	$410	$409	$406	$406	$679	$608	**$4521**

* See section following for an explanation of the assumptions underlying this estimate

Explanation of Methodology: Cost Avoidance Estimate for Herpes Antivirals

Assumptions needed to be made in order to estimate cost avoidance with this set of drugs given the level of available data. This is because dosing regimens and quantities dispensed per prescription vary widely for herpes antivirals according to 1) the disease being treated (*h. zoster*, *h simplex*) and 2) the reason for use (treatment, chronic suppression). Treatment of *h. simplex* costs less than treatment of *h. zoster*. There is also a difference in cost between famciclovir and valacyclovir for each regimen.

Regimen Costs of Herpes Antivirals in Switch Program		
Drug	**Dose**	**Cost**
Famciclovir	125 mg bid x 5 days (simplex) 500 mg q8h x 7 days (zoster)	$11.20 (simplex) $47.04 (zoster)
Valacyclovir	500 mg bid x 5 days (simplex) 1 gm tid x 7 days (zoster)	$20.30 (simplex) $30.03 (zoster)
Generic acyclovir	200 mg 5xd for 10 days (simplex) 800 mg 5xd for 7-10 days (zoster)	$1.00 (simplex) $12.00 (zoster)

Comparison of Cost Avoidance

Drug switched to acyclovir	**Cost avoidance if prescription written to treat *h. zoster***	**Cost avoidance if prescription written to treat *h. simplex***
Famciclovir	$35.04	$10.20
Valacyclovir	$18.03	$19.30

To estimate cost avoidance, we made the following assumptions:

- All prescriptions switched from valacyclovir to generic acyclovir were for the treatment of h. *simplex* (resulted in a cost avoidance of $19.30 per switch)
- All prescriptions switched from famciclovir to generic acyclovir were for the treatment of h. *zoster* (resulted in a cost avoidance of $35.04 per switch)
- Refills were not authorized on any famciclovir or valacyclovir prescriptions

For example, in the month of June, 8 of the 28 switches were for famciclovir prescriptions and 20 of the 28 were for valacyclovir prescriptions. To maximize estimated cost avoidance, it was assumed that all famciclovir switches were prescriptions written to treat h. *zoster* (8 switches @ $35.04 each = $280) and all Valrex switches were prescriptions written to treat h. *simplex* (20 switches @ $19.30 each = $386). Total cost avoidance in June is estimated at $666 ($280 + $386).

This estimate of monthly cost avoidance assumes maximal cost savings in the treatment of h. *simplex* and h. *zoster*.

May 00 NMOP Preferred/Non-Preferred Pairs Program Report:
Summary of Switch Rates and Estimated Cost Avoidances Jun 99 – Feb 00

Non-Preferred Drug	Preferred Drug	Switch Rate[1]	Estimated Cost Avoidance[1]	Total Number of Attempted Provider Contacts[2]	Estimated Cost Avoidance per Attempted Provider Contact[3]	Annualized Estimated Cost Avoidance
Cardizem CD Dilacor XR, Diltia XT, Diltiazem XR	**Tiazac**	69%	$273,599	3647	$75	$364,799
Procardia XL	**Adalat CC**	56%	$241,638	1415	$171	$322,184
Lodine XL, Relafen, Voltaren XR, DayPro, Naprelan	**Generic NSAIDs**	34%	$342,206	4128	$83	$456,275
Axid, Pepcid	**Generic ranitidine**	59%	$42,359	687	$62	$169,436
Vasotec	**Zestril**	55%	$12,069	265	$46	$144,828
Ditropan XL, Detrol	**Generic oxybutynin**	30%	$70,970	2486	$29	$94,627
Pletal	**Generic pentoxi-fylline**	21%	$466	23	$20	$5592
Valacyclovir, Famciclovir	**Generic acyclovir**	33%	$4521	562	$8	$6028
	Total	**$987,362**	**13,187**	**$75**	**$1,563,769**	

1. From May 2000 NMOP Preferred/Non-Preferred Pairs Program Report (Tables 1-8)
2. Assumes that each new prescription received for a non-preferred drug results in one attempted provider contact
3. Calculated as the total cost avoidance Jun 99 – Feb 00 divided by the total number of attempted provider contacts made for non-preferred drugs in this class during the same period

Appendix B: Quantity Limits for Selected High-Cost Topicals in the NMOP and Retail Pharmacy Network

Drug	Previous NMOP Limit	New Quantity Limits	Rationale
Imiquimod (Aldara)	**none**	**Retail:** 1 box of 12 single-use packets per 30 days (12 units) **Mail order:** 3 boxes of 12 single-use packets per 90 days (36 units)	Immune response modifier with an unknown mechanism of action, used to treat external genital and peri-anal warts. The manufacturer recommends dosing three times weekly, prior to sleep, to be left on for 6-10 hours, until total clearance or for maximum of 16 weeks. The product is supplied in boxes containing 12 single-use packets. AWP Cost: $10.40 per packet
Calcipotriene (Dovonex)		**Retail:** 300 gm or mL per 30 days* **Mail order:** 900 gm or mL per 90 days*	Synthetic vitamin D3 derivative used to treat moderate plaque psoriasis. The product is supplied as 0.005% ointment, cream, and solution in 30-, 60-, and 100-gm tubes and 60-mL bottle. AWP Cost: $1.55 per gm or mL.
Alitretinoin (Panretin)		**Retail:** 60 gm (1 tube) per 30 days **Mail order:** 180 gm (3 tubes) per 90 days	Retinoic acid derivative used to treat cutaneous lesions in patients with AIDs-related Kaposi's sarcoma. Directions are to apply sufficient gel to lesions twice daily and may gradually increase to 3-4 times daily, depending on tolerance. There is no established maximum dose. The product is supplied as a 0.1% 60-gm tube. According to the manufacturer, Ligand Pharmaceuticals, a 60-gm tube would be considered a 1 to 2-month supply based on surface area. AWP cost: $40.00 per gm
Becaplermin (Regranex)		**Retail:** 15 gm per 30 days* **Mail order:** 45 gm per 90 days*	Recombinant platelet-derived growth factor (rhPDGF) used to treat diabetic ulcers with an adequate blood supply. The amount applied once daily varies depending on the size of the ulcer area. The package labeling has a detailed calculation table. Dosage should be recalculated weekly or biweekly as the ulcer area changes. The product is supplied as a 0.01% gel in 2-, 7.5-, and 15-gm tubs. A 15-gm tube will express 60 cm of gel, which is adequate to treat one 7 cm^2 ulcer for 34 days. AWP cost: $27.50 per gm
Tazarotene (Tazorac)		**Retail:** 100 gm per 30 days* **Mail order:** 300 gm per 90 days*	Retinoid prodrug indicated for treatment of facial acne vulgaris of mild to moderate severity. It is also used to treat stable plaque psoriasis of up to 20% body surface area involvement. The product is supplied as 0.1% or 0.05% gel in 30- and 100-gm tubes. When treating facial acne, one 30-gm tube would last approximately 2 to 3 months. In treating psoriasis, one 100-gm tube would last approximately 1 month. There is no established maximum dose. AWP cost: $2.12 per gm

***Any combination of package sizes up to the maximum amount listed.**

Appendix C: Review of Ophthalmic Glaucoma Agents and BCF Recommendations—CDR Matt Nutaitis

Ophthalmic Glaucoma Agents Currently on the BCF

1. Timolol Ophthalmic Solution
   [Does not include timolol maleate gel (Timoptic XE)]
2. Betaxolol Ophthalmic Suspension (Betoptic; Alcon)
3. Pilocarpine Ophthalmic Gel
4. Pilocarpine Ophthalmic Solution
5. Dorzolamide Ophthalmic Solution (Trusopt; Merck)

Recommendations for BCF Changes

Removal of:

Betaxolol Ophthalmic Suspension
Pilocarpine Ophthalmic Gel
Dorzolamide Ophthalmic Solution

Addition of:

Brimonidine Ophthalmic Solution (Alphagan; Allergan)

Discussion

The review of the topical glaucoma agents and their presence on the BCF included a multi-phased decision process. The current BCF drugs were identified, input from a glaucoma specialist from each of the three services was solicited, and an adjustment to the BCF drugs was recommended.

The advisory group for this BCF decision was comprised of a representative from each of the services. The Army was represented by MAJ Brian Cavallero. LTC Flynn provided input for the Air Force, and CDR Diane Lundy supplied an opinion for the Navy.

Recommended BCF topical glaucoma agents: timolol ophthalmic solution, brimonidine ophthalmic solution, pilocarpine ophthalmic solution

- Due to pricing available through a DoD/VA mandatory source contract (awarded to Alcon Labs), timolol is the most cost-effective of the topical ophthalmic beta-blockers. The use of beta-blockers is common in the first line treatment of glaucoma, and thus, reason to include a beta-blocker on the BCF. The timolol products have a long track record of safety and efficacy, and are popular choices by ophthalmologists in the treatment of glaucoma patients. Retention of timolol ophthalmic solution on the BCF is recommended.

  The continued exception of timolol maleate gel (Timoptic XE, generics) from the BCF listing for timolol solution is recommended. Although this extended-release product is now generically available, it is still at least twice as costly as timolol solution on a daily basis. Local MTFs may decide to add timolol maleate gel to their formularies if they choose to do so. There is a DoD/VA mandatory source contract in effect for timolol maleate gel (awarded to Merck &

Co); however, this contract does not mandate inclusion of timolol ophthalmic gel on the BCF. Usage of timolol is about 56% timolol solution and 44% timolol maleate gel in terms of bottles purchased.

- Brimonidine (Alphagan; Allergan) is a safe and efficacious first line medication to treat glaucoma. In the Alpha Agonist class of anti-glaucoma medications, brimonidine is the least expensive, least allergenic, and is dosed as a BID medication, which assists in patient compliance and satisfaction. This group of medication also has a unique role in the prophylaxis of intraocular pressure spikes, a known complication of YAG laser capsulotomy. Its addition as a BCF drug was unanimous.

- Finally, continued inclusion of pilocarpine solution is recommended. It is inexpensive, efficacious and unique. It is used to treat acute angle closure and to prepare the eye for laser iridotomy procedures.

The recommendations for removal from the BCF are: dorzolamide ophthalmic solution (Trusopt; Merck), betaxolol ophthalmic suspension (Betoptic; Alcon), and pilocarpine ophthalmic gel.

- Clinically, dorzolamide is a second line medication. Brief stinging after the drop application influences patient compliance. The combination of expense and efficacy guided the decision to allow individual hospital formulary committees to consider this as a formulary drug, but not include it on the BCF.

- Betaxolol ophthalmic suspension has a smaller clinical role with the advent of multiple new anti-glaucoma agents. Removal from the BCF with local formulary consideration is recommended.

- Pilocarpine (Pilogel) ophthalmic gel has a very limited clinical role and also should be removed from the BCF.

Also considered for the BCF but not recommended for BCF addition at this time: latanoprost ophthalmic solution (Xalatan; Pharmacia).

- Latanoprost is effective and safe. However, latanoprost costs more than other agents and is not FDA-approved as a first line agent for glaucoma. Also, addition of a 4^{th} agent to treat glaucoma to the BCF was not felt to be necessary. The consultants agreed that local commands should be allowed to add latanoprost to their formularies if they so desire.

Appendix D: Oral Contraceptive Agents (OCPs)[1]

Monophasic OCPs with 20mcg ethinyl estradiol (EE)

Brand Name	Estrogen	Progestin	Cost/Cycle[2] (May 00 DAPA price)	BCF Item?
Alesse-28 Levlite-28	EE 20	0.10mg levonorgestrel	$6.00 $5.99	No
Loestrin FE 1/20	EE 20	1.00mg norethindrone acetate	$2.00 (28 day)	No

Monophasic OCPs with 30mcg EE

Levlen Levora Nordette	EE 30	0.15mg levonorgestrel	$1.28 $6.00 $6.00	No
Lo/Ovral Low-Ogestrel	**EE 30**	**0.30mg norgestrel**	**$8.00 $8.00**	**Yes**
Loestrin-FE 1.5/30	**EE 30**	**1.50mg norethindrone acetate**	**$2.00 (28 day)**	**Yes (added 11 May 00)**
Desogen Ortho-Cept Apri	EE 30	0.15mg desogestrel	$12.06 $16.57 not listed[3]	No

Monophasic OCPs with 35mcg EE

Brevicon Modicon Necon	EE 35	0.50mg norethindrone	$3.38 $16.76 $3.75	No
Demulen Zovia	**EE 35**	**1.00mg ethynodiol diacetate**	**$3.89 $3.75**	**Yes (added 11 May 00)**
Necon Norinyl Ortho-Novum	**EE 35**	**1.00mg norethindrone**	**$3.75 $3.81[4] $13.59**	**Yes**
Ovcon	EE 35	0.40mg norethindrone	$15.83	No
Ortho-Cyclen	EE 35	0.25mg norgestimate	$16.19	No

Biphasic OCPs

Mircette	EE 20/0.01mg	0.15mg desogestrel	$12.06	No
Jenest Necon 10/11 Ortho-Novum 10/11	EE 35	0.5mg/1.00mg norethindrone	$11.25 $3.75 $15.98	No

Triphasic OCPs

Tri-Norinyl	EE 35	0.5/1/0.5mg norethindrone	$3.81	No
Ortho-Novum 7/7/7	**EE 35**	**0.5/0.75/1mg norethindrone**	**$15.78[5]**	**Yes**
Ortho Tri-Cyclen	EE 35	0.18/0.215/0.25mg norgestimate	$16.35	No
Estrostep-FE	EE 20/30/35	1.00mg norethindrone acetate	$2.00	No
Trilevlen Triphasil Trivora	**EE 30/40/30**	**0.05/0.075/0.125mg levonorgestrel**	**$1.28 $6.00 $13.11**	**Yes**

Progestin-Only OCPs

Micronor Nor-Q.D.		**0.35mg norethindrone**	**$18.82 $6.30**	**Yes (added 11 May 00)**
Ovrette		0.075mg norgestrel	$15.63	No

1. OCPs with 50 mcg EE or mestranol not listed due to infrequency of use (about 2.5% of all cycles purchased)
2. DAPA prices listed are for 28-day packs, which represent approximately 95% of total use compared to 21-day packs. Prices do not reflect bulk discounts.
3. Recently approved. Per the manufacturer, FSS price is approximately $10.20 per cycle; DAPA price not yet listed
4. Norinyl 1/35 28-day packs available through the depot at approximately $5.30 per cycle, including the depot surcharge. This is higher than the $3.81 price through the prime vendor.
5. Ortho-Novum 7/7/7 (clinic packs) available through the depot at approximately $5.56 per cycle, including the depot surcharge. This is considerably lower than the $15.78 price through the prime vendor.

Appendix E: Formulary Changes

I. BCF Changes

A. *Addition of the following:*

1. Brimonidine Ophthalmic Solution (Alphagan; Allergan)—see Paragraph 5C7
2. Metronidazole vaginal gel (Metrogel Vaginal; 3M Pharmaceuticals)—see Paragraph 5C8
3. Ethinyl estradiol 30 mcg/1.5 mg norethindrone (Loestrin FE 1.5/30)—see Paragraph 5C11b
4. Ethinyl estradiol 35 mcg/1 mg ethynodiol diacetate (e.g., Demulen, Zovia)—see Paragraph 5C11c
5. 0.35 mg norethindrone (e.g., Micronor, Nor-Q.D.)—see Paragraph 5C11f
6. Extended release morphine (MS Contin or its AB-rated generic only) 15-, 30-, and 60-mg tablets [The BCF requirement does not include 100- or 200-mg tablets of MS Contin and does not include other extended release morphine products (e.g., Oramorph SR or Kadian)]. (see Paragraph 5C12)

B. *Removal of the following:*

1. Betaxolol Ophthalmic Suspension—see Paragraph 5C7
2. Dorzolamide Ophthalmic Solution—see Paragraph 5C7
3. Pilocarpine Ophthalmic Gel—see Paragraph 5C7

C. *Clarification*—The BCF listing for "oxycodone 5 mg /acetaminophen 325 and 500 mg" was clarified to specify that MTFs must have oxycodone/acetaminophen in the 5/325 and 5/500 mg strengths on their formularies. MTFs are not required to have the 2.5/325, 7.5/500, and 10/650 strengths on their formularies. (See Paragraph 5C9.)

II. NMOP Formulary Changes

A. *Added to the NMOP Formulary* (see Paragraph 5C1):

1. Levetiracetam tablets (Keppra; UCB Pharma)
2. Ciclopirox topical solution (Penlac Nail Lacquer; Dermik/Aventis)
3. Nedocromil sodium ophthalmic solution, 2% (Alocril; Allergan)
4. Cevimeline HCl capsules (Evoxac; Snowbrand Pharma)
5. Alosetron tablets (Lotronex; Glaxo)—added to the NMOP formulary for female patients only
6. Rivastigmine capsules (Exelon; Novartis)
7. Sotalol HCl (BetapaceAF™; Berlex)

B. *Excluded from the NMOP Formulary*

1. Dofetilide (Tikosyn; Pfizer) was excluded from the NMOP formulary and will not be available through the NMOP. (See Paragraph 5C2.)
2. Alosetron (Lotronex; Glaxo) was excluded from the NMOP formulary if prescribed for male patients. (See Paragraph 5C1.)

C. *Clarification*—The committee clarified the current listing for antihemophilic factors on the NMOP Covered Injectables List to read " Antihemophilic Factors (including Factor VII, Factor VIII, Factor IX, Factor IX Complex, and Anti-Inhibitor Factor Complex)." (See Paragraph 5C3.)

D. *Changes to the NMOP Preferred Drug Program*

1. Deletion of non-preferred/preferred pair for nitroglycerin patches (see Paragraph 4A2)
2. Change to calling program for herpes antivirals (see Paragraph 4C2)

III. *Quantity Limit Changes (NMOP and retail network)*

A. Quantity limits finalized and approved by committee, will be posted on the PEC website (see Paragraph 4A1).
B. Quantity limits for five high-cost topicals established (see Paragraph 4D and Appendix B).

IV. *Changes to the Prior Authorization Program (NMOP and retail network)*

A. The committee approved prior authorization criteria for the NMOP and retail network for terbinafine (Lamisil) and itraconazole (Sporanox) for treatment of onychomycosis (see Paragraph 4I).
B. The committee decided to revise prior authorization forms to include education for providers (see Paragraph 4K).

Appendix F: Reports Due to the Committee

I. *NMOP Preferred Drug Program Standing Report* (see Paragraph 4C1) — CDR Mark Brouker (PEC). Interim report due to co-chairs by 17 Jul 00, full report to committee at the next meeting.

II. *Report on Feasibility of Proposal Concerning Antivirals in the NMOP Preferred Drug Program* (see Paragraph 4C2—Mark Petruzzi (Merck-Medco). Report due to co-chairs by 17 Jul 00.

III. *Subcommittee Report on Quantity Limits for Topicals* (see Paragraph 4D)—Subcommittee members: Bill Hudson (chair); MAJ George Jones; MAJ Mickey Bellemin; Ray Nan Berry (Foundation Health); Kirby Davis (Anthem Alliance); William Hudson (Humana); Gene Lakey (TriWest); and Ron McDonald (Sierra Military Health Services). Interim report due to co-chairs by 17 Jul 00.

IV. *Subcommittee Report on Cost-Efficiency of Prior Authorizations in the NMOP* (see Paragraph 4H)—Subcommittee members to be named. Report due to co-chairs by 17 Jul 00.

Department of Defense
Pharmacoeconomic Center

1750 Greeley Rd., Bldg. 4011, Rm. 217
Fort Sam Houston, TX 78234-6190

MCCS-GPE 24 February 2000

MEMORANDUM FOR Assistant Secretary of Defense (Health Affairs)

SUBJECT: Minutes of the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee Meeting

1. In accordance with Health Affairs policy 98-025, a meeting of the DoD P&T committee convened at 0800 hours on 24 February 2000, at the Naval Amphibious Base Little Creek, Portsmouth, VA.

2. MEMBERS PRESENT:

CDR Terrance Egland, MC	Co-chairman
COL Daniel D. Remund, MS	Co-chairman
COL Rosa Stith, MC	Army
LTC Judith O'Connor, MC	Army
CDR Matt Nutaitis, MC	Navy
LCDR Kevin Cook, MSC	Navy
COL (select) Bill Sykora, MC	Air Force
COL (select) John R. Downs, MC	Air Force
MAJ George Jones, BSC	Air Force
LCDR Pamela Stewart Kuhn	Coast Guard (alternate)
Ronald L. Mosier	Department of Veterans Affairs (alternate)
LTC Greg Russie, BSC	Joint Readiness Clinical Advisory Board (alternate)
LTC Steven Humburg, MC	Health Affairs
MAJ Mickey Bellemin, BSC	Defense Supply Center Philadelphia (DSCP)
Trevor Rabie	Uniformed Services Family Health Plans (USFHP)
Ray Nan Berry	Foundation Health
Kirby Davis	Anthem Alliance
William Hudson	Humana, Inc
Gene Lakey	TriWest
Ron McDonald	Sierra Military Health Services

Daniele Doyle was absent.

3. OTHERS PRESENT:

CAPT Charlie Hostettler, MSC	DoD Pharmacy Program Director, TMA
COL Mike Heath, MS	Army Pharmacy Consultant; Chair, DoD Pharmacy Board of Directors
CAPT Bob Wilkens, MSC	Navy Pharmacy Specialty Leader
CAPT (select) Betsy Nolan, MSC	TRICARE, Mid-Atlantic Region
CDR Mark Brouker, MSC	DoD Pharmacoeconomic Center (PEC)
Howard Altschwager	Deputy General Counsel, TMA
David Chicoine	Uniformed Services Family Health Plans (USFHP)
Tom Kellenberger	Merck-Medco
Mark Petruzzi	Merck-Medco
Shana Trice	DoD Pharmacoeconomic Center (PEC)
Paul Vasquez	Defense Supply Center Philadelphia (DSCP)

4. ADMINISTRATIVE ISSUES:

A. The minutes from the last meeting were accepted as written. In response to a question from MAJ Bellemin, the committee confirmed that zolpidem (Ambien®) is subject to the standard quantity limit of a 30-day supply for controlled substances.

5. OLD BUSINESS

A. Review of Interim Decisions

1. *Advances in Medical Practice (AMP) Program*—Voting members of the DoD P&T Committee met via teleconference on 26 Jan 00 to recommend drugs for coverage by the AMP program. The minutes for the interim meeting are at Appendix A. (NOTE: The minutes for the interim meeting were not previously posted on the PEC website because it would have been premature to announce the drug recommendations before AMP program officials had a chance to review them.) At the request of AMP program officials, the P&T committee co-chairs subsequently recommended more drugs for coverage by the AMP program. The consolidated list of all drugs recommended by the DoD P&T Committee for coverage under the AMP program is at Appendix B. MTFs will be informed when AMP officials, TMA officials, and service resource management officers have approved the list of drugs and finalized procedures for reimbursing MTFs for expenditures on drugs covered by the AMP program.

2. *Additions to BCF due to Program Budget Decision (PBD) No. 41*—The DoD P&T Committee met via teleconference on 26 Jan 00 to add drugs to the Basic Core Formulary (BCF) in response to additional funding for MTF pharmacies provided by the PBD No. 41. The minutes for this meeting were previously posted on the PEC website. The committee added the following drugs to the BCF:

    - metformin
    - tamoxifen

- alendronate
- citalopram
- fluoxetine
- paroxetine
- sertraline
- sumatriptan autoinjector

The committee also modified the BCF to stipulate that all MTFs must have at least one agent from each of the following classes on their formularies:

- oral serotonin 5-HT_1 receptor agonists (naratriptan, rizatriptan, sumatriptan, zolmitriptan)
- low molecular weight heparins/heparinoids (ardeparin, dalteparin, danaparoid, enoxaparin)
- leukotriene antagonists (montelukast, zafirlukast, zileuton)
- second-generation antihistamines (cetirizine, fexofenadine, loratadine)

The PEC will furnish information to MTFs to assist them in selecting agents for their formularies.

B. National Mail Order Pharmacy (NMOP) Preferred Drug Program

When the NMOP receives a new prescription for a non-preferred drug, the NMOP contractor, Merck Medco, attempts to contact the prescriber to request a switch to a preferred drug if clinically appropriate. CDR Brouker reported the switch rates and estimated cost avoidance for non-preferred/preferred drug pairs in the NMOP (see Appendix C). MAJ Bellemin reported that Merck-Medco started calling prescribers on 1 Dec 99 regarding the new non-preferred/preferred drug pairs that were approved at the Aug 99 meeting. These drug pairs are: famotidine/ranitidine (Geneva brand); nizatidine/ranitidine (Geneva brand); nitroglycerin patches other than Nitro-Dur®/Nitro-Dur®; and enalapril/lisinopril (Zestril®). Data for the new non-preferred/preferred drug pairs will be reported at the next meeting.

C. Quantity Limits

1. The PEC and the Defense Supply Center Philadelphia (DSCP) continue to check the quantity limits that Merck Medco actually applies in the NMOP to ensure that they match the official quantity limits that are listed on the PEC website at http://www.pec.ha.osd.mil/NMOP/qtylimit.htm.

2. *Report of the subcommittee on quantity limits for topicals*—Bill Hudson (Humana) and MAJ George Jones recommended quantity limits for five high-cost topicals [imiquimod (Aldara); calcipotriene (Dovonex); altitretinoin (Panretin); becaplermin (Regranex); and tazarotene (Tazorac)]. The proposed quantity limits for most of the agents were expressed in terms of the maximum number of containers of any size that would be dispensed in a given time period (30 or 90 days). Several committee members expressed concern that this might be overly restrictive and supported the concept of expressing the quantity limits in

terms of the maximum number of grams or milliliters dispensed in a given time period, with the maximum quantity set to allow for the vast majority of all use. The P&T Committee did not approve the recommended quantity limits for the topical agents listed above. The P&T Committee asked the subcommittee to provide additional information concerning the frequency distribution of quantities dispensed for these agents in the retail networks and the NMOP in order to more accurately establish 1) if any quantity limitation is necessary, and 2) if so, what a reasonable limit would be.

3. *Change in quantity limit for azithromycin*—The committee approved a recommendation by Gene Lakey (Triwest) to increase the current 6-tablet per 30 day quantity limit for azithromycin (Zithromax®) 250-mg tablets to 10 tablets per 30 days. This change in the quantity limits is necessary to accommodate dosing requirements for older children for the treatment of pharyngitis/tonsillitis.

D. *Cost-efficiency of prior authorizations in the NMOP*—MAJ Bellemin reported on the prior authorization programs for sildenafil, etanercept, rofecoxib, and celecoxib in the NMOP.

1. *Sildenafil*—Merck Medco performed 7696 prior authorizations (4865 approved and 2831 denied) at a cost of $307,840 from September 99 through December 99. Based on utilization data from June through December 1999 and the current government price for sildenafil, it is estimated that prior authorization of sildenafil will provide a $47,280 cost avoidance during the next 12-month period.

2. *Etanercept*—Merck Medco performed 161 prior authorizations (152 approved and 9 denied) at a cost of $6440 from August 99 through December 99. Based on utilization data from June through December 1999 and the current government price for etanercept, it is estimated that prior authorization of etanercept will provide a $64,084 cost avoidance during the next 12-month period.

3. *COX-2 inhibitors (celecoxib, rofecoxib)*— Merck-Medco processed 9695 prescriptions for COX-2 inhibitors from August 99 through December 99. The automated prior authorization process approved 5574 of the prescriptions; 4121 required prescriber contact. Of these, 3100 were approved and 1021 were denied at a cost of $164,840. Based on COX-2 utilization data from June through December 1999 and the current government price for these agents, it is estimated that DoD will realize a $908,026 cost avoidance during the next 12-month period.

Several members commented that the cost avoidance is underestimated because the mere existence of the prior authorization program may cause physicians to write fewer prescriptions for a drug (usually referred to as the “sentinel effect”). Other members commented that the cost avoidance is overestimated because prescriptions that are initially denied are sometimes filled when resubmitted because the prescriber provides additional information that satisfies the prior authorization criteria. Cost avoidance was also overestimated because the analysis did not account for the cost of NSAIDs or other drugs that were prescribed when the prior authorization process denied the COX-2 prescription. The PEC staff will work with MAJ Bellemin to improve the validity of the cost avoidance estimates. MAJ Bellemin will continue to report on this subject as a standing report at each meeting. The report for the next meeting is due to the co-chairs by 11 Apr 00.

E. *Prior authorization for terbinafine*—The committee co-chairs finalized the prior authorization criteria for terbinafine in January, but TMA directed that implementation be held in abeyance until TMA clarified the definition of cosmetic vs. non-cosmetic use of terbinafine and its status as a covered benefit under TRICARE. CAPT Hostettler informed the committee during the meeting that TMA considers treatment of a documented infection to be a covered benefit under TRICARE and that such treatment should not be characterized as cosmetic.

The question of whether the prior authorization should apply only to terbinafine or to both terbinafine and itraconazole was reintroduced. Some committee members thought that prior authorizing only terbinafine might lead to increased use of itraconazole. Arguments favoring prior authorizing only terbinafine included:

- Prior authorization of itraconazole might be cost-inefficient. Itraconazole is used for many indications other than onychomycosis, so the NMOP might incur large prior authorization expenses with little impact on itraconazole usage.
- One MCSC director stated that, in their experience, institution of a prior authorization program focused only at terbinafine did not lead to increased usage of itraconazole.

Paul Vasquez commented that the NMOP might be able to ascertain (as a benefit issue) whether or not these medications were being prescribed for onychomycosis. The government would then incur the prior authorization fee only for prescriptions for treatment of onychomycosis. Mr. Vasquez will investigate this issue and report his findings to a subcommittee consisting of CDR Egland (chair), Paul Vasquez (DSCP), MAJ Bellemin (DSCP), and MAJ Ed Zastawny (PEC). The subcommittee will then develop a prior authorization proposal and present it at the next P&T committee meeting. An interim report is due to co-chairs by 11 Apr 99.

6. NEW BUSINESS

A. Prior Authorizations

1. *Prior authorization criteria and fax forms on the PEC website*—At the last meeting, the committee directed the PEC to post the prior authorization fax forms (instead of the prior authorization criteria) on the PEC website. MTFs and Managed Care Support Contractors (MCSCs) subsequently requested that the criteria be reinstated on the website. The committee approved the request. The PEC will post both the criteria and the fax forms on the website.

2. *Proposal for prior authorization of fertility drugs*—According to the Code of Federal Regulations (CFR) and TRICARE policy, fertility drugs are not a covered benefit when used to assist in non-coital reproduction methods. Some of the MCSCs have prior authorizations in place for fertility medications, but others do not. The NMOP does not have a prior authorization process for fertility agents and is currently filling a large number of prescriptions for these medications. The committee concluded that a prior authorization for fertility drugs should be established in order to comply with TRICARE policy. CAPT Hostettler will submit draft prior authorization criteria for fertility agents to the co-chairs. The co-chairs will finalize the criteria for approval at the May P&T Committee meeting. CDR Egland is the point of contact for this action.

3. *Proposal to modify COX-2 prior authorization criteria*—The committee discussed several proposals by Bill Hudson (Humana) concerning the prior authorization criteria for COX-2 inhibitors in the NMOP and retail network. The committee agreed that there is not enough clinical evidence to justify use of a COX-2 solely on the basis of recent use of a NSAID for the last 40 of 60 days and decided to remove this as a criterion for approval of the PA for COX-2 inhibitors. The committee also agreed to replace the phrase *"situations where the physician indicates that the patient has previously been unable to tolerate therapy with at least two different NSAIDs"* with the phrase *"situations where the physician indicates that the patient has previously failed an adequate trial with at least two different NSAIDs."* The committee made this change with the intent that "failing an adequate trial" would include both failures due to intolerance and failures due to lack of effectiveness at an dose and duration considered by the physician to constitute an adequate trial.

4. *Report of the Growth Hormone subcommittee*—Bill Hudson (Humana) submitted the subcommittee report, which included proposed criteria for prior authorization of growth hormone products. The P&T committee requested additional information before acting on the subcommittee's recommendation. The subcommittee is to finalize the prior authorization criteria and ensure that they clearly address the use of growth hormone products in adults and the off-label uses of growth hormone. The subcommittee should support the prior authorization criteria with a business case analysis that includes historical usage and cost data for growth hormone products in the NMOP and retail network pharmacies. The subcommittee should provide this information to CDR Egland by 11 Apr 00.

5. *Portability of Prior Authorizations*—Bill Hudson (Humana) proposed that prior authorizations should be portable between MCSCs and the NMOP. The committee assigned MAJ Bellemin to investigate the possibility of uploading all prior authorizations completed by the NMOP and the MCSCs to a common site that could be accessed by all parties. The committee also advised MAJ Bellemin, Merck-Medco, and the MCSCs to ensure compatibility of any such process with the Pharmacy Data Transaction Service (PDTS).

B. National pharmaceutical contracts

1. *Contracts awarded since last meeting*—New generic contracts that apply to both DoD and the VA have been awarded by the VA National Acquisition Center for: timolol maleate 0.25% and 0.5% ophthalmic solution, timolol maleate 0.25% and 0.5% ophthalmic gel; levobunolol 0.25% and 0.5% ophthalmic solution; and gemfibrozil 600-mg tablets.

2. *Albuterol inhaler contract*—Warrick is the contracted brand of albuterol inhaler. The FDA issued a Class I recall because some Warrick albuterol inhalers contained no active ingredient. Some MTFs had to purchase non-contracted brands of albuterol inhalers because the Warrick brand was not available. DSCP will take these issues under consideration in regard to renewal of the albuterol inhaler contract. The committee noted that MedWatch forms should be submitted when quality concerns are identified.

3. The PEC uses prime vendor purchase data to quantify the financial impact of national pharmaceutical contracts. COL Remund presented slides showing the cost avoidance associated with the ranitidine (Geneva brand), cimetidine (Sidmak brand), lisinopril (Zestril), diltiazem extended release (Tiazac), and albuterol inhaler (Warrick brand) contracts. These five contracts yielded nearly $6.5 million in cost avoidance for MTFs in FY 99.

4. COL Remund reported on other contracting issues:

   - *Nicotine Patches*— DoD/VA initiative (DoD lead) for 3-step product only. The contract solicitation was issued 15 Feb 00 and closes 15 Mar 00. An award is expected by 28 Apr 00. MTFs that purchase a 3-step nicotine patch will be required to purchase the contracted product. The contract does not stipulate that the nicotine patch will be listed on the BCF.

   - *Felodipine*— The VA will include DoD in the renewal of its Blanket Purchase Agreement (BPA) for felodipine (Plendil). Adding DoD utilization may decrease the BPA price for felodipine.

   - *Estrogen Replacement Therapy*—In light of proposed DAPA price reductions by Wyeth/Ayerst for PremPro and PremPhase, the committee decided not to proceed with a contracting initiative for estrogen replacement products at this time. The committee noted that the possibility should remain open in the future as new products continue to enter the market. The committee agreed that the presence of the incentive agreements should be considered in DoD's future deliberations with the VA. No changes were made to the BCF.

   - *Second Generation Antihistamines*— Pharmaceutical companies are reducing prices or developing incentive pricing agreements in response to the recent change in the BCF that requires each MTF to have at least one second generation antihistamine on its formulary. After the price reductions and/or incentive agreements are finalized, the committee will reassess the advisability of pursuing a national contract for a second generation antihistamine.

     CDR Egland commented that nasal corticosteroids are more cost-effective than second-generation antihistamines for treating symptoms of allergic rhinitis. He specifically referenced a recent review of the treatment of allergic rhinitis in the *American Journal of Managed Care* (Jan 2000 supplement issue).

   - *Furosemide and hydrochlorothiazide*— Pursuing a joint DoD/VA contract (VA lead). These contracts will select specific brands of these drugs for the BCF.

   - *Returned Goods* - Joint DoD/VA initiative (DoD lead). Anticipate that the solicitation for this contract will be issued in April 00.

C. *FY00 National Defense Authorization Act*—CAPT Hostettler and Mr. Altschwager briefed the committee on the ongoing efforts to implement the provisions pertaining to the uniform formulary and the DoD P&T Committee.

D. BCF and NMOP formulary issues:

1. The following drugs that were recently approved by the FDA were added to the NMOP Formulary. None of these drugs were added to the BCF.

    a. Ethinyl estradiol / norethindrone acetate tablets (FemHRT; Parke Davis)
    b. Exemestane tablets (Aromasin; Pharmacia & Upjohn)
    c. Estradiol / norgestimate tablets (Ortho-Prefest; Ortho McNeil)
    d. Aspirin / dipyridamole extended release capsules (Aggrenox; Boehringer-Ingelheim)
    e. Moxifloxacin hydrochloride tablets (Avelox; Bayer)
    f. Gatifloxacin tablets (Tequin; Bristol Myers Squibb)
    g. Oxcarbazepine tablets (Trileptal; Novartis)

2. The following drugs were excluded from the NMOP formulary for the reasons given. Neither of these drugs was added to the BCF. Both drugs will be available through retail network pharmacies.

    a. *Oseltamivir phosphate capsules (Tamiflu; Roche)*—Oseltamivir is a neuraminidase inhibitor for the treatment of uncomplicated acute illness due to influenza A and B virus in adults who have been symptomatic for less than 2 days. Due to the narrow treatment window for this agent, the committee agreed that this drug is not well suited for dispensing through a mail order pharmacy. A similar drug, zanamivir (Relenza; Glaxo), was excluded from the NMOP formulary at the Aug 99 meeting.

    b. *Bexarotene capsules (Targretin; Ligand Pharma)*—Bexarotene is indicated for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy. Bexarotene is Pregnancy Category X and carries a black box warning against use in pregnancy. Package labeling advises that a pregnancy test (for women of child-bearing age) should be obtained within one week prior to starting therapy and repeated at monthly intervals during therapy. In addition, labeling advises that "no more than a one month supply of Targretin® capsules should be given to the patient so that the results of pregnancy testing can be assessed and counseling regarding avoidance of pregnancy and birth defects can be reinforced." In light of this requirement and considering turn-around times for the mail order program, the committee decided that it was not feasible to provide bexarotene through the NMOP.

3. *Pantoprazole (Protonix; Wyeth-Ayerst)* is a new proton pump inhibitor. The national contract for omeprazole requires pantoprazole to be listed as a "non-contracted drug" on the NMOP Formulary. The national contract precludes MTFs from adding pantoprazole to their formularies.

4. *Nasal corticosteroids (BCF)*— At the May 99 meeting, the committee removed beclomethasone 42mcg/spray (Vancenase pockethaler; Schering) from the BCF due to a substantial DAPA price increase and specified that every MTF should have a nasal corticosteroid on its formulary. At the Aug 99 meeting, the committee selected fluticasone nasal spray (Flonase; Glaxo) for the BCF because it was the most cost-effective agent, it is approved for use in patients as young as 4 years old, it is dosed once a day, and allergy/immunology specialists expressed the opinion that fluticasone would be a good selection as a "workhorse" nasal corticosteroid on the BCF. Prime vendor data through the first quarter of FY00 show an increase in use of fluticasone following its selection as the BCF agent and a decrease in use of beclomethasone products following the removal of Vancenase pockethaler as the BCF selection.

   The PEC recently received prescription data from the civilian market that may affect the cost-effectiveness estimates for fluticasone and mometasone. The Aug 99 cost-effectiveness analysis was based on an adult maintenance dose of 2 puffs/day for fluticasone and 4 puffs/day for mometasone (derived from the product labeling). Civilian prescription data indicate that the prescribed puffs per day may be essentially the same for both drugs, which would make fluticasone and mometasone similar in cost-effectiveness. Mometasone was also recently approved for children as young as 3 years of age. The committee asked the PEC to analyze the dosing distribution for nasal corticosteroids within DoD and propose BCF changes if appropriate. The committee emphasized that it did not wish to make further additions to the BCF without complete information, but agreed that the presence of an additional nasal corticosteroid agent on the BCF could potentially spur competitive pricing.

5. *Consideration of Niaspan (niacin extended release; Kos Pharma) for the BCF*— Niacin is well known to have a positive effect on the lipid profile of patients with dyslipidemias and is particularly effective in raising high-density lipoprotein cholesterol (HDL-C). Patient intolerance to the common side effects of flushing and pruritis limits the usefulness of niacin in clinical practice. Sustained release forms of niacin may be tolerated better than immediate release forms, but sustained release forms have been associated with a higher incidence of liver toxicity. Niaspan is promoted as a once-daily product that is not associated with a higher incidence of liver toxicity. Niaspan costs significantly more than other sustained release forms of niacin.

   The committee is concerned that patient tolerance of niacin may be related more closely to the educational efforts regarding drug dosing than the specific dosage form that is used. Due to the limited data available, the committee also has concerns about the potential for liver toxicity with Niaspan. The committee asked the PEC to further investigate the associations between niacin dosage forms and patient tolerance and liver toxicity. The PEC will also evaluate usage patterns of all niacin products within DoD and obtain input from MTFs regarding the potential addition of Niaspan to the BCF. The PEC will provide a recommendation regarding the BCF status of Niaspan at the next meeting.

6. *Request for removal of dipivefrin ophthalmic solution (Propine, generics) from the BCF and review of ophthalmic glaucoma agents*—The committee removed dipivefrin from the BCF. Dipivefrin has been reported to have a relatively high rate of side effects relative to other available agents, which are at least equally effective. Dipivefrin represents approximately 2% of usage of glaucoma agents in DoD by number of bottles purchased, compared to timolol (Timoptic, generics) 33%, latanoprost (Xalatan) 21%, dorzolamide (Trusopt) 12%, and multiple other agents each representing 7% or less of total usage. CDR Matt Nutaitis, an ophthalmologist and allergy specialist, will undertake a review of ophthalmic glaucoma agents and make recommendations for BCF changes at the next meeting. An interim report is due to the co-chairs by 11 April.

7. *BCF status of cisapride (Propulsid; Janssen)*—The committee removed cisapride from the BCF based on recent FDA recommendations and labeling changes aimed at avoiding use of the medication in patients at known risk of rare but serious cardiac events associated with use of the drug. Labeling changes include the recommendation that an electrocardiogram, serum electrolytes, and serum creatinine be performed prior to initiation of therapy, as well as a list of contraindicated drugs and underlying conditions. With the continuing reports of heart rhythm disorders and deaths associated with use of cisapride, the committee agreed that the benefits of the drug are not likely to outweigh the known risks except for selected patients.

8. *Status of human chorionic gonadotropin injection in the NMOP*—The committee added human chorionic gonadotropin injection to the NMOP Covered Injectables list. This agent has historically been provided by the NMOP and was inadvertently omitted when the Covered Injectables list was formulated.

7. ADJOURNMENT: The meeting adjourned at 1600 hours. The next meeting will be held on Thursday, 11 May 2000, at Fort Sam Houston, Texas. All agenda items should be submitted to the co-chairs no later than 11 April 2000.

<signed>
DANIEL D. REMUND
COL, MS, USA
Co-chair

<signed>
TERRANCE EGLAND
CDR, MC, USN
Co-chair

LIST OF APPENDICES

APPENDIX A: Minutes of the Interim Meeting of the DoD P&T Committee, 26 Jan 00, concerning identification of drugs for the Advances in Medical Practice (AMP) Program;

APPENDIX B: Consolidated List of Drugs Recommended for the AMP Program by the DoD P&T Committee. **Note**: This list of drugs is **not** final. The list has been submitted to AMP officials, TMA officials, and resource management officers for final approval. MTFs will be notified of the final list of drugs and finalized procedures for reimbursement for expenditures on drugs covered by the AMP program as soon as they are approved.

APPENDIX C: NMOP Preferred Drug Program Report

APPENDIX D: Formulary Changes

APPENDIX E: Reports Due to the Committee

APPENDIX A: Minutes of the Interim Meeting of the DoD P&T Committee, 26 Jan 00, Concerning Identification of Drugs for the Advances in Medical Practice (AMP) Program

NOTE: After this interim meeting and at the request of AMP program officials, the P&T committee co-chairs subsequently recommended more drugs for coverage by the AMP program. See Appendix B for the consolidated list of all drugs recommended by the DoD P&T Committee for coverage under the AMP program.

Department of Defense
Pharmacoeconomic Center

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MCCS-GPE

26 January 2000

MEMORANDUM FOR Assistant Secretary of Defense (Health Affairs)

SUBJECT: Minutes of an Interim Meeting of the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee—Advances in Medical Practice (AMP) Program

1. In accordance with Health Affairs policy 98-025, an interim meeting of the DoD P&T Committee convened via teleconference at 1300 on 26 January 2000. The purpose of this meeting was to identify new drug usage that should be supported by Advances in Medical Practice (AMP) funds.

2. MEMBERS Participating in the Teleconference:

COL Daniel D. Remund, MS	Co-chairman
CDR Terrance Egland, MC	Co-chairman
COL Rosa Stith, MC	Army
LTC Judith O'Connor, MC	Army
Danielle Doyle	Army
LCDR Kevin Cook, MSC	Navy
LTC John R. Downs, MC	Air Force
MAJ George Jones, BSC	Air Force
CDR Robert W. Rist	Coast Guard

COL Daniel D. Remund voted as proxy for CDR Matt Nutaitis.
COL (select) Bill Sykora was absent.

3. OTHERS Participating in the Teleconference:

COL W. Michael Heath	Pharmacy Consultant, USA
COL Ardis Meier	Associate Chief, BSC for Pharmacy, USAF
CAPT Greg Hall	Director, Pharmacy Department, Portsmouth Naval Hospital

4. NEW BUSINESS

A. The AMP funds allocated for MTF pharmacies are intended to provide "seed money" to help MTFs purchase new drugs that are clinically beneficial, but which MTF pharmacies tend not to provide to patients because of insufficient funding. The plan is to use AMP money to support the usage of certain new drugs for the first year or two until funds can be programmed into the MTF budget "base" to support ongoing use of the drugs. The DoD Pharmacy Board of Directors is working with resource managers to design a mechanism to reimburse MTFs for their usage of drugs covered by the AMP program.

B. Based on recommendations provided by the PEC, the Committee recommends that AMP funds should be used to completely reimburse MTFs for FY 00 usage of the following drugs:

1. Etanercept (Enbrel)
2. Infliximab (Remicade)
3. Leflunomide (Arava)
4. Oral ribavirin / interferon alfa-2b combination (Rebetron)
5. Palivizumab (Synagis)
6. Coagulation Factor VIIa (Recombinant) (NovoSeven)

[Note: The Committee did **NOT** add these drugs to the Basic Core Formulary (BCF).]

C. Based on recommendations provided by the PEC, the Committee recommends that AMP funds should be used to reimburse MTFs for their FY 00 usage of COX-2 inhibitors as outlined below:

1. Use AMP funds to reimburse MTFs for 50% of their expenditures for COX-2 inhibitors. The reimbursement would occur regardless of the status of COX-2 inhibitors on the MTF formulary. [Note: The 50% reimbursement rate provides a financial incentive for MTFs to target the use of COX-2 inhibitors to patients who are increased risk for gastrointestinal problems secondary to NSAID use.]

2. Do not add a COX-2 inhibitor to the BCF.

3. Do not stipulate on the BCF that MTFs must have a COX-2 inhibitor on their formularies. Each MTF decides for itself whether to have a COX-2 inhibitor(s) on the MTF formulary.

4. Require MTFs to use prescribing guidelines, prior authorization, or other means to target the use of COX-2 inhibitors to patients who are at increased risk for GI problems secondary to NSAID use.

5. Pursue pricing agreements that are based on the status of COX-2 inhibitors on the MTF formulary.

6. Any new COX-2 inhibitor will be considered for addition to the list of drugs covered by AMP funds.

D. The PEC will provide cost projections for the drugs covered by the AMP program to the DoD Pharmacy Board of Directors and the AMP program managers.

5. ADJOURNMENT: The meeting adjourned at 1445 hours.

<signed>

DANIEL D. REMUND
COL, MS, USA
Co-chair

<signed>

TERRANCE EGLAND
CDR, MC, USN
Co-chair

APPENDIX B: Consolidated List of Drugs Recommended for the AMP Program by the DoD P&T Committee.

NOTE: This list of drugs is **not** final. The list has been submitted to AMP officials, TMA officials, and resource management officers for final approval. MTFs will be notified of the final list of drugs and finalized procedures for reimbursement for expenditures on drugs covered by the AMP program as soon as they are approved.

Background: The pharmacy portion of AMP funding for FY00 is intended to provide "seed money" to purchase drugs that are clinically beneficial but which MTF pharmacies tend not to provide because of insufficient funds. The drugs covered under the AMP program are newly approved, have had new indications approved since initial approval, or have an extremely high unit cost. Under current planning, AMP money will support the usage of certain new drugs for a period of two to three years until funds can be programmed into the MTF budget "base" to support the ongoing use of the drugs.

Department of Defense Pharmacy and Therapeutics (DoD P&T) Committee Recommendations: On 26 January 2000, the Department of Defense Pharmacy and Therapeutics (DoD P&T) committee recommended that the first seven drugs listed in Table 1 be funded through the AMP program. On 9 Feb 00, additional drugs were selected by an interim decision of committee co-chairs. Currently, none of the selected drugs are listed on the Basic Core Formulary (BCF). The committee recommended that none of the drugs be added to the BCF. The committee recommended using AMP funds to reimburse MTFs for 100% of their expenditures for all selected drugs with the exception of COX-2 inhibitors.

For COX-2 inhibitors, the committee recommended that AMP funds be used to reimburse MTFs for 50% of their costs (e.g., if a MTF spent $20,000 on COX-2 inhibitors for a given month, the AMP program would reimburse the MTF $10,000). The 50% reimbursement provision for COX-2 inhibitors should provide the financial incentive for MTFs to make these drugs more available to patients with a valid clinical need. Reimbursement at 100% would discourage MTF efforts to ensure appropriate use of these drugs. Lastly, the committee recommended that MTFs be required to use prescribing guidelines, prior authorization, or other means to target the use of COX-2 inhibitors to patients who are at increased risk for GI problems secondary to NSAID use.

Table 1 (continued): Consolidated List of Drugs Recommended for the AMP Program by the DoD P&T Committee.

Drug	Indication
These drugs selected for funding through the AMP program by the DoD Pharmacy & Therapeutics Committee via teleconference, 26 Jan 00.	
Etanercept (Enbrel; Immunex / Wyeth-Ayerst)	Moderately to severely active rheumatoid arthritis (RA) and polyarticular-course juvenile rheumatoid arthritis in patients with an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). May be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone.
Infliximab (Remicade; Centocor)	Moderately to severely active Crohn's disease for the reduction of signs and symptoms in patients who have an inadequate response to conventional therapies; and treatment of patients with fistulizing Crohn's disease for the reduction in the number of draining enterocutaneous fistula(s). Recently approved in combination with methotrexate for reduction in signs and symptoms of RA in patients who have had an inadequate response to methotrexate.
Leflunomide (Arava; Hoechst Marion Roussel)	Active RA to reduce signs and symptoms and to retard structural damage as evidenced by x-ray erosions and joint space narrowing in adults
Coagulation Factor VIIa (Recombinant) (NovoSeven; Novo Nordisk)	Treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX.
Oral ribavirin / interferon alfa-2b combination (Rebetron; Schering)	Treatment of chronic hepatitis C in patients with compensated liver disease who have relapsed following alpha interferon therapy, approved in December 98 for patients not previously treated with interferon.
Palivizumab (Synagis; MedImmune)	Prevention of serious lower respiratory tract disease caused by RSV in pediatric patients at high risk of RSV disease
Cyclooxygenase-2 (COX-2) inhibitors— Celecoxib (Celebrex; Searle/Pfizer); Rofecoxib (Vioxx; Merck)	Celecoxib is indicated for the treatment of osteoarthritis (OA) and rheumatoid arthritis (RA), and was very recently approved for reduction in the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP), as an adjunct to usual care (e.g., endoscopic surveillance, surgery). Rofecoxib is indicated for OA, acute pain, and primary dysmenorrhea. NOTE: For COX-2 inhibitors, the committee recommended that AMP funds be used to reimburse MTFs for 50% of their costs.
These drugs selected for funding through the AMP program by an interim decision of DoD Pharmacy & Therapeutics Committee co-chairs, 9 Feb 00.	
Glycoprotein IIb/IIIa inhibitors— • Eptifibatide (Integrilin; COR) • Tirofiban (Aggrastat; Merck) • Abciximab (ReoPro; Lilly)	Abciximab indicated for use as an adjunct to PTCA, tirofiban indicated for acute coronary syndrome, and eptifibatide indicated for both acute coronary syndrome or treatment of patients undergoing percutaneous coronary intervention (PCI)

Table 1 (continued): Consolidated List of Drugs Recommended for the AMP Program by the DoD P&T Committee

Drug	Indication
Immunosuppressants— • Cyclosporine (various manufacturers) • Mycophenolate mofetil (Cellcept; Roche) • Sirolimus (Rapamune; Wyeth-Ayerst) • Tacrolimus (Prograf; Fujisawa)	Cyclosporine: Prophylaxis of organ rejection in kidney, liver, and heart transplantation. RA (Neoral only), psoriasis (Neoral only). Multiple unapproved indications. Mycophenolate mofetil: Prophylaxis of organ rejection in kidney or heart transplantation. Sirolimus: Prophylaxis of organ rejection in kidney transplantation. Tacrolimus: Prophylaxis of organ rejection in liver transplantation.
Dornase alfa (Pulmozyme)	Daily administration in conjunction with standard therapies in the management of cystic fibrosis patients to reduce the frequency of respiratory infections requiring parenteral antibiotics and to improve pulmonary function
Interferon gamma 1b (Actimmune)	Reduction of the frequency and severity of serious infections associated with chronic granulomatous disease
$Alpha_1$-proteinase inhibitor (Prolastin)	Chronic replacement in patients with congenital alpha1-antitrypsin deficiency and clinically demonstrable panacinar emphysema.
Temozolomide (Temodar)	Oral chemotherapy agent for adult patients with refractory anaplastic astrocytoma; pending NDAs for other conditions.
Trastuzumab (Herceptin)	Treatment of metastatic breast cancer in patients with tumors that overexpress the HER2 protein
Rituzimab (Rituxan)	Treatment of patients with relapsed or refractory low-grade or follicular, CD20 positive, B-cell non-Hodgkin's Lymphoma.
Drugs for MS • Interferon beta 1a (Avonex) • Interferon beta 1b (Betaseron) • Glatiramer acetate (Copaxone)	Treatment of relapsing/remitting multiple sclerosis.
Colony Stimulating Factors • Filgrastim (Neupogen) • Sargramostim (Leukine)	To reduce the incidence and duration of neutropenia-related sequelae (e.g., infection, fever) associated with myelosuppressive chemotherapy, bone marrow transplant, severe chronic neutropenia, etc., and for the mobilization of hematopoietic progenitor cells into the peripheral blood for leukapheresis collection.

Table 1 (continued): Consolidated List of Drugs Recommended for the AMP Program by the DoD P&T Committee

Drug	Indication
Irinotecan (Camptosar)	Metastatic carcinoma of the colon or rectum.
Gemcitabine (Gemzar)	First-line treatment for locally advanced or metastatic pancreatic cancer and in combination with cisplatin for first-line treatment of inoperable, locally advanced or metastatic non-small cell lung cancer
Epoetin alfa [Recombinant human erythropoietin] (Epogen, Procrit)	Reduction of allogeneic blood transfusion in surgery patients and treatment of anemia from various causes, including chronic renal failure, zidovudine therapy in HIV-infected patients, and chemotherapy.
Becaplermin (Regranex)	Treatment of diabetic neuropathic ulcers in conjunction with debridement and good ulcer care.

APPENDIX C: NMOP Preferred Drug Program Report

The NMOP Preferred Drug Program

The purpose of the NMOP Preferred Drug Program is to encourage the use of drugs that are preferred on the basis of relative effectiveness, safety, and cost. The NMOP calls the prescriber on each new prescription for a non-preferred agent and requests a switch to a preferred drug. If the prescriber declines or if the prescriber cannot be contacted, the prescription is filled as written.

Methods of Calculating Cost Avoidance

The NMOP Preferred Drug Program achieves cost avoidance by shifting prescription market share to the preferred drugs. In general, cost avoidance is estimated by subtracting the actual expenditures for preferred and non-preferred drugs from the expenditures that would have been expected if the Preferred Drug Program did not exist (cost avoidance = expected expenditures – actual expenditures). The specific method used to calculate cost avoidance for a given set of preferred and non-preferred drugs depends on the distribution of prescriptions that would have been expected for preferred and non-preferred drugs if the Preferred Drug Program did not exist.

1. *Distribution of prescriptions expected to remain constant if Preferred Drug Program did not exist*—Examples include diltiazem extended release, nifedipine extended release, and the nonsteroidal anti-inflammatory drugs (NSAIDs).

   Calculation of "expected" expenditures is straightforward because we simply apply the baseline market share percentages that existed before the Preferred Drug Program was implemented. First, calculate the expected number of prescriptions for each preferred and non-preferred drug by multiplying the actual total number of prescriptions filled during the month by the percentage of the prescription market that each drug represented before the Preferred Drug Program was implemented. Second, calculate the expected expenditures by multiplying the expected number of prescriptions for each preferred and non-preferred drug by the current cost per prescription for that drug and then sum the products. Calculate the cost avoidance by subtracting the actual expenditures from the expected expenditures. [NOTE: This method accounts for the impact of both new and refill prescriptions on cost avoidance.]

2. *Distribution of prescriptions expected to change even if Preferred Drug Program did not exist*—Urinary agents (preferred drug: oxybutynin generic; non-preferred drugs Detrol, Ditropan XL) are an example. Because Detrol and Ditropan XL are relatively new agents, market share percentages are likely to change even if the Preferred Drug Program did not exist.

   Calculation of expected expenditures is not straightforward because we cannot simply apply the baseline market share percentages that existed before the Preferred Drug Program was implemented. We do not have a method for predicting what the market share percentages would have been in the absence of the Preferred Drug Program. For this set of drugs, cost avoidance was calculated by multiplying the number of prescriptions switched for each target drug by the difference in average cost per prescription between the target drug and oxybutynin. This method only accounts for the cost avoidance for the single new prescription that was switched at the time

of the phone call. It does not account for the cost avoidance that would be associated with any prescription refills. This method underestimates the cost avoidance.

3. *Drugs/drug classes for which the quantity dispensed (and cost) per prescription is highly variable*—An example is the anti-herpes drugs (preferred drug: acyclovir generic; non-preferred drugs Valtrex, Famvir). Analysis of the cost avoidance associated with this set of drugs proved difficult. Dosing regimens and quantities dispensed per prescripton vary widely for anti-herpes drugs according to the disease being treated (herpes zoster, herpes simplex) and the reason for use (treatment, prophylaxis). The cost avoidance calculation methods described above yielded results that do not readily correlate either with reported switches or the market share of acyclovir. For this reason, a cost avoidance estimate is not provided for the anti-herpes drugs in this report. Results of continued analysis will be presented at the May 00 meeting.

Non-Preferred/Preferred Drug Pairs

1. Extended Release Diltiazem

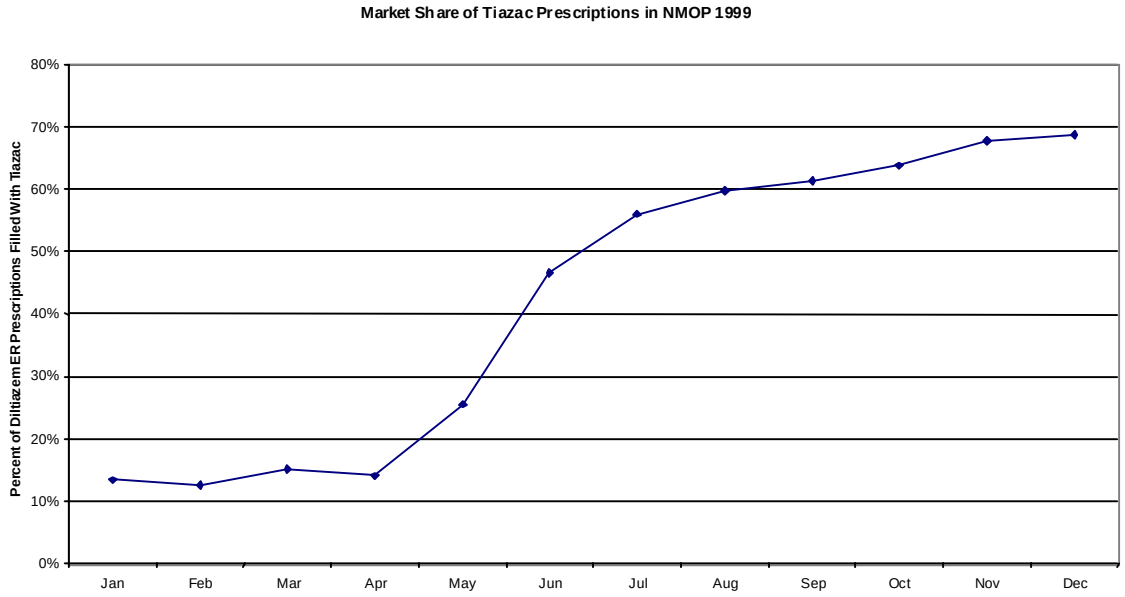
Tiazac was designated as the preferred diltiazem ER product in NMOP in May 99. Non-preferred diltiazem products include Cardizem CD, Diltia XT, Dilacor XR, and generic diltiazem ER.

Table 1: Prescriptions for Non-Preferred Diltiazem ER products in NMOP, Jun – Dec 99

Month	Jun	Jul	Aug	Sep	Oct	Nov	Dec	**Jun-Dec**
New Rxs Received	720	661	573	395	328	291	346	**3314**
Prescriber Contacts	653	616	540	352	301	263	311	**3036**
Switches	514	495	434	255	215	189	217	**2319**
Switch Rate*	71%	75%	76%	65%	66%	65%	63%	**70%**

* Percentage of new prescriptions received for non-preferred drugs that were switched to Tiazac

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



Monthly Cost Avoidance

Month	**Jun 99**	**Jul 99**	**Aug 99**	**Sep 99**	**Oct 99**	**Nov 99**	**Dec 99**	**Jun-Dec 99**
Cost avoidance	$21,796	$27,287	$31,098	$29,017	$28,112	$34,592	$30,123	**$202,025**

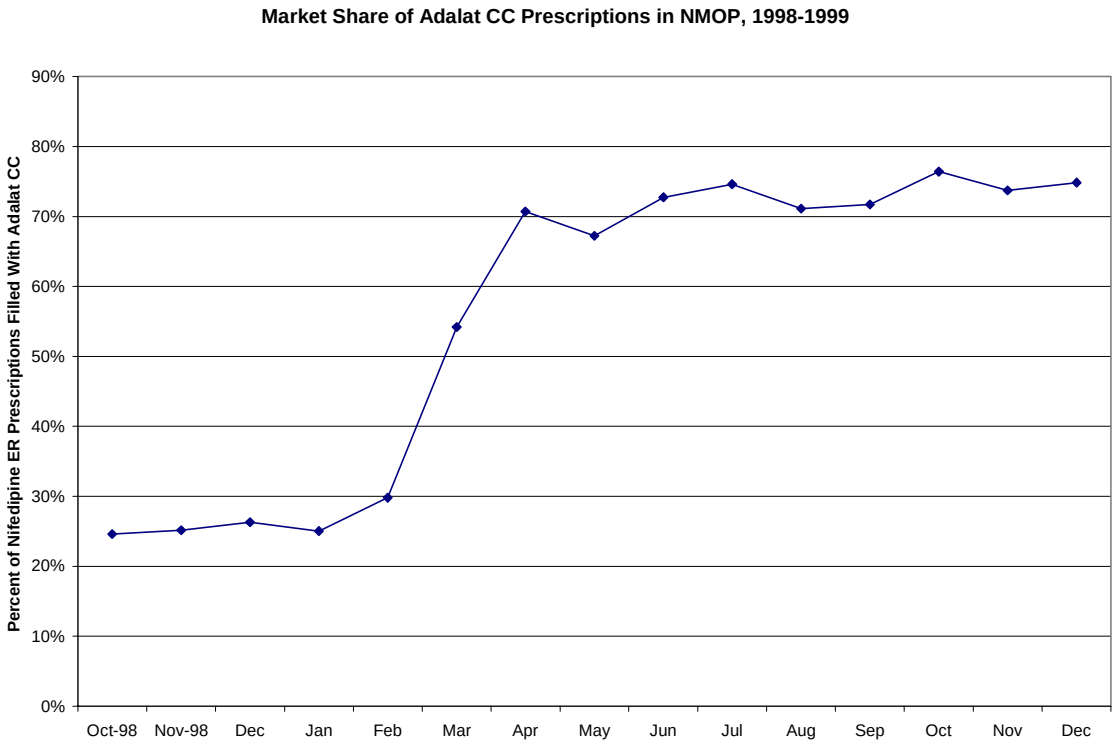
2. Extended Release Nifedipine

In Nov 98 the DOD P & T Committee selected Adalat CC as the preferred nifedipine ER product. Procardia XL is non-preferred.

Table 2: Prescriptions for Non-Preferred Nifedipine ER in NMOP, Jun – Dec 1999								
Month	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jun - Dec**
New Rxs Received	379	142	125	139	124	127	153	**1189**
Prescriber Contacts	345	132	102	120	114	101	129	**1043**
Switches	254	91	66	63	61	58	90	**683**
Switch Rate*	67%	64%	53%	45%	49%	46%	59%	**57%**

* Percentage of new prescriptions received for non-preferred drugs that were switched to Adalat CC

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



Monthly Cost Avoidance

Month	**Jun 99**	**Jul 99**	**Aug 99**	**Sep 99**	**Oct 99**	**Nov 99**	**Dec 99**	**Jun – Dec 99**
Cost Avoidance	$27,494	$26,624	$24,962	$24,510	$27,938	$26,122	$24,173	**$181,823**

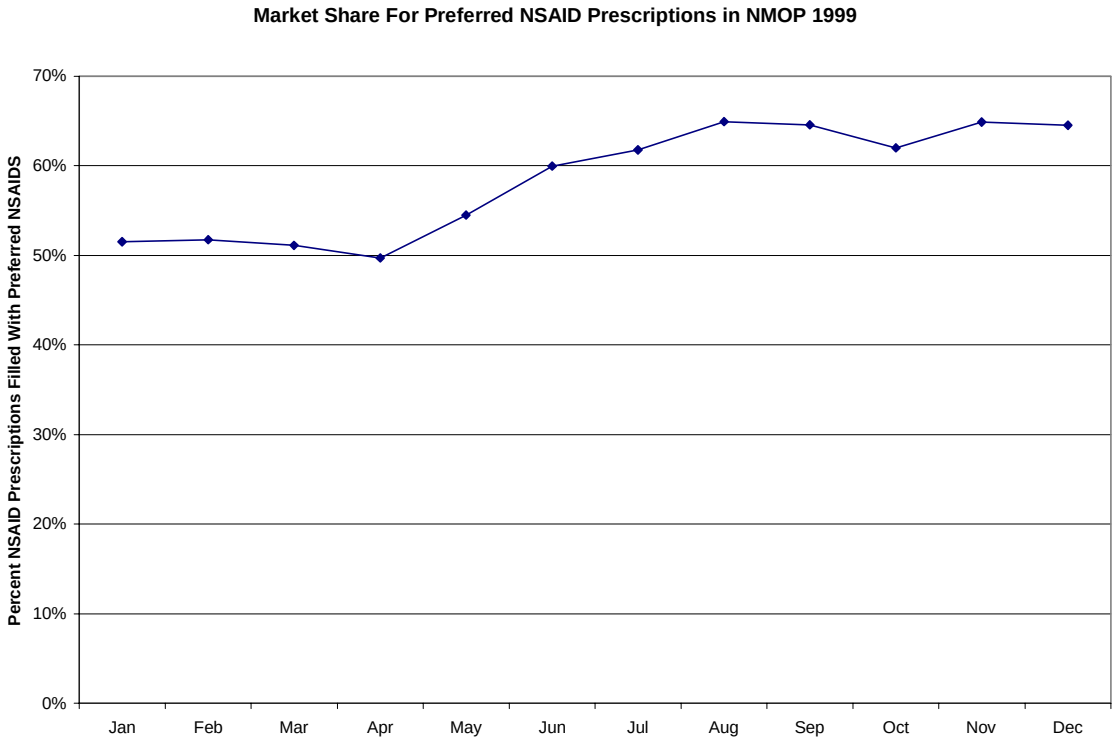
3. NSAIDS

Generic NSAIDs are preferred. Daypro, Relafen, Voltaren XR, Lodine XL, and Naprelan are non-preferred. Program started mid-May 99

Table 3: Prescriptions For Non-Preferred NSAIDs in NMOP, Jun – Dec 1999								
Month	Jun	Jul	Aug	Sep	Oct	Nov	Dec	**Jun - Dec**
New Rxs Received	617	596	549	456	432	361	434	**3445**
Prescriber Contacts	525	504	492	385	367	304	384	**2961**
Switches	244	220	248	153	150	140	136	**1291**
Switch Rate*	40%	37%	45%	34%	35%	39%	31%	**37%**

* Percentage of new prescriptions received for non-preferred drugs that were switched to generic NSAIDs

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



Monthly Cost Avoidance

Month	**Jun 99**	**Jul 99**	**Aug 99**	**Sep 99**	**Oct 99**	**Nov 99**	**Dec 99**	**Jun – Dec 99**
Cost Avoidance	$21,771	$19,929	$27,670	$29,294	$25,052	$36,465	$29,364	**$189,584**

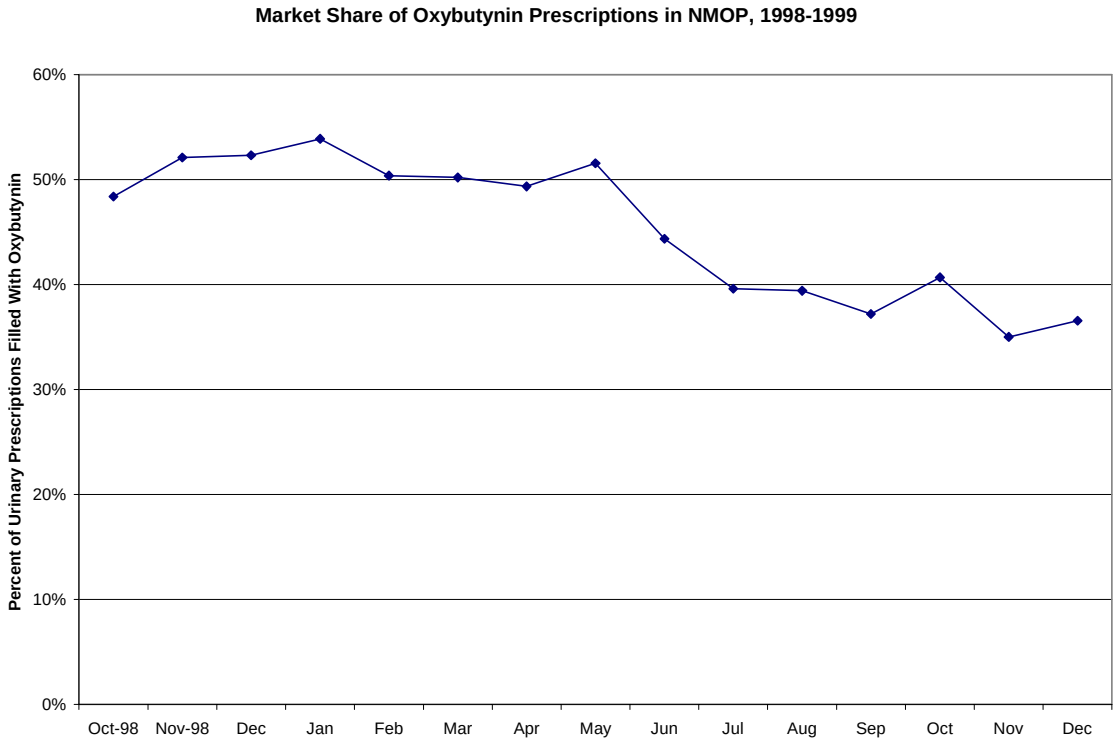
4. Urinary Agents

In November 1998, the DOD P & T Committee selected oxybutynin generic as the preferred urinary agent. Detrol and Ditropan XL are non-preferred.

Table 4: Prescriptions for Non-Preferred Urinary Drugs in NMOP, Jun – Dec 99								
Month	Jun	Jul	Aug	Sep	Oct	Nov	Dec	**Jun – Dec**
New Rxs Received	224	183	270	271	308	325	363	**1944**
Prescriber Contacts	195	158	233	236	270	256	331	**1679**
Switches	80	40	76	69	95	88	105	**553**
Switch Rate*	36%	22%	28%	25%	31%	27%	29%	**28%**

* Percentage of new prescriptions received for non-preferred drugs that were switched to oxybutynin generic

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



Monthly Cost Avoidance

Month	**Jun 99**	**Jul 99**	**Aug 99**	**Sep 99**	**Oct 99**	**Nov 99**	**Dec 99**	**Jun – Dec 99**
Cost Avoidance	$7,735	$4,355	$6,823	$6,575	$8,769	$8,414	$10,271	**$52,942**

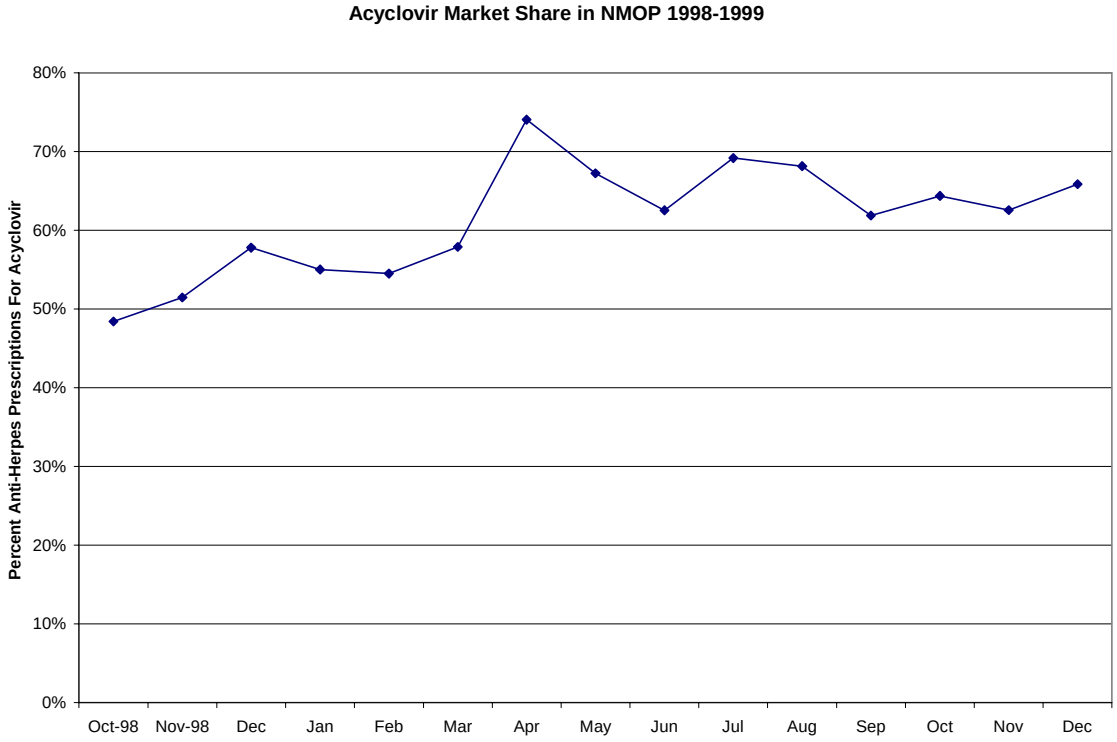
5. Anti-Herpes Drugs

Generic acyclovir is the preferred anti herpes drug. Famvir and Valtrex are non-preferred.

Table 5: Prescriptions for Non-Preferred Anti-Herpes Drugs in NMOP, Jun – Dec 1999								
Month	Jun	Jul	Aug	Sep	Oct	Nov	Dec	**Jun – Dec**
New Rxs Received	77	52	51	44	60	62	70	**416**
Prescriber Contacts	68	44	39	30	41	46	57	**325**
Switches	28	14	21	21	15	17	17	**133**
Switch Rate*	36%	27%	41%	48%	25%	27%	24%	**32%**

* Percentage of new prescriptions received for non-preferred drugs that were switched to acyclovir

Market Share Data (From NMOP adjudicated and non-adjudicated prescription claims files, Defense Supply Center Philadelphia)



APPENDIX D: FORMULARY CHANGES

I. BCF changes

A. BCF changes as a result of the 26 Jan 00 Interim Meeting:

1. Addition of the following:

a. metformin
b. tamoxifen
c. alendronate
d. citalopram
e. fluoxetine
f. paroxetine
g. sertraline
h. sumatriptan autoinjector

2. Specification that military treatment facilities (MTFs) must have at least one agent from each of the following classes on their formularies:

a. Oral serotonin 5-HT_1 receptor agonists (naratriptan, rizatriptan, sumatriptan, zolmitriptan)
b. Low molecular weight heparins/heparinoids (ardeparin, dalteparin, danaparoid, enoxaparin)
c. Leukotriene antagonists (montelukast, zafirlukast, zileuton)
d. Second-generation antihistamines (cetirizine, fexofenadine, loratadine)

B. Dipivefrin ophthalmic solution (Propine) removed from the BCF

C. Cisapride (Propulsid) removed from the BCF

II. NMOP Formulary Changes

A. Added to the NMOP Formulary:

1. Ethinyl estradiol / norethindrone acetate tablets (FemHRT; Parke Davis)
2. Exemestane tablets (Aromasin; Pharmacia & Upjohn)
3. Estradiol / norgestimate tablets (Ortho-Prefest; Ortho McNeil)
4. Aspirin / dipyridamole extended release capsules (Aggrenox; Boehringer-Ingelheim)
5. Moxifloxacin hydrochloride tablets (Avelox; Bayer)
6. Gatifloxacin tablets (Tequin; Bristol Myers Squibb)
7. Oxcarbazepine tablets (Trileptal; Novartis)

B. Excluded from the NMOP Formulary

1. Oseltamivir phosphate capsules (Tamiflu; Roche)
2. Bexarotene capsules (Targretin; Ligand Pharma)

APPENDIX D (continued): FORMULARY CHANGES

C. Pantoprazole (Protonix; Wyeth-Ayerst) listed as a “non-contracted drug” on the NMOP Formulary due to contractual requirements of the PPI contract

D. Human chorionic gonadotropin injection (various manufacturers) added to the NMOP Covered Injectables list (has historically been provided by the NMOP).

III. Quantity Limit Change (NMOP and retail network): Quantity limit for azithromycin (Zithromax) 250-mg tablets changed from 6 tablets per 30 days to 10 tablets per 30 days for both the NMOP and the retail network.