Department of Defense
Pharmacoeconomic Center

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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

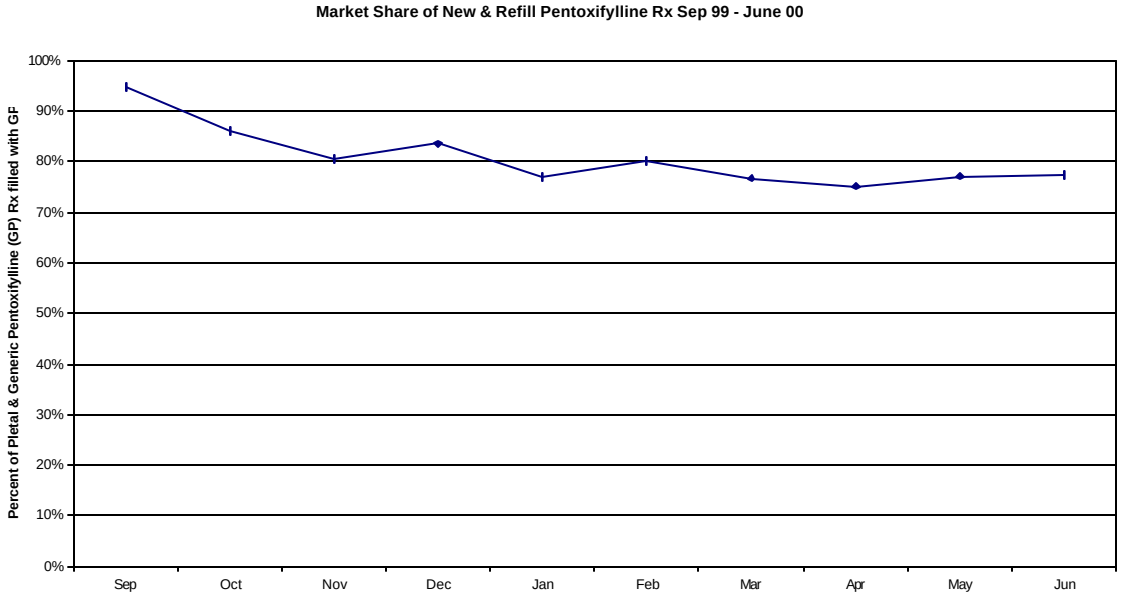
Summary of Switch Rates & Estimated Cost Avoidance for Pentoxifylline/Cilostazol, Feb 00 – Jun 00

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.]