Department of Defense
Pharmacoeconomic Center

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MCCS-GPE **8 AUGUST 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 August 2002, at the Uniformed Services University of the Health Sciences, Bethesda, Maryland

2. VOTING 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 Mike Heath, MS (Representing MAJ Brett Kelly, MS)	Army Pharmacy Consultant Chair, DoD Pharmacy Board of Directors
Col Bill Sykora, MC	Air Force
COL Ardis Meier, BSC (Representing LtCol George Jones, BSC)	Air Force Pharmacy Consultant
CAPT (select) Matt Nutaitis, MC	Navy
CDR Kevin Cook, MSC	Navy
CAPT Robert Rist	Coast Guard
Dick Rooney	Department of Veterans Affairs

VOTING MEMBERS ABSENT

COL Rosa Stith, MC	Army
Col John R. Downs, MC	Air Force
LTC (P) Joel Schmidt, MC	Army

OTHERS PRESENT

COL William Davies, MS, USA	DoD Pharmacy Program Director, TMA
Howard Altschwager	Deputy General Counsel, TMA
MAJ Mickey Bellemin, BSC	Defense Supply Center Philadelphia
CAPT Joe Torkildson, MC, USN	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
HM1 Lisa Drumm, USN	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	Medco Health
Ron McDonald	Sierra Military Health Services
Kelly Lenhart	Humana
William Hudson	Humana
Gene Lakey	TriWest
Ray Nan Berry	Health Net Federal Services
Trevor Rabie	Uniformed Services Family Health Plans (USFHP)

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 Davies reported that the comment period for the UF proposed rule has closed. The TMA Pharmacy Program Office is currently in the process of formulating responses to comments submitted by the public.

6. **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 5 new drugs or formulations (see Appendix A). The PEC also presented brief information on six additional new drugs or formulations not felt to require a complete review by the Committee. The Committee agreed that no further review was required (see Appendix B for comments).

7. NMOP AND RETAIL NETWORK ISSUES

A. Clarification of the NMOP quantity limits for antibiotics – LtCol Ed Zastawny (PEC) reported on a re-evaluation of the 30-day quantity limit that the DoD P&T Committee established in July 1998 for antibiotics dispensed through the NMOP. The Committee agreed that providers are unlikely to prescribe large quantities of antibiotics unless the patient needs long-term antibiotic therapy. The 30-day quantity limit increases the administrative burden for patients with a legitimate need for long-term antibiotic therapy because they have to reorder medication more frequently. More frequent reordering of medication also increases the risk that patients will run out of medication. Patients' costs are higher because they have to pay more copays.

The Committee concluded that the 30-day quantity limit probably creates more problems than it prevents and unanimously voted to eliminate the 30-day quantity limit on antibiotics in the NMOP. Antibiotics will be dispensed according to the general rule applied to other drugs in the NMOP (up to a 90 day supply). Existing quantity limits for specific antibiotics will remain in force. All quantity limits will be posted on the quantity limit page on the PEC website.

B. Clarification of the NMOP quantity limits for myeloid stimulants, interferon gamma, interferon alpha, and sandostatin injection – The current NMOP quantity limit for these products is 30 days. Because literature supports chronic use of the interferons and sandostatin for specific indications, the Committee unanimously voted to remove the 30-day quantity limit from interferon alpha, interferon gamma, and sandostatin. The Committee agreed that a 30-day quantity limit on myeloid stimulants was reasonable given the products' indications and uses. They noted that the NMOP quantity limit for PEG-filgrastim was set at 2 syringes per 45-day supply at the May 2002 meeting. The Committee voted to retain the 30-day quantity limit for myeloid stimulants, except for PEG-filgrastim, which will remain as 2 syringes per 45-day supply limit. The quantity limits will be posted on the PEC website quantity limit page. The NMOP will not use quantity limits other than those listed on the PEC website and will revise their database(s) accordingly.

C. Clarification of NMOP quantity limits for testosterone transdermal patches (Androderm) – Current NMOP quantity limit for Androderm patches is 30 days. Testosterone topical gel (Androgel) has a NMOP quantity limit of 90 days. Both are chronic replacement products with low abuse potential. The Committee voted unanimously to remove the 30-day quantity limit on all topical/transdermal testosterone or androgen replacement products.

8. **COST AVOIDANCE FROM NMOP PRIOR AUTHORIZATIONS (PAs)** –Shana Trice reported on the estimated cost avoidance due to PAs in the NMOP. The cost avoidance per prescription is based on the cost avoidance model that was outlined in the Aug 00 DoD P&T Committee minutes. The Committee did not make any changes to these PAs.

Drug	2nd Quarter FY 02	3rd Quarter FY 02
Sildenafil	$11.54	-$7.79
COX-2 inhibitors	$4.10	$2.65
Etanercept	$62.84	$15.30
Anakinra	-	$1132.00

Note: Cost avoidance due to the PA for antifungals for onychomycosis (ciclopirox, itraconazole, terbinafine) is not calculated using this model because the PA differs substantially from the other PAs. Unlike the other PAs, which authorize dispensing of new and refill prescriptions for a year, each course of therapy with antifungal medications for the treatment of onychomycosis goes through the PA process.

9. **SUBCOMMITTEE REPORT: PROVISION OF INJECTABLE DRUGS IN THE NMOP OR RETAIL NETWORK PHARMACIES** – At the May 2002 meeting the Committee asked the PEC to analyze the prescriptions filled in the retail network for injectable drugs to determine if there were additional drugs that should be added to the NMOP Covered Injectables List. CAPT Torkildson reported on the results of that analysis.

   A report was generated from PDTS listing all prescriptions filled for injectable drugs in the retail network and at the NMOP during the period 1 April 2001 – 3 May 2002. Prescriptions for drugs currently included on the NMOP Covered Injectables List were then excluded. Remaining prescriptions were then sorted based on volume of prescriptions filled and total cost to the government. The greatest volume of prescriptions filled for non-list items was for methotrexate, with 3,072 prescriptions filled over 12 months. No other non-listed medication had greater than 1,000 prescription fills. In contrast, over 39,000 prescriptions for NPH insulin, which is on the covered injectables list, were filled at retail pharmacies during the surveyed period. The drug with the highest total submitted cost due was colistimithate, with a total due of $65,792. Only colistimithate and hydromorphone had costs greater than $50,000. In contrast, the retail network cost for epoetin alpha, which is on the covered injectables list, was almost $5.9 million over the same period.

   The Committee decided to add dihydroergotamine 1 mg/ml, heparin sodium 5,000 & 10,000 units/ml, and promethazine 25 mg/ml to the NMOP Covered Injectables List. Because other migraine medications are subject to quantity limits and because use of dihydroergotamine should not exceed 6 ampules per week for safety reasons, the Committee established a quantity limit for dihydroergotamine: 3 boxes (30 ampules) per 30 days in the retail network and 9 boxes (90 ampules) per 90 days in the NMOP.

The Committee also recognized that a substantially greater opportunity for cost avoidance hinged on a more aggressive use of the NMOP by patients and providers to fill prescriptions for injectable drugs already available at the NMOP.

10. **CONTROLLED DISTRIBUTION OF PRESCRIPTION DRUGS** – All the Managed Care Support Contractors have established network agreements with CVS Procare Specialty Pharmacy, making CVS Procare the preferred site for DoD patients to obtain drugs requiring controlled distribution. The current plan is to use CVS Procare, whenever possible, for future drugs requiring controlled distribution. Information about specific drugs is available on the PEC website.

11. **ADJOURNMENT –** The meeting adjourned at 1100 hours. The next meeting will be held at the Uniformed Services University of the Health Sciences, Bethesda, Maryland starting at 0800 on Thursday, 21 November 2002. All agenda items should be submitted to the co-chairs no later than 18 October 2002.

<signed>	<signed>
DANIEL D. REMUND	TERRANCE EGLAND
COL, MS, USA	CDR, MC, USN
Co-chair	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**
Voriconazole (Vfend; Pfizer)	29 May 02; Treatment of invasive aspergillosis primarily due to *Aspergillus fumigatus* and treatment of serious fungal infections caused by *Scedosporium apiospermum* and *Fusarium spp*., including *Fusarium solani* in patients intolerant of, or refractory to, other therapy.	Oral 50 mg and 200 mg tablets were added to the NMOP Formulary; IV formulation was excluded (not for self-administration)	**Quantity Limits** General Rule applies **Prior Authorization:** None	Not added to the BCF **Similar BCF Drugs:** None. Fluconazole 150 mg for vaginal candidiasis has a different spectrum of activity
Etonogestrel / ethinyl estradiol vaginal ring (Nuva-Ring; Organon)	01 Oct 01; Vaginal ring composed of an estrogen and progestin indicated for the prevention of pregnancy.	Added to the NMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF Drugs:** None
Methylphenidate long-acting capsules (Ritalin LA; Novartis)	06 Jun 01; for the treatment of attention deficit hyperactivity disorder (ADHD) in children aged 6 to 12 years of age	Added to the NMOP Formulary **Note**: Schedule II controlled substance; would fall under standard rule in NMOP for Schedule II products for treatment of ADHD (90 days supply, no refills)	**Quantity Limits** NMOP: General rule for Schedule II controlled substances for treatment of ADHD applies. (90 days supply, no refills) **Prior Authorization** None	Not added to the BCF. Excluded from the current BCF listing for methylphenidate. **Similar BCF Drugs:** Methylphenidate extended release (Concerta)
Escitalopram (Lexapro; Forest)	Approvable at time of Committee meeting – FDA approval imminent (note: approved by the FDA 14 Aug 02); single-isomer formulation of the selective serotonin reuptake inhibitor citalopram (Celexa)	Added to the NMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF. Will reconsider possible BCF addition following formal FDA approval & availability of pricing information. **Similar BCF Drugs:** fluoxetine, paroxetine, sertraline, citalopram
Lovastatin extended-release tablets (Altocor; Andrx/Aura	27 Jun 02 (will not be marketed until Sept 02); indicated for use in addition to dietary restrictions to lower total cholesterol and LDL cholesterol; and to slow the progression of coronary atherosclerosis in patients with coronary heart disease. Also has indication for primary prevention of CHD in patients with elevated cholesterol (based on the AFCAPS/TexCAPS study).	Not added to the NMOP Formulary. Existence of the current statin contract precludes addition of Altocor to the NMOP formulary.	**Quantity Limits** N/A **Prior Authorization** None	Not added to the BCF. Existence of the current statin contract precludes addition of Altocor to the NMOP formulary.

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

Generic (Trade name; manufacturer)	**Indication**	**Comments**
Desloratadine orally disintegrating tablets (Clarinex Redi-tabs; Schering)	Treatment of allergy symptoms and chronic idiopathic urticaria	Line extension. Desloratadine tablets are already available; both formulations will be available from the NMOP. Consideration for the BCF precluded by current non-sedation antihistamine contract.
Fulvestrant for injection (IM) (Faslodex; Astra-Zeneca)	Treatment of hormone-receptor metastatic breast cancer in postmenopausal women	Not considered for the NMOP Formulary since the IM injection is not designed for self-administration.
Human insulin (rDNA origin) for injection (SC) in a 3 mL disposable prefilled syringe (InnoLet; NovoNordisk)	Human insulin (Novolin) in a 3 mL disposable prefilled syringe	Will be available from the NMOP. Existing BCF listings for Novolin insulin are for 10mL vials. MTFs may decide whether or not to add InnoLet or other alternative insulin delivery devices (e.g., insulin pens) to their formularies.
Treprostinol Na for Injection (Remodulin; United Therapeutics)	Continuous SC infusion for treatment of pulmonary hypertension with NYHA class II-IV symptoms	Restricted drug distribution
Urofollitropin for Injection (Bravelle; Ferring)	Fertility agent	Will be added to the NMOP Covered Injectables List, which already includes other brands of urofollitropin.
Ziprasidone for Injection (IM) (Geodon IM; Pfizer)	Acute episodes of paranoia, and schizophrenia	Not considered for the NMOP Formulary since the IM injection is not designed for self-administration. Emergent use agent not appropriate for the BCF.

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) Venlafaxine extended release capsules (Effexor XR) - contingent on signing of BPA (see Paragraph 10A)
2) Insulin glargine injection (Lantus)
3) Gabapentin (Neurontin)
4) Budesonide inhalation solution (Pulmicort Respules)
5) Meloxicam tablets (Mobic)
6) D, L-amphetamine 10-, 20-, 30-mg extended release capsules (Adderall XR)

B. Deletions from the BCF

1) Cimetidine oral
2) Methylphenidate SR (sustained release) tablets were removed from the BCF listing for methylphenidate.

C. Changes and clarifications to the BCF

1) The current BCF listing for methylphenidate was clarified to specify the following strengths for methylphenidate extended release (Concerta): 18-, 27-, 36-, and 54-mg
2) Existing BCF listings for Novolin insulin are for 10 ml vials. MTFs may decide whether or not to add alternative insulin delivery devices (e.g., insulin pens, InnoLet) to their formularies.
3) Precision products remain the only blood glucose strips on the BCF. MTFs are encouraged to transition to the newer Precision product, Precision Extra, as soon as possible.

D. Exclusions from the BCF

1) Methylphenidate long acting capsules (Ritalin LA, Novartis) were excluded from the BCF listing for methylphenidate.
2) Lovastatin extended-release tablets (Altocor; Andrx/Aura) – existing statin contract precludes addition to the BCF

2. NMOP FORMULARY CHANGES

A. *Additions to the NMOP Formulary*

1) Voriconazole 50- and 200-mg tablets (Vfend; Pfizer); injectable formulation not added since it is not for self-administration
2) Etonogestrel/ethinyl estradiol vaginal ring (Nuva-Ring; Organon)
3) Methylphenidate long acting capsules (Ritalin LA; Novartis) – General NMOP rule for schedule II controlled substances for treatment of ADHD applies (90 days supply; no refills)
4) Escitalopram tablets (Lexapro; Forest)

5) Bravelle brand of urofollitropin added to the NMOP Covered Injectables List, which already includes other brands of urofollitropin

6) Dihydroergotamine 1 mg/ml injection added to the NMOP Covered Injectables List

7) Heparin sodium 5,000 & 10,000 units/ml injection added to the NMOP Covered Injectables List

8) Promethazine 25 mg/ml injection added to the NMOP Covered Injectables List

9) InnoLet brand of human insulin for injection (3 mL prefilled syringes) added to the NMOP Covered Injectables List

B. *Exclusions from the NMOP Formulary*

1) Lovastatin extended-release tablets (Altocor; Andrx/Aura) – Existing statin contract precludes addition to the NMOP Formulary.

C. *Clarifications to the NMOP Formulary* - None

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

A. Quantity limit for dihydroergotamine 1 mg/ml injection: 3 boxes (30 ampules) per 30 days in the retail network, 9 boxes (90 ampules) per 90 days in the NMOP.

B. NMOP 30-day quantity limit for antibiotics was eliminated. Antibiotics will be dispensed consistent with the general rule applied to all other drugs in the NMOP (up to a 90 day supply), unless otherwise specified on the quantity limit page on the PEC website.

C. NMOP 30-day quantity limits for interferon alpha, interferon gamma, and sandostatin were removed. The quantity limit for myeloid stimulants remains 30 days, with the exception of PEG-filgrastim, which has a quantity limit of 2 syringes per 45 days in the NMOP, and 1 syringe per 21 days in the retail network.

D. NMOP 30-day quantity limit for topical/transdermal testosterone or androgen replacement products was removed.

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