Department of Defense
Pharmacoeconomic Center

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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

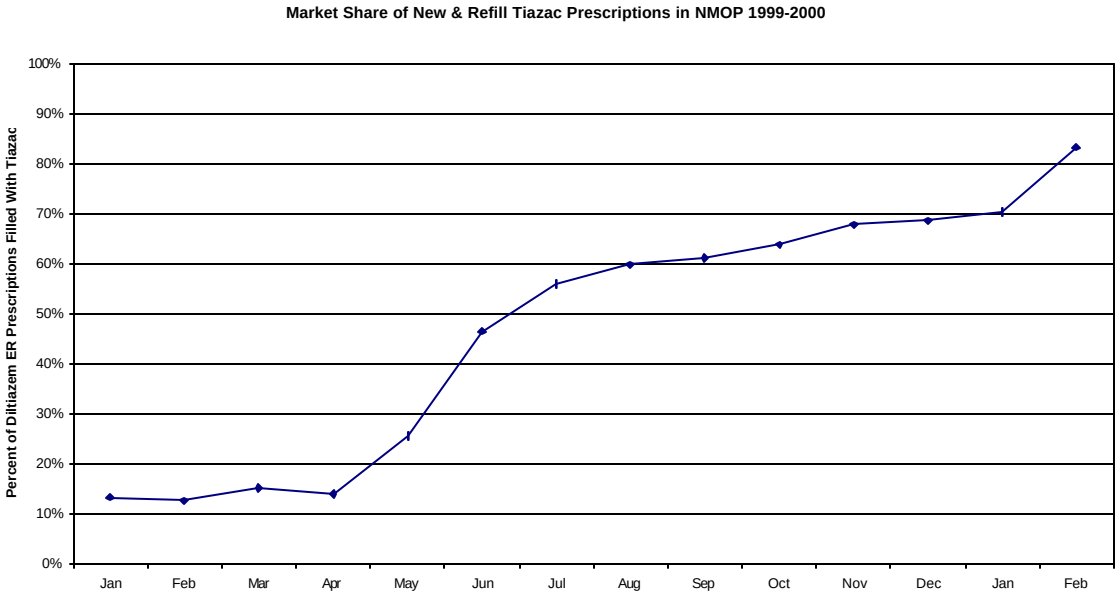
Tiazac was designated as the preferred diltiazem ER product in NMOP in May 99. Non-preferred diltiazems include Cardizem CD, Diltia XT, Dilacor XR, and generic diltiazem ER.

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

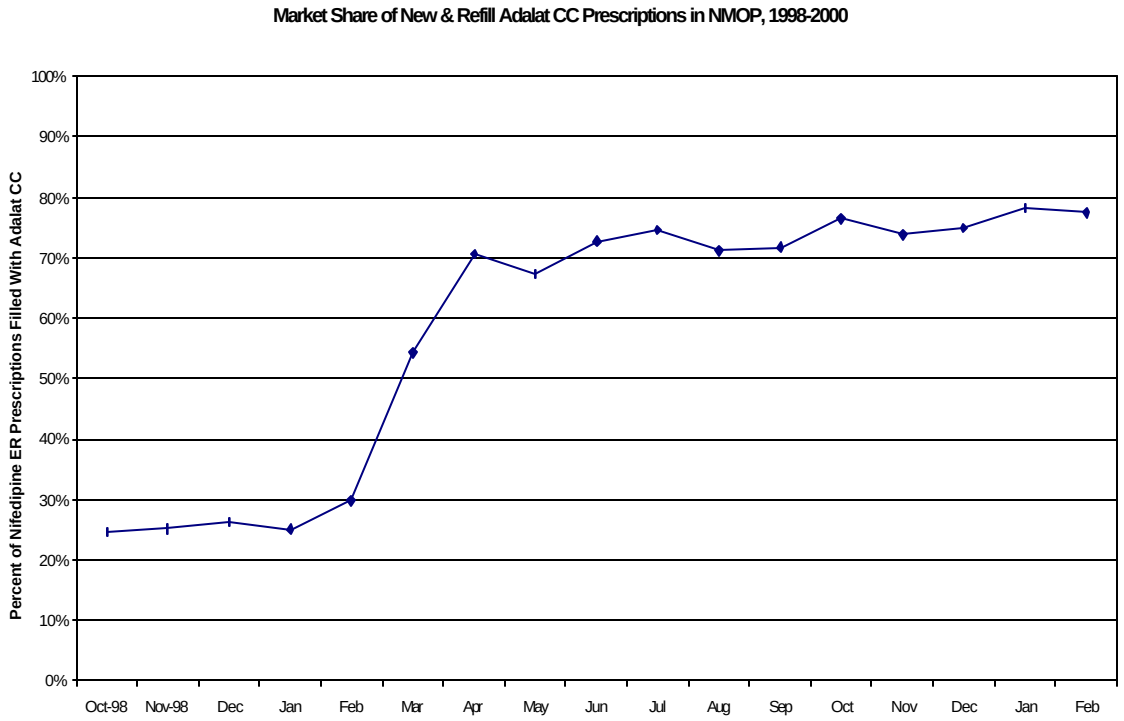
In Nov 98 the DOD P & T Committee selected Adalat CC as the preferred nifedipine ER product. Procardia XL is non-preferred.

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.

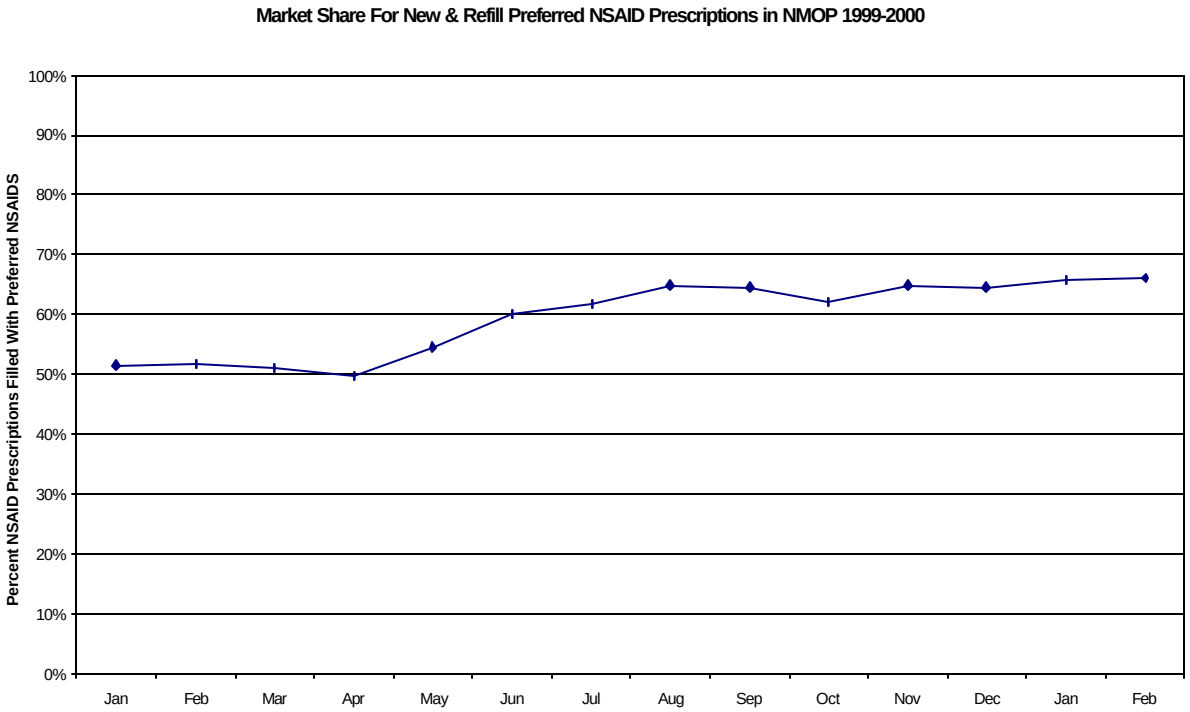
3. NSAIDS

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.

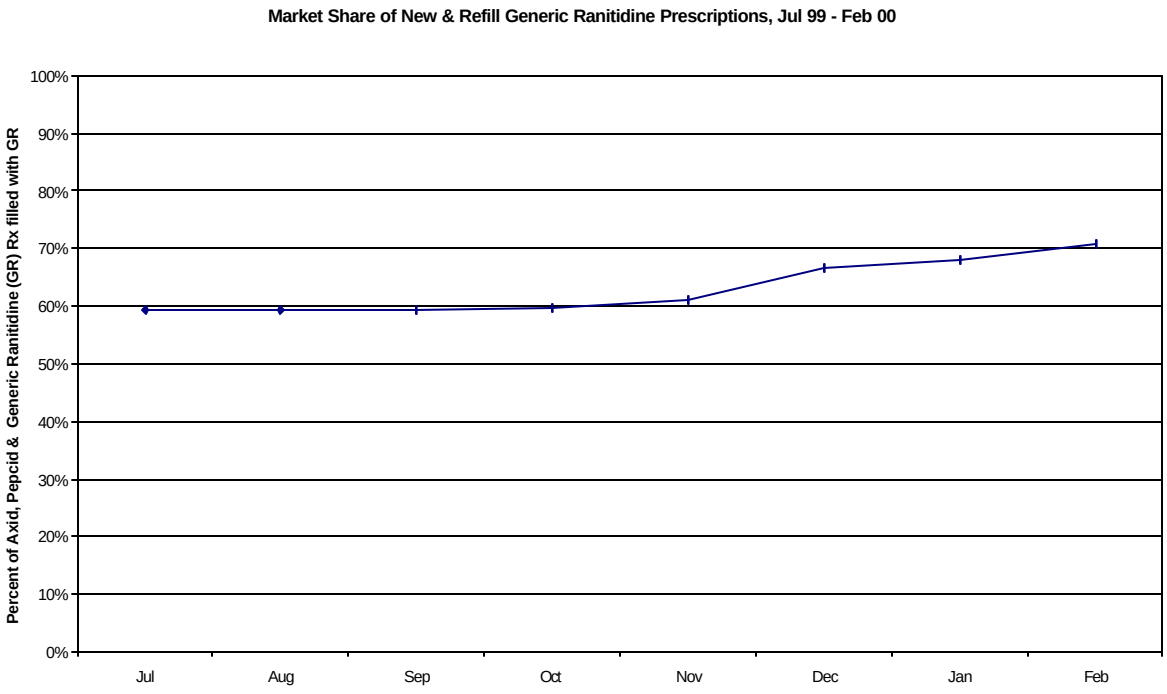
4. H2 Blockers

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.

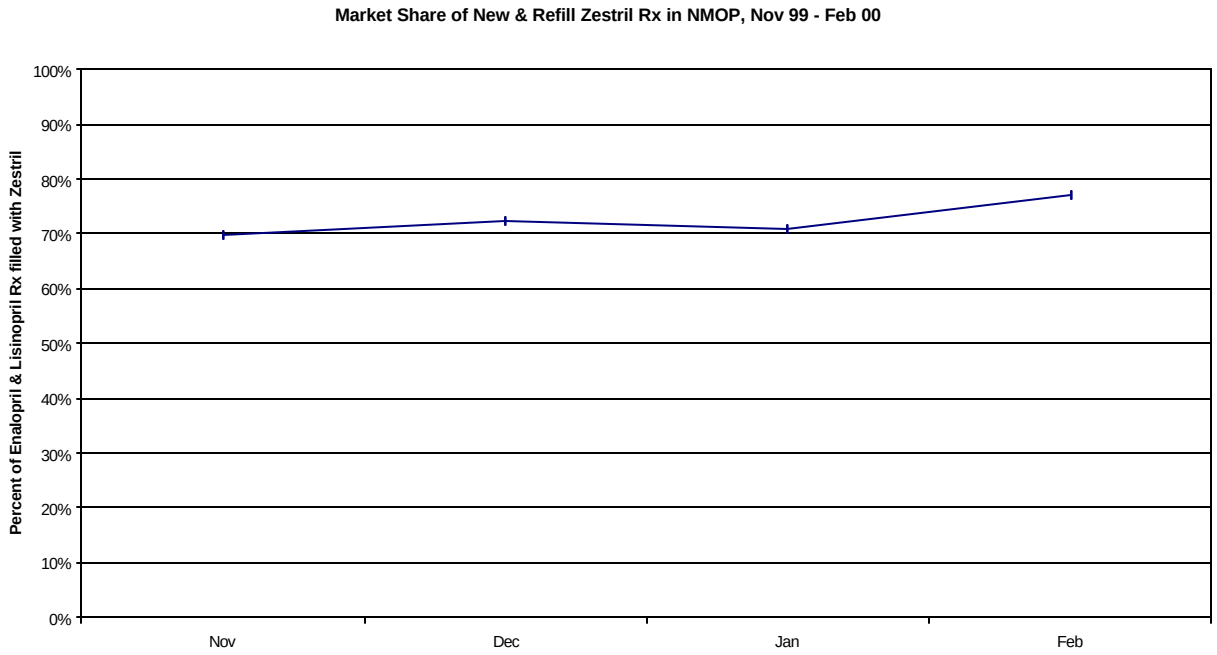
5. Enalapril

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.

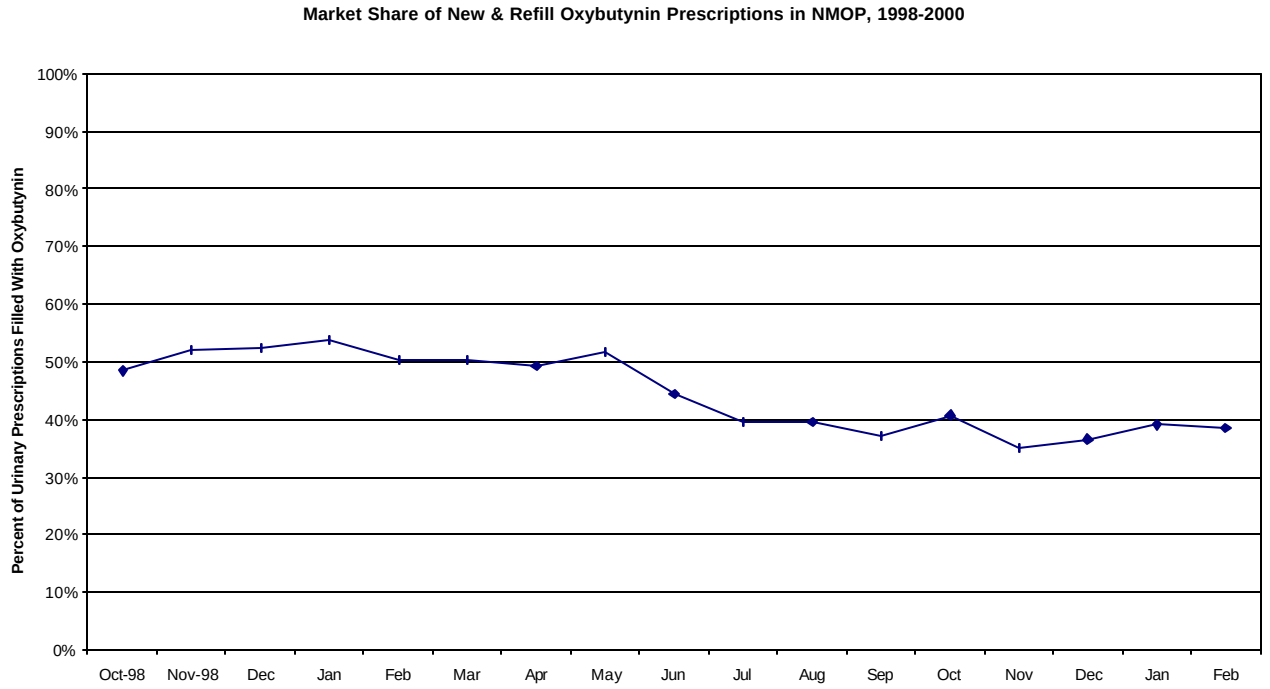
6. Urinary Agents

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.]

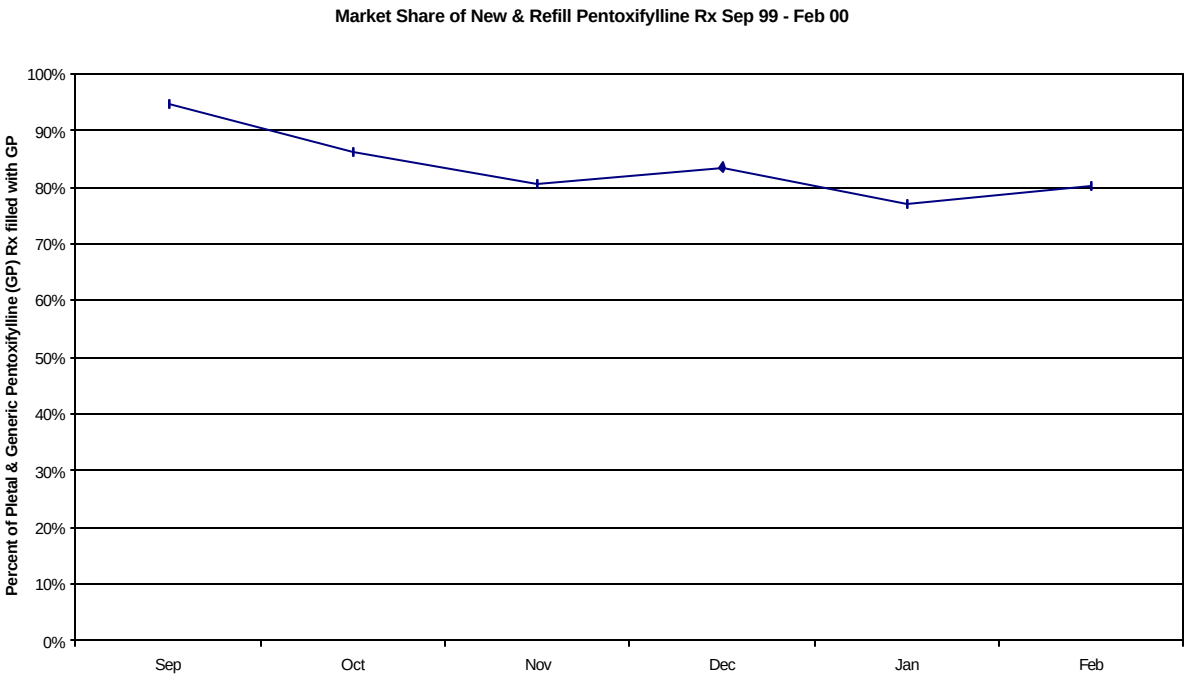
7. Cilostazol

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

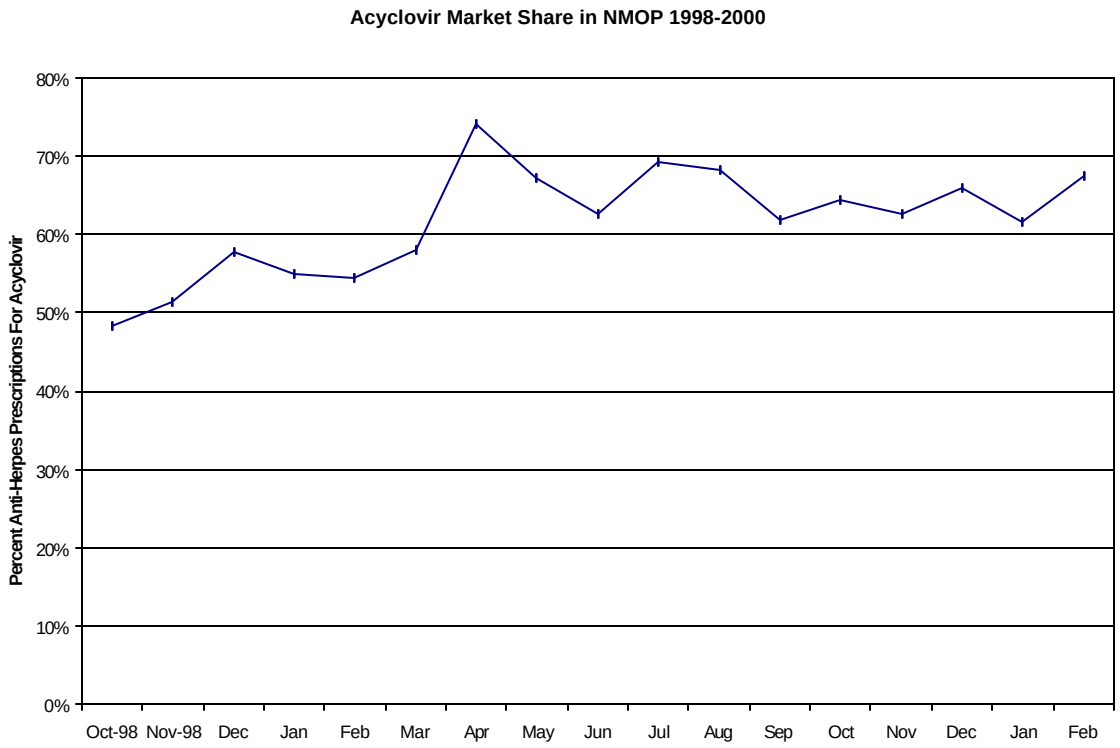
Generic acyclovir is the preferred herpes antiviral. Famciclovir (Famvir; SmithKline Beecham) and valacyclovir (Valtrex; Glaxo) are non-preferred agents. Famciclovir was selected as a non-preferred agent in Nov 98 and valacyclovir in Feb 99.

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.