Appendix B – Newly Approved Drugs

Medication & Mechanism of Action	FDA approval date; FDA-approved indications	Committee Recommendation
Acamprosate (Campral) tabs; Forest; glutamate receptor modulator (alcohol deterrent)	Jul 04: Maintenance of abstinence from alcohol in patients with alcohol dependence who are abstinent at treatment initiation. Treatment with Campral should be part of a comprehensive management program that includes psychosocial support.	No Uniform Formulary recommendation at this meeting. Consideration of Uniform Formulary status deferred until drug class is reviewed.
Apomorphine (Apokyn) SQ injection; Bertek ; dopamine agonist	April 04: Acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's Disease. Has been studied as an adjunct to other medications. Note: Not available at TMOP due to controlled distribution requirements.	No Uniform Formulary recommendation at this meeting. Consideration of Uniform Formulary status deferred until drug class is reviewed.
Duloxetine (Cymbalta) capsules; Eli Lilly; serotonin norepinephrine reuptake inhibitor (SNRI)	Aug 04: Treatment of major depressive disorder (MDD). Also indicated for management of neuropathic pain associated with diabetic peripheral neuropathy.	No Uniform Formulary recommendation at this meeting. Consideration of Uniform Formulary status deferred until drug class is reviewed.
Erlotinib (Tarceva) tabs; Genentech / OSI; human epidermal growth factor receptor type 1 (HER1/EGFR1) tyrosine kinase inhibitor	Nov 04: Treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen.	Quantity limits recommended due to precedent set by the other HER1/EGFR1, gefitinib (Iressa); potential for wastage; and high cost: Limit of 30 day supply in retail, 45 day supply in TMOP, up to 45 day supply in MTFs. No multiple fills for multiple cost shares in retail and TMOP. Consideration of Uniform Formulary status deferred until drug class is reviewed.
Ezetimibe / simvastatin (Vytorin) tabs; Merck Schering Plough; cholesterol absorption inhibitor plus statin	Aug 04: Primary Hypercholesterolemia: Indicated as adjunctive therapy to diet for the reduction of elevated total-C. LDL-C, Apo B, TG and non-HDL-C, and to increase HDL-C in patients with primary (heterozygous familial and non-familial) hypercholesterolemia or mixed hyperlipidemia. Homozygous Familial Hypercholesterolemia: Indicated for the reduction in elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia, as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable.	No Uniform Formulary recommendation at this meeting. Consideration of Uniform Formulary status deferred until drug class is reviewed.

Medication & Mechanism of Action	FDA approval date; FDA-approved indications	Committee Recommendation
Gemifloxacin (Factive) tabs; Oscient; fluoroquinolone antibiotic	April 03: Community-acquired pneumonia (includes multi-drug resistant strains of *Strep. pneumoniae);* and acute exacerbations of chronic bronchitis	No Uniform Formulary recommendation at this meeting. Consideration of Uniform Formulary status deferred until drug class is reviewed. Quantity limits recommended based on the maximum 7-day course of therapy and FDA safety recommendations noting a much higher incidence of rash—which can be severe—if treated for more than 10 days. The product is packaged only in 5s and 7s. Recommendation: Limit of 7 days supply (one course of therapy) per 30 days in retail, TMOP, and MTFs.
Lanthanum carbonate (Fosrenol) chewable tabs; Shire Phosphate binder (rare earth metal; trivalent cation)	Oct 04: Indicated to reduce serum phosphate in patients with End Stage Renal Disease (ESRD)	No Uniform Formulary recommendation at this meeting. Consideration of Uniform Formulary status deferred until drug class is reviewed.
Overactive Bladder Medications		
Darifenacin (Enablex) sustained release tabs; Novartis; muscarinic antagonist	Dec 04: Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency	No Uniform Formulary recommendation at this meeting. Consideration of Uniform Formulary status deferred until drug class is reviewed.
Solifenacin (Vesicare) tabs; GSK/Yamanouchi; muscarinic antagonist	Nov 04: Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency	
Trospium (Sanctura) tabs; Indevus; muscarinic antagonist	May 04: Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency	
Rifaximin (Xifaxan) tabs; Salix; rifampin derivative antibiotic (nonabsorbed)	May 04: Treatment of patients $\geq$12 years of age with traveler's diarrhea caused by non-invasive strains of *Escherichia coli.* Rifaximin should not be used in patients where *Campylobacter jejuni, Shigella* spp, or S*almonella* spp are suspected as causative pathogens. Rifaximin should not be used for diarrhea complicated by fever of bloody stools. (Orphan status for hepatic encephalopathy)	No Uniform Formulary recommendation at this meeting. Consideration of Uniform Formulary status deferred until drug class is reviewed.

Medication & Mechanism of Action	FDA approval date; FDA-approved indications	Committee Recommendation
Telithromycin (Ketek) tabs; Sanofi-Aventis; ketolide / macrolide antibiotic	April 04: Treatment of patients 18 years and older with the following conditions: community-acquired pneumonia due to *Streptococcus pneumoniae* (includes multi-drug resistant isolates [MDRSP]), *Haemophilus influenzae, Moraxella catarrhalis, Chlamydophila pneumoniae*, or *Mycoplasma pneumoniea***;** acute exacerbations of chronic bronchitis (AECB) due to *Streptococcus pneumoniae, Haemophilus influenzae*, or *Moraxella catarrhalis***;** sinusitis due to *Streptococcus pneumoniae, Haemophilus influenzae*, or *Moraxella catarrhalis* or *Staphylococcus aureus.*	No Uniform Formulary recommendation at this meeting. Consideration of Uniform Formulary status deferred until drug class is reviewed.
Tinidazole (Tindamax) tabs; Presutti Labs; anti-protozoal antibiotic	May 04: Treatment of trichomoniasis in post-pubertal female and male patients caused by *T. vaginalis*; giardiasis caused by *G. duodenalis* (also termed *G. lamblia*) in both adults and pediatric patients**;** intestinal amebiasis (amebic dysentery) and amebic liver abscess caused by *E. histolytica* in both adults and pediatric patients older than 3 years of age.	No Uniform Formulary recommendation at this meeting. Consideration of Uniform Formulary status deferred until drug class is reviewed.

14 July 2004

DECISION PAPER:
JULY 2004 PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

7. BASIC CORE FORMULARY (BCF) CHANGES

A. Estrogen Replacement Therapy Patches (Esclim):

The Committee recommended removing Esclim from the BCF because the price increased from $5.20 per cycle to $27.50 per cycle. (See paragraph 7. A. on page 4 of P&T Committee minutes)

TMA Director Decision: ■ Approved □ Disapproved
Approved, but modified as follows:

The Committee recommended changing the BCF listing to "estradiol patch" with no specific brand listed. (See paragraph 7. A. on page 4 of P&T Committee minutes)

TMA Director Decision: ■ Approved □ Disapproved
Approved, but modified as follows:

B. Ciprofloxacin (Cipro, generics):

The Committee recommended adding ciprofloxacin to the BCF because it is a cost-effective alternative to other fluoroquinolones for treating susceptible infections. (See paragraph 7. B. on pages 4 and 5 of P&T Committee minutes)

TMA Director Decision: ■ Approved □ Disapproved
Approved, but modified as follows:

C. Lamivudine/Zidovudine (Combivir):

The Committee recommended not adding Combivir to the BCF. (See paragraph 7. C. on page 5 of P&T Committee minutes)

TMA Director Decision: ■ Approved □ Disapproved
Approved, but modified as follows:

D. Erythromycin/Sulfisoxazole (Pediazole):

The Committee recommended removing erythromycin ethylsuccinate / sulfisoxazole from the BCF due to increasing microbial resistance, the absence of erythromycin ethylsuccinate / sulfisoxazole from current guidelines for acute otitis media, and low utilization at MTFs. (See paragraph 7. D. on page 5 of the P&T Committee minutes).

*TMA Director Decision***:** ■ Approved □ Disapproved
Approved, but modified as follows:

E. Ramipril (Altace):

The Committee recommended removing ramipril from the BCF because it is now significantly less cost effective than the other ACE inhibitors on the BCF. (See paragraph 7. E. on page 5 of the P&T Committee minutes)

*TMA Director Decision***:** ■ Approved □ Disapproved
Approved, but modified as follows:

12. PRIOR AUTHORIZATIONS

A. ***COMMITTEE ACTION****:* The Committee recommended retaining existing prior authorizations criteria for the following drugs (See paragraph 12. A. on page 7 of P&T Committee minutes and Appendix A for the rationale):

- Adalimumab (Humira®)

*TMA Director Decision***:** ■ Approved □ Disapproved
Approved, but modified as follows:

- Anakinra (Kineret®)

*TMA Director Decision***:** ■ Approved □ Disapproved
Approved, but modified as follows:

- Efalizumab (Raptiva®)

*TMA Director Decision***:** ■ Approved □ Disapproved
Approved, but modified as follows:

- Ciclopirox (Penlac)

*TMA Director Decision***:** ■ Approved □ Disapproved
Approved, but modified as follows:

- Itraconazole (Sporanox)

*TMA Director Decision***:** ■ Approved □ Disapproved
Approved, but modified as follows:

- Terbinafine (Lamisil)

*TMA Director Decision***:** ■ Approved □ Disapproved
Approved, but modified as follows:

- Human growth hormone (somatropin, somatrem)

*TMA Director Decision***:** ■ Approved □ Disapproved
Approved, but modified as follows:

- Injectable gonadotropins

*TMA Director Decision***:** ■ Approved □ Disapproved
Approved, but modified as follows:

B. ***COMMITTEE ACTION****:* The Committee recommended continuation of the requirement for prior authorization of etanercept (Enbrel), with the addition of a criterion that covers the new FDA-approved indication for the treatment of adult patients (≥18 years of age) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. (See paragraph 12. A. on page 7 and Appendix A of P&T Committee minutes for rationale)

*TMA Director Decision***:** ■ Approved □ Disapproved
Approved, but modified as follows:

C. ***COMMITTEE ACTION:*** The Committee recommended continuation of prior authorization of PDE-5 inhibitors, but with modifications designed to improve the efficiency of the prior authorization process. Contingent upon the ASD(HA) rescinding HA Policy 98-040, Practice Guidelines for the Evaluation of Patients Requesting Sildenafil (Viagra) for the Treatment of Male Impotence, the Committee recommended:

- Allowing male patients 50 years of age or older to receive PDE-5 inhibitors without going through the PA process, and
- Eliminating the drug interaction with nitrates from the PA criteria.

Note: The cumulative quantity limit of 6 tablets per 30 days in the retail network or 18 tablets per 90 days in the TMOP remain in effect. (See paragraph 12 B. on page 8 and Appendix A of P&T Committee minutes for rationale)

*TMA Director Decision***:** ■ Approved □ Disapproved

Approved, but modified as follows:

DECISION ON RECOMMENDATIONS

TMA Director decisions are as annotated above.

William Winkenwerder, Jr., M.D.
Date:
OCT 5 2004

Department of Defense
Pharmacy and Therapeutics Committee Minutes

14 July 2004

1. CONVENING

The DoD P&T Committee convened at 0800 hours on 13 and 14 July 2004 at the DoD Pharmacoeconomic Center (PEC), Fort Sam Houston, Texas.

2. VOTING MEMBERS PRESENT

CAPT Patricia Buss, MC	DoD P& T Committee Chair
COL Daniel Remund, MS	DoD P& T Committee Recorder
Col James Young, BSC (Representing COL William Davies)	Deputy Director, DoD Pharmacy Programs, TMA (Representing Director, DoD Pharmacy Programs, TMA)
Lt Col Gordon Wright Bates, Jr., MC	Air Force, OB/GYN Physician
Maj Nick Conger, MC	Air Force, Physician at Large
Col Phil Samples, BSC	Air Force, Pharmacy Officer
CDR William Hall, MC	Navy, Internal Medicine Physician
LCDR Suzanne Haney, MC (via VTC)	Navy, Pediatrics Physician
CDR Brian Alexander, MC	Navy, Physician at Large
LT Joseph Lawrence, MSC	Navy, Pharmacy Officer
COL Doreen Lounsbery, MC	Army, Internal Medicine Physician
MAJ Franklin H. Hauger, MC	Army, Family Practice Physician
COL Joel Schmidt, MC	Army, Physician at Large
COL Kent Maneval, MS (Representing MAJ Travis Watson, MS)	Joint Readiness Clinical Advisory Board (Representing Army, Pharmacy Officer)
CDR Patrick Marshall	Coast Guard, Pharmacy Officer
LTC Donald DeGroff, MS	Contracting Officer Representative, TMOP
CDR Jill Pettit, MSC	Contracting Officer Representative, TRRx
Joe Canzolino	Department of Veterans Affairs

VOTING MEMBERS ABSENT

COL Greg Wickern, MC (deployed)	Air Force, Internal Medicine Physician

NON-VOTING MEMBERS PRESENT

Howard Altschwager	Deputy General Counsel, TMA
Martha Taft	Resource Management Directorate, TMA
MAJ John Howe, MS	Defense Supply Center Philadelphia

NON-VOTING MEMBERS ABSENT

None	

OTHERS PRESENT

COL William Davies, MS	DoD Pharmacy Program Director, TMA
CDR Mary Fong	Coast Guard, Pharmacy Officer Alternate
COL Mike Heath, MS, USA (Via VTC July 13th only)	Army Pharmacy Consultant, Chairman Pharmacy Board of Directors
CAPT Betsy Nolan, MSC (Via VTC July 13th only)	Navy Pharmacy Specialty Leader
CDR Denise Graham, MSC	DoD Pharmacoeconomic Center
CDR Ted Briski, MSC	DoD Pharmacoeconomic Center
CAPT Don Nichols, MC	DoD Pharmacoeconomic Center
Lt Col Dave Bennett, BSC	DoD Pharmacoeconomic Center
Lt Col Barb Roach, MC	DoD Pharmacoeconomic Center
CPT Jill Dacus, MC	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
Dave Bretzke	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
Julie Liss	DoD Pharmacoeconomic Center
Elizabeth Hearin	DoD Pharmacoeconomic Center
Janet Daily	Department of Veterans Affairs
Paul Vasquez	Defense Supply Center Philadelphia
Lynn Burleson	Assistant General Counsel, TMA
CDR Mark Richerson, MSC	Future PEC Director

3. REVIEW MINUTES OF LAST MEETING

This is the first meeting of the restructured DoD Pharmacy and Therapeutics (P&T) Committee under the new charter established under the authority of 10 U.S.C. 1074g and 32 C.F.R. 199.21. The P&T Committee approved the minutes of the last meeting of the previous Committee with a correction to page 7 Section 6A of the Executive Council minutes regarding prices for salmeterol and formoterol: Based on current FSS prices and recommended dosing regimens, salmeterol costs $44.57 per month compared to $32.63 per month for formoterol.

4. INTERIM DECISIONS/ADMINISTRATIVE ISSUES

None.

5. ORIENTATION/EDUCATION OF THE DOD P&T COMMITTEE

TMA and PEC staff members briefed the Committee on the following:

- Overview of the DoD pharmacy benefit
- Overview of the Uniform Formulary and Basic Core Formulary
- DoD P&T Committee processes under the new charter
- Beneficiary Advisory Panel
- Ethical issues
- Drug class review process
- New drug review process

TMA, PEC, and DSC-P staff are working to revise certain provisions in existing pharmaceutical contracts are in conflict with provisions of the 32 C.F.R 199.21. Additionally, procedures are being developed for DoD to receive price information from pharmaceutical companies for consideration in Uniform Formulary decisions.

6. NATIONAL PHARMACEUTICAL CONTRACTS AND BLANKET PURCHASE AGREEMENTS (BPAS)

A. *New Contracts Awarded* – midazolam HCL 1 mg/mL and 5 mg/mL.

B. *Changes to Existing Contracts*—The next option year was exercised for contracts on the following drugs: ticlopidine, naproxen, propofol, ethinyl estradiol 35 mcg/ethynodiol diacetate 1 mg, ethinyl estradiol 35 mcg/norethindrone 1 mg, norethindrone 35 mcg, ondansetron, digoxin, simvastatin, acyclovir, valproic acid, nicotine patches, glyburide, benztropine, fluphenazine, chlorhexidine, indomethacin, ketoconazole cream, adsorbase ointment, paclitaxel, carbidopa/levodopa, and zolmitriptan.

C. *Contracts Pending Award* – amantadine, enalapril, salsalate, fluocinonide topical, nortriptyline, verapamil SA and insulin.

D. The Committee reviewed utilization and cost data for drug classes where national contracts or blanket purchase agreements currently exist: statins, triptans, fluoroquinolones, leutinizing hormone releasing hormone (LHRH) agonists, ophthalmic prostaglandins, thiazolidinediones (TZDs) and 2nd generation antihistamines. More information about DoD and DoD/VA national pharmaceutical contracts may be found on the Defense Supply Center Philadelphia (DSCP) DMM-Online website at http://dmmonline.dscp.dla.mil/pharm/contractlist.asp. Contract guidance for the oral fluoroquinolones, statins, leutinizing hormone releasing hormone (LHRH) agonists, and triptans are available on the PEC website at www.pec.ha.osd.mil/national_contracts.htm.

7. BASIC CORE FORMULARY (BCF) CHANGES AND CLARIFICATIONS

The committee voted (17 for, 0 opposed, 1 abstained) to require that any requests for BCF additions or deletions from individual providers must be approved by and forwarded through the MTF Pharmacy and Therapeutics Committee before being considered by this committee.

A. *Estrogen Replacement Therapy Patches (Esclim):* Esclim was added to the BCF in May 2003 on the basis of a BPA price of $5.20 per cycle (8 patches = 28 days supply) for all

strengths. Women's First Healthcare, the U.S. distributor of Esclim, filed for Chapter 11 reorganization on May 29, 2004. The FSS contract for Esclim was terminated subsequent to the filing for reorganization. The absence of the FSS contract has caused Esclim's price to increase to $27.50 per month, a 5-fold increase. Women's First Healthcare is in the process of selling their marketing rights to Esclim, but it will likely be one to three months before another FSS contract is in place. Prices for estradiol patches are displayed in Table 1 below.

Table 1. July 2004 FSS Prices per Cycle for Estradiol Patches

Brand	Manufacturer	Dosing Schedule	0.025 mg	0.0375 mg	0.05 mg	0.06 mg	0.075 mg	0.1 mg
Esclim	WFH	Twice weekly	$26.60 (formerly $5.20)	$26.86 (formerly $5.20)	$27.38 (formerly $5.20)		$27.89 (formerly $5.20)	$27.89 (formerly $5.20)
Estraderm	Novartis	Twice weekly			$17.94			$19.36
Climara	Berlex	Once weekly	$7.74	$17.85	$7.74	$18.45	$7.74	$7.74
Vivelle	Novartis	Twice weekly	$19.04	$19.59	$20.86		$20.76	$21.74
Vivelle Dot	Novartis	Twice weekly	$18.07	$16.35	$17.42		$17.21	$18.37
Alora	Watson	Twice weekly	$19.04		$18.22		$21.85	$18.89
Generic	Mylan	Once weekly			$11.18			$11.65

COMMITTEE ACTION: The Committee recommended (17 for, 0 opposed, 1 abstained) to remove Esclim from the BCF and change the BCF listing to "estradiol patch" with no specific brand listed. MTFs can decide if they want to switch to a different estradiol patch or continue to use Esclim with the anticipation that the price of Esclim will be reduced in the near future. The DoD P&T Committee will reconsider the class for BCF and/or Uniform Formulary selections once the pricing issue has resolved.

B. *Ciprofloxacin (Cipro, generics):* Ciprofloxacin prices have decreased significantly due to the availability of generic equivalents for Cipro. As shown in Table 2, ciprofloxacin now costs much less than other fluoroquinolones.

Table 2. July 2004 MTF Fluoroquinolone Prices

Gatifloxacin	Moxifloxacin	Levofloxacin	Ciprofloxacin (Bayer)*	Ciprofloxacin (PAR)	Ciprofloxacin (Ivax)
$1.35/tab (all strengths)	$1.55/tablet (all strengths)	$4.39/250 mg $5.06/500 mg $5.50/750 mg	$0.19/tab (all strengths) $0.40/tab XR	$0.28/250 mg $0.34/500 mg $0.40/750 mg	$0.06/250 mg $0.095/500 mg $0.12/750 mg

*NOTE: Bayer's Cipro prices are only available through direct purchase, not from Prime Vendors (PVs). Prices for Cipro similar to the direct prices from Bayer will be available at PVs in the near future**.** Ciprofloxacin (PAR) prices are based on commercial pricing. Ciprofloxacin (Ivax) are July 2004 FSS prices. Prices for gatifloxacin, moxifloxacin and levofloxacin are based on the most current contract, incentive agreement, and FSS prices, respectively, effective as of July 2004.

Ciprofloxacin lacks good gram-positive coverage, so gatifloxacin is still the preferred fluoroquinolone for the treatment of community acquired pneumonia (CAP) and sinusitis. The gatifloxacin contract allows ciprofloxacin to be on formularies for the treatment of conditions other than CAP or sinusitis. Ciprofloxacin is a cost effective alternative to other fluoroquinolones for treating susceptible infections.

COMMITTEE ACTION: The Committee recommended (17 for, 0 opposed, 1 abstained) addition of ciprofloxacin to the BCF, because it is a cost-effective alternative to other fluoroquinolones for treating susceptible infections.

C. *Lamivudine/Zidovudine (Combivir)*: An MTF provider requested the addition of Combivir (300mg zidovudine plus 150mg lamivudine given BID) to the BCF for HIV post-exposure prophylaxis (PEP). There is currently no medication on the BCF to fulfill the OSHA requirement for PEP. U.S. Public Health Service guidelines for PEP are available on the CDC website at www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm. Lamivudine and zidovudine are identified in the U.S. Public Health Service guidelines as an option for initial PEP prophylaxis. Some committee members expressed the opinion that this issue was already covered by the OSHA requirement and that medications for PEP prophylaxis should not be specified on the BCF, because they are not a primary care issue.

COMMITTEE ACTION: The Committee recommended (15 for, 1 opposed, 1 abstained, 1 absent from the room) to not add Combivir to the BCF. The Committee reminds MTFs of the requirement to have medications for PEP readily available for their facility healthcare workers in the event of blood borne exposure.

D. *Erythromycin/Sulfisoxazole (Pediazole):* An MTF provider requested removal of erythromycin ethylsuccinate / sulfisoxazole oral suspension (Pediazole) from the BCF. Erythromycin ethylsuccinate / sulfisoxazole is indicated for the treatment of acute otitis media caused by susceptible strains of *Haemophilus influenzae* in children.

The May 2004 guideline from the Subcommittee on Management of Acute Otitis Media (sponsored by the American Academy of Pediatrics and the American Academy of Family Physicians) does not include erythromycin ethylsuccinate / sulfisoxazole. MTF utilization of erythromycin ethylsuccinate / sulfisoxazole is extremely low, about 400 prescriptions per month. Provider responses support the removal of erythromycin ethylsuccinate / sulfisoxazole from the BCF.

COMMITTEE ACTION: The Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent from the room) to remove erythromycin ethylsuccinate / sulfisoxazole from the BCF, due to increasing microbial resistance, absence of erythromycin ethylsuccinate / sulfisoxazole from current guidelines for acute otitis media, and low utilization at MTFs.

E. *Ramipril (Altace):* Ramipril (Altace) has been priced at $0.12 per capsule for the past few years under a voluntary price reduction from Monarch. Monarch recently renegotiated the FSS price for ramipril and discontinued the voluntary price reduction. The FSS price for ramipril is now $0.52-$0.65 / capsule. The two other ACE inhibitors on the BCF are lisinopril ($0.04 to $0.18 per dose) and captopril ($0.01 to $0.05 per dose).

COMMITTEE ACTION: The Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent from the room) to remove ramipril from the BCF because it is now significantly less cost effective than the other ACE inhibitors on the BCF.

8. ANGIOTENSIN RECEPTOR BLOCKERS (ARBs)

Merck submitted a "pre-award" GAO protest of the blanket purchase agreement (BPA) request for price quotes that the Defense Supply Center Philadelphia (DSCP) issued to companies that market ARBs. DSCP decided to cancel the BPA request for price quotes. The Committee intends to evaluate the relative clinical effectiveness and relative cost effectiveness of the ARBs to make recommendations for the Uniform Formulary and BCF at a future meeting.

9. PROTON PUMP INHIBITORS (PPIs)

The Committee reviewed clinical information, and concluded that one or more proton pump inhibitors (PPIs) could potentially be classified as non-formulary on the Uniform Formulary if there are differences in the relative cost effectiveness of the PPIs. The committee intends to evaluate the relative clinical effectiveness and relative cost effectiveness of the PPIs to make recommendations for the Uniform Formulary and BCF at a future meeting.

10. NEW DRUGS

A. *Cinacalcet tablets (Sensipar)* were approved by the FDA in March 2004. Cinacalcet is a calcimimetic and is approved for treating secondary hyperparathyroidism (PTH) in dialysis patients with chronic kidney disease. It is also designated as an orphan drug for treating hypercalcemia associated with parathyroid carcinoma. Cinacalcet increases sensitivity of the calcium-sensing receptor on the PTH gland to extracellular calcium, directly reducing PTH levels, and accordingly reducing serum calcium levels. Serum concentrations of ionized PTH, calcium, phosphorus, and calcium/phosphorus double product normalized in 40% of dialysis patients receiving cinacalcet vs. 5% with placebo ($p = 0.001$). Patients must be monitored for development of hypocalcemia and resultant increased seizure risk.

   COMMITTEE ACTION: The Committee voted (17 for, 0 opposed, 1 abstained) to add cinacalcet to the TMOP formulary without requirements for prior authorization or quantity limits, but not to add it to the BCF.

B. *Sertaconazole 2% cream (Ertaczo)* is a topical antifungal of the azole class, similar to clotrimazole and miconazole. Sertaconazole was approved in December 2003 for treating interdigital tinea pedis in immunocompetent patients older than 12 years of age. Other topical antifungals have additional indications to include tinea cruris, tinea corporis, cutaneous candidiasis, and tinea versicolor. The two clinical trials used for FDA approval compared sertaconazole with a vehicle control, and showed significant improvements in complete cure rates (13.1% vs. 3.3% in study one and 27.3% vs. 4.9% in study two).

   COMMITTEE ACTION: The Committee voted (17 for, 0 opposed, 1 abstained) to add sertaconazole to the TMOP formulary without requirements for prior authorization or quantity limits, but not to add it to the BCF. Since 13 topical antifungals are available in the U.S., the Committee intends to evaluate topical antifungals to make recommendations for the Uniform Formulary and BCF at a future meeting.

11. ENFUVIRTIDE (FUZEON) INJECTION

Enfuvirtide (Fuzeon) is an injectable medication indicated in combination with other antiretroviral agents to treat HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. The injections are given subcutaneously twice daily and may be self-administered, although the first injection should be performed under the supervision of a qualified healthcare provider. As of April 26, 2004, enfuvirtide was removed from the restricted distribution program that had previously precluded it from being dispensed by the TMOP.

COMMITTEE ACTION: The Committee voted (16 for, 1 opposed, 1 abstained) to add enfuvirtide to the TMOP Covered Injectables List with quantity limit of 1 kit (30-days supply) in the retail network and 2 kits (60-day supply) in the TMOP. The quantity limits are intended to minimize potential wastage of a medication that has a current FSS price of $1,259.38/kit.

12. PRIOR AUTHORIZATIONS

A. *Current Prior Authorizations*: Prior authorizations (PAs) are currently performed in the TMOP and TRRx network pharmacies for:

- Phosphodiesterase-5 (PDE-5) inhibitors (sildenafil, tadalafil, vardenafil)
- Biologic agents for rheumatoid arthritis, psoriasis, or related conditions (etanercept, adalimumab, anakinra, efalizumab)
- Antifungals for onychomycosis (ciclopirox topical solution, itraconazole capsules, terbinafine tablets)
- Fertility agents (injectable gonadotropins)
  - Human growth hormone (somatropin, somatrem)

The Committee reviewed the background, rationale, and criteria for the prior authorizations, which are provided in Appendix A.

COMMITTEE ACTION: The Committee chose to make no recommendation (16 for, 0 opposed, 1 abstained, 1 absent from the room) to change prior authorizations with the existing criteria for the following:

- Adalimumab (Humira®)
- Anakinra (Kineret®)
- Efalizumab (Raptiva®)
  - Antifungals for onychomycosis
  - Growth hormone
  - Injectable gonadotropins

COMMITTEE ACTION: The Committee chose to make no recommendation (16 for, 0 against, 1 abstained, 1 absent from the room) to change the prior authorization of etanercept, except for adding an additional criterion that covers a new FDA-approved indication for the treatment of adult patients (≥18 years of age) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. The Committee decided not to include an age limitation in the PA criteria for etanercept since the medication has clinical trial evidence supporting safety in pediatric patients and an

FDA-approved indication in this age group (for juvenile rheumatoid arthritis). The previous criteria and the revised criteria are included in Appendix A.

B. *PDE-5 Inhibitor PA*: Health Affairs Policy 98-040, Practice Guidelines for the Evaluation of Patients Requesting Sildenafil (Viagra) for the Treatment of Male Impotence, which applies to all PDE-5 inhibitors, imposes prior authorization criteria on PDE-5 inhibitors. TRICARE covers the treatment of erectile dysfunction of organic etiology but not erectile dysfunction that is solely due to psychogenic causes. The PA for PDE-5 inhibitors is primarily based on this coverage issue. As males age, erectile dysfunction is increasingly likely to be at least partially due to organic causes. The efficiency of the PA for PDE-5 inhibitors could be improved by targeting the prior authorization process at the subset of patients who are most likely to have erectile dysfunction of psychogenic etiology (i.e., patients under the age of 50). The existing PDE-5 inhibitor PA criteria also deny coverage to patients who are also receiving nitrates, a well-known, potentially severe drug interaction. The Committee noted that since the policy was first issued, the Pharmacy Data Transaction Service (PDTS) now provides real-time, point-of-care alerts concerning drug interactions between PDE-5 inhibitors and nitrates, therefore, it would not be necessary to include this drug interaction in the PA criteria.

COMMITTEE ACTION: The Committee agreed to have the Chair of the Committee prepare a recommendation to the ASD(HA) to modify or rescind the policy and approve a prior authorization recommended by the Committee instead. If the ASD(HA) concurs in the recommendation to modify or rescind the Health Affairs Policy, the Committee recommended (16 for, 0 against, 1 abstained, 1 absent from the room) to continue prior authorization of PDE-5 inhibitors with modifications designed to improve the efficiency of the prior authorization process:

- Allowing male patients 50 years of age or older to receive PDE-5 inhibitors without going through the PA process, and
- Eliminating the drug interaction with nitrates from the PA criteria.

Since at least 85% of patients obtaining PDE-5 inhibitors through the retail network or mail order are ≥ 50 years of age, this would greatly decrease the administrative costs of performing the PA, while reducing the paperwork required on the part of beneficiaries and providers. The established quantity limits would continue to apply (no more than 6 per 30 days of any combination of PDE-5 inhibitors at retail network pharmacies or 18 per 90 days of any combination of PDE-5 inhibitors at mail order).

13. QUANTITY LIMITS

A. *Etanercept Quantity Limits*: The FDA approval of etanercept for the treatment of psoriasis necessitates a change in the quantity limits, because the recommended adult dosing of etanercept for psoriasis is higher than for other indications for the first 3 months of therapy.

COMMITTEE ACTION: The Committee voted (16 for, 0 opposed, 1 abstained, 1 absent from the room) to set the etanercept quantity limit at a six-week supply in mail order and a four-week supply in retail network pharmacies, with the number of vials dispensed based on the instructions for use on the prescription. The maximum days supply

dispensed at any one time in retail network pharmacies would continue to be limited to four weeks.

B. *Current Quantity Limits*: The Committee reviewed the existing quantity limits.

COMMITTEE ACTION: The Committee reviewed the quantity limits currently in place and voted (16 for, 0 opposed, 1 abstained, 1 absent from the room) that they be continued without change. The Committee members plan to review the list of quantity limits in greater detail and will bring comments to a future meeting. A list of quantity limits is available in Appendix B.

14. ADJOURNMENT

The meeting adjourned at 1730 hours. The date of the next meeting has not been determined.

Patricia Buss

PATRICIA L. BUSS
CAPT, MC, USN
Chair

List of Appendices

Appendix A – Prior Authorization Criteria in the TRICARE Mail Order Pharmacy and TRICARE Retail Pharmacy Programs

Background

Prior authorizations (PAs) have been a part of the mail order program since 1999. In the retail network, Managed Care Support Contractors (MCSCs) have generally used the same PAs and criteria approved by the DoD P&T Committee for the TMOP. Under 32 CFR 199.21(k), prior authorizations now apply across all points of service. PA Forms and criteria may be found at: www.pec.ha.osd.mil/PA_Criteria_and_forms.htm

Prior Authorization Medications

Phosphodiesterase-5 (PDE-5) Inhibitors – sildenafil (Viagra®), tadalafil (Cialis®), vardenafil (Levitra®)

A PA and quantity limit for sildenafil was put into place in mail order in Aug 1999, based on Health Affairs Policy 98-040, Practice Guidelines for the Evaluation of Patients Requesting Sildenafil (Viagra™) for the Treatment of Male Impotence, released 6 Aug 1998. Vardenafil was included in the PA program in Nov 2003 and tadalafil in Feb 2004. TMA has determined that provisions of the sildenafil policy apply to these new PDE-5 inhibitors.

Among other provisions, the policy requires that

- PDE-5 inhibitors will not be a formulary item for Military Treatment Facilities (MTFs), National Mail Order Pharmacy (NMOP, the previous mail order program), and for Managed Care Support Contractor retail networks (now the TRICARE Retail Pharmacy program).
- Physicians treating patients with erectile dysfunction may special order PDE-5 inhibitors when the results of their evaluation indicate the medication as the most optimal regimen for the patient. MTFs will not fill special orders from non-network civilian providers unless there is proof of compliance with the prescribing guidance contained in the Health Affairs Policy 98-040.
- Only 6 tablets may be dispensed per month. "Lost", "stolen", or "destroyed" tablets will not be replaced. Prescriptions filled through Standard CHAMPUS will be reimbursed for only 6 tablets per month and must be accompanied by proof of compliance with clinical guidelines.

The accompanying prescribing guidelines include establishing that the erectile dysfunction is organic in origin.

The PDE-5 inhibitors are currently non-formulary at TMOP, but available if PA criteria are met. The quantity limit of 6 per 30 days has been implemented across the class – that is, a patient may obtain only 6 tablets of any combination of these medications per 30 days in the retail network, and only 18 tablets of any combination of these medications per 90 days in mail order.

Existing PA Criteria for PDE-5 Inhibitors for the Treatment of Erectile Dysfunction

- Coverage not provided for female sexual dysfunction, males under 18 years of age, patients receiving any form of nitrate therapy, or psychogenic erectile dysfunction.
- Coverage provided for organic erectile dysfunction, erectile dysfunction with an organic component, or drug-induced erectile dysfunction where the causative drug cannot be altered or discontinued. Approval is good for 12 months.
- *Note:* PDE-5 inhibitors are subject to a cumulative quantity limit of 6 tablets per 30 days in the retail network or 18 tablets per 90 days in the TMOP.

Revised PA Criteria for PDE-5 Inhibitors for the Treatment of Erectile Dysfunction if the ASD(HA) concurs in the modification or rescission of HA Policy 98-040

- Coverage not provided for female sexual dysfunction, males under 18 years of age, or psychogenic erectile dysfunction.
- Coverage provided for organic erectile dysfunction, erectile dysfunction with an organic component, or drug-induced erectile dysfunction where the causative drug cannot be altered or discontinued. Approval is good for 12 months.
- *Note:* Prior authorization is required for coverage of PDE-5 inhibitors for erectile dysfunction for male patients 18 to 49 years of age. Prior authorization is not required for male patients 50 years of age and older.
- *Note:* PDE-5 inhibitors are subject to a cumulative quantity limit of 6 tablets per 30 days in the retail network or 18 tablets per 90 days in the TMOP.

Etanercept (Enbrel®)

The PA for etanercept was approved by the DoD P&T Committee in May 1999 and implemented in Aug 1999. The rationale for the PA was high cost and potential for inappropriate use.

A quantity limit of 8 vials (a 4-week supply) was initially set for the mail order program, then changed to a 6-week supply (12 vials) in Aug 1999 to allow time for refills to be ordered and received by patients. A quantity limit of 8 vials (a four-week supply) was established in retail.

Existing PA Criteria for Etanercept

- Coverage provided for the treatment of
    - Moderately to severely active rheumatoid arthritis
    - Active psoriatic arthritis
    - Active ankylosing spondylitis
    - 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).
- *Note:* Etanercept is subject to a quantity limit of 8 vials (four-week supply) in retail and 12 vials (six-week supply) in mail order.

Note: Criteria for etanercept and the other biologics have primarily been based on the FDA indications, which closely follow the available clinical evidence for these medications.

Revised PA Criteria for Etanercept

- Coverage provided for the treatment of:
    - Moderately to severely active rheumatoid arthritis
    - Active psoriatic arthritis
    - Active ankylosing spondylitis
    - Juvenile rheumatoid arthritis when the patient has an inadequate response to at least one DMARD
    - Chronic moderate to severe plaque psoriasis when the patient has tried and failed traditional therapy, such as phototherapy (e.g., UVB, PUVA) or systemic therapy (e.g., methotrexate, acitretin or cyclosporine) OR is not a candidate for phototherapy or systemic therapy
- Coverage NOT provided for concomitant use with adalimumab (Humira), anakinra (Kineret), or infliximab (Remicade).
- *Note:* Etanercept is subject to a quantity limit of a four-week supply in retail and a six-week supply in mail order (based on instructions for use on the prescription).

Adalimumab (Humira®)

A PA for adalimumab was implemented in mail order in March 2003. The rationale for the PA was high cost, potential for inappropriate use, and the existence of a PA for similar agents.

PA Criteria for Adalimumab

- 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).
- *Note:* Adalimumab is subject to a quantity limit of a 4-week supply in retail and a 6-week supply in mail order.

Anakinra (Kineret®)

History – A PA for anakinra was implemented in mail order in Feb 2002. The rationale for the PA was high cost, potential for inappropriate use, and the existence of a PA for a similar agent.

A quantity limit of a 6-week supply (6 packages of 7 syringes) at mail order was changed to a 8-week supply (2 packages of 28 syringes) at the April 2004 DoD P&T Committee meeting because of a packaging change by the manufacturer. The quantity limit is 28 syringes (1 package) in retail.

PA Criteria for Anakinra

- 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).
- *Note:* Anakinra is subject to a quantity limit of 28 syringes (4-week supply) in retail and 56 syringes (8-week supply) in mail order.

Efalizumab (Raptiva®)

A PA for efalizumab was implemented in mail order in Feb 2004. The rationale for the PA was high cost, potential for inappropriate use, and the existence of a PA for similar agents.

PA Criteria for Efalizumab

- Coverage provided for adults (age ≥ 18 years) who meet all the following criteria:
    - Chronic moderate to severe plaque psoriasis, defined as a minimum body surface area involvement of 10% or a body surface area involvement of less than 10%, but in critical areas (e.g., palms, soles, or face) and interfering with day-to-day activities;

    AND

    - Have tried and failed traditional therapy, such as phototherapy (e.g., UVB, PUVA) or systemic therapy (e.g., methotrexate, acitretin, or cyclosporine), OR are not candidates for phototherapy or systemic therapy;

    AND

    - A dermatologist recommends treatment with efalizumab.
- Coverage NOT provided for immunocompromised patients or those receiving immunosuppressive agents, children (age < 18 years), or patients with psoriatic arthritis without plaque psoriasis.
- *Note:* No special quantity limits

Injectable gonadotropins (fertility agents)- follitropin alfa, follitropin beta, menotropins, urofollitropin (Brand names include: Gonal-F®, Follistim®, Humegon®, Pergonal®, Repronex®, Fertinex®, Bravelle®)

The Code of Federal Regulations (CFR) excludes coverage by TRICARE of services and supplies used in conjunction with noncoital reproductive technologies (e.g., *in vitro* fertilization). Compliance with the CFR in regard to fertility agents dispensed by the National Mail Order Pharmacy (NMOP) program was discussed by the DoD P&T Committee as early as Feb 1999, although at that time the NMOP contract did not provide for a prior authorization mechanism. Managed Care Support Contractors were responsible for implementing this policy in their networks, but the NMOP lacked any mechanism to ascertain whether the medications were being used for coital or noncoital reproduction. In Feb 2000, the Committee concluded that a prior authorization should be established in order to comply with TRICARE policy.

PA Criteria for Injectable Gonadotropins

- Coverage is NOT provided if the fertility agent is being prescribed for use in conjunction with a noncoital reproductive technology, including but not limited to artificial insemination, in vitro fertilization, or gamete intrafallopian transfer.
- *Note*: the PA form makes allowances for male patients being treated with injectable gonadotropins (e.g., for induction of spermatogenesis).
- *Note:* Quantity limits (3600 IU per 30 days, with no refills) are also in effect for all the injectable gonadotropins. The "no refills" provision means that patients must submit a new prescription for each cycle of therapy, although the prior authorization is good for a year.

Antifungals for onychomycosis – ciclopirox topical solution (Penlac Nail Lacquer®), terbinafine tablets (Lamisil®), and itraconazole capsules (Sporanox®)

The PA was implemented in mail order in July 2000 for terbinafine and itraconazole, with ciclopirox topical solution added in May 2001.

Rationale for PA

Because of the potential side effects, cost, and requirements for liver function testing associated with systemic antifungal therapy for onychomycosis, verifying the presence of a fungal infection prior to treatment is good clinical practice. A study published in CUTIS (1999;64:407-10) showed that as many as 35% of patients empirically diagnosed with onychomycosis did not have a fungal infection. The FDA recommends 1) definitive diagnosis of a fungal infection, 2) pretreatment lab tests, and 3) avoidance of these drugs in patients with acute or chronic liver disease. Although ciclopirox is applied topically, the prolonged course of therapy (up to 48 weeks) supports verification of an active fungal infection prior to beginning treatment.

Because it takes time for the nail to grow out following a course of systemic treatment for onychomycosis, re-treatment with systemic agents prior to 6 months is typically not necessary. *Each course of treatment with terbinafine, itraconazole, or ciclopirox for the treatment of onychomycosis requires confirmation of an active fungal infection and a separate prior authorization form.*

Criteria for Antifungals for Onychomycosis

- Coverage NOT provided for treatment of onychomycosis not confirmed by a microbiological or histological test [KOH preparation, periodic acid Schiff stain (PAS stain), or culture].
- Coverage IS provided for treatment of onychomycosis confirmed by a microbiological or histological test [KOH preparation, periodic acid Schiff stain (PAS stain), or culture].
- For terbinafine and itraconazole, coverage is approved for 6 weeks for treatment of fingernail onychomycosis and 12 weeks for treatment of toenail onychomycosis. For ciclopirox, coverage is approved for up to 48 weeks for both fingernail and toenail onychomycosis.

- Each course of treatment for onychomycosis requires confirmation of an active fungal infection and a separate prior authorization form.
- For treatment of fungal infection other than onychomycosis, coverage is approved for 12 months.
- *Note:* the PA does not apply to other formulations of ciclopirox (e.g., cream, gel, topical suspension, or shampoo) or itraconazole (e.g., injection or oral solution), since these formulations are not typically used for the treatment of onychomycosis.

Growth hormone (somatropin & somatrem)
(Brand names include: Humatrope®, Genotropin®, Norditropin®, Norditropin Depot®, Saizen®, Serostim®, Protropin®, Tev-Tropin®, Nutropin®, Nutropin AQ®, and Zorbtive®)

The DoD P&T Committee evaluated a PA for growth hormone in Feb 2004, prompted by FDA approval of a growth hormone product (Humatrope) for the treatment of non-growth hormone dependent short stature, also known as idiopathic short stature (ISS). Treatment of ISS is not considered medically necessary, and thus is not covered by TRICARE. In April 2004, the Committee approved PA criteria (developed with the assistance of a panel of MTF pediatric and adult endocrinologists) for the use of growth hormone in adults and in children. The rationale for the PA was potential for inappropriate use, TRICARE coverage rules.

A PA for growth hormone products was implemented in mail order and the retail network as of 1 June 2004, with the implementation of the TRRx program. Some or all MCSCs may already have PAs in place for growth hormone. The growth hormone PA is currently in place for new patient starts only (patients presenting a new growth hormone prescription at a retail network pharmacy or the TMOP for whom there was no prescription fill for growth hormone in the preceding 180 days). The DoD P&T Committee recommended that patients who are currently receiving growth hormone in the TMOP and retail network (based on use within the last 180 days) should be required to fulfill PA requirements within 180 days after being notified about the existence of the PA.

PA Criteria for Growth Hormone

Coverage provided for:

- Growth hormone deficiency in children and adults as a result of pituitary disease, hypothalamic disease, surgery or radiation therapy
- Chronic renal insufficiency before renal transplantation with associated short stature
- Other known renal indications: autorecessive polycystic kidney disease, cystinosis and hypophosphatemic rickets in the pediatric population
- Short stature in patients with Turner Syndrome or Prader-Willi syndrome
- Infants born small for gestational age that have not reached age appropriate height by 24 months of age
- Human immunodeficiency virus-associated wasting in adults

Coverage NOT provided for:

- Idiopathic short stature
- Depression
- Aging
- Obesity

Appendix B - Quantity Limits in the TRICARE Mail Order Pharmacy and TRICARE Retail Pharmacy Programs

The Department of Defense Pharmacy and Therapeutics (P&T) Committee has implemented quantity limits on specific medications in the TRICARE Mail Order Pharmacy (TMOP) as well as the retail network pharmacies, based on Food and Drug Administration (FDA) recommendations for dosing. Quantity limits are a common practice in commercial health plans to help ensure beneficiaries receive the proper dose and recommended duration of therapy for their disease state to achieve the optimal outcome of their treated condition, while minimizing potential for adverse events, inappropriate therapy, and wastage.

Special Note about the TRICARE Retail Pharmacy (TRRx) Program: As of June 1, 2004, responsibility for DoD's TRICARE retail pharmacy network passed to a single contractor, Express-Scripts, Inc. (ESI), consolidating all of DoD's regional retail pharmacy contracts into a single national contract. The retail pharmacy quantity limits listed on this page continue to apply under the new contract.

Days Supply of Medication

The TMOP generally dispenses no more than a 90-day supply of medication.

Retail pharmacies generally dispense no more than a 30-day supply of medication. If a patient desires to obtain more than a 30-day supply at a retail pharmacy, he/she must pay an additional cost share for each additional 30-day supply increment, up to a 90-day supply (3 cost shares).

Quantity Limits

The quantity of medication dispensed to a patient is limited to **the lesser of**: (1) the amount of medication expected to be used in a 90-day period (TMOP) or a 30-day period (retail pharmacy network) based on the directions for use on the prescription, or (2) the quantity limit identified in the table below. The amount of medication obtained by a patient from other Military Health System pharmacy points of service will be taken into account in the application of these quantity limits.

Refills

If the amount dispensed is reduced because of an established quantity limit, refills will be authorized unless the item is designated “no refills allowed” in the table below. For example, the TMOP quantity limit for adalimumab (Humira) is six 40-mg prefilled syringes per six-week period. Therefore, if the TMOP receives a prescription written for 18 prefilled syringes of 40 mg adalimumab (Humira) injection with no refills, the prescription will be filled with 6 syringes, the patient will be charged the applicable cost share, and two refills (of 6 syringes each) will be authorized. The patient will be authorized to obtain a refill (for another 6 syringes) 6 weeks after the original prescription was filled, and will be charged the applicable cost share.

Note: Drugs are listed by generic name. Brand name(s) are supplied in parentheses for convenience only. Quantity limits apply to both brand name and generic versions of listed medications.

Quantity limits developed by the DoD P&T Committee may be superceded by applicable federal and/or state laws.

Drug	TMOP Limits	Retail Pharmacy Limits
Antibiotics		
Azithromycin (Zithromax) 250mg tablets	10 tablets per 30 days	10 tablets per 30 days
Azithromycin (Zithromax) 600mg tablets	24 tablets per 90 days	8 tablets per 30 days
Antiemetics		
Aprepitant (Emend) capsules in convenience packs (one 125 mg capsule and two 80 mg capsules)	6 packs per 90 days	2 packs per 30 days
Aprepitant (Emend) 80 mg capsules	12 capsules per 90 days	4 capsules per 30 days
Aprepitant (Emend) 125 mg capsules	6 capsules per 90 days	2 capsules per 30 days
Granisetron (Kytril) 1mg tablets	24 tablets per 90 days	8 tablets per 30 days
Ondansetron (Zofran) (Zofran; Zofran ODT) 4 and 8 mg tablets and orally disintegrating tablets	45 tablets per 90 days	15 tablets per 30 days
Dolasetron (Anzemet) 50 and 100 mg tablets	15 tablets per 90 days	5 tablets per 30 days
Antifungals		
Fluconazole (Diflucan) 150 mg oral tablets	3 tablets per 90 days	1 Tablet per 30 days
Antimigraine Drugs		
Almotriptan (Axert) 6.25 and 12.5 mg tablets	36 tablets per 90 days	12 tablets per 30 days
Dihydroergotamine (Migranal) 1 mL ampules for nasal spray	90 ampules per 90 days	30 ampules per 30 days
Dihydroergotamine 1 mg/ml injection	90 ampules per 90 days (9 boxes of 10 ampules)	30 ampules per 30 days (3 boxes)
Eletriptan (Relpax)	36 tablets per 90 days	12 tablets per 30 days
Frovatriptan (Frova) 2.5 mg tablets	27 tablets per 90 days	9 tablets per 30 days
Naratriptan (Amerge) 1 and 2.5 mg tablets	27 tablets per 90 days	9 tablets per 30 days
Rizatriptan (Maxalt; Maxalt MLT) 5 and 10 mg tablets and orally-disintegrating tablets	36 tablets per 90 days	12 tablets per 30 days
Sumatriptan (Imitrex) 25, 50 mg tablets	54 tablets per 90 days	18 tablets per 30 days
Sumatriptan (Imitrex) 100 mg tablets	27 tablets per 90 days	9 tablets per 30 days
Sumatriptan (Imitrex) injection 6mg/0.5mL autoinjector (syringes)	24 syringes per 90 days	8 syringes per 30 days
Sumatriptan (Imitrex) injection 6mg/0.5mL vials	24 vials per 90 days	8 vials per 30 days
Sumatriptan (Imitrex) 5mg/100 µL and 20 mg/100 µL nasal spray	18 unit dose nasal sprays per 90 days	6 unit dose nasal sprays per 30 days
Zolmitriptan nasal spray 5 mg/100 µL nasal spray	36 unit dose nasal sprays per 90 days	12 unit dose nasal sprays per 30 days
Zolmitriptan (Zomig; Zomig-ZMT) 2.5 and 5 mg tablets and orally-disintegrating tablets	24 tablets per 90 days	8 tablets per 30 days

Drug	TMOP Limits	Retail Pharmacy Limits
Controlled Substances		
Schedule II drugs	NO refills per federal law; state law may impose additional restrictions	
Schedule III and IV drugs	Per federal law, prescriptions may not be filled or refilled for more than 6 months after the date of the prescription or refilled more than 5 times. State law may impose additional restrictions.	
Testosterone buccal system mucoadhesive (Striant)	180 systems per 90 days (3 cartons of 60 systems)	60 systems per 30 days (1 carton of 60 systems)
Fertility Agents		
Follitroprin alpha for injection (Gonal-F) 37.5 IU ampules	96 ampules (3,600 IU) per 30 days - no refills	96 ampules (3,600 IU) per 30 days - no refills
Follitroprin alpha for injection (Gonal-F) 75 IU ampules	48 ampules (3,600 IU) per 30 days - no refills	48 ampules (3,600 IU) per 30 days - no refills
Follitroprin alpha for injection (Gonal-F) 150 IU ampules	24 ampules (3,600 IU) per 30 days - no refills	24 ampules (3,600 IU) per 30 days - no refills
Follitroprin alpha for injection (Gonal-F) 600 IU/mL kit	6 kits (3,600 IU) per 30 days - no refills	6 kits (3,600 IU) per 30 days - no refills
Follitroprin beta for injection (Follistim) 75 IU vials	48 vials (3,600) IU per 30 days - no refills	48 vials (3,600 IU) per 30 days - no refills
Follitropin beta for injection (Follistim AQ) 300 IU vials	12 cartridges (3,600 IU) per 30 days - no refills	12 cartridges (3,600 IU) per 30 days - no refills
Follitropin beta for injection (Follistim AQ) 600 IU vials	6 cartridges (3,600 IU) per 30 days - no refills	6 cartridges (3,600 IU) per 30 days - no refills
Menotropins for injection (Humegon) 75 IU ampules	48 ampules (3,600 IU) per 30 days - no refills	48 ampules (3,600 IU) per 30 days - no refills
Menotropins for injection (Humegon) 150 IU ampules	24 ampules (3,600 IU) per 30 days - no refills	24 ampules (3,600 IU) per 30 days - no refills
Menotropins for injection (Pergonal) 75 IU ampules	48 ampules (3,600 IU) per 30 days - no refills	48 ampules (3,600 IU) per 30 days - no refills
Menotropins for injection (Pergonal) 150 IU ampules	24 ampules (3,600 IU) per 30 days - no refills	24 ampules (3,600 IU) per 30 days - no refills
Menotropins for injection (Repronex) 75 IU vials	48 vials (3,600) IU per 30 days - no refills	48 vials (3,600 IU) per 30 days - no refills
Urofollitropin for injection (Fertinex) 75 IU ampules	48 ampules (3,600 IU) per 30 days - no refills	48 ampules (3,600 IU) per 30 days - no refills
Urofollitropin for injection (Fertinex) 150 IU ampules	24 ampules (3,600 IU) per 30 days - no refills	24 ampules (3,600 IU) per 30 days - no refills
Urofollitropin for injection (Bravelle) 75 IU ampules	48 ampules (3,600 IU) per 30 days - no refills	48 ampules (3,600 IU) per 30 days - no refills
Impotence Agents		
Drug	TMOP Limits	Retail Pharmacy Limits
Alprostadil injection (Caverject, Edex) 5, 10, 20, and 40 mcg syringes (kits) and vials	18 syringes or vials per 90 days	6 syringes or vials per 30 days
Alprostadil intraurethral pellet (Muse) 125, 250, 500, and 1000 mcg pellets	18 pellets per 90 days	6 pellets per 30 days

Drug	TMOP Limits	Retail Pharmacy Limits
Oral phosphodiesterase-5 (PDE-5) inhibitors Sildenafil (Viagra) 25-, 50-, and 100-mg tablets Tadalafil (Cialis) 5-, 10-, and 20-mg tablets Vardenafil (Levitra) 2.5-, 5-, 10-, and 20-mg tablets	18 tablets per 90 days Quantity limit applies collectively to all strengths of sildenafil, tadalafil, and vardenafil. No more than 18 tablets of any combination of these medications per 90-day supply will be dispensed in the TMOP.	6 tablets per 30 days Quantity limit applies collectively to all strengths of sildenafil, tadalafil, and vardenafil.No more than 6 tablets per 30-day supply of any combination of these medications will be dispensed in the retail network
Miscellaneous		
All syringes & needles	600 syringes and/or needles per 90 days	200 syringes and/or needles per 30 days
Adalimumab (Humira) 40 mg prefilled syringes	6 syringes per 42 days (6 weeks) (3 packages of 2 syringes)	4 syringes per 28 days (4 weeks) (2 packages of 6 syringes)
Anakinra (Kineret) 100 mg/0.67 mL single use prefilled syringes	56 syringes per 56 days (8 weeks) (2 packages of 28 syringes)	28 syringes per 28 days (4 weeks) (1 package of 28 syringes)
Glucose test strips (includes blood and urine test strips)	600 strips per 90 days	200 strips per 30 days
Butorphanol (Stadol) metered dose nasal spray 2.5 mL bottles	15mL per 45 days (6 bottles)	10mL per 30 days (4 bottles)
Dornase alpha (Pulmozyme) inhalant solution 2.5 mL ampule	900 mL per 90 days (360 ampules)	300mL per 30 days (120 ampules)
Enfuvirtide (Fuzeon) injection kit	2 kits (60-day supply)	1 kit (30-day supply)
Etanercept (Enbrel) injection 25mg vial	6 weeks supply based on instructions for use on the prescription	4 weeks supply based on instructions for use on the prescription
Fluoxetine 90 mg capsule (Prozac Weekly)	12 capsules per 90 days (3 blister packs)	4 capsules per 30 days (1 blister pack)
Gefitinib tablets (Iressa)	45 tablets per 45 days	30 tablets per 30 days
Imitinab capsules (Gleevec)	45 days supply	general rule applies (30 days supply)
Ketorolac (Toradol) 10mg tablets	20 tablets (5 day supply) per 30 days	20 tablets (5 day supply) per 30 days
Ketorolac (Toradol) injection IV or IM 15mg/mL - 1mL TUBEX® or vial	Not available at TMOP	40 TUBEX® units or vials per 30 days (600 mg - 5 day supply)
Ketorolac (Toradol) injection IV or IM 30mg/mL 1mL TUBEX® or vial	Not available at TMOP	20 TUBEX® units or vials per 30 days (600 mg - 5 day supply)
Ketorolac (Toradol) injection IM 30mg/mL 2 mL (60 mg) TUBEX® or vial	Not available at TMOP	10 TUBEX® units or vials per 30 days (600 mg - 5 day supply)
PEG-filgrastim (Neulasta) 6 mg/0.6 mL injection	1.2 mL per 45 days (2 syringes)	0.6 mL per 21 days (1 syringe)
Tramadol (Ultram) 50 mg tablets; tramadol / acetaminophen (Ultracet) 37.5/325 mg tablets	720 tablets per 90 days	240 tablets per 30 days
Nasal Inhalers		
Beclomethasone (Beconase, Vancenase) 42 mcg nasal inhaler	100.8 gm per 90 days (15 6.7-gm inhalers or 6 16.8-gm inhalers)	33.5 gm per 30 days (5 6.7-gm inhalers or 2 16.8-gm inhalers)

Drug	TMOP Limits	Retail Pharmacy Limits
Beclomethasone AQ (Beconase AQ, Vancenase AQ) nasal inhaler 42 mcg	150 gm per 90 days (6 25-gm inhalers)	50 gm per 30 days (2 25-gm inhalers)
Beclomethasone AQ (Vancenase AQ) nasal inhaler 84 mcg	57 gm per 90 days (3 19-gm inhalers)	19 gm per 30 days (1 19-gm inhaler)
Budesonide (Rhinocort) 32mcg nasal inhaler	42 gm per 90 days (6 7-gm inhalers)	14 gm per 30 days (2 7-gm inhalers)
Budesonide AQ (Rhinocort AQ) 32mcg nasal spray	30 mL per 90 days (3 10-mL inhalers)	10 mL per 30 days (1 10-mL inhaler)
Flunisolide (Nasalide) nasal solution 0.025%	225 mL per 90 days (9 25-mL inhalers)	75 mL per 30 days (3 25-mL inhalers)
Fluticasone (Flonase) 0.05% nasal spray	48 gm per 90 days (3 16-gm inhalers)	16 gm per 30 days (1 16-gm inhaler)
Ipratropium bromide (Atrovent) 0.03% and 0.06% nasal spray	90 mL per 90 days (3 30-mL inhalers or 6 15-mL inhalers)	30 mL per 30 days (1 30-mL inhaler or 2 15-mL inhalers)
Mometasone (Nasonex) nasal inhaler 50mcg	51 gm per 90 days (3 17-gm inhalers)	17 gm per 30 days (1 17-gm inhaler)
Triamcinolone AQ (Nasacort AQ) 55mcg nasal spray	99 gm per 90 days (6 16.5-gm inhalers)	33 gm per 30 days (2 16.5-gm inhalers)
Triamcinolone (Nasacort) 55mcg nasal spray	90 gm per 90 days (9 10-gm inhalers)	30 gm per 30 days (3 10-gm inhalers)
Triamcinolone (Tri-nasal) 50 mcg nasal spray	90 mL per 90 days (6 15-mL inhalers)	30 mL per 30 days (2 15-mL inhalers)
Oral Inhalers and Inhalant Solutions		
Albuterol (AccuNeb) inhalant solution 0.63mg/3mL and 1.25mg/3mL	1650mL per 90 days (22 boxes of 25 = 550 nebules)	600 mL per 30 days (8 boxes of 25 = 200 nebules)
Albuterol (Proventil) 0.083% inhalant solution 3 mL	1650 mL per 90 days (22 boxes of 25 = 550 nebules)	600 mL per 30 days (8 boxes of 25 = 200 nebules)
Albuterol (Proventil) 0.5% inhalant solution 20 mL	180 mL (9 bottles) per 90 days	60 mL (3 bottles) per 30 days
Albuterol (Proventil) 90mcg metered dose inhaler	102 gm per 90 days (6 17-gm inhalers)	34 gm per 30 days (2 17-gm inhalers)
Albuterol HFA (Proventil HFA, Ventolin HFA) 90 mcg	108 gm per 90 days (6 18-gm inhalers or 16 6.7-gm inhalers)	36 gm per 30 days (2 18-gm inhalers or 5 6.7-gm inhalers)
Albuterol sulfate 3 mg / ipratropium bromide 0.5 mg per 3 mL inhalent solution (DuoNeb)	1620 mL per 90 days (540 vials)	540 mL per 30 days (180 vials)
Beclomethasone 42 mcg (Beclovent) oral inhaler	160.8 gm per 90 days (24 6.7-gm inhalers or 9 16.8-gm inhalers)	53.6 gm per 30 days (8 6.7-gm inhalers or 3 16.8-gm inhalers)
Beclomethasone 84 mcg (Vanceril DS) oral inhaler	129.6 gm per 90 days (24 5.4-gm inhalers or 9 12.2-gm inhalers)	43.2 gm per 30 days (8 5.4-gm inhalers or 3 12.2-gm inhalers)
Beclomethasone dipropionate HFA 40 mcg inhalation aerosol (QVar)	87.6 gm per 90 days (12 inhalers)	29.2 gm per 30 days (4 inhalers)

Drug	TMOP Limits	Retail Pharmacy Limits
Beclomethasone dipropionate HFA 80 mcg inhalation aerosol (QVar)	43.8 gm per 90 days (6 inhalers)	33.6 gm per 30 days (2 inhalers)
Bitolterol (Tornalate) 0.8% oral inhaler	90 mL per 90 days (6 inhalers)	30 mL per 30 days (2 inhalers)
Bitolterol (Tornalate) inhalant solution 0.2%	720 mL per 90 days (24 30-mL bottles or 12 60-mL bottles)	240 mL per 30 days (8 30-mL bottles or 4 60-mL bottles)
Budesonide (Pulmicort) oral inhaler	6 inhalers per 90 days	2 inhalers per 30 days
Budesonide 0.25 mg Inhalation Suspension (Pulmicort Respules®)	720 mL per 90 days (12 boxes of 30 Respules®)	240 mL per 30 days (4 boxes of 30 Respules®)
Budesonide 0.5 mg Inhalation Suspension (Pulmicort Respules®)	360 mL per 90 days (6 boxes of 30 Respules®)	120 mL per 30 days (2 boxes of 30 Respules®)
Cromolyn sodium (Intal) oral inhaler 800mcg	85.2 gm per 90 days (9 8.1-gm inhalers or 6 14.2 gm inhalers)	28.4 gm per 30 days (3 8.1-gm inhalers or 2 14.2-gm inhalers)
Cromolyn sodium (Intal) nebulizing solution 20 mg/ 2 mL unit dose ampules	1080 mL per 90 days (9 boxes = 540 ampules)	360 mL per 30 days (3 boxes = 180 ampules)
Flunisolide (Aerobid; Aerobid-M) oral inhaler 250 mcg	63 gm per 90 days (9 inhalers)	21 gm per 30 days (3 inhalers)
Fluticasone (Flovent) 44-, 110-, and 200-mcg oral inhalers	94.8 gm per 90 days (12 7.9-gm inhalers or 6 13-gm inhalers)	31.6 gm per 30 days (4 7.9-gm inhalers or 2 13-gm inhalers)
Fluticasone (Flovent) 50-, 100-, and 250 -mcg Rotadisks®	720 doses per 90 days (12 boxes of 60 Rotadisks®)	240 doses per 30 days (4 boxes of 60 Rotadisks®)
Fluticasone / salmeterol (Advair) powder for inhalation 100 mcg/50 mcg; 250 mcg/50 mcg; and 500 mcg/50 mcg	180 doses per 90 days (3 inhalers)	60 doses per 30 days (1 inhaler)
Formoterol fumarate (Foradil) powder for inhalation 12 mcg	180 doses per 90 days (3 inhalers)	60 doses per 30 days (1 inhaler)
Ipratropium (Atrovent) 0.02% inhalant solution (2.5mL unit dose ampules)	1350 mL per 90 days (21 boxes of 25 ampules [525 ampules] or 18 boxes of 30 ampules [540 ampules] or 9 boxes of 60 ampules [540 ampules])	450 mL per 30 days (7 boxes of 25 ampules [175 ampules] or 6 boxes of 30 ampules [180 ampules] or 3 boxes of 60 ampules [180 ampules]
Ipratropium (Atrovent) oral inhaler 18 mcg	89 gm per 90 days (6 14.7-gm inhalers)	30 gm per 30 days (2 14.7-gm inhalers)
Levalbuterol (Xopenex) inhalant solution 0.63/3 mL or 1.25 mg/3mL ampules	1080 mL per 90 days (15 boxes of 24 ampules [360 ampules] or 4 boxes of 96 ampules [384 ampules])	360 mL per 30 days (5 boxes of 24 ampules [120 ampules] or 2 boxes of 96 ampules [192 ampules])
Metaproterenol (Alupent) inhalant solution 0.4% or 0.6% 2.5mL unit dose ampules	1250 mL per 90 days (18 boxes of 25 ampules [450 ampules] or 5 boxes of 100 ampules [500 ampules])	500 mL per 30 days (6 boxes of 25 ampules [150 ampules] or 2 boxes of 100 ampules [200 ampules])
Metaproterenol (Alupent) inhalant solution 5% 10mL	180 mL per 90 days (18 10-mL bottles or 6 30-mL bottles)	60 mL per 30 days (6 10-mL bottles or 2 30-mL bottles)

Drug	TMOP Limits	Retail Pharmacy Limits
Metaproterenol (Alupent) oral inhaler 650mcg	84 gm per 90 days (12 7-gm inhalers or 6 14-gm inhalers)	28 gm per 30 days (4 7-gm inhalers or 2 14-gm inhalers)
Nedocromil (Tilade) oral inhaler	145.8 gm per 90 days (9 16.2-gm inhalers)	48.6 gm per 30 days (3 16.2-gm inhalers)
Pirbuterol (Maxair) oral Autohaler®	42 gm per 90 days (3 14-gm inhalers or 15 2.8-gm inhalers)	14 gm per 30 days (1 14-gm inhaler or 5 2.8-gm inhalers)
Pirbuterol (Maxair) oral inhaler	153.6 gm per 90 days (6 25.6-gm inhalers)	51.2 gm per 30 days (2 25.6-gm inhalers)
Salmeterol (Serevent DISKUS®) 50mcg oral inhalation powder Please note: production of salmeterol metered dose oral inhalers has been discontinued. The salmeterol dry powder inhaler (Serevent Diskus) is now the only formulation available. Click here for additional information.	180 doses (blister packs) per 90 days (3 boxes of 60 blister packs)	60 doses (blister packs) per 30 days (1 box of 60 blister packs)
Tiotropium bromide (Spiriva HandiHaler) inhalation powder	90 capsules for inhalation per 90 days (3 packages of 30 caps)	30 capsules for inhalation per 30 days (1 package of 30 caps)
Triamcinolone (Azmacort) oral inhaler 20gm	120 gm per 90 days (6 20-gm inhalers)	40 gm per 30 days (2 20-gm inhalers)
Topicals		
Imiquimod (Aldara) 5% cream	36 single use packets per 90 days (3 boxes of 12 packets)	12 single use packets per 30 days (1 box of 12 packets)
Calcipotriene (Dovonex) 0.005% cream or ointment (30-, 60-, or 100-gm Tubes)	900 gm per 90 days	300 gm per 30 days
Calcipotriene (Dovonex) 0.005% solution	900 mL per 90 days (15 60-mL bottles)	300 mL per 30 days (5 60-mL bottles)
Alitretinoin (Panretin) 0.1% gel	180 gm per 90 days (3 60-gm tubes)	60 gm per 30 days (1 60-gm tube)
Becaplermin (Regranex) 0.01% gel (2-, 7.5- or 15-gm tubes)	45 gm per 90 days	15 gm per 30 days
Tazarotene (Tazorac) 0.05% or 0.1% gel (30- or 100-gm tubes)	300 gm per 90 days	100 gm per 30 days

Correction - The next meetings of the DoD P&T Committee have been changed to Tuesday 13 July and Wednesday 14 July, 2004.

Department of Defense Pharmacoeconomic Center

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

MCCS-GPE **20 APRIL 2004**

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 20 April 2004 at the DoD Pharmacoeconomic Center, Fort Sam Houston, Texas.

2. VOTING MEMBERS PRESENT

COL Daniel D. Remund, MS	DoD P& T Committee Co-chair
CAPT Terrance Egland, MC (via VTC)	DoD P& T Committee Co-chair
COL Mike Heath, MS (For MAJ Travis Watson)	Army
COL Joel Schmidt, MC	Army
COL Doreen Lounsbery, MC	Army
LtCol Gordon Wright Bates, Jr, MC	Air Force
Col Phil Samples, BSC	Air Force
CAPT Matt Nutaitis, MC	Navy
CDR Mark Richerson, MSC	Navy
CDR Patrick Marshall	Coast Guard
Rance Hutchings, Pharm.D. (For Dr. Trevor Rabie)	Uniformed Services Family Health Plans (USFHP)
Joe Canzolino	Department of Veterans Affairs

VOTING MEMBERS ABSENT

Col James E. Cox, Jr. MC	Air Force

OTHERS PRESENT

COL William Davies, MS, USA	DoD Pharmacy Program Director, TMA
CAPT Patricia Buss, MC, USN	Chief Medical Officer Representative, TMA
COL James Young, BSC, USAF	DoD Pharmacy Program Assistant Director, TMA
COL Kent Maneval, MS, USA	Joint Readiness Clinical Advisory Board
CDR Denise Graham, MSC, USN	DoD Pharmacoeconomic Center
CDR Ted Briski, MSC, USN (via TC)	DoD Pharmacoeconomic Center
CDR Don Nichols, MC, USN	DoD Pharmacoeconomic Center
LtCol Dave Bennett, BSC, USAF	DoD Pharmacoeconomic Center
LtCol Barb Roach, MC, USAF	DoD Pharmacoeconomic Center
CPT Jill Dacus, MC, USA	DoD Pharmacoeconomic Center
Dave Bretzke	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
Elizabeth Hearin	DoD Pharmacoeconomic Center
Lisa LeGette	Express Scripts
Elaine Furmaga	Department of Veterans Affairs
Four pharmacists	Iraq Ministry of Health

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

4. **INTERIM/ADMINISTRATIVE DECISIONS** – None

5. **UNIFORM FORMULARY (UF) PROPOSED RULE** – COL William Davies, DoD Pharmacy Program Director, TMA, updated the Committee on the current status of the Uniform Formulary. The final Uniform Formulary Rule was published 1 Apr 2004. It is available at: http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/04-7129.htm.

6. **TRICARE RETAIL PHARMACY (TRRx) UPDATE –** Libby Hearin (PEC) updated the Committee on the status of the TRICARE Retail Pharmacy (TRRx) Program implementation. TRRx establishes a retail pharmacy network that will provide outpatient prescription services to TRICARE beneficiaries throughout the United States, Guam, Puerto Rico, and the U.S. Virgin Islands. Express-Scripts, Inc (ESI) is the contractor for TRRx. ESI is also the contractor for the TRICARE Mail Order Pharmacy (TMOP).

   Beneficiary and provider information concerning TRRx is currently available on the TRICARE Pharmacy site (www.tricare.osd.mil/pharmacy) and on ESI's site at www.express-scripts.com. ESI marketing materials include benefit guides, pharmacy information cards, and introductory letters with a list of network pharmacies closest to beneficiaries. Mail-outs to beneficiary households, TRICARE Service Centers, and placement on the TRICARE SMART site (www.tricare.osd.mil/smart) for MTFs begin 22 Apr 2004.

7. **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 two new drugs and one new combination product. The Committee also confirmed the status of two new formulations of existing products (see Appendix A).

7. **ENFUVIRTIDE (FUZEON)** – The manufacturer of enfuvirtide (Fuzeon) has discontinued the controlled distribution program for this product. Under the controlled distribution program, enfuvirtide was previously available in the retail network only through a specialty pharmacy (Chronimed) and was not available in the TMOP. MTFs could purchase enfuvirtide through a special arrangement with Chronimed, but were not able to use the prime vendor system to obtain the product.

   The manufacturer reports that shipping to wholesalers started 14 Apr 2004. The product is expected to be available through U.S. retail and specialty pharmacies staring 26 Apr 2004. MTFs should be able to order Fuzeon from wholesalers as of 26 Apr 2004. Additional information is available at www.pec.ha.osd.mil/Controlled_Distribution_Drugs.htm or from the manufacturer's website (www.fuzeon.com) or help line (1-877-438-9366).

   Enfuvirtide is approved for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. It is given via subcutaneous injection twice daily and may be self-administered by the patient. The Committee will consider Fuzeon for addition to the TMOP Covered Injectables List as soon as it is clear that supplies of enfuvirtide are adequate and that the TMOP will have no difficulty obtaining the product.

9. **SERMORELIN (GEREF, SERONO)** – The Geref brand of sermorelin (growth hormone releasing hormone) has been withdrawn from the market. The diagnostic product (Geref Diagnostic) is still available. Since the therapeutic product is no longer available, the Committee removed sermorelin from the TMOP Covered Injectables List.

10. **KETOROLAC ORAL** – Currently, ketorolac (Toradol) tablets are available from the TMOP with a quantity limit of 5 days supply per 30 days. Express-Scripts does not typically make ketorolac tablets available through mail order plans, so they requested that the Committee consider discontinuing availability of ketorolac tablets at the TMOP. In the 6-month period from Oct 2003 to Mar 2004, the TMOP filled 41 prescriptions for ketorolac tablets, none of which exceeded 20 tablets (a 5-day supply at maximum recommended dosing). The Committee decided that since some patients do fill prescriptions for ketorolac tablets through the TMOP and since there is no indication that patients are receiving excessive quantities of ketorolac, ketorolac tablets will remain on the TMOP Formulary with the current quantity limits.

11. **QUININE** – Quinine has historically been used for nocturnal leg cramps, but this has never been an FDA-approved indication. In 1994-1995, the FDA halted the sale and distribution of OTC quinine sulfate for leg cramps due to its serious risks (Federal Register, 22 Aug 1994). In 1995, the FDA sent letters to manufacturers ordering a halt to the promotion of prescription quinine for leg cramps (FDA Consumer, 1995). In 1998, the FDA halted the sale and distribution of OTC quinine for malaria (Federal Register, 20 Mar 1998). In Feb 1999, the DoD P&T Committee excluded quinine from the National Mail Order Pharmacy (the

previous mail order program), based on the FDA's actions. Since a formulary does not exist in the retail network, the Committee could not take similar action in regard to the availability of quinine in the retail network. Quinine continues to be available in the retail network.

The only FDA-approved indication for quinine is as a prescription drug for the second-line treatment of malaria, but the vast majority of quinine prescriptions are most likely for treatment of leg cramps. Quinine is also available in food products and dietary supplements.

The Committee agreed that drugs available in the TMOP and the retail network should be consistent whenever reasonable and possible. The Committee considered three options:

- Make quinine available without formulary restriction in both TMOP & the retail network (TRRx).
- Subject quinine to formulary restrictions in both TMOP and TRRx.
- Maintain the status quo.

Background

Nocturnal leg cramps are a common problem in elderly patients. Nonpharmacological treatments (e.g., stretching, heat, correction of dehydration or electrolyte imbalances) are considered first-line therapies. Besides quinine, medications that have been used to treat nocturnal leg cramps include gabapentin, verapamil, muscle relaxants, vitamin E, magnesium, and B-complex vitamins.

Efficacy

Two systematic reviews of quinine for leg cramps support its efficacy for this condition:

- In 1995, Man-Son-Hing M et al (BMJ 1995; 310:13-7) reviewed six placebo-controlled cross-over trials including 107 patients, mostly elderly. Patients received 200-300mg quinine sulfate/day over 2- 4 weeks. Compared to placebo, quinine resulted in 8.83 fewer cramps over 4 weeks (95% CI 4.16 , 13.49) based on 5 trials in 82 pts, a relative risk reduction of 43% (95% CI 21%, 65%). There was a 27.5% reduction (95% CI 30.6%, 24.4%) in the number of nights with cramps, based on 2 trials in 51 pts. There was no statistically significant change in the severity or duration of cramps.
- In 1998, Man-Son-Hing M & Wells G, (J Gen Intern Med 1998; 13:600-6) published an updated meta-analysis including pooled individual patient data (combined n=659) from 8 randomized, double-blind, placebo-controlled trials (7 cross-over trials), 4 of which were unpublished. Patients taking quinine had 3.6 (95% CI 2.15 , 5.05) fewer leg cramps over 4 weeks compared to placebo, a relative risk reduction of 21% (95% CI 12% , 30%). Investigators concluded that while publication bias was present (almost all published studies reported higher efficacy than unpublished studies), quinine still appeared to be more effective than placebo in reducing the frequency of nocturnal leg cramps.

Safety/Tolerability

- The FDA's 1994-1995 regulatory actions were based on 157 reports of quinine-associated adverse drug reactions (1969 through mid-1992), 105 of which involved dosing within recommendations. The reports included 16 deaths and 40 hospitalizations.
- Adverse effects at doses used for leg cramps include dizziness, fever, nausea and vomiting, diarrhea, visual or auditory disturbances, and thrombocytopenia (rare but

potentially fatal). Quinine should NOT be used in pregnancy (Category X), should be used with caution in patients with renal failure, and should be avoided in patients with hepatic failure. Patients with a history of immune mediated thrombocytopenia or G-6-PD deficiency should not receive quinine.

- Brinker & Beitz (Am J Hematol 2002; 70:313-7) reported on a case series of thrombocytopenia associated with quinine. Of 397 adverse drug reactions for quinine reported to the FDA from 1974 – 2000, there were 141 reports of apparently isolated thrombocytopenia. After eliminating cases confounded by disease or drug therapy, investigators focused on 64 reports. The typical presentation of thrombocytopenia appeared to be rapid (median time-to-onset 7 days) and severe (hospitalization in 57 cases). Investigators suggested that clinicians evaluating patients with new-onset thrombocytopenia watch for quinine use, including food and dietary supplements.
- Kojouri et al (Ann Intern Med 2001;135:1047-51) reported that 11% of 132 consecutive cases of thrombotic thrombocytopenic purpura-hemolytic uremic syndrome (TTP-HUS) were associated with quinine. They commented that the toxicity appeared immune-mediated, with a sudden onset. Women may be more susceptible than men.
- Quinine has a long half-life, is protein-bound, and is metabolized by CYP450. It has several potentially dangerous drug-drug interactions, including elevation of digoxin levels and increased effect of anticoagulants.

Other Factors

Various criteria, guidelines, and recommendations from published reviews conclude that while quinine should not be used first-line, cautious use may be justified in patients with severe symptoms who have failed other treatments.

- The VA's nonformulary criteria for use (available at www.vapbm.org) recommend reserving use of quinine for nocturnal leg cramps for patients who have failed other modalities and who have severe symptoms requiring treatment. Patients should be advised of the potential for adverse drug reactions.
- Similar advice is provided by the UK National Health System's PRODIGY guidance, (http://www.prodigy.nhs.uk/guidance.asp?gt=Leg%20cramps) which recommends non-drug treatment first-line, with drug treatment only in people with regular cramps significantly affecting quality of life. The guidance suggests that clinicians monitor the risk-benefit ratio with quinine due to the potentially toxic effects.
- The April 2004 Pharmacist's Letter succinctly summarizes the dilemma, suggesting that pharmacists "help people understand pros and cons and decide for themselves…"

Quinine Utilization

- A total of 28,655 DoD beneficiaries received at least one prescription for quinine at MTFs or retail pharmacies in the six months from Oct 2003 to Mar 2004. Of these, 20,557 received quinine prescriptions in retail pharmacies, 8,369 at MTF pharmacies (does not add to 28,655 because some beneficiaries used both points of services).
- Utilization of quinine is increasing, most likely due to the increased numbers of patients 65 years of age and older using the retail network.

The Committee agreed that the non-availability of quinine in the TMOP probably did not decrease the use of quinine for nocturnal leg cramps, since patients could readily fill these prescriptions at retail network pharmacies. The Committee voted to add quinine to the TMOP Formulary. Quinine will be available from the TMOP and retail network without a prior authorization or other formulary restriction. Considerations included:

- Clinical evidence of efficacy of quinine in the treatment of nocturnal leg cramps and the existence of criteria, guidelines, and reviews supporting cautious use in patients for whom the benefits outweigh the considerable risks.
- The absence of an FDA-mandated special distribution process or special monitoring requirements for quinine.
- The incongruence of denying prescriptions for quinine in the TMOP while filling prescriptions for quinine in retail pharmacies.

The Committee noted that the TMOP provides a patient information insert with all medications, including quinine. Patients using the TMOP have access to a toll-free number for pharmacist consultation. Individual providers and pharmacists should assess the patient-specific benefits and risks of this medication and educate patients accordingly.

12. QUANTITY LIMITS

A. Follitropin beta (Follistim AQ) – All injectable gonadotropins, including follitropin, currently have a quantity limit of 3600 IU per 30 days (no refills) in both TMOP and the retail network. These products are also subject to prior authorization. Follistim AQ is a new formulation of follitropin beta in a pre-filled, pre-mixed cartridge for use with the "Follistim Pen." It is supplied in a box containing 4 needles and 1 prefilled cartridge containing either 300 or 600 IU of follitropin beta. The Committee established quantity limits for this new formulation consistent with existing products. These quantity limits apply to both TMOP and retail:

- 300 IU cartridge: 12 cartridges (3600 IU) per 30 days, no refills
- 600 IU cartridge: 6 cartridges (3600 IU) per 30 days, no refills

B. Anakinra (Kineret)- As of 23 Feb 2004, Amgen stopped selling 7-syringe packs of anakinra. Anakinra is now available only as 28-syringe packs (4 weeks supply). The current quantity limit for anakinra in the TMOP is a 6-week supply (6 packages of 7 syringes). The Committee voted to change the quantity limits for anakinra to the following:

- TMOP: 56 syringes = 2 packages of 28 syringes per 56 days (8 weeks supply);
- Retail: 28 syringes = 1 package of 28 syringes per 28 days (4 weeks supply)

The Committee decided to assess the impact of the increased quantity limit on utilization of anakinra before considering any changes to the current 6-week quantity limits for etanercept (Enbrel) and adalimumab (Humira), which are similar injectable agents also used for the treatment of rheumatoid arthritis and available from the TMOP.

13. PRIOR AUTHORIZATIONS (PAS)

A. Implementation of the Growth Hormone PA – The Committee recommended implementation of the PA in both TMOP and the retail network as of 1 Jun 2004 for new patients only (i.e., patients presenting a new growth hormone prescription at a retail

network pharmacy or the TMOP for whom there was no prescription fill for growth hormone in the preceding 180 days).

The Committee recommended that patients who are currently receiving growth hormone in the TMOP and retail network (based on use within the last 180 days) should be required to fulfill PA requirements within 180 days after being notified about the existence of the PA. A method to notify patients who are currently receiving growth hormone from the TMOP or a retail network pharmacy has not been finalized.

A total of 1147 DoD beneficiaries received at least one prescription for growth hormone during the six-month period from Oct 2003 to Mar 2004. Of these, 220 received growth hormone prescriptions in retail pharmacies, 443 at MTF pharmacies, and 506 in the TMOP (does not add to 1147 because some beneficiaries used more than one point of service).

14. ADJOURNMENT – The meeting adjourned at 1130 hours. The next meeting is scheduled for 29 and 30 June at the PEC. All agenda items should be submitted to the co-chairs no later than 4 June 2004.

<signed>	<signed>
DANIEL D. REMUND	TERRANCE EGLAND
COL, MS, USA	CDR, MC, USN
Co-chair	Co-chair

List of Appendices

APPENDIX A: DOD P&T COMMITTEE FORMULARY DECISIONS REGARDING NEWLY APPROVED DRUGS

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**
Amlodipine besylate / atorvastatin tablets (Caduet; Pfizer)	2 Feb 2004. Combination tablet approved for patients for whom treatment with both amlodipine and atorvastatin is appropriate; i.e., hyperlipidemia AND hypertension, chronic stable angina, or vasospastic angina Launch date is 27 Apr 2004.	Not added to the TMOP Formulary Atorvastatin is not on the TMOP Formulary due to provisions of the statin contract; amlodipine is available from the TMOP	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents:** Nifedipine sustained release, simvastatin (contract statin)
Epinastine HCl 0.05% ophthalmic solution (Elestat; Allergan)	12 Oct 2003 (not launched until Jan 2004). Topically active antihistamine with mast cell stabilizing properties, indicated for the prevention of itching associated with allergic conjunctivitis.	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents:** There are no ophthalmic antihistamine products on the BCF.
Tiotropium bromide inhalation powder (Spiriva HandiHaler; Boehringer / Pfizer)	30 Apr 2004 (Launch date is not expected until 11 Jun 2004). Tiotropium bromide is an anticholinergic with specificity for muscarinic receptors. It is indicated for the long-term, once daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. It is not indicated to relieve dyspnea associated with COPD. The product consists of a capsule containing a dry powder formulation of tiotropium bromide, intended for use with the HandiHaler oral inhalation device.	Added to the TMOP Formulary	**Quantity Limits** TMOP: 90 caps per 90 days (3 packages of 30 caps for inhalation) Retail: 30 caps per 30 days (1 package of 30 caps for inhalation) **Prior Authorization** None	Not added to the BCF **Similar BCF agents**: Albuterol MDI; Ipratropium MDI (Atrovent); albuterol /ipratropium MDI (Combivent); salmeterol / fluticasone (Advair Diskus) and salmeterol DPI (Serevent Diskus)
Mycophenolic acid delayed-release tablets (Myfortic; Novartis)	Immunosuppressant approved for the prophylaxis of organ rejection in patients receiving renal transplants. It is administered in combination with cyclosporine and corticosteroids. This product is a new formulation of mycophenolate mofetil (Cellcept).	Added to the TMOP Formulary as a line extension	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents:** none
Clozapine orally disintegrating tablets (Fazaclo; Alamo Pharmaceuticals)	Clozapine is an atypical antipsychotic agent approved for schizophrenia. This product is formulated as an orally disintegrating tablet.	Not added to the TMOP Formulary. Clozapine is excluded from the TMOP due to monitoring requirements and dispensing restrictions mandated by the FDA.	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents**: Quetiapine (Seroquel) and risperidone (Risperidal)

APPENDIX B: COMBINED SUMMARY OF FORMULARY CHANGES FROM THE APRIL 2004 DOD P&T EXECUTIVE COUNCIL & DOD P&T COMMITTEE MEETINGS

1. **BCF CHANGES**

   A. *Additions to the BCF - None*

   B. *Deletions, changes, clarifications or exclusions from the BCF*

      1) Fexofenadine (Allegra) was removed from the BCF. There is no longer a second generation antihistamine on the BCF. The BCF now states that MTFs must have at least one second generation antihistamine on their formularies. The Council strongly encourages all MTFs to include loratadine on their formularies.

2. **TMOP FORMULARY CHANGES**

   A. *Additions to the TMOP Formulary*

      1) Epinastine HCl 0.05% ophthalmic solution (Elestat; Allergan)
      2) Tiotropium bromide inhalation powder (Spiriva HandiHaler; Boehringer/Pfizer) – has quantity limits (see Section 3 below)
      3) Mycophenolic acid delayed-release tablets (Myfortic; Novartis)
      4) Quinine

   B. *Exclusions from the TMOP Formulary*

      1) Amlodipine/atorvastatin (Caduet; Pfizer) (combination tablets) – excluded from the TMOP Formulary due to current statin contract
      2) Clozapine orally disintegrating tablets (Fazaclo; Alamo Pharmaceuticals) – excluded from the TMOP Formulary due to monitoring requirements and dispensing restrictions mandated by the FDA
      3) Sermorelin (Geref, Serono) – removed from the TMOP Covered Injectables list

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

   A. Quantity limits for follitropin beta injection (Follistim AQ) for both TMOP and retail:

      - 300 IU cartridge: 12 cartridges (3600 IU) per 30 days, no refills
      - 600 IU cartridge: 6 cartridges (3600 IU) per 30 days, no refills

   B. TMOP quantity limits for Anakinra (Kineret) were changed to an 8-week rather than a 6-week supply, to accommodate discontinuation of the 7-syringe pack. Anakinra is now available in 28-syringe packs only. Quantity limits in the retail network remain unchanged.

      - TMOP: 56 syringes = 2 packages of 28 syringes per 56 days (8 weeks supply);
      - Retail: 28 syringes = 1 package of 28 syringes per 28 days (4 weeks supply)

   C. Quantity limits for tiotropium bromide inhalation powder (Spiriva)

      - TMOP: 90 caps per 90 days (3 packages of 30 caps for inhalation)
      - Retail: 30 caps per 30 days (1 package of 30 caps for inhalation)

4. **CHANGES TO THE TMOP PRIOR AUTHORIZATION (PA) PROGRAM**

   A. *Growth Hormone* – The Committee recommended implementation of the PA in both TMOP and the retail network as of 1 Jun 2004 for new patients only (i.e., patients presenting a new growth hormone prescription at a retail network pharmacy or the TMOP for whom there was no prescription fill for growth hormone in the preceding 180 days). A method to notify patients who are currently receiving growth hormone from the TMOP or a retail network pharmacy about the existence of the PA has not been finalized.

Corrections - Page 7 amended to correct prices for formoterol and salmeterol, following initial dissemination of these minutes on 13 May 2004

The next meetings of the DoD P&T Committee have been changed to Tuesday 13 July and Wednesday 14 July, 2004.

Department of Defense Pharmacoeconomic Center

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

MCCS-GPE **20 April 2004**

MEMORANDUM FOR: Executive Director, TRICARE Management Activity (TMA)

SUBJECT: Minutes of the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Executive Council Meeting

1. The DoD P&T Executive Council convened at 1300 hours on 20 April 2004 at the DoD Pharmacoeconomic Center, Fort Sam Houston, Texas.

2. VOTING MEMBERS PRESENT

COL Daniel D. Remund, MS	DoD P& T Committee Co-chair
CDR Terrance Egland, MC (Via VTC)	DoD P& T Committee Co-chair
COL Joel Schmidt, MC	Army
COL Doreen Lounsbery, MC	Army
MAJ Travis Watson, MS (Via VTC)	Army
LtCol Gordon Wright Bates, Jr., MC	Air Force
Col Phil Samples, BSC	Air Force
CAPT Matt Nutaitis, MC	Navy
CDR Mark Richerson, MSC	Navy
CDR Patrick Marshall	Coast Guard
Joe Canzolino	Department of Veterans Affairs

VOTING MEMBERS ABSENT

COL James E. Cox, Jr., MC	Air Force

OTHERS PRESENT

COL William Davies, MS	DoD Pharmacy Program Director, TMA
CAPT Patricia Buss, MC	Deputy Chief Medical Officer Representative, TMA
COL Mike Heath, MS, USA (Via VTC)	Army Pharmacy Consultant, Chairman Pharmacy Board of Directors
CAPT Betsy Nolan, MSC (Via VTC)	Navy Pharmacy Specialty Leader
COL James Young, BSC, USAF (Via VTC)	DoD Pharmacy Program Assistant Director, TMA
COL Kent Maneval, MS	Joint Readiness Clinical Advisory Board
CDR Don Nichols, MC	DoD Pharmacoeconomic Center
CDR Denise Graham, MSC	DoD Pharmacoeconomic Center
CDR Ted Briski, MSC	DoD Pharmacoeconomic Center
LtCol Dave Bennett, BSC	DoD Pharmacoeconomic Center
LtCol Barb Roach, MC	DoD Pharmacoeconomic Center
CPT Jill Dacus, MC	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
Dave Bretzke	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
Elizabeth Hearin	DoD Pharmacoeconomic Center
Elaine Furmaga	Department of Veterans Affairs
Four pharmacists	Iraq Ministry of Health

3. REVIEW MINUTES OF LAST MEETING

The minutes from the last meeting were accepted as written.

4. INTERIM DECISIONS/ADMINISTRATIVE ISSUES

None.

5. NATIONAL PHARMACEUTICAL CONTRACTS AND BLANKET PURCHASE AGREEMENT (BPA) AWARDS, RENEWALS AND TERMINATIONS

A. *New Contracts Awarded* – tramadol (Caraco) and ranitidine (Golden State Medical). The Council encourages MTF pharmacies to order these products from the contracted companies.

B. *Changes to Existing Contracts*

1) The next option year was exercised for contracts on the following drugs: 35 mcg ethinyl estradiol/1 mg ethynodiol diacetate (Pharmacia/Pfizer), zolmitriptan (AstraZeneca), etodolac (Taro), hydrochlorothiazide (Ivax), and glyburide (Pharmacia/Pfizer).

2) Additional NDCs were added to existing contracts for metoprolol 50 mg (Caraco), NDC# 57664-0477-08, and tramadol 50 mg (Caraco), NDC# 57664-0377-13.

3) Contracts for insulin syringes (BD), isosorbide mononitrate (Schwarz), and capsaicin cream (Qualitest) were extended.

4) The contracts for levobunolol, timolol, prazosin, verapamil and nortriptyline have no more options years left. They will be reevaluated for resolicitation.

C. *Contracts Pending Award* – amantadine, enalapril, salsalate, and insulin

D. More information about DoD and DoD/VA national pharmaceutical contracts may be found on the Defense Supply Center Philadelphia (DSCP) DMM-Online website at http://dmmonline.dscp.dla.mil/pharm/contractlist.asp. Contract guidance for the oral fluoroquinolones, statins, leutinizing hormone releasing hormone (LHRH) agonists, and triptans are available on the PEC website at www.pec.ha.osd.mil/national_contracts.htm.

E. The Council reviewed the top 40 drug classes by MTF expenditure for FY 2003. National pharmaceutical contracts or incentive price agreements exist for medications in many of these drug classes. The remaining classes are likely targets for procurement initiatives in the future.

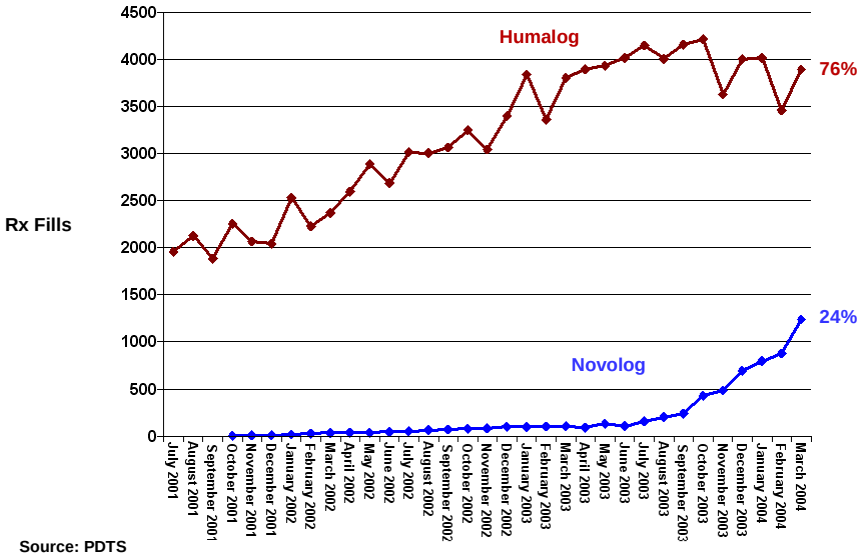
MTF Expenditures by Drug Class,* FY 2003**

Rank	Drug Class	$		Rank	Drug Class	$
1	Antihistamines †	$88 M		21	Metformin †	$22 M
2	NSAIDs †	$86 M		22	Leukotriene antagonists	$21 M
3	Lipotropics †	$83 M		23	Glucocorticoids	$20 M
4	SSRIs †	$64 M		24	Macrolides	$19 M
5	PPIs & H2 blockers †	$61 M		25	Antifungals	$19 M
6	Bisphosphonates †	$45 M		26	Antimalarials	$18 M
7	Calcium channel blockers†	$45 M		27	Hematinics †	$17 M
8	ACE inhibitors †	$43 M		28	Antimigraine agents †	$17 M
9	Vaccines (Hep A & B) †	$38 M		29	Beta-adrenergics (e.g., albuterol) †	$16 M
10	Anticonvulsants †	$37 M		30	Estrogenic agents †	$15 M
11	Salmeterol / fluticasone (Advair)	$31 M		31	Antipsychotics †	$15 M
12	Thiazolidinediones†	$30 M		32	Vaccines/Toxoids	$14 M
13	Quinolones †	$28 M		33	Vaccines, Gram (-) Bacilli	$13 M
14	Antiplatelet agents †	$27 M		34	Bupropion †	$13 M
15	Penicillins	$24 M		35	Miotics / intraocular pressure agents †	$13 M
16	Blood glucose diagnostics †	$24 M		36	Beta blockers †	$12 M
17	Contraceptives †	$23 M		37	Insulins †	$11 M
18	Narcotic analgesics	$22 M		38	ADHD drugs †	$10 M
19	Aqueous nasal steroids †	$22 M		39	Serotonin-norepi reuptake inhibitors	$10 M
20	ARBs	$22 M		40	Sedative/hypnotics	$10 M
Top 20 classes = $843 M 52% of total expenditures				**Top 40 classes = $1,148 M 70% of total expenditures**		

* Drug classes based on First Data Bank HIC-3 classifications
** Expenditures based on DoD Prime Vendor data. May underestimate expenditures in some drug classes, especially products not always ordered through the pharmacy prime vendor system (e.g., vaccines, blood glucose test strips)
† National pharmaceutical contracts or incentive price agreements exist.

F. The Council reviewed utilization of the rapidly-acting insulin analogue products, insulin lispro (Humalog) and insulin apart (Novolog). Due to a voluntary price reduction, Novolog costs only $17.16 per 10 mL vial while the FSS price for Humalog is $31.96 per 10 mL vial. MTFs are saving money by using Novolog rather than Humalog.

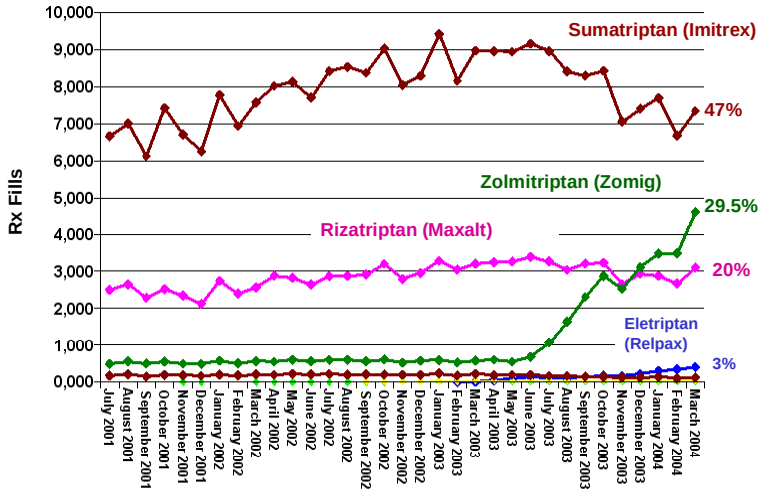
MTF Rx Fills, Humalog vs. Novolog, Jul 01 – Mar 04



Source: PDTS

G. The Council reviewed MTF utilization of the triptans and compliance with the joint DoD/VA contract for zolmitriptan. Zolmitriptan at $3.20 per tablet (contract price) costs at least 20% less than any other triptan. Zolmitriptan should be used as the first-line triptan for all new patient starts unless there is a medical necessity to use a different triptan.

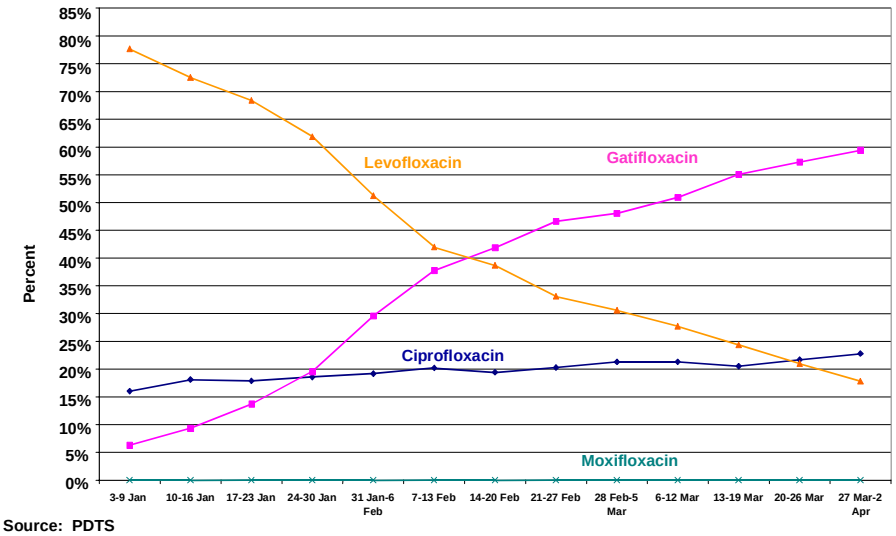
MTF Triptan Rx Fills, Jul 01 – Mar 04



Source: PDTS

H. The Council reviewed MTF utilization of the oral fluoroquinolones and compliance with the joint DoD/VA contract for gatifloxacin. Gatifloxacin is the contract oral fluoroquinolone for the treatment of community-acquired pneumonia and sinusitis. The contract price for gatifloxacin 400 mg is $1.35 per tablet, compared to the FSS price of $5.06 per tablet for levofloxacin 500 mg. The following graph shows the weekly MTF market share for each of the oral fluoroquinolones over the last 3 months. As of the week ending 2 April 2004, almost 60% of oral fluoroquinolone prescriptions were for gatifloxacin.

MTF Oral Fluoroquinolone Rx Market Shares, Weeks Ending 8 Jan 04 – 2 Apr 04



Source: PDTS

6. BCF CHANGES AND CLARIFICATIONS

A. *Long Acting Beta Agonists*

CDR Denise Graham and CPT Jill Dacus (PEC) presented an analysis comparing the long-acting beta agonists salmeterol (Serevent Diskus), which is currently on the BCF, and formoterol (Foradil). The Council considered whether formoterol should be added to the BCF and whether salmeterol should be removed from the BCF.

Efficacy/Safety/Tolerability

Formoterol is a long acting beta-2 agonist indicated for the maintenance treatment of asthma, the prevention of bronchospasm in adults and children 5 years of age and older with reversible obstructive airways disease, acute prevention of exercise-induced bronchospasm, and maintenance treatment of bronchoconstriction in patients with Chronic Obstructive Pulmonary Disease (COPD). Clinical studies have shown comparable efficacy with formoterol compared to salmeterol in the maintenance treatment of asthma and the treatment of reversible obstructive airway disease. Safety and tolerability of the two drugs appear similar.

Formoterol has a faster onset of action than salmeterol, but this may not be a significant clinical advantage since salmeterol and formoterol are not indicated for acute bronchoconstriction. Acute bronchoconstriction should be treated with a

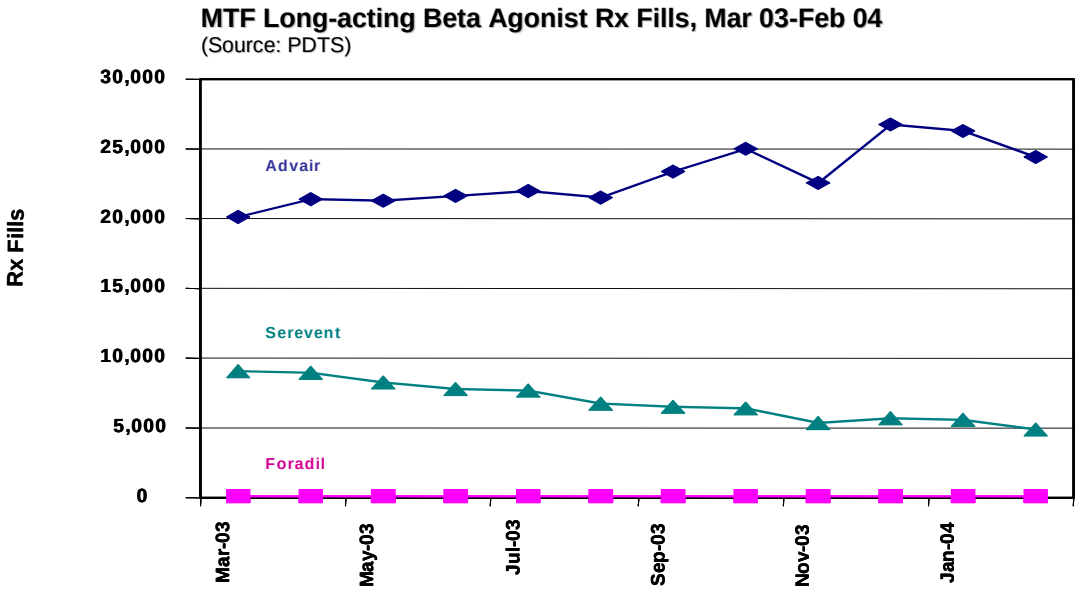
short-acting beta agonist (e.g., albuterol). Salmeterol and formoterol are typically used as adjunctive therapy with inhaled corticosteroids in patients with asthma and with ipratropium in patients with COPD.

Other Factors

- Fewer than 10% of MTFs (14/149) currently have formoterol on formulary. Salmeterol is on the BCF as a single agent (Serevent) and in combination with fluticasone (Advair).
- Patients may find the salmeterol inhaler device (Serevent Diskus) easier to use than the formoterol device (Foradil Aerolizer). Serevent Diskus is packaged as a self-contained dry powder inhaler device preloaded with 28 or 60 doses of 50 mcg of salmeterol. An indicator on top provides the number of doses remaining. Foradil Diskus is a small cylindrical device that is loaded by the patient with a capsule containing 12 mcg of formoterol and squeezed to pierce the capsule. The patient must open the device after inhaling to ensure that the entire dose was delivered. Formoterol capsules come in 12- or 60-count blister packs.
- Salmeterol may be stored at room temperature, and must be used within 6 weeks after opening the foil packet. Formoterol requires refrigeration while stored in the pharmacy, although the patient may store the product at room temperature for up to 4 months after dispensing.

Utilization

As of Feb 2004, MTFs were filling approximately 84 formoterol prescriptions per month, compared to 4,879 prescriptions per month for salmeterol. MTFs fill about 25,000 prescriptions per month for the combination salmeterol/fluticasone product (Advair).



Cost

Based on current FSS prices and recommended dosing regimens, salmeterol costs $44.57 per month compared to $32.63 per month for formoterol. The manufacturer of formoterol has offered a voluntary price reduction for formoterol to all DoD accounts at $31.50 per 60 doses regardless of BCF status. In addition they are offering a MTF based incentive agreement where MTFs can obtain a lower price in exchange for local formulary status and market share performance.

Conclusion

The Council voted unanimously not to add formoterol to the BCF. Long-acting beta agonist usage (as a single agent) is declining steadily. Formoterol may be more difficult for patients to use than salmeterol. Formoterol requires refrigeration prior to dispensing. Formoterol does not offer a significant clinical advantage over salmeterol. Although formoterol costs less than salmeterol, the Council doubted that MTFs would significantly shift usage from salmeterol to formoterol, especially in light of the overall decline in usage of long-acting beta agonists relative to the combination product (Advair). A formoterol/inhaled corticosteroid product (formoterol/budesonide) is not expected until 2006 or later.

The council voted not to remove salmeterol from the BCF in order to maintain uniform availability of a long-acting beta agonist product across MTFs.

7. ANGIOTENSIN RECEPTOR BLOCKERS (ARBS)

Bristol Myers Squibb submitted a “pre-award” GAO protest of the blanket purchase agreement (BPA) request for price quotes that the Defense Supply Center Philadelphia (DSCP) issued to pharmaceutical companies that market ARBs. Pending the resolution of this protest, the Council made no final decision regarding the addition of an ARB to the BCF.

8. SECOND-GENERATION ANTIHISTAMINES

The Claritin brand of loratadine is available through a joint DoD/VA blanket purchase agreement for $0.38 per 10-mg tablet. Generic loratadine is available at prices as low as $0.12 per 10-mg tablet and is expected to drop to as low as $0.07 per 10-mg tablet. Fexofenadine 180 mg costs $0.85 per tablet (incentive agreement price for having fexofenadine on the BCF). Fexofenadine 180 mg will likely increase to the FSS price of $1.42 per tablet if fexofenadine is removed from the BCF. The FSS price for cetirizine 10 mg is $0.96 per tablet.

At its February 2004 meeting the Council considered a proposal to remove fexofenadine from the BCF because some MTF pharmacy personnel had stated that the presence of fexofenadine on the BCF inhibits their ability to increase their use of the much less expensive loratadine. The Council voted at that time to keep fexofenadine on the BCF out of concern that MTFs may not shift enough of the market share to loratadine to offset the negative financial impact of a fexofenadine price increase. The Council did not want to remove fexofenadine from the MTF unless there was evidence that MTFs could shift more usage to loratadine.

The loratadine market share at MTFs has risen rapidly since the last meeting. Loratadine accounted for 14% of MTF prescription fills for second generation antihistamines in March 2004—nearly double the 7.5% market share that loratadine had in the first quarter of FY 2004. Loratadine accounted for over 20% of new MTF prescriptions for second generation antihistamines during the first two weeks of April 2004. An April 2004 PEC survey of 209 MTF providers indicated that 2 out of 3 would be willing to prescribe loratadine 1st line if the price was $0.10/tab or less. As of 1 May 2004, loratadine should be available from local wholesalers in bottles of 500 at $0.07/tab.

The Council reviewed several market-share and price scenarios and concluded that MTFs would likely need to achieve a loratadine market share of 25% to 32% in order to break-even financially in the second-generation antihistamine class (depending on the future prices of the second generation antihistamines and their market shares). Based on MTF performance over the last three months in shifting market-share to loratadine, the Council felt confident that MTFs will shift enough market share to loratadine to generate significant savings in this drug class. The Council voted to remove fexofenadine from the BCF, which means there is no longer a second generation antihistamine on the BCF. The BCF will now state that MTFs must have at least one second generation antihistamine on their formularies. The Council strongly encourages all MTFs to include loratadine on their formularies.

9. ADJOURNMENT

The meeting adjourned at 1730 hours. The next meeting is scheduled for 29 and 30 June at the PEC. All agenda items should be submitted to the co-chairs no later than 4 June 2004.

<signed>	<signed>
DANIEL D. REMUND	TERRANCE EGLAND
COL, MS, USA	CDR, MC, USN
Co-chair	Co-chair

Department of Defense
Pharmacoeconomic Center

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

MCCS-GPE **12 FEBRUARY 2004**

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 12 February 2004 at the DoD Pharmacoeconomic Center, Fort Sam Houston, Texas.

2. VOTING MEMBERS PRESENT

COL Daniel D. Remund, MS	DoD P& T Committee Co-chair
CAPT Terrance Egland, MC	DoD P& T Committee Co-chair
COL Joel Schmidt, MC	Army
COL Doreen Lounsbery, MC	Army
LTC Emery Spaar, MS (For MAJ Travis Watson, MS)	Army
Col Mark Nadeau, MC (For Col Bill Sykora, MC)	Air Force
LtCol Phil Samples, BSC	Air Force
CAPT Matt Nutaitis, MC	Navy
CDR Mark Richerson, MSC	Navy
CDR Patrick Marshall	Coast Guard
Dr. Trevor Rabie	Uniformed Services Family Health Plans (USFHP)
Joe Canzolino	Department of Veterans Affairs

VOTING MEMBERS ABSENT

Col John R. Downs, MC	Air Force

OTHERS PRESENT

COL William Davies, MS, USA	DoD Pharmacy Program Director, TMA
CAPT Patricia Buss, MC, USN	Chief Medical Officer Representative, TMA
LTC Bates Gordon, MC, USAF	
COL Kent Maneval, MS, USA	Joint Readiness Clinical Advisory Board
LTC Don DeGroff, MS	DoD Pharmacoeconomic Center
CDR Denise Graham, MSC, USN	DoD Pharmacoeconomic Center
CDR Ted Briski, MSC, USN (via TC)	DoD Pharmacoeconomic Center
CDR Don Nichols, MC, USN	DoD Pharmacoeconomic Center
CDR Jill Pettit, MSC, USN	DoD Pharmacoeconomic Center
HM1 Lisa Drumm	DoD Pharmacoeconomic Center
LtCol Dave Bennett, BSC, USAF (Via TC)	DoD Pharmacoeconomic Center
LtCol Barb Roach, MC, USAF	DoD Pharmacoeconomic Center
CPT Jill Dacus, MC, USA	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
David Bretzke (via TC)	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
Elizabeth Hearin	DoD Pharmacoeconomic Center
Lisa LeGette	Express Scripts
Howard Mazzafro	Express Scripts
Debbie Khachikian	Department of Veterans Affairs
Paul Vasquez	Defense Supply Center Philadelphia
Gene Lakey	TriWest
Rance Hutchings, Pharm.D.	Uniformed Services Family Health Plans (USFHP)
Capt Garrett Heitmann, BSC, USAF	Pharmacy Practice Resident

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

4. **INTERIM/ADMINISTRATIVE DECISIONS** – None

5. **UNIFORM FORMULARY (UF) PROPOSED RULE** – COL William Davies, DoD Pharmacy Program Director, TMA, updated the Committee on the current status of the Uniform Formulary and revisions to the DoD P&T Committee Charter. The FY 2004 National Defense Authorization Act changes the membership of the DoD P&T Committee to include only government members. The DoD P&T Committee will therefore not be subject to the provisions of the Federal Advisory Committee Act (FACA), which would have required public meetings of the DoD P&T Committee. Non-government entities will have a chance to review and comment on recommendations made by the Committee as part of the Beneficiary Advisory Panel, which will include representatives from non-government organizations and associations representing the views and interests of a large number of beneficiaries. Meetings of the Beneficiary Advisory Panel will be held in accordance with FACA.

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 8 new drugs or formulations (see Appendix A).

7. MAIL ORDER AND RETAIL NETWORK ISSUES

A. *Pegvisomant (Somavert)* –The Committee removed pegvisomant from the TMOP Covered Injectables List. Pegvisomant is subject to a controlled distribution process and it is not feasible to provide it through the TMOP.

B. *Desmopressin acetate (DDAVP) injection* – The Committee added desmopressin (DDAVP) injection to the TMOP Covered Injectables List.

C. *Use of Non-Formulary Drugs* – The Committee reviewed utilization of non-formulary drugs in the TMOP: atorvastatin (Lipitor), fluvastatin (Lescol), fluvastatin extended release (Lescol XL), lovastatin extended release (Altocor), rosuvastatin (Crestor), and esomeprazole (Nexium). Non-formulary drugs are supposed to be available from the TMOP only when the TMOP contractor validates that there is a medical necessity to use the non-formulary drug in lieu of a formulary drug. When Express-Scripts receives a prescription for a non-formulary drug, they contact the prescriber (typically by fax) and attempt to change the non-formulary drug to a formulary drug or obtain information that validates the medical necessity to use the non-formulary drug. The prescription is returned to the patient unfilled if they are unable to contact the prescriber. The Committee noted that use of esomeprazole and the lower strengths of atorvastatin were higher in the TMOP than expected. The Committee asked the PEC to work with Express-Scripts to review the criteria that are used to validate the medical necessity of using non-formulary drugs and revise the criteria if necessary.

8. PRIOR AUTHORIZATIONS (PAs)

A. *PDE-5 Inhibitors* – Health Affairs Policy 98-040, "Practice Guidelines for the Evaluation of Patients Requesting Sildenafil, (Viagra), for the Treatment of Male Impotence" applies to tadalafil (Cialis). The Committee approved changes to the PA criteria for PDE-5 inhibitors to include tadalafil (Cialis). Please see Appendix A for details.

B. *Growth Hormone* – On July 23rd 2003 the FDA approved Humatrope (somatropin [rDNA origin] for injection) as a treatment for non-growth hormone dependent short stature, also known as idiopathic short stature (ISS). Treatment of ISS is not considered medically necessary, and thus is not covered by TRICARE.

CDR Don Nichols (PEC) presented proposed PA criteria for the use of growth hormone in adults and children. The PA criteria were developed by reviewing the literature, preparing draft criteria, soliciting interactive review and comment from a group of approximately 22 pediatric and adult endocrinologists, and then fine-tuning the criteria and TMOP prior authorization form. The Committee approved the criteria outlined below for the retail and mail order (TMOP) points of service:

- Coverage provided for:
  - Growth Hormone Deficiency in children and adults as a result of pituitary disease, hypothalamic disease, surgery or radiation therapy

- Chronic renal insufficiency before renal transplantation with associated short stature
- Other known renal indications: autorecessive polycystic kidney disease, cystinosis and hypophosphatemic rickets in the pediatric population
- Short stature in patients with Turner Syndrome or Prader-Willi syndrome
- Infants born small for gestational age that have not reached age appropriate height by 24 months of age
- Human immunodeficiency virus-associated wasting in adults

- Coverage NOT provided for:
  - Idiopathic Short Stature
  - Depression, Aging or Obesity

The growth hormone PA will not be implemented until a beneficiary notification process has been finalized as part of implementation of the TRICARE Retail Pharmacy (TRRx) contract. A one-year grace period will be allowed for patients who previously received growth hormone to obtain a PA once beneficiary notification has been implemented. A copy of the growth hormone PA form is included as Appendix C, but the form will not be posted on the PEC website until the PA process is implemented. MTFs are encouraged to adopt the growth hormone PA criteria in order to increase the uniformity of the pharmacy benefit across all points of service. MTFs should be aware that under the portable prior authorization process, patients who receive growth hormone at MTFs would be automatically approved to receive growth hormone at TMOP or retail.

C. *Efalizumab Injection (Raptiva*) – Capt Jill Dacus (PEC) presented information to the Committee regarding efalizumab, a biologic agent recently approved by the FDA for the treatment of chronic moderate to severe plaque psoriasis in adults $\geq$ 18 years old. Efalizumab is an IgG1 humanized monoclonal antibody to the alpha chain of CD11a of leukocyte function associated antigen type 1 (LFA-1) that inhibits activation of T-cells, interferes with their adhesion to the endothelium, and slows T-cell migration. Efalizumab is administered via subcutaneous injection at a maintenance dose of 1 mg/kg per week; patients may self-administer efalizumab after training.

Adverse effects noted during clinical trials with efalizumab include a typical “first dose” reaction (headache, chills, fever, nausea, and myalgia within 2 days following the first two injections), rare thrombocytopenia (0.3% of patients [8/2762] experienced platelets < 52,000 mm^3), and an increase in serious infection rate compared to placebo (0.4% vs. 0.1%). There was also a slight excess of malignancies in patients receiving efalizumab (1.8 per 100 patient-years vs. 1.6 per 100 patient-years with placebo); it is not clear if this represents a true increase in risk. Less than 1% of patients discontinued treatment due to adverse effects. Of note is the observation that patients discontinuing treatment tended to have poorer results on restarting treatment.

The Committee considered the following to determine whether or not to institute a PA for efalizumab, and to establish criteria.

- Other biologic agents, including etanercept, adalimumab, and anakinra, all have prior authorization criteria.
- MTF dermatologists surveyed agreed that efalizumab's place in therapy should be second line after topicals, phototherapy and systemic therapy, and that dermatologists should recommend therapeutic intervention with efalizumab based on the extent and severity of plaque psoriasis.
- Efalizumab has a very narrow indication due to the specificity of its action, and should be used only for chronic moderate to severe plaque psoriasis.
- Since efalizumab inhibits T cells, it should be not be used in children whose immune systems may still be maturing.
- Efalizumab is an immunosuppressant and should not be used in conjunction with other immunosuppressive medications, or in patients whose immune systems are otherwise suppressed.
- Like other biologic agents, treatment with efalizumab is costly (about $10,000 per year based on FSS pricing).

The Committee placed efalizumab on the TMOP Covered Injectable List with the PA criteria listed below. The Committee did not establish special quantity limits for efalizumab; patients may obtain up to a 90-day supply at the TMOP and up to a 30-day supply at retail network pharmacies.

- Coverage provided for:
  - Adults (age ≥ 18 years) with chronic moderate to severe plaque psoriasis, defined as a minimum body surface area involvement of 10% OR a body surface area involvement of less than 10%, but in critical areas (e.g. palms, soles or face) and interfering with day-to-day activities

    AND
  - Have tried and failed traditional therapy, such as phototherapy (e.g. UVB, PUVA) or systemic therapy (e.g., methotrexate, acitretin or cyclosporine) OR are not candidates for phototherapy or systemic therapy

    AND
  - A dermatologist recommends treatment with efalizumab.
- Coverage NOT provided for:
  - Immunocompromised patients or those receiving immunosuppressive agents. These patients should not receive concurrent therapy with efalizumab because of the possibility of increased risk of infections and malignancies.
  - Children (age < 18 years)
  - Patients with psoriatic arthritis without plaque psoriasis

TMOP prior authorization form for efalizumab injection (Raptiva) is available on the PEC website at http://www.pec.ha.osd.mil/PA_Criteria_and_forms.htm.

D. *Revision of Prior Authorization Forms* - The Committee agreed that the TMOP prior authorization forms should include language whereby the prescriber certifies that all information on the form is accurate. The wording of the statement will be coordinated with TMA legal counsel and Express-Scripts. The Committee also agreed that the term "benefit" used in the PA forms should be changed to "coverage," since PA criteria do not determine what the TRICARE benefit is, but do establish criteria under which drugs are covered or not covered.

E. *Cox II Inhibitors* – The Committee voted to discontinue the TMOP PA for COX-2 inhibitors after considering the following:

- The costs of processing COX-2 inhibitor PAs in the TMOP probably exceed any cost-savings that are generated by the PA process.
  - About 88% of COX-2 inhibitor PAs are approved on first review, with an additional 2% approved upon resubmission. It costs DoD more to process the PAs than DoD saves by not filling 10% of the prescriptions submitted.
  - Given the absence of a PA for COX-2 inhibitors in the retail network, the PA process in the TMOP probably shifts some prescriptions to the retail network where the drug acquisition cost is the highest.
  - Although it is impossible to accurately estimate the cost-savings due to the sentinel effect of the PA (i.e., when the requirement to obtain prior authorization causes a provider to refrain from writing a prescription for the drug), the sentinel effect probably does not outweigh the cost of processing the PAs and the incremental cost of shifting prescriptions to the retail network.
- We should not continue the incongruity of having a PA for COX-2 inhibitors in the TMOP but not having a PA for COX-2 inhibitors in the retail network. The administrative burden of instituting a PA for COX-2 inhibitors in the retail network would further complicate the impending implementation of the TRICARE Retail Pharmacy (TRRx) contract and the Uniform Formulary. Discontinuing the COX-2 inhibitor PA in the TMOP will reduce the administrative burden.
- COX-2 inhibitors could possibly be competed for formulary position on the Uniform Formulary. DoD will likely save more money by competing COX-2 inhibitors for formulary position than attempting to institute a PA in the retail network.

The Committee emphasized that removing the PA requirement for COX-2 inhibitors in the TMOP does not mean that MTFs should discontinue their efforts to target the usage of COX-2 inhibitors toward patients who are at high risk for gastrointestinal adverse effects.

9. ADJOURNMENT – The meeting adjourned at 1230 hours. The next meeting will be held at Fort Sam Houston, TX at 0800 on Tuesday, 20 April 2004. This meeting would normally be held in May, but the meeting will be held in April in order to accommodate training of Iraqi pharmacists in formulary management procedures. All agenda items should be submitted to the co-chairs no later than 19 March 2004.

<signed>
DANIEL D. REMUND
COL, MS, USA
Co-chair

<signed>
TERRANCE EGLAND
CDR, MC, USN
Co-chair

List of Appendices

APPENDIX A: DOD P&T COMMITTEE FORMULARY DECISIONS REGARDING NEWLY APPROVED DRUGS

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**
Alfuzosin HCL extended release tablets (Uroxatral; Sanofi)	12 Jun 03: Indicated for the treatment of signs and symptoms of BPH. Not indicated for treating hypertension. Alfuzosin selectively blocks post-synaptic alpha1 receptors in the prostate.	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents:** The alpha-blockers terazosin and prazosin are on the BCF (mandatory source contracts). Doxazosin and tamsulosin are not on the BCF.
Efalizumab injection (Raptiva; Genentech)	27 Oct 03. Injectable biologic monoclonal antibody. Indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. The 1 mg/kg dose is administered SQ weekly, but must be reconstituted from single-use 125 mg vials.	Added to the TMOP Formulary and TMOP Covered Injectables List	**Quantity Limits** General rule applies **Prior Authorization** Yes. See Paragraph 8C for criteria and further discussion	Not added to the BCF **Similar BCF agents:** There are no injectable products for psoriasis on the BCF.
Notes Regarding Efalizumab: Efalizumab is the only biologic approved for psoriasis that can be self-administered by subcutaneous injection. Another biologic product, alefacept [Amevive; Biogen] is approved for psoriasis, but it is typically administered as an IM injection in the physician office or clinic. The FSS cost of one efalizumab vial is $204, resulting in an anticipated yearly cost of $10,608.				
Eplerenone tablets (Inspra; Pfizer)	10 Oct 03: Aldosterone antagonist approved to improve survival of stable patients with left ventricular systolic dysfunction (ejection fraction <40%) and clinical evidence of congestive heart failure after an acute myocardial infarction. Eplerenone is also indicated for hypertension, and may be used alone or in combination with other anti-hypertensive agents.	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents**: Another aldosterone antagonist, spironolactone, is on the BCF.
Estradiol / levonorgestrel transdermal system (Climara Pro; Berlex)	28 Nov 03: Combination estrogen / progestin patch applied once weekly for hormonal replacement therapy. It is indicated for treatment of moderate-to-severe vasomotor symptoms associated with menopause in women with an intact uterus. It is not indicated for osteoporosis.	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents:** There are no combination estrogen/progestin patches on the BCF. The estrogen patch Esclim is on the 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**
Lansoprazole delayed release capsule / naproxen tablets kit (Prevacid NapraPAC; TAP)	28 Nov 03: Combination package of lansoprazole with naproxen. Available in 15 mg lansoprazole with either 375 mg or 500 mg of naproxen. Indicated for risk reduction of NSAID-associated gastric ulcers in patients with a history of documented gastric ulcer who require the use of an NSAID in the treatment of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis. Supplied as a weekly blister card; packages contain 28 days of therapy.	Not added to the TMOP Formulary	**Quantity Limits** N/A **Prior Authorization** N/A	Not added to the BCF **Similar BCF agents:** The components of this co-packaged combination are on the BCF: lansoprazole capsules (BPA price), and naproxen tablets (mandatory generic sole source contract).
Notes Regarding Lansoprazole/Naproxen: Prevacid NapraPAC co-packages existing dosage forms/strengths of naproxen and lansoprazole together; it does not combine the two ingredients in a single dosage form. The product is intended to facilitate prophylaxis of NSAID-associated gastrointestinal events (e.g., GI bleeding) with a PPI. The Committee's primary concern about this product arose from its cost relative to the individual components, both of which are on the BCF. A BPA price of $0.65 per capsule is in effect for lansoprazole, while naproxen tablets cost $0.05-$0.06, depending on strength (generic sole source contract pricing). An FSS price for Prevacid NapraPAC was not yet available at the time of the meeting. While the FSS price for Prevacid NapraPAC will doubtless be much lower than the prime vendor pricing in effect at the time of the meeting ($3.67 per day), it is not yet clear if the product will cost substantially more than the current $0.75-0.77 per day for naproxen plus lansoprazole, based on BPA and contract pricing. Due to the prospect of excessive cost and the Committee's doubts about the value of the packaging, Prevacid NapraPAC was not added to the TMOP formulary. The Committee was unable to isolate any circumstance in which it would be considered clinically necessary for a patient to receive the co-packaged product rather than lansoprazole and naproxen in separate packaging.			
Memantine tablets (Namenda; Forest)	16 Oct 03: Indicated for the treatment of moderate to severe Alzheimer's Disease (AD). Memantine is a N-methyl-D-aspartate (NMDA) receptor antagonist with a chemical structure unrelated to that of other available AD agents, including the cholinesterase inhibitors.	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents:** There are no NMDA receptor antagonists on the BCF. Donepezil (Aricept), a cholinesterase inhibitor indicated for the treatment of mild to moderate Alzheimers, was added to the BCF at the 11 February 2004 DoD P&T Executive Council Meeting
Notes Regarding Memantine: Memantine is the first product labeled for use in patients with moderate to severe Alzheimer's disease. The cholinesterase inhibitors (donepezil, galantamine, and rivastigmine) are labeled for use in patients with mild to moderate disease. Memantine has been studied both as monotherapy and in combination with cholinesterase inhibitors. Monotherapy studies showed a statistically significant slowing in cognitive and functional decline in patients with moderate to severe AD treated with memantine compared to placebo. Required caregiver time was significantly less for memantine treated patients than placebo, with a difference between groups of 45.8 hours per month. The clinical trial comparing combination therapy (donepezil plus memantine) vs. donepezil plus placebo in moderate to severe AD, showed patients on the combination therapy experienced significantly better outcomes than patients treated with donepezil and placebo on measures of cognition, activities of daily living, global outcomes, and behavior. It is unclear if combination therapy provides sufficiently improved outcomes to justify the incremental cost.			

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**
Olanzapine / Fluoxetine capsules (Symbyax: Lilly)	2 Jan 03: Combination of olanzapine (atypical antipsychotic) and fluoxetine (SSRI) in the same capsule. Symbyax is indicated for the treatment of depressive episodes associated with bipolar disorder.	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF. The BCF listing for fluoxetine was clarified to exclude Symbyax. **Similar BCF agents:** The atypical antipsychotics quetiapine and risperidone are on the BCF. There are multiple SSRIs on the BCF, including fluoxetine.
Notes Regarding Olanzapine/Fluoxetine: Olanzapine / fluoxetine capsules (Symbyax) are available in 6 mg or 12 mg olanzapine in combination with either 25 or 50 mg of fluoxetine. Single ingredient tablets of olanzapine (Zyprexa) come in 2.5, 5, 7.5, 10 or 15 mg; fluoxetine capsules are available in 10, 20, or 40 mg. The FSS prices for Symbyax are consistent with those for olanzapine, on a cost / mg basis.				
Tadalafil (Cialis; Bayer/ GSK)	21 Nov 03. Approved for the treatment of erectile dysfunction.	Not added to the TMOP formulary	**Quantity Limits** *TMOP:* 18 tablets of any combination of the three oral PDE-5 inhibitors per 90 days (collective quantity limit). *Retail:* 6 tablets of any combination of the three oral PDE-5 inhibitors per 30 days (collective quantity limit). **Prior Authorization** Yes, see notes below.	Not added to the BCF **Similar BCF agents**: There are no PDE-5 Inhibitors on the BCF.

Notes Regarding Tadalafil: Tadalafil is the third phosphodiesterase-5 (PDE-5) inhibitor to reach the market. It is similar to sildenafil (Viagra) and vardenafil (Levitra) in terms of efficacy and safety; the primary differences are a longer onset of action (45 minutes vs ~ 27 minutes with sildenafil and vardenafil) and duration of action (36 hours vs 4 hours with sildenafil and vardenafil).

Concomitant use of all 3 PDE-5 inhibitors is contraindicated with nitrates due to the risk of hypotension. Labeling for the three products differs with respect to concomitant use with alpha blockers. Tadalafil is contraindicated for use with alpha blockers, with the exception of tamsulosin (Flomax) 0.4 mg. Concomitant use of vardenafil is contraindicated with alpha blockers. Sildenafil labeling does not contain a contraindication for concomitant use with alpha blockers, although a warning against concomitant use of sildenafil at doses above 25 mg within 4 hours of taking an alpha blocker is listed under precautions in the package labeling.

- **TMOP & Retail Network**: Tadalafil will have the same non-formulary status in the TMOP as sildenafil and vardenafil. The three oral PDE-5 inhibitors will be available only if prior authorization criteria are met. Tadalafil will be subject to the same prior authorization process as sildenafil and vardenafil, consistent with guidelines in the Health Affairs Sildenafil Policy. A quantity limit of 18 tablets per 90 days will apply in the TMOP. A quality limit of 6 tablets per 30 days will apply in the retail network. The quantity limit will apply collectively to all oral PDE-5 inhibitors. This means that no more than 6 tablets per 30-day supply of any combination of these medications will be dispensed in the retail network and no more than 18 tablets per 90-day supply will be dispensed in the TMOP.
- **BCF & MTF Formularies:** Guidelines listed in the Health Affairs Sildenafil Policy will also apply to vardenafil and tadalafil.

APPENDIX B: COMBINED SUMMARY OF FORMULARY CHANGES FROM THE NOVEMBER 2003 DOD P&T EXECUTIVE COUNCIL & THE DOD P&T COMMITTEE MEETINGS

1. **BCF CHANGES**
   A. *Additions to the BCF*
      1) Gatifloxacin oral (does not include the parenteral formulation)
      2) Bupropion sustained release 100- and 150-mg tablets
      3) Donepezil 5- and 10-mg tablets
   B. *Deletions, changes, clarifications or exclusions from the BCF*
      1) Levofloxacin oral was removed from the BCF
      2) The current BCF listing for prednisolone oral was clarified to specify prednisolone 15 mg/5 mL oral syrup
2. **TMOP FORMULARY CHANGES**
   A. *Additions to the TMOP Formulary*
      1) Alfuzosin tablets (Uroxatral)
      2) Efalizumab (Raptiva) injection – requires prior authorization, added to TMOP Covered Injectables List
      3) Eplerenone tablets (Inspra)
      4) Estradiol/levonorgestrel transdermal patch (ClimaraPro)
      5) Memantine (Namenda)
      6) Olanzapine/fluoxetine capsules (Symbyax)
      7) Desmopressin acetate (DDAVP) injection – added to TMOP Covered Injectables List
   B. *Exclusions from the TMOP Formulary*
      1) Lansoprazole/naproxen (co-packaged as Prevacid NapraPAC)
      2) Tadalafil (Cialis) – same non-formulary status in TMOP as sildenafil; available from the TMOP if prior authorization criteria are met. Quantity limits apply (see below).
3. **QUANTITY LIMIT CHANGES (RETAIL NETWORK AND TMOP)**
   A. Quantity limits for vardenafil tablets (Levitra) – will apply collectively to all oral PDE-5 inhibitors, including sildenafil (Viagra) and tadalafil (Cialis).
      - TMOP: 18 tablets per 90 days (any combination of oral PDE-5 inhibitors)
      - Retail: 6 tablets per 30 days (any combination of oral PDE-5 inhibitors)
4. **CHANGES TO THE TMOP PRIOR AUTHORIZATION (PA) PROGRAM**
   A. Vardenafil will be subject to the same prior authorization process as sildenafil, consistent with guidelines in the Health Affairs Sildenafil Policy.
   B. The COX-2 PA was discontinued (please see Section 8E for more information).
   C. A PA was instituted for efalizumab (Raptiva)
   D. The Committee approved PA criteria for growth hormone, however implementation was delayed due to communication issues related to the TRRx contract.

APPENDIX C: TMOP PRIOR AUTHORIZATION FORM FOR GROWTH HORMONE

Growth Hormone Prior Authorization Request Form

To be completed and signed by the prescriber. To be used only for prescriptions which are to be filled through the Department of Defense (DoD) TRICARE Mail Order Pharmacy (TMOP). Express Scripts is the TMOP contractor for DoD.

Your patient receives their prescription drug benefit from the Department of Defense (DoD). The DoD prescription drug benefit plan requires that we review certain requests for coverage with the prescribing physician. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage can be provided. Before giving the prescription to the patient, please make a copy of this form, complete the following questions and give the completed form, along with the prescription, to the patient. Please instruct the patient to send this completed form, along with the prescription, to Express Scripts for processing. If Express-Scripts already has your patient's prescription and has requested that you complete this form, the completed form may be faxed to: (877) 895-1900 (toll-free) or (602) 586-3911 (commercial). A copy of this form and explanations of the underlying clinical rationale and criteria for approval are available at http://www.pec.ha.osd.mil/PA_Criteria_and_forms.htm.

Drug for which Prior Authorization is requested: Growth Hormone _____

Step 1 **Please complete patient and physician information (Please Print)**

Patient Name:		Physician Name:	
Address:		Address:	
Member #:		Phone #:	
		Secure Fax #:	

Step 2 **Please complete the clinical assessment**

1. Is the patient a child (<18 years old)?	☐ Yes Please proceed to question 5	☐ No Please proceed to question 2
2. Is the patient an adult with lowered growth hormone levels secondary to the normal ageing process, obesity or depression?	☐ Yes Coverage not approved	☐ No Please proceed to question 3
3. Is the patient an adult with growth hormone deficiency as a result of pituitary disease, hypothalamic disease, trauma, surgery, or radiation therapy, acquired as an adult or diagnosed during childhood?	☐ Yes Coverage approved	☐ No Please proceed to question 4
4. Does the patient have Short Bowel Syndrome or Acquired Immunodeficiency Syndrome (AIDS) wasting or cachexia?	☐ Yes Coverage approved	☐ No Coverage not approved
5. Is the patient a child with non-growth hormone deficient short stature (Idiopathic Short Stature)?	☐ Yes Coverage not approved	☐ No Please proceed to question 6
6. Is the patient a child with growth hormone deficiency, Turner's Syndrome, Prader-Willi Syndrome, chronic renal insufficiency (or other known renal indications) or a child born small for gestational age whose epiphyses have not closed?	☐ Yes Please proceed to question 7	☐ No Coverage not approved
7. Has the patient been evaluated by a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment?	☐ Yes Coverage approved	☐ No Coverage not approved

Step 3 **I certify the above is correct and accurate to the best of my knowledge**

Please sign and date:

_____ _____

Prescriber Signature Date

Latest revision: February 2004

Department of Defense
Pharmacoeconomic Center

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

MCCS-GPE **11 February 2004**

MEMORANDUM FOR: Executive Director, TRICARE Management Activity (TMA)

SUBJECT: Minutes of the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Executive Council Meeting

1. The DoD P&T Executive Council convened at 0800 hours on 11 February 2004 at the DoD Pharmacoeconomic Center, Fort Sam Houston, Texas.

2. VOTING MEMBERS PRESENT

COL Daniel D. Remund, MS	DoD P& T Committee Co-chair
CDR Terrance Egland, MC	DoD P& T Committee Co-chair
COL Joel Schmidt, MC	Army
COL Doreen Lounsbery, MC	Army
LTC Emery Spaar, MS (For MAJ Travis Watson, MS)	Army
COL John R. Downs, MC	Air Force
Col Mark Nadeau, MC (For COL Bill Sykora, MC)	Air Force
LtCol Phil Samples, BSC	Air Force
CAPT Matt Nutaitis, MC	Navy
CDR Mark Richerson, MSC	Navy
CDR Patrick Marshall	Coast Guard
Joe Canzolino	Department of Veterans Affairs

VOTING MEMBERS ABSENT

None	

OTHERS PRESENT

COL William Davies, MS	DoD Pharmacy Program Director, TMA
CAPT Patricia Buss, MC	Deputy Chief Medical Officer Representative, TMA
Howard Altschwager	Deputy General Counsel, TMA
Paul Vasquez	Defense Supply Center Philadelphia
COL Kent Maneval, MS	Joint Readiness Clinical Advisory Board
CAPT Don Nichols, MC	DoD Pharmacoeconomic Center
CDR Denise Graham, MSC	DoD Pharmacoeconomic Center
CDR Ted Briski, MSC (via telephone)	DoD Pharmacoeconomic Center
LtCol Dave Bennett, BSC (via telephone)	DoD Pharmacoeconomic Center
LtCol Barb Roach, MC	DoD Pharmacoeconomic Center
CPT Jill Dacus, MC	DoD Pharmacoeconomic Center
SFC Agustin Serrano	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
Dave Bretzke (via telephone)	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
Elizabeth Hearin	DoD Pharmacoeconomic Center
Debbie Khachikian	Department of Veterans Affairs

3. REVIEW MINUTES OF LAST MEETING

The minutes from the last meeting were accepted as written.

4. INTERIM DECISIONS/ADMINISTRATIVE ISSUES

The DoD Pharmacy and Therapeutics Executive Council held an interim meeting by email on 8 January 2004 and voted to add gatifloxacin (Tequin) to the Basic Core Formulary (BCF) and remove levofloxacin from the BCF. These BCF changes were made in response to a joint DoD/VA open class contract for gatifloxacin that became effective 15 January 2004 and in response to levofloxacin price increases. The contract designates gatifloxacin as the "workhorse" fluoroquinolone on the BCF for the indications of community acquired pneumonia and acute sinusitis at a contract price of $1.35/tablet for all oral dosage strengths. The levofloxacin 500 mg price increased from $2.01 to $5.06 on 31 January 2004. The Council concurred with the contract implementation guidance that the PEC previously issued to MTFs (www.pec.ha.osd.mil/national_contracts.htm). In light of the large price increase for levofloxacin, MTFs should remove levofloxacin from their formularies. Levofloxacin should only be used in cases of medical necessity—when gatifloxacin and other fluoroquinolones will not meet the clinical need of a patient. MTFs must rapidly decrease their use of levofloxacin in order to maximize the potential cost savings from the gatifloxacin contract.

5. NATIONAL PHARMACEUTICAL CONTRACTS AND BLANKET PURCHASE AGREEMENT (BPA) AWARDS, RENEWALS AND TERMINATIONS

A. The next option year was exercised for contracts on the following drugs: colchicine, micronized glyburide, goserelin, ibuprofen, lactulose, permethrin and verapamil.

B. The next option year was not exercised for Forest Pharmaceutical's diltiazem (Tiazac) sustained release due to availability of an AB-rated generic at $0.26 per capsule from Inwood, Forest's generic product line. The generic price became effective 15 December 2003 for the following strengths and NDCs:

Diltiazem SA 120mg Capsules	00259-3687-90	#90	$23.40
Diltiazem SA 180mg Capsules	00259-3688-90	#90	$23.40
Diltiazem SA 240mg Capsules	00259-3689-90	#90	$23.40
Diltiazem SA 300mg Capsules	00259-3690-90	#90	$23.40
Diltiazem SA 360mg Capsules	00259-3691-90	#90	$23.40

C. DSCP signed incentive agreements for Aranesp, Amgen's darbepoetin alfa, and Betaseron, Berlex's interferon beta-1b. The exact content and considerations offered in these agreements can be obtained from local Amgen or Berlex representatives or a copy can also be obtained via e-mail by directing a request to Ted.Briski@amedd.army.mil.

D. Incentive agreements are available on the DSCP website at http://dmmonline.dscp.dla.mil/pharm/incentives.asp. Incentive agreements currently apply to the products listed below. MTFs should ensure they are receiving the correct price for these products:

Alendronate (Fosamax)
Azathioprine (Imuran)
BG Strips (Precision QID, XTRA)
Celecoxib (Celebrex)
Cyclosporine (Gengraf)
Darbpoetin (Aranesp)
Dorzolamide/Timolol (Cosopt)
Estradiol (Esclim)
Estropipate (Ortho Est)
Erythropoetin (Procrit)
Fexofenadine (Allegra)
Fluticasone (Flonase)
Hepatitis A Vaccine (Havrix, Vaqta)
Hepatitis A & B Vaccine (Twinrix)
Hepatitis B Vaccine (Recombivax HB, Engerix-B)
Interferon Beta (Betaseron)
Isometheptene/APAP/Dichloralphenazone (Midrin)
Lansoprazole (Prevacid)
Latanaprost (Xalatan)
Leuprolide (Lupron)
Loratadine (Claritin)
Methylphenidate (Concerta)
Methylphenidate (Metadate CD)
Nisoldipine (Sular)
Olanzapine (Zyprexa)
Pimecrolimus (Elidel)
Phenytoin (Bertek, Mylan generic)
Quetiapine (Seroquel)
Risedronate (Actonel)
Risperidone (Risperdal)
Rizatriptan (Maxalt)
Rofecoxib (Vioxx)
Rosiglitazone (Avandia)
Tolterodine (Detrol, Detrol LA)
Travoprost (Travatan)
Valdecoxib (Bextra)
Warfarin (Coumadin)

6. BCF CHANGES AND CLARIFICATIONS

A. *Bupropion SR* – CPT Jill Dacus (PEC) presented an analysis regarding the proposed addition of bupropion sustained release (SR) to the BCF, which was suggested by the Council at the November 2003 meeting while discussing the new once-daily formulation of bupropion (Wellbutrin XL). The FDA recently approved generic equivalents to GSK's Wellbutrin SR 100 mg; generics for the 150 mg strength are expected to follow in the near future.

Efficacy/Safety/Tolerability – Bupropion SR is a dopamine-reuptake blocker indicated for the treatment of depression and, as Zyban, for smoking cessation. The comparative efficacy of bupropion SR compared to other antidepressants on the BCF is unknown. Bupropion is useful for the treatment of depression in patients who have unacceptable adverse effects, such as sexual dysfunction or weight gain, with the selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants (TCAs). It is not considered a first line antidepressant due to an increased incidence of seizures (about 0.1% at 100-300 mg/day, increasing to 0.4% at the maximum recommended dose of 400 mg/day). There is no evidence that the once-daily formulation of bupropion (Wellbutrin XL) differs from twice-daily bupropion SR with regard to safety or efficacy; the FDA approved both formulations based on bioequivalency studies vs. the immediate release (3 times daily) formulation.

Other Factors – Bupropion SR 100 mg and 150 mg are on 80% (143/179) and 90% (161/179) of MTF formularies, respectively, with the less-widely used 200-mg strength on only 25% of MTF formularies. As of Dec 2003, MTF prescriptions for bupropion SR totaled about 18,000 per month (14,000 for Wellbutrin SR and 4,000 for Zyban). It is unknown how many Wellbutrin SR prescriptions were prescribed for smoking cessation rather than depression. There are about 100,000 MTF prescriptions for SSRIs (the most commonly prescribed antidepressant class) each month.

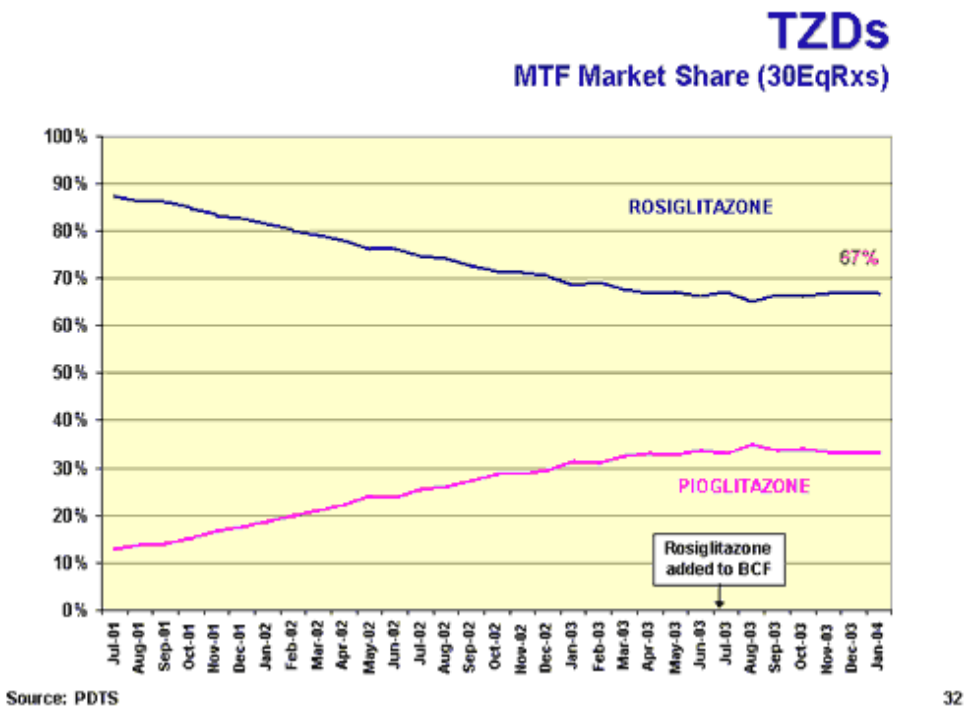
Cost – The current monthly cost for Wellbutrin SR is slightly higher than the newly introduced Wellbutrin XL ($60 vs. $58 per month, based on a typical daily dose of 300 mg). However, prices for bupropion SR should fall as generic competition increases.

The council voted unanimously to add bupropion SR 100 mg and 150 mg to the BCF based on its clinical utility in treating depressed patients who experience unacceptable adverse effects on SSRIs or TCAs, its broad representation on MTF formularies, and the increasing availability of generics. The BCF listing excludes Zyban. The presence of bupropion SR 100 mg and 150 mg on the BCF does not affect the ability of MTFs to place restrictions on the use of bupropion SR for smoking cessation if they so desire. For example, MTFs may institute and/or continue requirements that patients participate in counseling programs when bupropion SR is used for smoking cessation.

B. *Prednisolone Oral* – The BCF listing for prednisolone oral does not specify which dosage forms or strengths are on the BCF. MTF prescription data show minimal usage of prednisolone tablets. The most commonly utilized dosage form and strength is the 15 mg/5 mL syrup. The Council clarified the BCF listing for prednisolone oral to specify prednisolone 15 mg/5 mL syrup.

7. Thiazolidinediones (TZDs)

In June 2003, DoD and VA entered into an incentive agreement with GlaxoSmithKline to place rosiglitazone (Avandia), on the BCF as DoD's preferred thiazolidinedione (TZD) in exchange for a significant discount. The agreement requires that rosiglitazone maintain at least a 65% market share for DoD to achieve a substantial discount. Rosiglitazone's MTF market share had decreased from almost 90% in July 2001 to 67% in June 2003. Since the incentive agreement was implemented, rosiglitazone's market share has stabilized at 67%.



8. TRIPTANS

The zolmitriptan contract stipulates that zolmitriptan must be used for new patient starts on oral triptan therapy unless there is a medical necessity to use a different triptan. MTFs are permitted to have a second triptan on their local formulary for use by patients who have failed zolmitriptan. The contract does not mandate that patients who are already using other triptans be switched to zolmitriptan.

An analysis of prescription data for all MTFs in aggregate for December 2003 revealed that zolmitriptan was used for only 31% of new patient starts. The percentage of new patient starts for zolmitriptan varied significantly across MTFs, ranging from almost no use to as high as 81% (166/205) at Ft Bragg and 100% (22/22) at Pope AFB.

MTFs could achieve substantial cost avoidance by increasing the use of zolmitriptan for new patient starts. Zolmitriptan costs only $3.20 per dose regardless of strength. The price of other triptans depends on the formulary status at the individual MTF and any incentive agreements that may apply. However, prime vendor data for the first quarter of FY 04 show that the average cost per tablet for triptans other than zolmitriptan was $5.00. (Note: This

does not take into account the effect of rebates that an MTF may have obtained.) On average, MTFs could save $1.80 per dose by using zolmitriptan instead of other triptans.

9. CHOLINESTERASE INHIBITORS

CDR Briski presented an analysis of incentive agreements that have been proposed for donepezil (Aricept), galantamine (Reminyl) and rivastigmine (Exelon). Although the cholinesterase inhibitors have similar efficacy, donepezil is dosed once a day versus the twice daily dosing of galantamine and rivastigmine, requires fewer dosage titration steps to therapeutic dose, and appears to be better tolerated.

Donepezil accounted for 86% of the prescriptions filled at MTFs for cholinesterase inhibitors during the first quarter of FY 04. The results of a recently released clinical trial will probably help donepezil maintain or even increase its market share. The clinical trial compared donepezil in conjunction with memantine (an *N*-methyl-D-aspartate (NMDA) receptor antagonist) against donepezil plus placebo in moderate to severe Alzheimer's Disease. Patients treated with donepezil and memantine experienced significantly better outcomes than patients treated with donepezil and placebo on measures of cognition, activities of daily living, global outcome, and behavior.

Given the current and anticipated future usage trends for cholinesterase inhibitors and the pricing offered in the proposed incentive agreements, the analysis showed that DoD would obtain the greatest economic benefit by accepting the donepezil incentive agreement. The Council voted to add donepezil to the BCF and advise DSCP to accept the proposed incentive agreement for donepezil.

10. ANGIOTENSIN RECEPTOR BLOCKERS (ARBS)

A GAO protest caused the VA National Acquisition Center to withdraw the joint DoD/VA solicitation for an ARB in December 2003. The Council reviewed updated clinical information, usage data and cost data in order to formulate a DoD procurement strategy for the ARBs. The Council concluded that significant price reductions could be obtained by selecting one or more ARBs for addition to the BCF. The Council voted to have the PEC work with the Defense Supply Center Philadelphia (DCSP) to issue a BPA request for price quote for ARBs. The Council will consider the price quotes and clinical information about the ARBs to select at least one, but no more than two ARBs for addition to the BCF.

11. SECOND GENERATION ANTIHISTAMINES

The Council reviewed MTF usage and cost data for second generation antihistamines. MTF expenditures for second generation antihistamines are approaching $100 million annually. Although generic and brand name versions of loratadine are available at much lower prices than other second generation antihistamines, loratadine accounted for only 7.6% of the prescriptions for second generation antihistamines filled at MTF pharmacies during the first quarter of FY 04. Cetirizine (Zyrtec) and fexofenadine (Allegra) accounted for 47% and 45% of the prescriptions, respectively.

The Claritin brand of loratadine is available through a joint DoD/VA blanket purchase agreement for $0.38 per 10-mg tablet. Generic loratadine is available at prices as low as $0.12 per 10-mg tablet. Fexofenadine 180 mg costs $0.85 per tablet (incentive agreement

price for having fexofenadine on the BCF). The fexofenadine 180 mg price would increase to $1.42 per tablet if fexofenadine were not on the BCF. Cetirizine 10 mg costs $0.96 per tablet (Feb 2004 FSS price).

Some MTF pharmacy personnel have stated that the presence of fexofenadine on the BCF inhibits their ability to increase the use of loratadine at their MTFs. The Council considered a proposal to remove fexofenadine from the BCF. The Council was concerned that removal of fexofenadine from the BCF would not result in a large enough shift in market share to loratadine to make up for the negative financial impact of a fexofenadine price increase. The Council voted to keep fexofenadine on the BCF until there is evidence that MTFs are able to shift more usage to loratadine. The PEC will provide information to MTFs to assist them in this endeavor. The Council encourages MTFs to maximize the use of loratadine in lieu of other second generation antihistamines.

12. ADJOURNMENT

The meeting adjourned at 1400 hours. The next meeting will be held at Fort Sam Houston, TX at 0800 on Tuesday, 20 April 2004. This meeting would normally be held in May, but the meeting will be held in April in order to accommodate training of Iraqi pharmacists in formulary management procedures. All agenda items should be submitted to the co-chairs no later than 19 March 2004.

<signed>	<signed>
DANIEL D. REMUND	TERRANCE EGLAND
COL, MS, USA	CDR, MC, USN
Co-chair	Co-chair