

Department of Defense Pharmacoeconomic Center

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

MCCS-GPE

8 FEB 2001

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

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

1. A meeting of the DoD P&T committee convened at 0800 hours on 8 February 2001,
at Ft Sam Houston, TX.

2. **MEMBERS PRESENT:**

CDR Terrance Eglund, MC	Co-chair
COL Daniel D. Remund, MS	Co-chair
COL Mark Nadeau, MC	Air Force (alternate)
COL (select) John R. Downs, MC	Air Force
MAJ George Jones, BSC	Air Force
CDR Matt Nutaitis, MC	Navy
MAJ Brett Kelly, MS	Army
CDR Robert Rist	Coast Guard
Ronald L. Mosier	Department of Veterans Affairs
MAJ Mickey Bellemin, BSC	Defense Supply Center Philadelphia (DSCP)
Trevor Rabie	Uniformed Services Family Health Plans (USFHP)
Ray Nan Berry	Health Net Federal Services
Kirby Davis	Anthem Alliance
William Hudson	Humana, Inc
Gene Lakey	TriWest

MEMBERS ABSENT:

COL Rosa Stith, MC	Army
LTC Judith O'Connor, MC	Army
CDR Kevin Cook, MSC	Navy
Ron McDonald	Sierra Military Health Services
Joint Readiness Clinical Advisory Board Representative	

OTHERS PRESENT:

CAPT Joe Torkildson, MC
COL Mike Heath, MS

CDR Mark Brouker, MSC
COL William Davies, MS

LTC Don De Groff, MS
LTC Ed Zastawny, BSC
LCDR Ted Briski, MSC
MAJ Cheryl Filby, MS
CAPT Krissa Crawford, BSC

HM3 Cory Beckner
Angela Allerman
David Chicoine
Eugene Moore
Mark Petruzzi
Elizabeth Scaturro
Carol Scott
Shana Trice
Dana Dallas
Paul Vasquez

DoD Pharmacoeconomic Center
Army Pharmacy Consultant,
DoD Pharmacy Board of Directors
DoD Pharmacoeconomic Center
DoD Pharmacy Program Director,
Tricare Management Activity (TMA)
DoD Pharmacoeconomic Center
DoD Pharmacoeconomic Center
Lead Agent Office, Region 9
Defense Supply Center Philadelphia
Pharmacy Practice Resident,
Wilford Hall Medical Center
DoD Pharmacoeconomic Center
DoD Pharmacoeconomic Center
Uniformed Services Family Health Plan
DoD Pharmacoeconomic Center
Merck-Medco
Merck-Medco
DoD Pharmacoeconomic Center
DoD Pharmacoeconomic Center
Defense Supply Center Philadelphia
Defense Supply Center Philadelphia

3. ADMINISTRATIVE ISSUES

The minutes from the last meeting were accepted as written.

4. **REPORT FROM THE DOD EXECUTIVE COUNCIL MEETING** – COL Remund reported that the DoD P&T Executive Council added 12 drugs to the Basic Core Formulary (BCF) at the 7 Feb 01 meeting. Budget shortfalls in the Defense Health Program for FY 01 forced the Council to be very conservative in adding drugs to the BCF.
5. **IMPLEMENTATION OF FY 00 AND FY 01 NATIONAL DEFENSE AUTHORIZATION ACTS** – COL Davies briefed the Committee on the ongoing efforts to implement the pharmacy benefit provisions of the FY 00 and FY 01 National Defense Authorization Acts.
6. **BCF AND NATIONAL MAIL ORDER PHARMACY (NMOP) FORMULARY ISSUES** – The Committee determined the NMOP formulary status; NMOP or retail network formulary restrictions (NMOP Preferred Drug Program, quantity limits, or prior authorization); and the BCF status for six new drugs listed in Appendix A.
7. **NON-PREFERRED/PREFERRED DRUG PAIRS IN THE NMOP** – Eugene Moore (PEC) reported cost avoidance associated with the NMOP Preferred Drug Program (see Appendix B).

8. **PRIOR AUTHORIZATIONS**

- A. *Cost avoidance from NMOP prior authorizations (PAs)* – Shana Trice (PEC) reported on the estimated cost avoidance due to NMOP prior authorizations. The cost avoidance per prescription is based on the cost avoidance model that was outlined in the Aug 00 DoD P&T Committee minutes.

PA Cost Avoidance per New Prescription Submitted to the NMOP

Drug	3 rd Quarter FY 00	4 th Quarter FY 00	1 st Quarter FY 01
Sildenafil	\$13.60	\$26.46	Not calculated
COX-2 inhibitors	\$11.66	\$18.56	\$10.95
Etanercept	\$327.20	\$111.86	\$7.89

- 1) *Sildenafil* – Data reported by Merck Medco and DSCP suggest that a large number of the PAs performed during the first quarter FY 01 were for sildenafil refills. PA cost avoidance was not calculated for the first quarter of FY 01 because the cost avoidance model was not designed to account for prior authorization of refill prescriptions. The PEC will work with Merck Medco and DSCP to revise the model.
- 2) *Etanercept* – The large drop in the PA cost avoidance for etanercept is due to fewer prescription denials through the PA process (see following table).

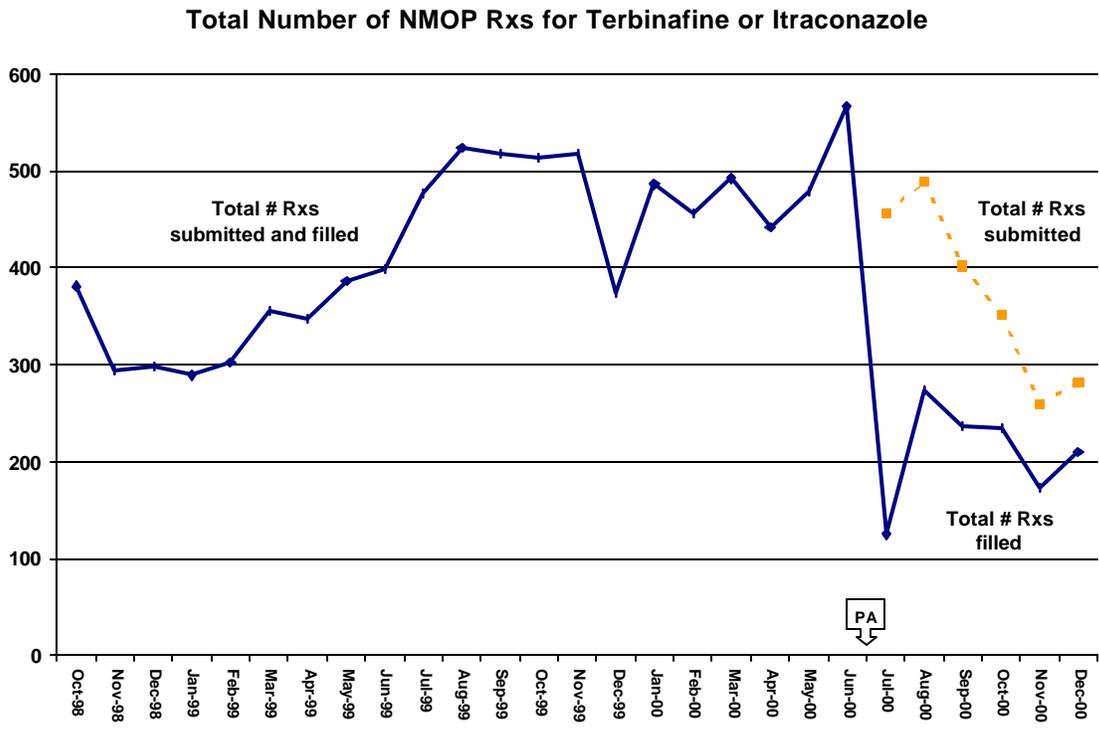
NMOP PA Data for Etanercept

	3 rd Quarter FY 00	4 th Quarter FY 00	1 st Quarter FY 01
Total number of Rxs filled (new and refill)	441	495	612
Total number of Rxs that went through the PA process	41	64	58
Total number of Rxs denied as a result of the PA process	11	5	1
Estimated cost avoidance per new Rx submitted	\$327.20	\$111.86	\$7.89

The Committee discussed the possibility of modifying or discontinuing the PA for etanercept since the cost avoidance is so minimal. The Committee refrained from changing the etanercept PA because this analysis does not assess the PA cost avoidance in the retail pharmacy networks (which probably fill many more prescriptions for etanercept than the NMOP). The Committee encouraged the MCSC pharmacy directors to voluntarily provide data to the PEC for analysis of the etanercept PA cost avoidance in the retail networks (the MCSC pharmacy directors are not contractually required to submit the data). The PEC will furnish a list of data elements in the cost avoidance model to the MCSC pharmacy directors.

- B. *Antifungals for onychomycosis* – The PA for onychomycosis began on 1 Jul 00 in the NMOP. Comparing the six-month time periods before and after the PA took effect, prescription fills for terbinafine and itraconazole dropped from an average of 491 per month (range 444-569) to an average of 211 per month (range 129-239). Prescription fills for terbinafine and itraconazole dropped because (1) prescriptions submitted to the NMOP were denied when they did not meet

the PA criteria, and (2) fewer prescriptions for terbinafine and itraconazole were submitted to the NMOP due to the “sentinel” effect of the PA. The sentinel effect occurs because providers prescribe the drug less frequently when they know the drug is subject to prior authorization. The following graph illustrates the reduction in the number of prescriptions submitted and the number of prescriptions filled for terbinafine and itraconazole after the PA began.



- C. *Revision of PA forms* – Merck-Medco added clinical rationale language to the PA forms it faxes to prescribers for sildenafil and etanercept. The clinical rationale language is not yet in place on the Merck-Medco PA fax forms for COX-2 inhibitors or antifungals for onychomycosis.
- D. *Changes to COX-2 inhibitor criteria to include Familial Adenomatous Polyposis (FAP)* – At the Aug 00 meeting, the Committee approved a change in the criteria for the COX-2 inhibitors to allow use of celecoxib for familial adenomatous polyposis. Merck-Medco has revised their fax form. The PEC will reflect the changes on its website.
- E. *Proposal to change the COX-2 inhibitor PA to reflect findings of the Celecoxib Long-term Arthritis Safety Study (CLASS)* – The annualized incidence rates of upper GI ulcer complications alone and combined with symptomatic ulcers were not significantly different for celecoxib versus NSAIDS for patients in the CLASS study who were also receiving low dose aspirin. The data, however, were limited: the number of patient-years of therapy for patients also receiving low dose aspirin was relatively low, results were based on a maximum of 6 months of therapy, and the dropout rates in both the celecoxib and NSAID group were high (40-45%).

The CLASS study suggests that the use of even low doses of aspirin may reduce or eliminate the GI protective effect of COX-2 selective NSAIDs compared to conventional NSAIDs. However, the Committee agreed that the data are insufficient to change the PA criteria to preclude usage of COX-2 inhibitors by patients taking low dose aspirin. The Committee requested that the PEC revise the clinical rationale language on the PA forms to include information on the results of the CLASS study in regard to the use of COX-2 inhibitors in patients currently receiving low dose aspirin.

- F. *Prior authorization of ciclopirox topical solution (Penlac Nail Lacquer) in the NMOP and retail network* – LTC Ed Zastawny (PEC) reported on a request from one of the MCSCs to add ciclopirox topical solution to the existing PA for antifungals for onychomycosis. Since other drugs for onychomycosis require prior authorization to ensure that they are used only when clinically appropriate (when a fungal infection is present), the Committee agreed that the same standard should be applied to ciclopirox. The committee voted to institute a PA for ciclopirox topical solution that requires confirmation of a fungal infection.

9. **STATUS OF LOW MOLECULAR WEIGHT HEPARINS (LMWHs) IN THE NMOP AND RETAIL NETWORK**

The Committee discussed the potential need to have LMWHs available through the NMOP. LMWHs are increasingly used in the outpatient sector and in some cases may be appropriately used for extended time periods (e.g., for pregnant women requiring anticoagulation). Dr. Rabie pointed out that there is now solid literature for 30 days of anticoagulation after joint replacement. While most clinicians switch patients from LMWHs to warfarin as soon as warfarin levels are therapeutic, some may opt to keep patients on enoxaparin or dalteparin for 30 days. The Committee asked the PEC to assess the opinions of providers about the necessity to have the LMWHs available through the NMOP.

10. **CONTROLLED DISTRIBUTION OF ALENDRONATE (FOSAMAX) 40 MG (FOR PAGET'S DISEASE)** – Alendronate 40 mg is no longer available through MTF pharmacies or retail network pharmacies, but is available through the NMOP. Most DoD beneficiaries who are age 65 and over cannot use the NMOP until 1 April 01. MAJ Bellemin reported that DSCP has worked out a procedure with Merck-Medco to honor prescriptions submitted by these DoD beneficiaries through their MTF pharmacies until they are eligible to use the NMOP on 1 April 01. Information about the interim procedure has been provided to the pharmacy consultants/specialty leaders for dissemination to MTF pharmacies.

11. **CONTROLLED DISTRIBUTION OF DOFETILIDE (TIKOSYN)** – Because of specialized educational requirements mandated by the FDA, dofetilide is only available for outpatient use through Stadtlander's Pharmacy/CVS Procure (which is a non-network pharmacy for DoD beneficiaries). COL Davies reported that the 50% copay penalty for using a non-network pharmacy can be waived retroactively, but the process is cumbersome. Attempts to establish a centrally funded process for supplying dofetilide to patients have thus far been unsuccessful.

12. **CONTROLLED DISTRIBUTION OF ETANERCEPT (ENBREL)**

Although a plan to supply etanercept only through the NMOP had been contemplated, LTC De Groff reported that etanercept would continue to be available through MTF pharmacies, retail network pharmacies, and the NMOP. Immunex and Wyeth/Ayerst have allotted supplies to MTF pharmacies based on historical usage data, so MTF pharmacies (unlike retail pharmacies) are not required to submit patient enrollment numbers to obtain etanercept. DoD beneficiaries can therefore obtain etanercept from MTF pharmacies even if they did not enroll with Immunex. However, unregistered patients may experience problems if they need to obtain etanercept from a source other than an MTF pharmacy.

13. **ADJOURNMENT** – The meeting adjourned at 1200 hours. The date and location for the next meeting have not been determined. All agenda items should be submitted to the co-chairs no later than 15 April 01.

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

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

List of Appendices

- APPENDIX A: NEWLY APPROVED DRUGS CONSIDERED FOR THE NMOP FORMULARY AND BCF**
- APPENDIX B: SUMMARY OF COST AVOIDANCE ASSOCIATED WITH THE NMOP PREFERRED DRUG PROGRAM**
- APPENDIX C: DRUGS ADDED TO THE BCF AND NMOP FORMULARY AT THE DOD P&T EXECUTIVE COUNCIL MEETING AND THE DOD P&T COMMITTEE MEETING**
- APPENDIX D: ITEMS TO BE ADDRESSED AT THE NEXT MEETING**

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

Generic name (Trade name; manufacturer)	Indication, FDA approval date	NMOP Formulary Status	NMOP or retail network formulary restrictions	BCF Status
Abacavir / lamivudine / zidovudine (Trizivir; Glaxo)	Approved 14 Nov 00 for use alone or in combination with other antiretroviral agents for treating HIV. Trizivir is intended only for patients whose regimen would otherwise include all three individual medications.	Added	NMOP Preferred Drug Program No Quantity Limits General rule applies Prior Authorization No	Not added
Sodium phosphate, dibasic, anhydrous / sodium phosphate monobasic, monohydrate (Visicol; Inkine)	Approved 21 September 2000 for cleansing of the bowel as a preparation for colonoscopy in adults 18 years of age or older.	Added	NMOP Preferred Drug Program No Quantity Limits General rule applies Prior Authorization No	Not added
Balsalazide disodium (Colazal; Salix)	Approved 18 Jul 00 for the treatment of mildly to moderately active ulcerative colitis. Oral prodrug of 5-aminosalicylic acid (5-ASA) in which the sulfapyridine moiety of sulfasalazine has been replaced with an inert carrier molecule.	Added	NMOP Preferred Drug Program No Quantity Limits General rule applies Prior Authorization No	Not added
Telmisartan/HCTZ (Micardis HCT; Boehringer-Ingelheim)	Approved 11 Nov 00 for treatment of hypertension. As a fixed-dose combination, telmisartan/HCTZ is not indicated for initial therapy.	Added	NMOP Preferred Drug Program No Quantity Limits General rule applies Prior Authorization No	Not added
Tacrolimus ointment (Protopic; Fujisawa)	Approved 8 Dec 00 for short-term and intermittent long-term therapy in the treatment of patients with moderate to severe atopic dermatitis (AD) in whom the use of alternative conventional therapies is deemed inadvisable because of potential risks or in the treatment of patients who are not adequately responsive to or are intolerant of alternative conventional therapies. Indicated as 0.03% and 0.1% ointment for adults and only 0.03% ointment for children aged 2 to 15 years.	Added	NMOP Preferred Drug Program No Quantity Limits General rule applies; monitor quantities dispensed Prior Authorization No	Not added

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

Generic name (Trade name; manufacturer)	Indication, FDA approval date	NMOP Formulary Status	NMOP or retail network formulary restrictions	BCF Status			
Nateglinide (Starlix; Novartis)	Approved 22 Dec 00 as monotherapy in patients with type 2 diabetes mellitus whose hyperglycemia cannot be adequately controlled by diet and physical exercise, and who have not been chronically treated with other anti-diabetic agents (treatment-naïve patients). Nateglinide is also indicated for use in combination with metformin. Nateglinide may be added to but not substituted for metformin in patients already receiving metformin who still have inadequately controlled hyperglycemia. Patients receiving glyburide or sulfonylureas who have inadequately controlled hyperglycemia should not be switched to nateglinide, nor should nateglinide be added to their treatment regimen.	Added	<table border="1"> <tr> <td data-bbox="997 401 1235 556"> NMOP Preferred Drug Program No </td> </tr> <tr> <td data-bbox="997 556 1235 711"> Quantity Limits General rule applies </td> </tr> <tr> <td data-bbox="997 711 1235 911"> Prior Authorization No </td> </tr> </table>	NMOP Preferred Drug Program No	Quantity Limits General rule applies	Prior Authorization No	Not added
NMOP Preferred Drug Program No							
Quantity Limits General rule applies							
Prior Authorization No							

APPENDIX B: SUMMARY OF COST AVOIDANCE ASSOCIATED WITH THE NATIONAL MAIL ORDER PHARMACY (NMOP) PREFERRED DRUG PROGRAM

Summary of Switch Rates and Estimated Cost Avoidances FY 00

Non Preferred Drug	Preferred Drug	Switch Rate	Estimated Cost Avoidance	Total Attempted Provider Contacts	Estimated Cost Avoidance per Attempted Provider Contact
Cardizem CD, Dilacor XR, Cartia XT, Diltiazem XR	Tiazac	68%	\$535,437	2904	\$184
Procardia XL ¹	Adalat CC	53%	\$313,918	1137	\$276
Lodine XL, Relafen, Voltaren XR, Daypro, Naprelan	Generic NSAIDs	33%	\$396,134	4118	\$96
H2 Blockers	Generic Ranitidine	38%	\$273,739	2485	\$110
Vasotec ²	Zestril	45%	\$141,394	2741	\$51
Famvir, Valtrex ³	Acyclovir	24%	\$6,783	1018	\$7
Pletal ⁴	Pentoxifylline	12%	\$3424	280	\$12
Ditropan XL, Detrol	Generic Oxybutynin	29%	\$115,346	4003	\$29
Summary			\$1,779,392	17,668	\$101

Notes:

1. Calls for Procardia XL have diminished significantly (from 135 per month in Jun 00 to 7 per month in Dec 00), due to the introduction of generic equivalents for some strengths of Procardia XL. Procardia XL will be removed from the list of non-preferred drugs when generic equivalents are available for all strengths of Procardia XL.
2. Vasotec was removed from the list of non-preferred drugs when a generic equivalent became available at a competitive price in Dec 00.
3. At the May 00 meeting, the committee changed the criteria for Famvir and Valtrex so that calls would be made only for prescriptions written for chronic use (> 30 day supply). This change took effect 1 July 00.
4. Pletal was removed from the list of non-preferred drugs at the Aug 00 meeting (effective Sep 00), due to a low switch rate.

APPENDIX C: COMBINED SUMMARY OF FORMULARY CHANGES FROM THE DOD P&T EXECUTIVE COUNCIL MEETING AND THE DOD P&T COMMITTEE MEETING

1. BCF CHANGES

A. *Additions to the BCF* (See the 7 Feb 01 P&T Executive Council Minutes, Paragraph 10B and Appendix C)

- 1) Clindamycin 150-mg capsules
- 2) Loperamide 2-mg capsules
- 3) Chlorhexidine gluconate 0.12% oral rinse (e.g., Peridex[®], Periogard[®], generics)
- 4) Amoxicillin/clavulanic acid oral (tablets and suspension)
- 5) Fluconazole oral, 150-mg tablets only. Includes only the single-dose regimen for treatment of vaginal candidiasis.
- 6) Metoclopramide oral
- 7) Mupirocin 1% ointment
- 8) Metoprolol 50- and 100-mg oral. Does not include Toprol XL.
- 9) Fluticasone oral inhaler
- 10) Lactulose syrup
- 11) Methotrexate oral
- 12) Nitrofurantoin macrocrystals (generic equivalents to Macrochantin).
Does not include Macrobid.

B. *Changes and clarifications to the BCF* - None

2. NMOP FORMULARY CHANGES

A. *Additions to the NMOP Formulary* (See Appendix A)

- 1) Abacavir / lamivudine / zidovudine (Trizivir; Glaxo)
- 2) Sodium phosphate, dibasic, anhydrous / sodium phosphate monobasic, monohydrate (Visicol; Inkind)
- 3) Balsalazide disodium (Colazal; Salix)
- 4) Telmisartan/HCTZ (Micardis HCT; Boehringer-Ingelheim)
- 5) Tacrolimus ointment (Protopic; Fujisawa)
- 6) Nateglinide (Starlix; Novartis)

B. *Exclusions from the NMOP Formulary* – None

C. *Changes to the NMOP Preferred Drug Program* (See Appendix B)

- 1) Procardia XL will be removed from the list of non-preferred drugs when generic equivalents are available for all strengths of Procardia XL.
- 2) Vasotec was removed from the list of non-preferred drugs when a generic equivalent became available at a competitive price in Dec 00.

3. QUANTITY LIMIT CHANGES (NMOP AND RETAIL NETWORK) - None

4. CHANGES TO THE PRIOR AUTHORIZATION PROGRAM (NMOP AND RETAIL NETWORK)

A. A prior authorization that requires diagnostic verification of a fungal infection will be instituted for ciclopirox topical solution (Penlac Nail Lacquer) (See Paragraph 8F).

APPENDIX D: ITEMS TO BE ADDRESSED AT THE NEXT MEETING

1. *NMOP Preferred Drug Program Report* – See Paragraph 7 and Appendix B
2. *NMOP Prior Authorization Program Report* – See Paragraph 8
3. *Status of the Prior Authorization for Etanercept* – See Paragraph 8A3
4. *Status of Low Molecular Weight Heparins in the NMOP* – See Paragraph 9
5. *Controlled Distribution of Dofetilide (Tikosyn)* – See Paragraph 11
6. *Controlled Distribution of Etanercept (Enbrel)* – See Paragraph 12