Department of Defense
Pharmacoeconomic Center

2421 Dickman Rd., Bldg. 1001, Rm. 310
Fort Sam Houston, TX 78234-5081

MCCS-GPE **7 MAY 2003**

MEMORANDUM FOR: Executive Director, 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 7 May 2003, at the DoD Pharmacoeconomic Center, Fort Sam Houston, Texas.

2. VOTING MEMBERS PRESENT

CDR Terrance Egland, MC	DoD P& T Committee Co-chair
COL Daniel D. Remund, MS	DoD P& T Committee Co-chair
COL Joel Schmidt, MC	Army
COL Doreen Lounsbery, MC	Army
MAJ Travis Watson, MS	Army
COL John R. Downs, MC	Air Force
COL Mark Nadeau, MC (For COL Bill Sykora, MC)	Air Force
LtCol Ed Zastawny, BSC (For LtCol George Jones, BSC)	Air Force
CDR (sel) Debra Arsenault, MC (For CAPT Matt Nutaitis, MC)	Navy
CDR Mark Richerson, MSC	Navy
CAPT Robert Rist	Coast Guard
Dr. Trevor Rabie	Uniformed Services Family Health Plan
Mark Geraci (For Mike Valentino)	Department of Veterans Affairs

VOTING MEMBERS ABSENT

None	

OTHERS PRESENT

COL William Davies, MS	DoD Pharmacy Program Director, TMA
COL Geoffrey Rake, MC (via TC)	Medical Director, TMA
Howard Altschwager	Deputy General Counsel, TMA
COL Mike Heath, MS (via VTC)	Army Pharmacy Consultant, Chairman Pharmacy Board of Directors
CAPT Betsy Nolan, MSC (VTC)	Navy Pharmacy Specialty Leader
CAPT Joe Torkildson, MC, USN	DoD Pharmacoeconomic Center
LTC Don DeGroff, MS	DoD Pharmacoeconomic Center
CDR Denise Graham, MSC, USN	DoD Pharmacoeconomic Center
LtCol Dave Bennett, USAF, BSC	DoD Pharmacoeconomic Center
LtCol Barb Roach, USAF, MC	DoD Pharmacoeconomic Center
CDR (sel) Ted Briski, MSC, USN	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
David Bretzke	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
LTC Marc Caouette, MS	Joint Readiness Clinical Advisory Board
Lisa LeGette	Express Scripts
Howard Mazzafro	Express Scripts
MAJ John Howe, MS	Defense Supply Center Philadelphia
Gene Lakey	TriWest

3. **REVIEW MINUTES OF LAST MEETING/ADMINISTRATIVE ISSUES** – The minutes from the last meeting were accepted as written.

4. **INTERIM DECISIONS** – No interim decisions.

5. **UNIFORM FORMULARY (UF) PROPOSED RULE**- COL William Davies, DoD Pharmacy Program Director, TMA, stated that the current plan is to implement the Uniform Formulary in conjunction with the TRICARE Retail Pharmacy contract. The proposed date for implementation of the Tricare Retail Pharmacy (TRRx) is April 2004.

6. **BCF AND TRICARE MAIL ORDER PHARMACY (TMOP) FORMULARY ISSUES** – The Committee determined the TMOP formulary status, TMOP or retail network formulary restrictions (quantity limits or prior authorization), and Basic Core Formulary (BCF) status for 6 new drugs or formulations (see Appendix A). The PEC also presented brief information on four additional new drugs or formulations not requiring a complete review by the Committee (see Appendix B). The Committee agreed that no further review was required.

7. MAIL ORDER AND RETAIL NETWORK ISSUES

A. *Statins* – The high potency statin contact was awarded to Merck for simvastatin (Zocor). The contract states that the BCF and Mail Order Pharmacy formulary will also contain a generic form of lovastatin and may contain one of the statins that is not extensively metabolized by the cytochrome P450 3A4 isoenzyme system. The Committee voted unanimously to add generic lovastatin, lovastatin extended release (Altocor), lovastatin/Niaspan (Advicor), and pravastatin (Pravachol) to the TMOP formulary.

B. *Guaifenesin* – At the November 2002 meeting, the P&T Committee was informed that:

> "As of 12 Jul 2002, Mucinex (Adams Labs) became the first single ingredient guaifenesin extended release product to be 1) approved as safe and effective under a New Drug Application (NDA) and 2) to be approved as an over-the-counter (OTC) product. As a consequence of approval, the FDA has sent warning letters to manufacturers of guaifenesin extended release products explaining that currently marketed single ingredient guaifenesin extended release products without an approved application are considered misbranded and in violation of section 505(a) of the Food, Drug, and Cosmetic Act (FDCA). In addition, provisions of the Durham-Humphrey amendment (products cannot be marketed as both Rx and OTC products) effectively mean all single ingredient extended release will be OTC products. At least one affected manufacturer is known to be petitioning this action, but it is not known if any single ingredient guaifenesin extended release product other than Mucinex will continue to be available in the near future. *Since single ingredient guaifenesin extended release products are now OTC products, they will no longer be available from the NMOP and will not be included on the NMOP Formulary. Prescription extended release guaifenesin products will be dispensed by the NMOP as long as current supplies permit.*" (Emphasis added)

The FDA subsequently issued a letter to manufacturers in February 2003 that allowed them to continue manufacturing guaifenesin extended release products until 21May 2003 and continue distribution of such products until 23 October 2003. In the absence of additional actions on this matter, it is expected that legend extended release guaifenesin products will be available until early November 2003.

In light of the FDA's action, the Committee clarified the status of guaifenesin on the TMOP formulary. Single ingredient guaifenesin extended release products will remain on the TMOP formulary and be dispensed from the TMOP as long as they are available as legend drugs.

C. *Legend Vitamins* – Several questions have arisen recently regarding the availability of legend vitamins from the TMOP. According to Chapter 7 of the TRICARE Policy Manual, "Vitamins may be cost-shared only when used as a specific treatment of a medical condition." Operationally, the question is "do all prescriptions for vitamins require an individual determination that they meet the above requirement? Conversely, can prescriptions for certain vitamins be determined to be covered by virtue of their FDA-approved indications and the lack of a potential for off-label use that would not meet the above requirement?" An example of such a product would be a combination of

folic acid, cobalamin (B12) and pyridoxine (B6), indicated as "treatment for hyperhomocysteinemia, homocystinuria, dialysis, end stage renal failure and in conditions associated with cardiovascular disease, cerebrovascular disease, and peripheral vascular disease." The single MCSC pharmacy representative present at the meeting indicated that in his region, phone calls are made on all vitamin prescriptions to verify compliance with the above requirement, except in the case of prenatal vitamins prescribed to women under the age of 45, which are presumed to be medically necessary. This exception is based on a decision made by the DoD P&T Committee in July 1998 to continue to provide prenatal vitamins to females under the age of 45 without a requirement to document pregnancy.

The subsequent discussion focused on how to make the determination that vitamins are being prescribed for a specific medical condition. The TMA General Counsel advised that in general this would be an administrative decision that would be handled as a collaborative effort of Express Scripts, the PEC, and the TMA General Counsel. In most cases the P&T Committee would not be involved in this process, but in some circumstances the Committee might determine that a particular legend vitamin product, by virtue of its FDA-approved indication(s) and a low probability of use that would not be covered by TRICARE, could appropriately be placed on the TMOP formulary. He recommended that in that case a specific statement be included in the minutes stating the specific intended use of the product. The Committee took no further action at this time.

D. "*Line extension" rules for the TMOP* –At the last meeting, the Committee asked for a review of the "line extension" rules for the TMOP, which provide for availability of generic equivalents, new dosage forms, and new formulations of products already on the TMOP formulary without a formal Committee decision. These rules were carried over from the previous National Mail Order Pharmacy (NMOP) program, but there are operational differences between the two programs that affect the manner in which the rules are applied.

   For the NMOP program, the mail order contractor (Medco) maintained the file of available items and was responsible for applying line extension rules to determine inclusion or exclusion of new products, along with the NMOP Contracting Officer's Technical Representative (COTR). New molecular entities and other products requiring Committee approval were not added to the file of available items until publication of the minutes of the Committee meeting in which they were approved.

   For the TMOP program, the task of maintaining computerized rules defining which items are available through the TMOP now rests with WebMD as a part of the Pharmacy Data Transaction Service (PDTS). Instead of a file of available items, those items not included in the TMOP Formulary are "blocked" using a combination of First Data Bank categories and drug classification codes. Accordingly, it is necessary to review the addition of new products to First Data Bank on an ongoing basis in order to identify new molecular entities and other products that require Committee review. This is now being accomplished by the PEC on a weekly basis, with approval by the TMOP Contracting Officer's Representative (COR).

   The Committee approved the line extension rules outlined below. The Committee noted that these are guidelines rather than absolute rules, acknowledging the need for the PEC

and TMOP COR to use their judgment to deal with circumstances not covered by the rules:

- Medications outlined below are added to the TMOP Formulary without formal action by the DoD P&T Committee unless the PEC or TMOP COR identifies a reason for the P&T Committee to be involved in the decision:
  - Generic equivalent, new dosage form, or new formulation of an agent already on the TMOP Formulary
  - New drug entity in a therapeutic class/category for which the Committee has previously approved automatic inclusion for new drug entities. Currently the only drug class to which this applies is AIDS/HIV drugs. The Committee will review drugs automatically included under this provision at the next scheduled meeting.
  - New combination products of medications that are already on the TMOP Formulary.

8. **CONTROLLED DISTRIBUTION OF PRESCRIPTION DRUGS** – Buprenorphine and buprenorphine/naloxone (Subutex/Suboxone) were recently approved for the treatment of opioid dependence and are subject to a controlled distribution process. Subutex/Suboxone are NOT a covered benefit under TRICARE rules. Champus Basic Program benefits; Part 199.4 states: "Drug maintenance programs when one addictive drug is substituted on a maintenance basis (such as methadone substituted for heroin) are not covered. This exclusion applies even in areas outside the United States where addictive drugs are dispensed legally by physicians on a maintenance dosage level."

9. **ADJOURNMENT –** The meeting adjourned at 1030 hours. The next meeting will be held at TRICARE Management Activity (TMA), conference room 815 Skyline Building 6, 5111 Leesburg Pike, Falls Church, VA at 0800 on Wednesday, 6 August 2003. All agenda items should be submitted to the co-chairs no later than 18 July 2003.

<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 TRICARE MAIL ORDER PHARMACY (TMOP) FORMULARY AND THE DOD BASIC CORE FORMULARY (BCF)

Generic name (Trade name; manufacturer)	**FDA approval date, drug class, FDA-approved indication**	**TMOP Formulary status**	**TMOP and/or retail network formulary restrictions**	**BCF status**
Estradiol acetate vaginal ring (Femring; Galen)	24 Mar 03: Indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause as well as symptoms of vulvar and vaginal atrophy. The ring is designed for self-insertion and delivers a steady estrogen dose for 3 months. Two doses: 50 or 100 mcg released daily.	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization:** None	Not added to the BCF **Similar BCF agents:** None
Pegvisomant injection (Somavert; Pfizer)	04 Apr 03: Growth hormone receptor antagonist indicated for the treatment of patients with acromegaly who have failed to respond to currently available therapies, such as surgery, radiation therapy, or other medical therapies, or for whom these therapies are not appropriate. Decreases insulin-like growth factor-1 (IGF-1) concentrations As an orphan drug, usage of this product is expected to be infrequent; however, the product is listed in First Data Bank and ESI anticipates no difficulty obtaining it for patients using the TMOP.	Added to the TMOP Formulary & TMOP Covered Injectables List Intended for self-administration; daily subcutaneous injections; must be refrigerated	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents:** None
Gatifloxacin ophthalmic solution (Zymar; Allergan)	31 Mar 03: 0.3% solution is indicated for treating bacterial conjunctivitis caused by susceptible strains of bacteria	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents**: None
Cyclosporine ophthalmic solution 0.05% (Restasis; Allergan)	29 Jan 03: 0.05% solution is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca (KCS)	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents**: None

Generic name (Trade name; manufacturer)	**FDA approval date, drug class, FDA-approved indication**	**TMOP Formulary status**	**TMOP and/or retail network formulary restrictions**	**BCF status**
Aprepitant capsules (Emend; Merck)	26 Mar 03 (priority review): A substance P / neurokinin 1 (NK1) receptor antagonist indicated for use in combination with other antiemetic agents for preventing acute and delayed nausea and vomiting associated with highly emetogenic cancer chemotherapy (including high-dose cisplatin). First medication specifically labeled for delayed nausea and vomiting. 125 mg dose on day 1 (1 hour prior to chemotherapy), followed by 80 mg QAM on days 2 and 3. Still requires concomitant administration of ondansetron and dexamethasone	Added to the TMOP Formulary	**Quantity Limits** Rationale for the quantity limits includes the potential for inappropriate use and wastage, FDA requirement for the manufacturer to monitor off label uses; and existing quantity limits for 5-HT3 antagonists. Quantity limits are set to provide for the possibility that chemotherapy is on a 3-week cycle, rather than once per month. Most patients will require less. Packaged in convenience packs (one 125 mg; two 80 mg capsules) and in 30-count bottles **Retail:** Convenience packs: 2 packs per 30 days; 125 mg caps: 2 per 30 days; 80 mg caps: 4 per 30 days **TMOP**: Convenience packs: 6 packs per 90 days; 125 mg caps: 6 per 90 days; 80 mg caps: 12 per 90 days **Prior Authorization** None	Not added to the BCF **Similar BCF agents:** None
Enfuvirtide injection (Fuzeon; Roche/ Trimeris)	13 Mar 03 (accelerated approval). New modality for treating HIV (fusion inhibitor) that blocks the interaction of HIV with CD4+ cells. Indicated for use in combination with other antiretroviral agents for treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. Product is self-administered SQ BID, and is available in a convenience kit of 60 vials with supplied diluent. Complicated 100-step manufacturing process has resulted in a limited supply for about 12,000-15,000 patients worldwide. Product will be allotted on a first-come, first-serve basis through a sole distributor, Chronimed. Physicians must enroll patients via fax. Details on the Fuzeon Progressive Distribution Program may be found at www.fuzeon.com. Anticipated yearly cost is $20,000.	Not added to the TMOP Formulary & Covered Injectables List. Due to the restricted distribution process, ESI and the PEC will look into the feasibility of supplying enfuvirtide through the TMOP and readdress the issue at the August DoD P&T Committee meeting	**Quantity Limits** Patient needs are established as part of the distribution process; no specific quantity limits are needed. **Prior Authorization** None	Not added to the BCF **Similar BCF agents**: None

APPENDIX B: NEWLY APPROVED DRUGS NOT REQUIRING FULL REVIEW BY THE P&T COMMITTEE

Generic name (Trade name; manufacturer)	**Comments**
Isotretinoin capsules (Claravis; Barr)	AB rated generic to Accutane (Roche brand of isotretinoin). Not added to the TMOP Formulary because isotretinoin is excluded from the TMOP Formulary due to controlled distribution requirements. Generics from Bertek (Amnesteem) and Ranbaxy (Sotret) were evaluated in Mar 2003.
Conjugated estrogen/medroxyprogesterone acetate (Prempro 0.45/1.5; Wyeth)	Low-dose formulation of Prempro contains 0.45 mg of estrogen, and 1.5 mg of progestin (instead of 0.625 / 2.5 mg). Automatically added to TMOP as a line extension. Prempro is on the BCF.
Propranolol extended release capsules (InnoPran XL; Reliant)	Indicated for hypertension; the only beta-blocker formulation specifically indicated for QHS dosing. This product was approved under an NDA and is not a generic equivalent to the other propranolol extended release product, Inderal LA (Wyeth). Generic equivalents to Wyeth's Inderal LA have been discontinued. Innopran XL is available in 80 and 120 mg capsules; Inderal LA in 60, 80, 120 and 160 mg capsules. Automatically added to TMOP as a line extension. Not considered for BCF addition, since the other propranolol extended release product was removed from the BCF in Nov 1999 due both to limited supply (both Inderal LA and generics were manufactured by Wyeth) and low usage in DoD.
Metformin extended release tablets 750 mg (Glucophage XR; Bristol-Meyers Squibb)	Automatically added to TMOP as a line extension. Not considered for the BCF since extended release metformin is specifically excluded from the existing BCF listing for immediate release metformin.

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*

      1) Estradiol transdermal system (Esclim)
      2) Risperidone (Risperdal)
      3) Quetiapine (Seroquel)
      4) Pimecrolimus cream (Elidel)
      5) Nitroglycerin patches (Nitrodur) [Schering brand per existing VA/DoD contract]
      6) Isosorbide mononitrate sustained release [Schwarz Pharma brand per existing VA/DoD contract]

   B. *Deletions, changes, clarifications or exclusions from the BCF* - None

2. **TMOP FORMULARY CHANGES**

   A. *Additions to the TMOP Formulary*

      1) Estradiol acetate vaginal ring (Femring; Galen)
      2) Pegvisomant injection (Somavert; Pfizer) – added to the TMOP Covered Injectables List
      3) Gatifloxacin ophthalmic solution (Zymar; Allergan)
      4) Cyclosporine ophthalmic solution (Restasis; Allergan)
      5) Aprepitant capsules (Emend; Merck) – quantity limits apply, see below
      6) Pravastatin
      7) Lovastatin
      8) Lovastatin extended release (Altocor)
      9) Lovastatin/niacin extended release combination (Advicor)

   B. *Exclusions from the TMOP Formulary* - None

   C. *Deletions, changes, or clarifications to the TMOP Formulary* - None

3. **QUANTITY LIMIT CHANGES (RETAIL NETWORK AND TMOP)**

   A. Quantity limit for aprepitant (Emend; Merck):

      - Convenience packs (convenience packs contain one 125 mg capsule and two 80 mg capsules): 2 packs per 30-day supply (Retail); 6 packs per 90-day supply (TMOP)
      - 80 mg capsules: 4 capsules per 30 days (Retail); 12 capsules per 90 supply (TMOP)
      - 125 mg capsules: 2 capsules per 30 days (Retail); 6 capsules per 90-day supply (TMOP)

4. **CHANGES TO THE TMOP PRIOR AUTHORIZATION PROGRAM** - None