

# Department of Defense Pharmacoeconomic Center

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Fort Sam Houston, TX 78234-6190

**MCCS-GPE**

**16 NOV 00**

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

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

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

**2. MEMBERS PRESENT:**

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

**MEMBERS ABSENT:**

|                    |      |
|--------------------|------|
| COL Rosa Stith, MC | Army |
|--------------------|------|

## **OTHERS PRESENT:**

CAPT Joe Torkildson  
COL Mike Heath, MS

CDR Mark Brouker, MSC  
LTC (P) William Davies

LTC Don De Groff, MS  
LTC Steven Humburg  
MAJ Cheryl Filby, MS  
LCDR Mark Richerson  
MAJ Barbara Roach, MS  
MAJ Ed Zastawny  
HM3 Cory Beckner  
Angela Allerman  
Howard Altschwager  
David Chicoine  
Eugene Moore  
Jeremy Johnson

Mark Petruzzi  
Elizabeth Scaturro  
Carol Scott  
David Spiler  
Shana Trice  
Vincent Valinotti  
Paul Vasquez  
Eric Vetter

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  
Health Affairs  
Defense Supply Center Philadelphia  
DoD Pharmacoeconomic Center  
DoD Pharmacoeconomic Center  
DoD Pharmacoeconomic Center  
DoD Pharmacoeconomic Center  
DoD Pharmacoeconomic Center  
Deputy General Counsel, TMA  
Uniformed Services Family Health Plan  
DoD Pharmacoeconomic Center  
Family Practice Pharmacy Resident,  
University of Texas Pharmacy Program  
Merck-Medco  
Merck-Medco  
DoD Pharmacoeconomic Center  
Merck-Medco  
DoD Pharmacoeconomic Center  
Defense Supply Center Philadelphia  
Defense Supply Center Philadelphia  
Pharm.D. Student,  
Ferris State University

## **ADMINISTRATIVE ISSUES**

The minutes from the last meeting were corrected as below:

- The heading for Paragraph 11G was changed to “General Accounting Office (GAO) Report—Review of Drug Classes for Contracting Potential.”
- Paragraph 16 (Formulary Controls in the Retail Pharmacy Network) was revised to delete the sentence “MCSCs can not currently impose prior authorizations beyond those approved by the DoD P&T committee.”

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

- Quantity limit for testosterone gel (Androgel) – The normal quantity limit for a Schedule III drug would be a 30-day supply. An exception was made to allow prescriptions for Androgel to be filled for up to a 90-day supply, based on its chronic use and the lower potential for overuse compared to other testosterone formulations.
  - Coverage of perindopril (Aceon; Solvay) through the National Mail Order Pharmacy (NMOP) program – Perindopril was approved in 1993, but only recently marketed. Perindopril was added to the NMOP Formulary.
  - The co-chairs decided to establish and have the first meeting of the DoD Executive Council as a separate committee composed solely of federal employees. The DoD P&T Executive Council is responsible for performing certain inherently governmental functions relevant to a pharmacy benefits program and providing other direction and assistance to the P&T committee. The first meeting of the DoD Executive Council was held 15 Nov 00. Minutes of the meeting will be posted on the PEC website.
4. **PROCEDURE FOR REQUESTING BCF CHANGES** – At the last meeting, the committee appointed a subcommittee to develop standard procedures for MTFs to request changes to the Basic Core Formulary (BCF) and to propose agenda items for the DoD P&T Committee. MAJ George Jones presented findings of the subcommittee, including a proposed form to be placed on the PEC website to facilitate requests from MTF providers and other DoD personnel for additions, deletions, or changes to the BCF.

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

5. **IMPLEMENTATION OF FY00 AND FY01 NATIONAL DEFENSE AUTHORIZATION ACTS** – LTC Davies briefed the committee on the ongoing efforts to implement the provisions of the FY00 and FY01 National Defense Authorization Acts pertaining to the Uniform Formulary and the DoD P&T Committee.
6. **LINEZOLID USAGE IN THE RETAIL NETWORK** – The managed care support contractors (MCSCs) reported that linezolid usage had been minimal and appears appropriate. The committee agreed that a prior authorization is not necessary and closed the issue.

## 7. BCF AND NMOP FORMULARY ISSUES

- A. The committee considered the eighteen newly approved drugs listed in Appendix A. For each drug, the committee determined status on the NMOP Formulary; the necessity for NMOP or retail network formulary restrictions (NMOP Preferred Drug Program, quantity limits, or prior authorization); and status on the BCF.
- B. *Mifepristone (Mifeprex, RU-486; Danco Labs)*, approved 28 Sep 00 for medical termination of intrauterine pregnancy, through day 49 of pregnancy. Because the drug will only be available via direct shipment to qualified providers and because of existing DoD policies regarding termination of pregnancy, mifepristone was excluded from the NMOP and will not be a covered benefit through network providers. COL Davies addressed the issue of how mifepristone will be incorporated into existing medical care directives in the MTFs. He stated that TMA and Health Affairs is working on a policy to clarify the distribution of mifepristone and the processes that will need to be followed to obtain the drug. He stated that although there are potential uses for mifepristone other than termination of pregnancy, availability of the drug is likely to be limited by the FDA-approved indication and distribution process.

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

## 9. PRIOR AUTHORIZATIONS

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

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

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

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

- B. *Status of changes in prior authorization criteria for etanercept and COX-2s* – The changes in criteria for etanercept and COX-2s discussed at the February and August meetings have been completed, with the exception of the revision of the COX-2 PA to reflect approval of celecoxib for familial adenomatous polyposis (FAP). This change is in progress.
- C. *Revision of prior authorization forms to reflect the rationale for the prior authorization* – The PA forms on the PEC website, which are mailed in by beneficiaries with their prescriptions after being completed by prescribers, have been changed to include the clinical rationale for the prior authorization. Merck-Medco is in the process of adding the clinical rationale language to the forms it faxes to prescribers.
- D. *Proposal to increase the length of time for which etanercept is approved* – The committee considered a proposal to increase the length of time for which etanercept PAs are approved from one year to five years, which is Merck-Medco's current standard for etanercept in other health plans. Reports of rare cases of demyelinating disorders and pancytopenia in patients receiving etanercept engendered concern on the part of committee members about lengthening the approval period. The committee decided not to make any changes to the etanercept PA at this time.
- E. *Proposal to change the COX-2 PA to reflect findings of the Celecoxib Long-term Arthritis Safety Study (CLASS)* – For patients taking aspirin in the CLASS study, the annualized incidence rates of upper GI ulcer complications alone and combined with symptomatic ulcers were not significantly different for celecoxib versus NSAIDs. These results indicate that celecoxib confers no GI safety benefit over NSAIDs for patients who take aspirin for cardioprotection. The PA criteria for COX-2 inhibitors may need to be revised so that usage of COX-2 inhibitors is not approved for patients who take aspirin for cardioprotection. The committee asked the PEC to further evaluate the consequences and costs of making such a change in the COX-2 PA criteria.

## 10. NMOP AND RETAIL NETWORK QUANTITY LIMITS

- A. *Report of the subcommittee on quantity limits for proton pump inhibitors (PPIs)* – Bill Hudson (Humana) reported that the subcommittee considered two clinical questions 1) is there undetected disease that is being masked by chronic PPI therapy, and 2) do people really need long-term therapy with these drugs? With the assistance of expert opinion, the subcommittee concluded that there is probably very little undetected disease masked by PPI use. They also concluded that a substantial number of patients do need some type of long-term therapy, although many of these patients could be managed with a H2 blocker such as ranitidine instead of a PPI. The committee decided not to institute specific quantity limits for the PPIs in the NMOP and retail network.
- B. *Quantity limits for isometheptene 65 / dichloralphenazone 100 / acetaminophen 325 mg oral (Midrin, generics)* – Because the status of this combination drug is being changed to

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

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

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

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

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

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

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

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

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

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

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

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

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

## **List of Appendices**

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

**APPENDIX B: ITEMS TO BE ADDRESSED AT THE NEXT MEETING**



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

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

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

| Generic name<br>(Trade name;<br>manufacturer)                         | Indication,<br>approval date   | NMOP<br>Formulary<br>Status  | NMOP or<br>retail<br>network<br>formulary<br>restrictions  | BCF Status   |  |                                  |  |
|---|--|--|--|--|--|----------------------------------|--|
| <b>Tinzaparin injection</b><br>(Innohep;<br>Dupont)                   | Approved 18 Jul 00 for treatment of acute symptomatic deep vein thrombosis with or without pulmonary embolism when administered in conjunction with warfarin sodium. Safety and effectiveness were established in hospitalized patients. | Not added. The low molecular weight heparins (LMWHs) are not currently available through the NMOP. | Non-applicable   | The BCF listing for LMWHs specifies that "all MTFs must have at least one of the following products on the MTF formulary: ardeparin (Normiflo®); dalteparin (Fragmin®); danaparoid (Orgaran®); or enoxaparin (Lovenox®). MTFs will select the specific brand."<br>The listing was amended to include tinzaparin as an option and to remove ardeparin, which is no longer available.<br>The committee agreed that the class should be reviewed to assess the need for having the LMWHs available through the NMOP, the need for a prior authorization process at the NMOP/retail network to control inappropriately extended use, and the potential for contracting/incentive price agreements to reduce the unit cost of LMWH therapy. The VA is currently completing a LMWH clinical review, with a target date of Dec 00. The committee agreed that such an action could be done in conjunction with the VA. |  |                                  |  |
| <b>Candesartan/<br/>HCTZ tablets</b><br>(Atacand HCT;<br>AstraZeneca) | Approved 5 Sep 00 for treatment of hypertension  | Added  | <table border="1"> <tr> <td data-bbox="894 1247 1084 1388"> <b>NMOP Preferred Drug Program</b><br/>No             </td> </tr> <tr> <td data-bbox="894 1388 1084 1535"> <b>Quantity Limits</b><br/>General rule applies             </td> </tr> <tr> <td data-bbox="894 1535 1084 1671"> <b>Prior Authorization</b><br/>No             </td> </tr> </table> | <b>NMOP Preferred Drug Program</b><br>No   | <b>Quantity Limits</b><br>General rule applies | <b>Prior Authorization</b><br>No | Not added.<br>The committee noted that there are currently no angiotensin receptor blockers (ARBs) on the BCF. While the clinical usefulness of the ARBs appears to be limited to patients who cannot tolerate ACE inhibitors due to cough, the comment was made that in light of increasing utilization it might be reasonable to review this class. The VA does not have a clinical review scheduled in the near future. |
| <b>NMOP Preferred Drug Program</b><br>No                              |  |  |  |  |  |                                  |  |
| <b>Quantity Limits</b><br>General rule applies                        |  |  |  |  |  |                                  |  |
| <b>Prior Authorization</b><br>No                                      |  |  |  |  |  |                                  |  |

| Generic name<br>(Trade name;<br>manufacturer)  | Indication,<br>approval date   | NMOP<br>Formulary<br>Status | NMOP or<br>retail<br>network<br>formulary<br>restrictions   | BCF Status                               |  |                                  |   |
|--|--|-----------------------------|---|--|--|----------------------------------|---|
| <b>Cole-sevelam HCl</b><br>(Welchol;<br>GelTex<br>Pharma/<br>Sankyo Parke<br>Davis)  | Approved 30 May 00 as adjunctive therapy to diet and exercise for the reduction of elevated LDL cholesterol in patients with primary hypercholesterolemia, administered alone or in combination with an HMG-CoA reductase inhibitor (non-absorbed agent) | Added                       | <table border="1"> <tr> <td data-bbox="894 321 1089 499"> <b>NMOP Preferred Drug Program</b><br/>No             </td> </tr> <tr> <td data-bbox="894 499 1089 678"> <b>Quantity Limits</b><br/>General rule applies             </td> </tr> <tr> <td data-bbox="894 678 1089 852"> <b>Prior Authorization</b><br/>No             </td> </tr> </table>  | <b>NMOP Preferred Drug Program</b><br>No | <b>Quantity Limits</b><br>General rule applies   | <b>Prior Authorization</b><br>No | Not added. Colestipol, a bile acid sequestrant, is on the BCF. The committee asked the PEC to obtain more information to establish if a bile acid sequestrant continues to be required on the BCF and if colesevelam's apparent advantages of reduced constipation and fewer drug interactions make it a better choice for the BCF. The committee agreed that the PEC should wait until the Adult Treatment Panel III Guidelines are out and bring the issue back to the committee for consideration. |
| <b>NMOP Preferred Drug Program</b><br>No   |  |                             |   |  |  |                                  |   |
| <b>Quantity Limits</b><br>General rule applies   |  |                             |   |  |  |                                  |   |
| <b>Prior Authorization</b><br>No   |  |                             |   |  |  |                                  |   |
| <b>Beclo-methasone dipropionate HFA inhalation aerosol</b><br>(QVar; 3M<br>Pharma)   | Approved 15 Sep 00 for the maintenance treatment of asthma as prophylactic therapy; and for asthma patients who require systemic corticosteroid administration, where adding QVar may reduce or eliminate the need for the systemic corticosteroids      | Added                       | <table border="1"> <tr> <td data-bbox="894 852 1089 968"> <b>NMOP Preferred Drug Program</b><br/>No             </td> </tr> <tr> <td data-bbox="894 968 1089 1346"> <b>Quantity Limits</b><br/> <b>40-mcg strength:</b><br/>4 inhalers per 30 days,<br/>12 inhalers per 90 days<br/><br/> <b>80-mcg strength:</b><br/>2 inhalers per 30 days,<br/>6 inhalers per 90 days.             </td> </tr> <tr> <td data-bbox="894 1346 1089 1484"> <b>Prior Authorization</b><br/>No             </td> </tr> </table> | <b>NMOP Preferred Drug Program</b><br>No | <b>Quantity Limits</b><br><b>40-mcg strength:</b><br>4 inhalers per 30 days,<br>12 inhalers per 90 days<br><br><b>80-mcg strength:</b><br>2 inhalers per 30 days,<br>6 inhalers per 90 days. | <b>Prior Authorization</b><br>No | Not added   |
| <b>NMOP Preferred Drug Program</b><br>No   |  |                             |   |  |  |                                  |   |
| <b>Quantity Limits</b><br><b>40-mcg strength:</b><br>4 inhalers per 30 days,<br>12 inhalers per 90 days<br><br><b>80-mcg strength:</b><br>2 inhalers per 30 days,<br>6 inhalers per 90 days. |  |                             |   |  |  |                                  |   |
| <b>Prior Authorization</b><br>No   |  |                             |   |  |  |                                  |   |

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

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

| Generic name<br>(Trade name; manufacturer)                            | Indication, approval date   | NMOP Formulary Status  | NMOP or retail network formulary restrictions  | BCF Status                               |  |                                  |           |
|---|---|--|--|--|--|----------------------------------|-----------|
| <b>Lopinavir/ritonavir solution</b><br>(Kaletra; Abbott)              | Approved 15 Sep 00 for the treatment of HIV-1 infection in adults and pediatric patients age six months and older   | Added  | <table border="1"> <tr> <td data-bbox="894 344 1086 457"> <b>NMOP Preferred Drug Program</b><br/>No             </td> </tr> <tr> <td data-bbox="894 457 1086 571"> <b>Quantity Limits</b><br/>General rule applies             </td> </tr> <tr> <td data-bbox="894 571 1086 667"> <b>Prior Authorization</b><br/>No             </td> </tr> </table> | <b>NMOP Preferred Drug Program</b><br>No | <b>Quantity Limits</b><br>General rule applies | <b>Prior Authorization</b><br>No | Not added |
| <b>NMOP Preferred Drug Program</b><br>No                              |   |  |  |  |  |                                  |           |
| <b>Quantity Limits</b><br>General rule applies                        |   |  |  |  |  |                                  |           |
| <b>Prior Authorization</b><br>No                                      |   |  |  |  |  |                                  |           |
| <b>Eflornithine HCl 13.9% cream</b><br>(Vaniqa; Bristol-Myers Squibb) | Approved 28 Jul 00 for the reduction of unwanted facial hair in women   | Excluded<br><br>Drugs intended for purely cosmetic purposes are not covered under the TRICARE benefit.   | Non-applicable   | Not added                                |  |                                  |           |
| <b>Bexarotene gel</b><br>(Targretin gel; Ligand)                      | Approved 29 Jun 00 for the topical treatment of cutaneous lesions in patients with early-stage (TNM Stage IA and IB) cutaneous T-cell lymphoma (CTCL) who have refractory or persistent disease after other therapies or who have not tolerated other therapies | Excluded<br><br>It does not appear feasible to meet strict requirements for avoiding pregnancy (including limiting to a one month supply, monthly pregnancy tests, and frequent counseling) in a mail-order program. Oral bexarotene was excluded from the NMOP Formulary in Feb 00. | Non-applicable   | Not added                                |  |                                  |           |

## **APPENDIX B: ITEMS TO BE ADDRESSED AT THE NEXT MEETING**

1. Report of the subcommittee to develop standard procedures for MTFs to request BCF changes and propose agenda items for the DoD P&T Committee and follow-up on placement of a form on the PEC website for MTF providers and other DoD personnel involved in the prescribing process to propose additions, deletions, or changes to the BCF. Subcommittee members include: MAJ George Jones (chair), MAJ Barbara Roach (PEC), MAJ Brett Kelly, CDR Matt Nutaitis, MAJ Mickey Bellemin, LTC Judith O'Connor.
2. NMOP preferred drug program standing report – CDR Mark Brouker (PEC)
3. NMOP prior authorization program standing report – MAJ Mickey Bellemin, Shana Trice (PEC)
4. Controlled distribution of alendronate (Fosamax) 40 mg (for Paget's Disease)
5. Controlled distribution of dofetilide (Tikosyn)
6. Controlled distribution of etanercept (Enbrel)