Department of Defense
Pharmacoeconomic Center

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MCCS-GPE **16 AUGUST 2001**

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 16 August 2001, at the Non-Commissioned Officers Club, Ft. Sam Houston, TX.

2. MEMBERS PRESENT

CDR Terrance Egland, MC	DoD P& T Committee Co-chair
COL Daniel D. Remund, MS	DoD P& T Committee Co-chair
COL John R. Downs, MC	Air Force
LtCol (select) 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, MS	Army
CAPT Robert Rist	Coast Guard
LTC Mike Kieffer, MS	Joint Readiness Clinical Advisory Board
MAJ Mickey Bellemin, BSC	Defense Supply Center Philadelphia (DSCP)
William Hudson	Humana, Inc
Gene Lakey	TriWest
Trevor Rabie	Uniformed Services Family Health Plans (USFHP)

MEMBERS ABSENT

COL Rosa Stith, MC	Army
Dick Rooney	Department of Veterans Affairs
Ray Nan Berry	Health Net Federal Services
Ron McDonald	Sierra Military Health Services

OTHERS PRESENT

COL William Davies, MS	DoD Pharmacy Program Director, TMA
COL Mike Heath, MS	Army Pharmacy Consultant; Chair, DoD Pharmacy Board of Directors
CAPT Joe Torkildson, MC	DoD Pharmacoeconomic Center
LtCol Gary Blamire, MSC	Lead Agent Office, Region 6
LTC Don De Groff, MS	DoD Pharmacoeconomic Center
LTC Doreen Lounsbery, MC	DoD Pharmacoeconomic Center
LtCol Ed Zastawny, BSC	DoD Pharmacoeconomic Center
LCDR Ted Briski, MSC	DoD Pharmacoeconomic Center
MAJ Cheryl Filby, MS	Defense Supply Center Philadelphia
MAJ Barbara Roach, MC	DoD Pharmacoeconomic Center
Capt Andrew Meadows, BSC	Baylor University Resident
SFC Augustin Serrano	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
David Bretzke	DoD Pharmacoeconomic Center
David Chicoine	Uniformed Services Family Health Plan
Eugene Moore	DoD Pharmacoeconomic Center
Mark Petruzzi	Merck-Medco
Carol Scott	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
Paul Vasquez	Defense Supply Center Philadelphia
Gina Wu	Merck-Medco

3. **REVIEW MINUTES OF LAST MEETING / ADMINISTRATIVE ISSUES** – The minutes from the last meeting erroneously listed Shannon Rogers as an employee of Merck-Medco. Ms. Rogers is an employee of Humana.

4. **UNIFORM FORMULARY**– COL Davies reported that a draft of the Uniform Formulary regulation is being staffed in TMA.

5. 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 the 6 new drugs listed below. See Appendix A for more information.

- Almotriptan 6.25- and 12.5-mg tablets (Axert; Pharmacia & Upjohn)
- Drospirenone 0.3 mg / ethinyl estradiol 30 mcg tablets (Yasmin; Berlex);
- Desogestrel/ethinyl estradiol tablet (Cyclessa; Organon)
- Valganciclovir tablets (Valcyte; Syntex)
- Albuterol sulfate 3 mg and ipratropium bromide 0.5 mg per 3 mL (DuoNeb Solution for Inhalation; Dey Labs)
- Insulin aspart injection (NovoLog; Novo Nordisk)

6. USAGE PATTERNS OF DRUGS FORMERLY ON NMOP PREFERRED DRUG PROGRAM – On 1 April 2001, Merck-Medco (the NMOP contractor) ceased making calls to physicians concerning all non-preferred/preferred drug pairs in the NMOP Preferred Drug Program except diltiazem. The committee was interested in seeing how discontinuation of the preferred drug program affected usage patterns of these drugs. Oxybutynin immediate release and Adalat CC experienced the largest drop in market share versus the non-preferred products. The market share changes for ranitidine, acyclovir, and generic NSAIDs were much smaller. Except for the antiviral drugs (acyclovir, famciclovir, valacyclovir), all the products experienced sharp increases in prescription volume because of the implementation of the TRICARE Senior Pharmacy Program.

7. PRIOR AUTHORIZATIONS

A. *Temporary lapse in the NMOP Prior Authorization Program* – Prior authorizations in the NMOP were temporarily suspended in April and early May due to sharp increases in workload associated with the expansion of the pharmacy benefit to all beneficiaries over 65 years of age. Table 1 shows when specific PAs were "turned off" in the NMOP. Initial implementation of the PA for ciclopirox topical solution (Penlac) was delayed to 10 May 2001.

Table 1: Temporary suspension of NMOP PAs due to the Apr 01 benefit change

Drug	"Turned off"	"Turned back on"
Antifungals for onychomycosis [itraconazole (Sporanox), terbinafine (Lamisil)]	10 April 01	1 May 01
Antifungals for onychomycosis [(ciclopirox top solution (Penlac)]	NA	10 May 01
COX-2 inhibitors [celecoxib (Celebrex), rofecoxib (Vioxx)]	14 April 01	30 April 01
Etanercept (Enbrel)	14 April 01	30 April 01
Sildenafil (Viagra)	10 April 01	10 May 01

B. *Cost avoidance from NMOP prior authorizations (PAs)* – Shana Trice (PEC) reported that cost avoidance analyses were not completed for this quarter due to the temporary suspension of the NMOP PA Program. Merck-Medco is now supplying data that identifies new and refill prescriptions, which should improve the accuracy of cost avoidance analyses.

C. *Utilization of the NMOP and retail network pharmacies for drugs subject to PA* – An analysis of the potential shift of patients with prescriptions for COX-2 inhibitors from the NMOP to the retail network is underway, using data from PDTS.

D. *Revision of NMOP PA forms* – Changes to clinical rationale language for the COX-2 inhibitors were delayed by the temporary suspension of the NMOP PA program. Further discussion with Merck-Medco is required to incorporate clinical rationale language for this drug class into the fax forms used by Merck-Medco. Changes to clinical rationale language for the antifungals for onychomycosis to reflect safety announcements by the Food and Drug Administration (FDA) concerning terbinafine and itraconazole are in progress.

E. *Status of the PA for sildenafil (Viagra) in the NMOP and retail network* – MAJ Bellemin commented that the sildenafil PA is responsible for the most patient complaints of all PAs in the NMOP. He suggested that quantity limits already in effect (6 tabs per 30 days for the retail network; 18 tabs per 90 days for the NMOP) might be sufficient to control over-utilization without a PA. The PA for sildenafil was established by a Health Affairs policy, so the PA cannot be discontinued unless the policy is changed. Other drugs similar to sildenafil may be on the market soon, which may provide an impetus to change the sildenafil policy. .

COL Davies commented that the information in the current sildenafil PA regarding drug interactions and contraindications has a questionable impact on prescribing, since the second most frequently reported potential drug-drug interaction in PDTS is concomitant sildenafil and nitrate use. The committee agreed that the potential impact of removing the PA for sildenafil should be assessed more completely before recommending any policy changes to Health Affairs. Bill Hudson (Humana) will present data from the MCSCs and MAJ Bellemin will present data from the NMOP at the next meeting for assessment of the potential impact of removing the sildenafil PA.

8. **RATIONALE FOR QUANTITY LIMITS** – COL Remund reported that the PEC will add to its website an explanation of the rationale for placing quantity limits on certain drugs.

9. **PROPOSED QUANTITY LIMITS FOR OXYCONTIN** – Bill Hudson (Humana) proposed a 120 tablet per 30 days quantity limit for oxycodone extended release (Oxycontin) for the NMOP and retail network due to increasing abuse and misuse of this product.

Some committee members stated that the quantity limit would adversely affect patients who have a legitimate need for large quantities of Oxycontin, and may have little or no impact on patients who are abusing or diverting it. Person who are abusing or diverting Oxycontin will more likely submit prescriptions to multiple pharmacies than a single prescription for a large quantity. Pharmacists can use the information in patient profiles and the advisory messages provided by PDTS to identify these patients. A quantity limit on Oxycontin may set a precedent for limits on other pain medications, which would be inconsistent with the movement toward more adequate treatment of pain. The committee voted against the proposed quantity limit.

10. **REVIEW OF INJECTABLE MEDICATIONS AVAILABLE THROUGH THE NMOP** – The PEC review of the NMOP Covered Injectables list identified goserelin (Zoladex) and leuprolide (Lupron) depot as items that are not labeled for self-administration or commonly used in an outpatient setting. During the 4-month period from Mar – Jun 2001, 15 patients received prescriptions for Zoladex and 63 patients received prescriptions for Lupron Depot from the NMOP.

Lupron is available in both subcutaneous and depot dosage forms and is indicated for a variety of disease states. The subcutaneous form is commonly administered in the home setting. Lupron Depot is an intramuscular injection and is not designed for self-administration, but several facilities have programs that teach caregivers to give IM dosage forms such as Lupron Depot at home (e.g., monthly injections for precocious puberty). The committee decided that both the subcutaneous and depot formulations of Lupron should remain on the NMOP Covered Injectables List.

Goserelin (Zoladex) is an implant that requires insertion under sterile conditions and is not routinely administered outside of a hospital or clinic. The assumption is that virtually all Zoladex prescriptions are taken to physician offices or clinics for administration. The committee's understanding is that TRICARE regulations and policies do not specifically prohibit patients from getting prescriptions filled at the NMOP or retail pharmacies for subsequent administration in a physician office or clinic. The committee decided that Zoladex should remain on the NMOP Covered Injectables List.

The committee then discussed numerous issues pertaining to patients obtaining injectable products from the NMOP or retail pharmacies for subsequent administration in provider offices or clinics:

- Safety concerns about patients transporting hazardous products such as cytotoxic agents
- Quality control concerns about products that are sensitive to heat or moisture
- Payment of unnecessary copays by patients if the injectable product should have been provided as part of the physician office visit
- Payment of excess costs by the government if the expense of the injectable product should have been covered as part of the payment for the office visit
- Coverage for drugs administered in provider offices under Medicare Part B for some patients
- The fact that some providers might not stock certain injectables in their offices, making it necessary for the patient to obtain these products from the NMOP or a retail pharmacy
- The need to allow for medical necessity overrides of any general policy concerning injectable medications. For example, some injectable drugs have clinically accepted uses via non-injectable routes of administration (e.g., colistin vials used for home nebulization).

COL Davies requested that the DoD P&T Committee provide a recommendation to TMA concerning any needed policy interpretations or policy changes. A subcommittee was appointed to work on this issue. Subcommittee members are: LtCol (select) George Jones (chair), LTC (P) Joel Schmidt, MAJ Brett Kelly, MAJ Mickey Bellemin, and Bill Hudson. LTC DeGroff will provide data from the Pharmacy Data Transaction Service to the workgroup. COL Remund noted that the data needs go beyond what PDTS could provide, since the workgroup also needed to know what drugs patients were having difficulty getting. MAJ Bellemin said that the NMOP had a list of complaints, while COL Davies can supply information from congressional complaints to TMA and some of the MCSCs have records of prescription denials.

11. CONTROLLED DISTRIBUTION OF DOFETILIDE (TIKOSYN) – Because of specialized educational requirements mandated by the FDA, dofetilide is only available for outpatient use through Stadtlander's Pharmacy/CVS Procare (which is a non-network pharmacy for DoD beneficiaries). LTC DeGroff reported that a centralized policy and procedure is being worked out with Pfizer so that DoD patients are not forced to pay the copay for a non-network pharmacy. Under the procedure, all prescriptions outside the MTF would still go through Stadtlander's/CVS Procare, but would be paid through a central billing mechanism. The patient would pay only the copay, with the rest billed to a central account at FSS pricing, and the drug would be mailed from Stadtlander's/CVS Procare to the patient. COL De Groff estimated that about 220 patients in DoD might use this process. Clinical reviews for dofetilide, which has multiple drug-drug interactions, are being done out of the PDTS database.

12. ADJOURNMENT – The meeting adjourned at 1200 hours. The next meeting will be held at 0800 on 15 November 2001 in the Washington DC area (specific location to be determined). All agenda items should be submitted to the co-chairs no later than 19 October 2001.

<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 or retail network formulary restrictions**	**BCF Status**
Almotriptan 6.25- and 12.5-mg tablets (Axert; Pharmacia & Upjohn)	7 May 01; treatment of migraine with and without aura in adults. Not intended for the prophylactic therapy of migraine or in the treatment of basilar or hemiplegic migraine. Safety and effectiveness in cluster headaches not established.	Added to NMOP Formulary	**Quantity Limits** **6.25-mg tab:** NMOP: 36 tablets per 90 days; Retail Network: 12 tablets per 30 days **12.5-mg tabs:** NMOP: 36 tablets per 90 days; Retail Network: 12 tablets per 30 days **Rationale for Quantity Limits** Safety and efficacy of treating more than 4 migraines a month with this class of drugs not established. Patients experiencing more frequent migraines are likely to be candidates for routine prophylactic treatment (e.g., with beta-blockers or selective serotonin reuptake inhibitors). Recommended quantity limits for the retail network are based on the treatment of 4 headaches a month, rounding up to the next full box, if necessary. Quantity limits for the NMOP were calculated as three times the limit for the retail network to maintain consistency across points of service. **Prior Authorization** No	Not added to the BCF **BCF drugs in this class:** sumatriptan oral and sumatriptan autoinjector
Drospirenone 0.3 mg / ethinyl estradiol 30 mcg tablets (Yasmin; Berlex)	11 May 01; prevention of pregnancy	Added to NMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** No	Not added to the BCF **BCF drugs in this class**: multiple oral contraceptives
Desogestrel/ ethinyl estradiol tablets (Cyclessa; Organon)	22 Dec 2000; prevention of pregnancy	Added to NMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** No	Not added to the BCF **BCF drugs in this class:** multiple oral contraceptives
Valganciclovir tablets (Valcyte; Syntex)	29 March 2001; treatment of cytomegalovirus retinitis in AIDS patients	Added to NMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** No	Not added to the BCF **BCF drugs in this class:** None

Generic name (Trade name; manufacturer)	**FDA approval date, drug class, FDA-approved indication**	**NMOP Formulary Status**	**NMOP or retail network formulary restrictions**	**BCF Status**
Albuterol sulfate 3 mg and ipratropium bromide 0.5 mg per 3 mL (DuoNeb Solution for Inhalation; Dey Labs)	21 Mar 2001; bronchospasm associated with COPD in patients requiring more than one bronchodilator medication	Added to NMOP Formulary	**Quantity Limits** NMOP: 540 vials per 90 days; retail network: 180 vials per 30 days **Rationale for Quantity Limits** Based on maximum recommended doses (up to 6 treatments per day). Quantity limits for both ipratropium and albuterol vials for inhalation are currently in effect. **Prior Authorization** No	Not added to the BCF **BCF drugs in this class:** albuterol and ipratropium vials for inhalation
Insulin aspart injection (NovoLog; Novo Nordisk)	8 Jun 2000 (available Sep 2001); with an intermediate or long-acting insulin for treatment of adult patients with diabetes mellitus or those with hyperglycemia	Added to the NMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** No	Not added to the BCF **BCF drugs in this class:** No rapid-acting insulin analogs on the BCF; insulins on the BCF are Novolin N, R, 70/30

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** (See Minutes of the 15 August DoD P&T Executive Council Meeting)
   A. *Additions to the BCF*
      1) Rabeprazole oral – effective 1 Oct 2001
      2) Montelukast oral
      3) Amiodarone oral
      4) Clindamycin phosphate 1% topical solution
   B. *Deletions from the BCF*
      1) Cerivastatin oral – due to market withdrawal
      2) Omeprazole oral – effective 1 Oct 2001
      3) Quinidine sulfate oral
      4) Quinidine gluconate oral
      5) Primidone oral
   C. *Changes and clarifications to the BCF*
      1) The PPI class will be open effective 1 Oct 2001. As of 1 Oct 2001, MTFs must add rabeprazole (Aciphex) to their formularies (see above), but may have other PPIs on their formularies in addition to rabeprazole.
2. **NMOP FORMULARY CHANGES**
   A. *Additions to the NMOP Formulary* (See Appendix A for details)
      1) Almotriptan tablets (Axert; Pharmacia & Upjohn) - quantity limits apply
      2) Drospirenone 0.3 mg and ethinyl estradiol 30 mcg tablets (Yasmin; Berlex)
      3) Desogestrel 0.1/0.125/0.15 mg and ethinyl estradiol 25 mcg tablets (Cyclessa; Organon)
      4) Valganciclovir tablets (Valcyte; Syntex)
      5) Albuterol sulfate 3 mg and ipratropium bromide 0.5 mg per 3 mL (DuoNeb Solution for Inhalation; Dey Labs) – quantity limits apply
      6) Insulin aspart injection (NovoLog; Novo Nordisk)
   B. *Exclusions from the NMOP Formulary* – None
3. **QUANTITY LIMIT CHANGES (NMOP AND RETAIL NETWORK)**
   A. Quantity limit for almotriptan 6.25- and 12.5-mg tablets (Axert; Pharmacia & Upjohn) – NMOP: 36 tablets per 90 days; retail network: 12 tablets per 30 days
   B. Quantity limit for albuterol sulfate 3 mg and ipratropium bromide 0.5 mg per 3 mL (DuoNeb Solution for Inhalation; Dey Labs) – NMOP: 540 vials per 90 days; retail network: 180 vials per 30 days
4. **CHANGES TO THE PRIOR AUTHORIZATION PROGRAM (NMOP AND RETAIL NETWORK)** – None