Department of Defense
Pharmacoeconomic Center

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MCCS-GPE **8 MAY 2002**

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 8 May 2002, at the Commissioned Officers Club, Fort Sam Houston, TX

2. MEMBERS PRESENT

CDR Terrance Egland, MC, USN	DoD P& T Committee Co-chair
COL Daniel D. Remund, MS, USA	DoD P& T Committee Co-chair
Col John R. Downs, MC	Air Force
Col Mark Nadeau, MC (For Col Bill Sykora, MC)	Air Force
LtCol George Jones, BSC	Air Force
CAPT (select) Matt Nutaitis, MC	Navy
CDR Kevin Cook, MSC	Navy
LTC (P) Joel Schmidt, MC	Army
MAJ Brett Kelly	Army
CAPT Robert Rist	Coast Guard
Dick Rooney	Department of Veterans Affairs
LTC Mike Kieffer, MS	Joint Readiness Clinical Advisory Board
MAJ Mickey Bellemin, BSC	Defense Supply Center Philadelphia
William Hudson	Humana
Gene Lakey	TriWest
Ray Nan Berry	Health Net Federal Services
Trevor Rabie	Uniformed Services Family Health Plans (USFHP)

MEMBERS ABSENT

COL Rosa Stith, MC	Army
Ron McDonald	Sierra Military Health Services

OTHERS PRESENT

COL William Davies, MS, USA	DoD Pharmacy Program Director, TMA
Howard Altschwager	Deputy General Counsel, TMA
CAPT Joe Torkildson, MC, USN	DoD Pharmacoeconomic Center
LTC Don DeGroff	DoD Pharmacoeconomic Center
LtCol Ed Zastawny, USAF, BSC	DoD Pharmacoeconomic Center
CDR Denise Graham, MSC, USN	DoD Pharmacoeconomic Center
Maj Barb Roach, USAF, MC	DoD Pharmacoeconomic Center
LCDR Ted Briski, MSC, USN	DoD Pharmacoeconomic Center
SFC Agustin Serrano	DoD Pharmacoeconomic Center
HM1 Lisa Drumm	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
David Bretzke	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
Paul Vasquez	Defense Supply Center Philadelphia
David Chicoine	Uniformed Services Family Health Plan
Mark Petruzzi	Merck-Medco
Elizabeth Scaturro	Merck-Medco Managed Care
David Spiler	Merck-Medco
CAPT Howard Hays	USPHS/Indian Health
CAPT Samuel Hope	USPHS/Indian Health
CAPT Robert Pittman	USPHS/Indian Health
LCDR Thomas Berry	USPHS/Indian Health

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

4. **INTERIM DECISIONS** – COL Remund reported on interim decisions:

   - Interferon beta 1a (Rebif) was added to the NMOP covered injectables list because interferon beta 1a (Avonex) and interferon beta 1b (Betaseron) were already included on the list.
   - In response to safety concerns raised by the FDA, Roche Laboratories implemented the System to Manage Accutane Related Teratogenicity (SMART) program on 10 April 02. The SMART program includes prescribing restrictions that make it infeasible for the NMOP to continue to fill Accutane prescriptions, so Accutane was removed from the NMOP Formulary.

5. **UNIFORM FORMULARY (UF) PROPOSED RULE**- COL Davies presented an extensive description of the UF proposed rule. The UF Proposed Rule was posted on the following website: http://frwebgate.access.gpo.gov/cgi-bin/multidb.cgi; Federal Register, Vol 67, No 71, FRI 12 Apr 2002; Civilian Health and Medical Program of the Uniformed Services. The proposed rule will be open to public comment until 11 June 2002. Comments may be submitted by email to: uniformulary@tma.osd.mil.

6. **ACADEMY OF MANAGED CARE PHARMACY (AMCP) FORMAT FOR FORMULARY SUBMISSIONS** – The AMCP developed the Format for Formulary Submissions in order to (1) improve the timeliness, quality, scope, and relevance of information available to P&T committees, and (2) streamline the data acquisition and review process for managed care organization staff pharmacists. The Format requires pharmaceutical companies to construct "dossiers" that provide drug information in a standardized format. Each dossier contains the following sections: product information, supporting clinical and economic information, an impact model report (to predict system-wide consequences of formulary changes), clinical value and overall cost, supporting information. COL Remund reported that the PEC will ask pharmaceutical companies to submit dossiers on new agents. Use of the AMCP Format will hopefully reduce the burden on the PEC staff for compiling drug information and allow more time for analyzing the information.

7. **BCF AND NATIONAL MAIL ORDER PHARMACY (NMOP) FORMULARY ISSUES** – The Committee determined the NMOP formulary status, NMOP or retail network formulary restrictions (quantity limits or prior authorization), and Basic Core Formulary (BCF) status for 7 new drugs or formulations (see Appendix A).

8. **REEVALUATION OF SILDENAFIL (VIAGRA) POLICY** – Tabled until the meeting in August 02.

9. **NMOP AND RETAIL NETWORK ISSUES**

   A. Clarification of the "line extension rule" for the NMOP Formulary – Shana Trice (PEC) reported on the current process for determining the formulary status of new formulations and dosage forms of medications that are already on the NMOP Formulary. Non-injectable medications in the following categories are added to the NMOP Formulary without formal action by the DoD P&T Committee unless the NMOP contractor and the NMOP Contracting Officer's Technical Representative (COTR) identify a reason for the P&T Committee to be involved in the decision:

   a. Generic equivalent of an agent already on the NMOP formulary
   b. New dosage form of an agent already on the NMOP formulary
   c. New formulation of an agent already on the NMOP formulary
   d. 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 non-injectable medications that are already on the NMOP Formulary are added to the NMOP Formulary only upon the decision of the P&T Committee or by the co-chairs through the interim decision mechanism. This does not apply to therapeutic classes/categories in which the Committee has previously approved automatic inclusion for new drug entities (i.e., AIDS/HIV drugs).

   The Committee agreed that the current process is working and should be retained, but emphasized that the preceding categories should be applied as guidelines rather than absolute rules. If Merck-Medco personnel and the NMOP COTR agree that further review is warranted for any reason, the issue should be referred to the PEC for further investigation and a recommendation for the co-chairs and/or the Committee.

The Committee agreed that the same guidelines could be applied to addition of injectable medications to the NMOP Covered Injectables List, since Merck-Medco personnel and the NMOP COTR will look at new dosage forms, formulations, and combination products and will refer issues to the PEC for further review as needed.

B. Clarification of the NMOP quantity limits for antibiotics – Subsequent to a patient question regarding a quantity limit on an antibiotic prescription filled through the NMOP, Lt Col Zastawny presented information regarding quantity limits on antibiotics through the NMOP.

A general 30-day quantity limit on antibiotics from the NMOP and a list of antibiotics exempted from the 30-day quantity limit rule were approved by the Committee at the July 1998 meeting (http://www.pec.ha.osd.mil/PTC/ptmin078.pdf), and posted with the July 1998 P&T minutes. This information was never published on the PEC website's quantity limit page, so most committee members, providers, and patients are unaware of the 30-day quantity limit on antibiotics or the antibiotics that were exempt from the 30-day limit. The NMOP contractor, however, has applied the 30-day quantity limit to antibiotic prescriptions filled through the NMOP. According to the NMOP COTR, antibiotic quantity limits in the NMOP have caused very few complaints over the past 3 years.

The Committee decided to table this topic until the August 2002 meeting in order to allow members time to review the antibiotic quantity limits and make informed decisions.

10. PRIOR AUTHORIZATIONS (PAs)

A. Report on PA drugs – Shana Trice (PEC) reported that all changes to NMOP PA criteria approved at the last meeting had been completed and that PA forms, criteria, and clinical rationale explanations were posted on the PEC website.

B. Proposed revision to anakinra PA criteria – Given the current shortage of etanercept, the Committee discussed revising the anakinra PA criteria to make it easier for patients unable to obtain etanercept to be started on anakinra. They decided to make no changes because it does not appear that existing etanercept patients have been unable to receive etanercept for continuation of therapy (although the NMOP reported delays of some days in supplying etanercept to patients) and because making the administrative change to NMOP PA criteria would require at least 90 days.

C. Cost avoidance from NMOP PAs – The Committee approved the recommendation to report cost avoidance of NMOP PAs at every other meeting. The next report will be at the August 02 meeting.

11. SUBCOMMITTEE REPORT: PROVISION OF INJECTABLE DRUGS IN THE NMOP OR RETAIL NETWORK PHARMACIES

– Lt Col George Jones reported that the subcommittee was uncertain about what it was supposed to do. The subsequent discussion focused on the possibility of applying the NMOP Covered Injectables List to the retail network to define what injectable products would be available from retail network pharmacies. COL Davies pointed out that the DoD P&T Committee does not have the authority to make such a decision, as this would constitute a change in the pharmacy benefit by making a group of drugs unavailable in both purchased care venues. Another committee member again stated the opinion that this was a safety issue, but the Committee felt that in general this was not the case. The Committee decided to disband the subcommittee.

The Committee subsequently considered that there may be injectable drugs being dispensed in the retail network that are not being dispensed through the NMOP that in fact could be provided through the NMOP. The PEC will use prescription data from PDTS to analyze this issue. Mr. Bill Hudson from Humana Health Care, one of the members of the original subcommittee, also expressed an interest in remaining involved with this issue. The Committee agreed with this course of action.

12. CONTROLLED DISTRIBUTION OF PRESCRIPTION DRUGS – The FDA has mandated controlled or restricted distribution mechanisms for several agents. The current status of those agents within the DoD is:

A. Schering, the manufacturer of pegylated interferon (PEG-Intron), emplaced a mechanism to allow DoD activities to order directly. Details will be available on the PEC website.

B. Pfizer, the manufacturer of dofetilide (Tikosyn), emplaced a mechanism to allow DoD activities to order directly, and the Managed Care Support Contractors are providing the drug through their retail pharmacy networks. Details will be available on the PEC website.

C. Members of the DoD Pharmacy Board of Directors are working with Roche and the FDA to establish a mechanism for Accutane to be prescribed via electronic physician order entry instead of requiring hard copy prescriptions.

D. Etanercept (Enbrel) is in short supply. Current patients' needs are being met. New patients are being placed on a waiting list. Relief is not expected soon. Providers are being advised to consider alternative therapy.

E. Actelion, the manufacture of bosentan (Tracleer), maintains five specialty distributors to distribute Tracleer. CVS Procare is one of the specialty distributors, and is part of the TRICARE retail network. All Tracleer patients should enroll into the Tracleer Access Program (TAP) by using the toll-free telephone number 866-228-3546. At that time they will be assigned to CVS Procare as their specialty pharmacy. None of the other specialty pharmacies are part of the MCSC retail pharmacy networks. Using any pharmacy other than CVS Procare would result in an out-of-network claim, which requires advance payment for the drug and the filing of a paper claim; the patient would only be reimbursed the cost of the drug minus a cost share, which is substantially greater than the network's $9.00 copay.

13. ADJOURNMENT – The meeting adjourned at 1200 hours. The next meeting will be held at the Uniformed Services University of the Health Sciences, Bethesda, Maryland starting at 0800 on Thursday, 08 August 2002. All agenda items should be submitted to the co-chairs no later than 08 July 2002.

<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 NATIONAL MAIL ORDER PHARMACY FORMULARY AND DOD BASIC CORE FORMULARY

Generic name (Trade name; manufacturer)	**FDA approval date, drug class, FDA-approved indication**	**NMOP Formulary Status**	**NMOP and/or retail network formulary restrictions**	**BCF Status**
Pegfilgrastim injection (Neulasta; Amgen)	31 Jan 02; pegylated form of filgrastim (G-CSF) indicated to reduce the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving chemotherapy associated with a clinically significant incidence of febrile neutropenia.	**Note**: Filgrastim and Epogen are both on the NMOP covered injectables list. Added to the NMOP Formulary and Covered Injectables List	**Quantity Limits** 2 syringes per 45 day supply (NMOP); 1 syringes per 21 day supply (retail network). **Rationale for quantity limits:** Potential for excessive cost due to product wastage. **Prior Authorization:** None	Not added to the BCF **Similar BCF Drugs:** None
Comments regarding pegfilgrastim injection: Pegfilgrastim is given once per chemotherapy cycle as a single dose of 6 mg administered at least 24 hours after chemotherapy. Filgrastim is administered daily for up to 14 days following chemotherapy. Pegfilgrastim, at $1730/syringe, is somewhat more costly than a 10-day course of filgrastim at a daily dose of 300 mg per day ($1037) or 480 mcg per day ($1640). Because patients may decline further courses of chemotherapy due to unacceptable toxicity, the potential for product wastage is significant. Because pegfilgrastim should not be administered during the 14 days before chemotherapy because of the potential for an increase in the sensitivity of rapidly dividing myeloid cells to cytotoxic chemotherapy, it is not suitable for chemotherapy cycles much shorter than 21 days. A quantity limit of 2 syringes per 45 days (NMOP) or 1 syringe per 21 days (retail) allows a sufficient supply to cover the next chemotherapy cycle and a sufficient time to order the next needed dose				
Norelgestromin / ethinyl estradiol transdermal patch (Ortho-Evra; Ortho-Biotec)	20 Nov 01; prevention of pregnancy; first contraceptive available in a transdermal formulation; the ethinyl estradiol component is equivalent to 20 mcg of EE/day (low-dose estrogen). Norelgestromin is produced following oral administration of norgestimate, the progestin component found in Ortho-Cyclen and Ortho-Tricyclen.	Added to the NMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF Drugs:** None
Budesonide capsules (Entocort EC; Astra Zeneca)	02 Oct 01; glucocorticoid for the treatment of mild to moderate active Crohn's disease involving the ilieum and/or ascending colon (acute flares)	Added to the NMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF Drugs:** None

Generic name (Trade name; manufacturer)	**FDA approval date, drug class, FDA-approved indication**	**NMOP Formulary Status**	**NMOP and/or retail network formulary restrictions**	**BCF Status**
Morphine sulfate extended release capsules (Avinza; Ligand)	20 Mar 02; launched on 2 May 02. Modified-release formulation of morphine sulfate intended for once-daily administration indicated for the relief of moderate to severe pain requiring continuous, around-the-clock opioid therapy for an extended period of time; not intended for prn use.	Added to the NMOP Formulary.	**Quantity Limits:** General rule for Schedule II controlled substances applies; limited to 30 days supply at the NMOP **Rationale for quantity limits:** Existing quantity limits for Schedule II controlled substances **Prior Authorization** None	The current BCF listing for morphine sulfate extended release was clarified to exclude Avinza. **Similar BCF Drugs:** Morphine sulfate extended release (MS Contin and generic equivalents)
Olmesartan medoxomil (Benicar; Sanyko / Forrest)	25 Apr 02; approved for hypertension. This is the 7th Angiotensin Receptor Blocker (ARB) to be approved in the U.S.	Added to the NMOP Formulary.	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF Drugs:** None
Extended phenytoin sodium, 200 mg and 300 mg capsules (Phenytek; Bertek)	6 Dec 01; new branded formulation of phenytoin sodium indicated for the treatment of generalized tonic-clonic and complex partial seizures and prevention and treatment of seizures during or following neurosurgery 200 and 300 mg Phenytek capsules are bioequivalent to 2 and 3 Dilantin 100-mg capsules, respectively	Added to NMOP Formulary as a line extension.	**Quantity Limits** General rule applies **Prior Authorization** None	The current BCF listing for phenytoin oral was clarified to exclude Phenytek. **Similar BCF Drugs:** Oral phenytoin
Paroxetine controlled-release tablets (Paxil CR; GlaxoSmithKline)**)**	Approved for depression Feb 99 but not marketed until FDA approval for panic disorder was obtained in Feb 02. This new formulation of paroxetine does NOT extend the dosing interval (once-daily); a polymer matrix controls the dissolution rate over 4-5 hours and an enteric coating delays release until tablets have left the stomach, potentially improving tolerability. Because of reduced bioavailability, Paxil CR strengths are higher (12.5-, 25-, 37.5-mg) than Paxil immediate release (10-,20-,30-,40-mg).	Added to the NMOP Formulary	**Quantity Limits:** General rule applies **Prior Authorization:** None	The current BCF listing for paroxetine oral was clarified to exclude Paxil CR, pending a more thorough review in 6 months. **Similar BCF Drugs:** paroxetine, fluoxetine, citalopram, sertraline
Comments concerning paroxetine controlled-release tablets – The Committee agreed that information concerning the potential advantages of Paxil CR compared to immediate release paroxetine was not sufficiently complete to mandate that Paxil CR be added to all MTF formularies at this time. In addition, they wanted to obtain provider opinions concerning the utility of the new formulation that were not available at the time of the meeting. Paxil CR will be reviewed again in 6 months. It will be excluded from the BCF pending review.				

APPENDIX B: 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) Combivent (ipratropium/albuterol sulfate) oral inhaler
   2) Raloxifene (Evista)
   3) Pseudoephedrine/Guaifenesin 600/120 mg extended release (Entex PSE equivalent).
   4) Levonorgestrel 0.75 mg (Plan B)—added to the BCF on 3 April 2002, but subsequently deleted from the BCF on 8 May 2002.

   B. Deletions from the BCF

   1) Propranolol LA
   2) Levonorgestrel 0.75 mg (Plan B)—deleted from the BCF on 8 May 2002

   C. Changes and clarifications to the BCF

   1) The current BCF listing for carbinoxamine/pseudoephedrine drops was changed to the "new" formulation (1 mg/15 mg per ml) since this is the only formulation available.

   A. Exclusions from the BCF

   1) Morphine sulfate extended release capsules (Avinza; Ligand)
   2) Extended phenytoin sodium, 200- and 300 mg capsules (Phenytek; Bertek)
   3) Paroxetine controlled-release tablets (Paxil CR; GlaxoSmithKline) – pending more thorough review in 6 months.

2. **NMOP FORMULARY CHANGES**

   A. Additions to the NMOP Formulary (See Appendix A for details)

   1) Pegfilgrastim injection (Neulasta; Amgen) – added to the NMOP Covered Injectables List. Quantity limits apply, see below
   2) Norelgestromin/ethinyl estradiol transdermal patch (Ortho-Evra; Ortho-Biotec) –
   3) Budesonide capsules (Entocort EC; Astra Zeneca)
   4) Morphine sulfate extended release capsules (Avinza; Ligand)
   5) Olmesartan medoxomil (Benicar; Sanyko/Forrest)
   6) Extended phenytoin sodium 200- and 300 mg capsules (Phenytek; Bertek)
   7) Paroxetine controlled-release tablets (Paxil CR; GlaxoSmithKline)

   B. Exclusions from the NMOP Formulary -None

   C. Clarifications to the NMOP Formulary - None

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

   A. Quantity limit for Pegfilgrastim Injection (Neulasta; Amgen): 2 syringes per 45-day supply (NMOP); 1 syringe per 21-day supply (retail network).

4. **CHANGES TO THE PRIOR AUTHORIZATION PROGRAM (NMOP AND RETAIL NETWORK)** - None