Department of Defense
Pharmacoeconomic Center

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

MCCS-GPE **6 MARCH 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 6 March 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
MAJ Travis Watson, MS	Army
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 Matt Nutaitis, MC	Navy
CDR Mark Richerson, MSC	Navy
CAPT Robert Rist	Coast Guard
Mike Valentino	Department of Veterans Affairs
Dr. Trevor Rabie	Uniformed Services Family Health Plan
COL Doreen Lounsbery, MC	Army

VOTING MEMBERS ABSENT

None	

OTHERS PRESENT

COL William Davies, MS	DoD Pharmacy Program Director, TMA
Howard Altschwager	Deputy General Counsel, TMA
COL Mike Heath, MS	Army Pharmacy Consultant, Chairman Pharmacy Board of Directors
CAPT Betsy Nolan, MSC	Navy Pharmacy Specialty Leader
David Chicoine	Uniformed Services Family Health Plan
CAPT Joe Torkildson, MC, USN	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
Lisa LeGette	Express Scripts
Mark Hughes	Express Scripts
MAJ John Howe, MS	Defense Supply Center Philadelphia
Kathy Tortorice	Department of Veterans Affairs
Shannon Rogers	Humana
William Hudson	Humana
Gene Lakey	TriWest
Ray Nan Berry (via T-Con)	Health Net Federal Services
Ron McDonald (via T-Con)	Sierra

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

4. **INTERIM/ ADMINISTRATIVE DECISIONS** – Trovafloxacin was excluded from the NMOP/TMOP since its use is reserved for "patients with serious, life- or limb-threatening infections who receive their initial therapy in an inpatient health care facility," and is restricted to a two-week period.

5. **UNIFORM FORMULARY (UF) PROPOSED RULE**- COL William Davies, DoD Pharmacy Program Director, TMA, stated that the responses to the public comments on the proposed rule are nearly finalized and will undergo a legal review.

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 fourteen 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. *Implementation of the TMOP on 1 March 2003* - COL Davies (TMA) and Lisa LeGette from Express Scripts (the contractor for the TMOP program) provided an overview of the implementation of the TRICARE Mail Order Pharmacy program, and the progress of the changeover from the previous National Mail Order Pharmacy (NMOP) program. Shana Trice (PEC) reviewed the new TMOP Formulary page on the PEC website and explained changes from the old NMOP Formulary page. She also discussed revisions to the DoD Quantity Limits page to better reflect implementation of the quantity limits at the TMOP.

The URL for the TMOP Formulary page is: www.pec.ha.osd.mil/TMOP/TMOPhome.htm. Comprehensive benefit information for the TMOP may be found on the TRICARE website at: http://www.tricare.osd.mil/pharmacy/tmop.cfm, while the Express-Scripts website (www.express-scripts.com; click on the DoD seal) provides beneficiaries with the ability to register for the TMOP online, download registration forms, order refills, check order status, etc.

B. *New "line extension" rule for the TMOP* – The Council agreed that newly approved combination products involving addition of a diuretic to another antihypertensive medication may be automatically added to the TMOP Formulary as a line extension, pending confirmation by the Committee at the next scheduled meeting. The Committee asked for a review of "line extension rules" for the TMOP at the next meeting in May 2003. The rules currently in effect are those previously approved for the NMOP; however, there are operational differences between the two programs that affect the manner in which the rules are applied.

8. PRIOR AUTHORIZATIONS (PAs)

The Committee approved prior authorization criteria for adalimumab (Humira) and modifications to prior authorization criteria for etanercept (Enbrel) and anakinra (Kineret) (see Appendix D).

9. CONTROLLED DISTRIBUTION OF PRESCRIPTION DRUGS – Buprenorphine & buprenorphine/naloxone (Subutex/Suboxone) are subject to a controlled distribution process, but it is not clear to the Committee that these medications are covered under TRICARE rules. Enfuvirtide (Fuzeon) a new HIV medication will be manufactured on a limited scale, however the distribution process is unknown. Further information on both these products should be available by the next meeting. Peginterferon-alfa 2b (PEG-Intron) and etanercept (Enbrel) are no longer under controlled distribution.

10. ADJOURNMENT – The meeting adjourned at 1130 hours. The next meeting will be held at Fort Sam Houston, TX at 0800 on Wednesday, 7 May 2003. All agenda items should be submitted to the co-chairs no later than 18 April 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 FORMULARY AND DOD BASIC CORE FORMULARY

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**
Nitazoxanide 100 mg/5 mL oral suspension (Alinia; Romark Labs)	22 Nov 02: Treatment of diarrhea caused by *Cryptosporidium parvum* and *Giardia lamblia*, in pediatric patients 1 through 11 years of age. Nitazoxanide is given every 12 hours for 3 days. Nitazoxanide is the first anti-parasitic product approved specifically for treating cryptosporidiosis and the only drug approved for treatment of giardiasis in ages 1-11 years that is available in a suspension formulation. A tablet formulation of nitazoxanide for adults with intestinal parasites is "approvable" at the FDA.	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization:** None	Not added to the BCF **Similar BCF agents:** Metronidazole oral tablets; requires extemporaneous compounding to make a suspension.
Eletriptan tablets (Relpax; Pfizer)	26 Dec 02: Indicated for the acute treatment of migraine attacks with and without aura in adults. This is the 7th 5-HT receptor agonist (triptan) marketed.	Added to the TMOP Formulary	**Quantity Limits** Quantity limits exist for other triptans. Packaged in 12's. **Retail**: 12 tablets/30 days" **TMOP:** 36 tablets/90 days **Prior Authorization** None	Not added to the BCF **Similar BCF agents:** sumatriptan oral tablets and auto-injector. **Note:** A contracting initiative for the triptan class is underway.
Aripiprazole tablets (Abilify; BMS)	15 Nov 02: Atypical antipsychotic indicated for the treatment of schizophrenia. Unlike other atypical antipsychotics, aripiprazole functions as a partial agonist at dopamine D_2 receptors; the clinical significance of this difference is unknown.	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents**: None **Note:** Addition of one or more atypical antipsychotics to the BCF is under discussion.
Teriparitide (rDNA origin) injection (Forteo; Lilly)	26 Nov 02: Recombinant parathyroid hormone (PTH); stimulates new bone formation by increasing osteoblast activity. Teriparitide is indicated for the treatment of men and postmenopausal women with osteoporosis who are at high risk for fracture, including those with a history of osteoporotic fracture, multiple risk factors for fracture, or who have failed or are intolerant of previous osteoporosis therapy. Once-daily subcutaneous administration; may be self-injected. The injection device is similar to Lilly's insulin pen. Requires refrigeration. Black box warning for osteosarcoma in rodent studies. Patient medication guide must be dispensed with the product.	Added to the TMOP Formulary & TMOP Covered Injectables List	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents**: Alendronate tablets are on the BCF. Potential contracting initiative for alendronate or risedronate is under consideration.

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**
Atomoxetine capsules (Strattera; Lilly)	26 Nov 02: Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children (down to age 6 years). Atomoxetine is a highly selective norepinephrine re-uptake inhibitor. It is the only non-controlled medication approved for the treatment of ADHD and the only medication approved for the treatment of ADHD in adults.	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents:** Existing products for ADHD are all Schedule II controlled substances: methylphenidate ER (specific brand is Concerta); methylphenidate IR; D,L amphetamine ER (Adderall XR).
Adalimumab injection (Humira; Abbott)	2 Jan 03: Monoclonal antibody that binds to tumor necrosis factor (TNF) alpha. Indicated for reducing the signs and symptoms and inhibiting the progression of structural damage in adults with moderately to severely active RA who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Can be used alone or in combination with methotrexate. Administered as a single dose 40 mg subcutaneous (SQ) injection every two weeks (patients not on methotrexate may require weekly administration). May be self-injected. Other similar biologics – etanercept, and infliximab, both TNF inhibitors, and anakinra, an interleukin-1 inhibitor – are also indicated for RA. Etanercept is also indicated for juvenile RA and psoriatic arthritis; infliximab for Crohn's disease. Etanercept (Enbrel) is administered SQ twice a week; infliximab (Remicade) as a monthly IV infusion, and anakinra (Kineret) as a daily SQ injection. Adalimumab contains the same black box warnings as other TNF blockers for emergence of serious infections during treatment, including disseminated or extrapulmonary tuberculosis.	Added to the TMOP Formulary & Covered Injectables List	**Quantity Limits** **TMOP**: 6 syringes per 6 weeks (3 packs of 2 syringes) **Retail:** 4 syringes per 4 weeks (2 packs of 2 syringes) **Note**: the quantity limits allow for the possibility of once weekly administration of adalimumab in some patients. Quantity limits are in place for both etanercept and anakinra. **Prior Authorization** ▪ Yes. See Appendix D for criteria.	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 (Amnesteem; Bertek); (Sotret; Ranbaxy)	AB rated generics to Accutane (Roche brand of isotretinoin). Isotretinoin is excluded from the TMOP Formulary.
Ciprofloxacin extended-release tablets (Cipro XR; Bayer)	Approved for uncomplicated UTI caused *by E. coli*, *Proteus*, *Enterococcus*, and *Staphylococcus*; 3-day regimen. Automatically added to TMOP Formulary as a line extension. Ciprofloxacin is not on the BCF.
Stavudine extended release capsules (Zerit XR; BMS)	Nucleoside reverse transcriptase inhibitor for HIV. Automatically added to TMOP Formulary as a line extension. Stavudine is not on the BCF.
Alprazolam extended release capsules (Xanax XR; Pharmacia)	Approved for panic disorder. Automatically added to TMOP Formulary as a line extension. Alprazolam is not on the BCF.
Alpha-1 proteinase inhibitor, human injection (Aralast; Baxter/Alpha)	Orphan drug for hereditary emphysema/alpha 1 antitrypsin deficiency. Requires IV infusion. Not considered for the TMOP Covered Injectables List since it is not designed for self-administration. Not considered for the BCF due to the specialized nature of the indication.
Testosterone gel 1% topical (Testim; Auxilium Pharmaceuticals)	Approved for treatment of primary hypogonadism; 2nd testosterone gel on the market. Not generically substitutable for Androgel; both are reference listed drugs. Automatically added to TMOP Formulary as a line extension. Schedule III controlled medication. Although the general rule limits controlled medications to a 30-day supply at the TMOP, Testim falls under an already established exception to this rule that provides for up to a 90-day supply at the TMOP for commercially available topical testosterone products. Testosterone gel is not on the BCF.
Azelaic acid gel 15% topical (Finacea; Berlex)	Approved for mild to moderate rosacea. A similar product, azelaic acid 20% cream (Fineven; Berlex), approved for acne, is already available from the TMOP. Automatically added to TMOP Formulary as a line extension. Azelaic acid products are not on the BCF.
70% insulin aspart protamine suspension/30% insulin aspart injection (Novolog Mix 70/30 vials & pens; Novo Nordisk)	Biphasic insulin produced by adding protamine to Novolog. Automatically added to TMOP Formulary as a line extension.
Insulin aspart injection (Novolog flex pen; Novo Nordisk)	New packaging for insulin aspart. Automatically added to TMOP Formulary as a line extension.
Alefacept injection (Amevive; Biogen)	Biologic for moderate to severe plaque psoriasis given as a weekly IV bolus or IM injection. Not considered for the TMOP Covered Injectables List since it is not designed for self-administration. Not considered for the BCF due to the specialized nature of the indication.
Ribavirin capsules (Copegus; Roche)	Roche brand of ribavirin for use in combination with pegylated interferon. The Schering brand of ribavirin (Rebetol) is already available from the TMOP. Automatically added to TMOP Formulary as a line extension. Ribavirin is not on the BCF.
Diltiazem graded release tablet (Cardizem LA; Biovail)	New controlled release once-daily formulation of diltiazem; may be dosed in the morning or at bedtime. Not generically substitutable for Cardizem CD or Tiazac. Anticipated availability April 2003. Automatically added to TMOP Formulary as a line extension. Tiazac is the BCF selection for a once-daily diltiazem product.
Cyclobenzaprine tablets (Flexeril; McNeil)	New lower 5 mg dosage form. Automatically added to TMOP Formulary as a line extension. Cyclobenzaprine is not on the BCF.
Eprosartan/HCTZ tablets (Teveten HCT; GSK)	New combination of an angiotensin receptor blocker with hydrochlorothiazide. Automatically added to TMOP Formulary as a line extension. A VA/DoD solicitation for angiotensin receptor blockers is in progress.

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) Chlorthalidone
      2) Benztropine
      3) Trihexyphenidyl
      4) Amantadine
      5) Lansoprazole
      6) Goserelin (Zoladex) 1- and 3-month products for the treatment of prostate cancer

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

2. **TMOP FORMULARY CHANGES**

   A. *Additions to the TMOP Formulary*

      1) Nitazoxanide oral suspension (Alinia; Romark Labs)
      2) Eletriptan tablets (Relpax; Pfizer) – quantity limits apply, see below
      3) Aripiprazole tablets (Abilify; BMS)
      4) Teriparitide (rDNA origin) injection (Forteo; Lilly) – added to the TMOP Covered Injectables List
      5) Atomoxetine capsules (Strattera; Lilly)
      6) Adalimumab injection (Humira; Abbott) – added to the TMOP Covered Injectables List with prior authorization criteria; quantity limits apply, see below

   B. *Exclusions from the TMOP Formulary*

      1) Trovafloxacin (Trovan; Pfizer) – specifically excluded from the TMOP Formulary, since its use is reserved for "patients with serious, life- or limb-threatening infections who receive their initial therapy in an inpatient health care facility," and is restricted to a two-week period.

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

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

   A. Quantity limit for eletriptan tablets (Relpax; Pfizer): 12 tablets (1 pack) per 30-day supply (retail); 36 tablets (3 packs) per 90-day supply (TMOP); consistent with existing quantity limits for other triptans (within limitations of package size)

   B. Quantity limit for adalimumab injection (Humira; Abbott): 4 syringes (2 packs of 2 syringes) per 4 weeks (retail); 6 syringes (3 packs of 2 syringes) per 6 weeks (TMOP)

4. **CHANGES TO THE TMOP PRIOR AUTHORIZATION PROGRAM**

   A. Prior authorization criteria established for adalimumab injection (Humira; Abbott) – see Appendix D

   B. Prior authorization criteria for etanercept and anakinra modified – see Appendix D

APPENDIX D: PRIOR AUTHORIZATION CRITERIA FOR ADALIMUMAB (HUMIRA) & CHANGES TO PRIOR AUTHORIZATION CRITERIA FOR ETANERCEPT (ENBREL) AND ANAKINRA (KINERET)

Drug	FDA Indications	New TMOP Prior Authorization Criteria
Adalimumab (Humira)	• Reducing signs and symptoms and inhibiting the progression of structural damage in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more DMARDs.	• Coverage provided for the treatment of moderately to severely active rheumatoid arthritis in patients 18 years of age or older when the patient has had an inadequate response to at least one disease-modifying antirheumatic drug (DMARD). • Coverage NOT provided for concomitant use with anakinra (Kineret), etanercept (Enbrel), or infliximab (Remicade).
Anakinra (Kineret)	• Reduction in signs and symptoms of moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs).	• Coverage provided for the treatment of moderately to severely active rheumatoid arthritis in patients 18 years of age or older when the patient has had an inadequate response to at least one disease-modifying antirheumatic drug (DMARD). • Coverage NOT provided for concomitant use with adalimumab (Humira), etanercept (Enbrel) or infliximab (Remicade). *Changes to previous criteria:* • Listing adalimumab, etanercept, and infliximab as DMARDs. • Adding adalimumab to the statement: "Coverage NOT provided for concomitant use with etanercept (Enbrel) or infliximab (Remicade)." • Making criteria more consistent with package labeling and with criteria for adalimumab by changing the previous requirement that the patient fail (or be unable to take) MTX AND fail at least one other DMARD.
Etanercept (Enbrel)	• Reducing signs and symptoms and inhibiting the progression of structural damage in patients with moderately to severely active rheumatoid arthritis. • Reducing signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more DMARDs. • Reducing signs and symptoms of active arthritis in patients with psoriatic arthritis.	• Coverage provided for the treatment of moderately to severely active rheumatoid arthritis OR active psoriatic arthritis. • Coverage provided for the treatment of juvenile rheumatoid arthritis when the patient has an inadequate response to at least one disease-modifying antirheumatic drug (DMARD). • Coverage NOT provided for concomitant use with adalimumab (Humira), anakinra (Kineret), or infliximab (Remicade). *Changes to previous criteria:* • Listing adalimumab, anakinra, and infliximab as DMARDs. • Adding the provision that coverage is not provided for concomitant use with adalimumab, anakinra, or infliximab.

For all three prior authorizations:

The following are examples of DMARDs:

- o adalimumab
- o anakinra
- o etanercept
- o infliximab
- o azathioprine
- o hydroxychloroquine
- o gold compounds, oral/injectable (e.g., auranofin, aurothioglucose, gold sodium thiomalate)
- o leflunomide
- o methotrexate
- o d-penicillamine
- o sulfasalazine