

Department of Defense Pharmacoeconomic Center

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

MCCS-GPE

14 NOVEMBER 2003

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

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

1. A meeting of the DoD P&T Committee convened at 0800 hours on 14 November 2003, at the DoD Pharmacoeconomic Center, Fort Sam Houston, Texas.

2. VOTING MEMBERS PRESENT

COL Daniel D. Remund, MS	DoD P& T Committee Co-chair
COL Joel Schmidt, MC	Army
COL Doreen Lounsbery, MC	Army
MAJ Travis Watson, MS	Army
Col John R. Downs, MC	Air Force
Col Mark Nadeau, MC (For Col Bill Sykora, MC)	Air Force
LtCol George Jones, BSC	Air Force
CAPT Matt Nutaitis, MC	Navy
CDR Mark Richerson, MSC	Navy
CAPT Dennis Alder	Coast Guard
Dr. Trevor Rabie	Uniformed Services Family Health Plans (USFHP)
Joe Canzolino (For Mike Valentino)	Department of Veterans Affairs

VOTING MEMBERS ABSENT

CAPT Terrance Egland, MC	DoD P& T Committee Co-chair
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OTHERS PRESENT

COL William Davies, MS, USA	DoD Pharmacy Program Director, TMA
CAPT Patricia Buss, MC, USN	Chief Medical Officer Representative, TMA
Howard Altschwager	Deputy General Counsel, TMA
LtCol Phil Samples, BSC, USAF	Air Force Pharmacy Consultant
COL Mike Heath, MS, USA	Army Pharmacy Consultant, Chairman Pharmacy Board of Directors
LTC Kent Maneval, MS, USA	Joint Readiness Clinical Advisory Board
Joe Torkildson, MD	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
Shana Trice	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
David Bretzke (via TC)	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
Lisa LeGette	Express Scripts
MAJ John Howe, MS, USA	Defense Supply Center Philadelphia
Gene Lakey	TriWest
William Hudson	Humana
Ron McDonald (via TC)	Sierra
Rance Hutchings, Pharm.D.	Uniformed Services Family Health Plans (USFHP)
LTC Gwendolyn Thompson, MS, USA	Pharmacy Practice Resident
CPT Jon Feagler, MS, USA	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 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.

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 5 new drugs or formulations (see Appendix A).

7. PRIOR AUTHORIZATIONS (PAs)

A. *Growth Hormone* – Humatrope (somatropin [rDNA origin] for injection) was recently approved by the FDA as a treatment for non-growth hormone-dependent short stature, also known as Idiopathic Short Stature (ISS). This is the first FDA approval of a growth hormone product for ISS. Information regarding the use of growth hormone in pediatric growth disorders and potential costs in the treatment of ISS were presented by the PEC. Information regarding the use of somatropin in ISS considered by the FDA's Endocrinologic & Metabolic Drugs Advisory Committee as part of its review of Humatrope may be found on the FDA website at:
<http://www.fda.gov/ohrms/dockets/ac/cder03.html#EndocrinologicMetabolicDrugs> (click on information from the 10 June 2003 meeting). For a brief overview, FDA summary slides from this advisory committee meeting are available at:
http://www.fda.gov/ohrms/dockets/ac/03/slides/3957S1_03_FDA%20Slides.ppt.

Patients who have a growth hormone deficiency experience medical problems in addition to short stature (e.g. truncal adiposity, immature physical appearance, delayed puberty and decreased bone maturation), therefore it is medically necessary to provide growth hormone therapy to patients who have a growth hormone deficiency. Patients with ISS do not experience medical problems in addition to short stature; therefore it is not medically necessary to provide growth hormone therapy to patients with ISS. Since TRICARE will only pay for therapies that are medically necessary, TRICARE will not pay for growth hormone to treat ISS. The Council directed the PEC to develop a prior authorization for the use of growth hormone in adults and children. The prior authorization criteria will allow coverage for treatment of growth hormone deficiency and will deny coverage for treatment of ISS.

8. MAIL ORDER AND RETAIL NETWORK ISSUES

A. *Carisoprodol Status on the TMOP Formulary* – As of 9/19/2003, carisoprodol (Soma, generics) is classified as a Schedule IV controlled substance in the State of Arizona. Since the dispensing location for the TMOP is in Arizona, carisoprodol is subject to the same TMOP requirements as other Schedule IV controlled substances (limited to a 30-day supply and a maximum of 5 refills in a 6-month period).

B. *Pravigard PAC Status on the TMOP Formulary* – The price for Pravigard PAC (pravastatin and aspirin packaged together) recently decreased from \$1.84-\$2.70 to \$0.74 - \$1.49. Pravigard PAC is now the same price as brand name Pravachol. The Committee voted to add Pravigard PAC to the TMOP formulary.

C. *Serevent Diskus Quantity Limits* – The Committee revised quantity limits for the dry powder formulation of salmeterol (Serevent Diskus), which is twice as potent as the now discontinued metered dose inhaler formulation. The maximum recommended dose for Serevent Diskus is 1 inhalation twice daily. The new quantity limits are 1 inhaler (60 unit-dose blister packs) per 30 days at retail and 3 inhalers (180 unit-dose blister packs) per 90 days in the TMOP.

D. *Zolmitriptan Nasal Spray Quantity Limits* – The Committee approved new quantity limits for zolmitriptan nasal spray. The product is packaged 6 unit-doses per box. One or two unit-doses may be required per headache. Given the package size and package labeling indicating that the safety of treating more than 4 headaches with zolmitriptan in a 30 day period is not established, the Committee set quantity limits for zolmitriptan nasal spray at 36 units (6 boxes) per 90 days in the TMOP and 12 units (2 boxes) per 30 days in retail.

9. **ADJOURNMENT** – The meeting adjourned at 1200 hours. The next meeting will be held at Fort Sam Houston, TX at 0800 on Thursday, 12 February 2004. All agenda items should be submitted to the co-chairs no later than 05 January 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

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

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
Bupropion HCl extended release tablets (Wellbutrin XL; GSK)	09 Sep 03. Indicated for the treatment of major depressive disorder in patients 18 years and older.	Added to the TMOP Formulary	Quantity Limits General rule applies Prior Authorization: None	Not added to the BCF Similar BCF agents: None. Several antidepressants are on the BCF, including 4 SSRIs, 4 TCAs, venlafaxine ER, and trazodone.
<p>Bupropion HCl extended release tablets (Wellbutrin XL) are available in 150 mg and 300 mg formulations and are dosed once daily. Bupropion sustained release tablets are dosed BID and are available in 100, 150 and 200 mg tablets for depression (Wellbutrin SR), and 150 mg tablets for smoking cessation (Zyban). Generic versions are currently available only for bupropion immediate release tablets, which are available in 75 and 100 mg tablets and dosed TID. Generic versions of bupropion SR are expected to be available in the near future.</p> <p>Potential disadvantages related to the introduction of the Wellbutrin XL formulation include</p> <ul style="list-style-type: none"> • Medication errors due to confusion about tablet strengths and differences in maximum dosages between the sustained and extended release products; • Lack of clinical trial information for the extended release product, which was approved based on bioequivalency data; • And potential misuse for smoking cessation. <p>The potential advantage of the once-daily product for depression is largely based on convenience.</p> <p>Since the two peaks associated with bupropion SR are felt to be beneficial for smoking cessation, the once daily, extended release formulation is not expected to be as effective for this purpose as a twice-daily product. The extended release product is not FDA approved for smoking cessation.</p>				
Ciprofloxacin 0.3% / dexamethasone 0.1% otic suspension (Ciprodex; Alcon)	18 Sep 03. Indicated for pediatric patients older than 6 months with acute otitis media with tympanostomy tubes, and for acute otitis externa in patients older than 6 months of age.	Added to the TMOP Formulary	Quantity Limits General rule applies Prior Authorization None	Not added to the BCF Similar BCF agents: There are no otic fluoroquinolones on the BCF. Neomycin / polymyxin B/ hydrocortisone otic suspension (Cortisporin, generics) is on the BCF.
<p>Current otic preparations for treatment of ear infections include:</p> <ul style="list-style-type: none"> • Ciprodex Otic (Alcon) – 0.3% ciprofloxacin/0.1% dexamethasone sterile suspension is approved in pediatric patients down to age 6 months with middle ear infections (otitis media) and tympanostomy tubes. (FSS \$3.99/mL) • Cipro HC Otic (Alcon) – 0.2% ciprofloxacin/1% hydrocortisone non-sterile solution is approved for patients down to 1 year of age for acute otitis externa only. (FSS \$3.99/mL) • Floxin Otic (Daiichi) and generic equivalents – 0.3% ofloxacin without a steroid component is a sterile solution approved for use in children down to 1 year of age for otitis externa, chronic suppurative otitis media, and acute otitis media in patients with tympanostomy tubes, and specifically for perforated tympanic membranes. (FSS \$3.50/mL) • Cortisporin-TC Otic (Monarch) and generics – neomycin 3.3mg/polymyxin 3mg/hydrocortisone 1% is a non-sterile suspension approved for patients down to 2 years of age for otitis externa only and is not approved for use when the tympanic membrane is perforated. (FSS \$0.58/mL) <p>Currently, the BCF only contains one otic preparation for the treatment of ear infections, neomycin/polymyxin/hydrocortisone (Cortisporin Otic, generics), which is indicated for otitis externa only. Treatment options for otitis media will be reviewed at the February meeting to consider additional agents for BCF addition.</p>				

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
Levonorgestrel 0.15 mg / ethinyl estradiol 30 mcg tablets (Seasonale; Barr)	05 Sep 03: Prevention of pregnancy. Consists of 84 active tablets followed by 7 inert tablets (extended cycle use), reducing the number of yearly cycles from 12-13 to 4. The active ingredient/dosage strength of Seasonale is the same as Nordette, a monophasic oral contraceptive.	Added to the TMOP Formulary Note: In the Retail Network, 3 co-pays will be charged, as the product inherently contains a 90-day supply of medication.	Quantity Limits General rule applies. Prior Authorization None	Not added to the BCF Similar BCF agents : There are several monophasic and triphasic oral contraceptives on the BCF, including LoEstrin, Lo-Ovral, and Triphasil.
Rosuvastatin tablets (Crestor; AstraZeneca)	14 Aug 03: Indicated as 1) an adjunct to diet to reduce TC, LDL, ApoB, non-HDL and TG and to increase HDL in primary hypercholesterolemia and mixed dyslipidemias; 2) as an adjunct to diet in patients with elevated TG levels; 3) to reduce LDL, TC, and Apo B in patients with homozygous familial hypercholesterolemia.	Not added to the TMOP Formulary. Medical necessity requirement must be met. (see comments)	Quantity Limits General rule applies to the Retail Network. Prior Authorization None	Not added to the BCF. The existing statin contract precludes BCF addition of rosuvastatin. (see comments) Similar BCF agents : Simvastatin and pravastatin.
<p>Due to the existing DoD high potency statin contract awarded to simvastatin, rosuvastatin is reserved for patients who have a medical necessity to use a statin other than simvastatin. Examples of medical necessity include, but are not limited to:</p> <ul style="list-style-type: none"> • Insufficient reduction of LDL-cholesterol after an adequate trial of simvastatin 80 mg • Patient is on long term therapy with a CYP-3A4 inhibitor or another medication known to interact with simvastatin • Patient experiences unacceptable side effects with simvastatin 				
Vardenafil tablets (Levitra; Bayer / GSK)	19 Aug 03. Approved for the treatment of erectile dysfunction defined as the consistent or recurrent inability to attain and /or maintain a penile erection sufficient for sexual performance. Other drugs in the same class include sildenafil (Viagra), and tadalafil (Cialis), which was approved by the FDA on 21 Nov 03. Tadalafil (Cialis) will be reviewed by the Committee to determine TMOP status at the February 2004 meeting.	Not added to the TMOP Formulary	Quantity Limits Vardenafil quantity limits will be collectively 6 tablets per month with sildenafil and other oral impotency drugs. Prior Authorization Vardenafil will be subject to the same PA process as sildenafil (Viagra), consistent with the Health Affairs Sildenafil Policy	Not added to the BCF Similar BCF agents : There are no phosphodiesterase inhibitors on the BCF.
<p>Notes about Vardenafil: Vardenafil is the second phosphodiesterase-5 (PDE-5) inhibitor to reach the market. It is similar to sildenafil in terms of pharmacokinetics (including onset of action), efficacy and safety. Concomitant use of either drug is contraindicated with nitrates due to the risk of hypotension. 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.</p> <ul style="list-style-type: none"> • TMOP & Retail Network: Vardenafil will have the same non-formulary status in the TMOP as sildenafil does. Both drugs will be available only if prior authorization criteria are met. Vardenafil will be subject to the same prior authorization process as sildenafil, 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. 				

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- None

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

- 1) Cyclobenzaprine – the BCF listing for cyclobenzaprine oral was clarified to exclude the 5 mg strength (high cost; only available as brand Flexeril).
- 2) Zolmitriptan – the BCF listing for zolmitriptan does not include zolmitriptan nasal spray (high cost; not on contract)
- 3) Lansoprazole – the BCF listing for lansoprazole was clarified to exclude the oral disintegrating tablets and delayed release suspension (high cost; capsules have FDA-approved alternative administration options for use in patients with difficulty swallowing).

2. TMOP FORMULARY CHANGES

A. Additions to the TMOP Formulary

- 1) Bupropion HCL extended release tablets (Wellbutrin XL)
- 2) Ciprofloxacin 0.3%/dexamethasone 0.1% otic suspension (Ciprodex)
- 3) Levonorgestrel 0.15 mg/ethinyl estradiol 30 mcg tablets (Seasonale)
- 4) Pravastatin/buffered aspirin (Pravigard PAC)

B. Exclusions from the TMOP Formulary

- 1) Vardenafil tablets (Levitra) – same non-formulary status in TMOP as sildenafil; available from the TMOP if prior authorization criteria are met. Quantity limits apply (see below)
- 2) Rosuvastatin tablets (Crestor) – Due to existing DoD high potency statin contract awarded to simvastatin, rosuvastatin is available through the TMOP only for patients with evidence of medical necessity.

C. Deletions, changes, or clarifications to the TMOP Formulary

- 1) Carisoprodol (Soma, generics) – classified as a Schedule IV controlled substance in Arizona, where the TMOP dispensing facility is located. Subject to the same restrictions as a federally scheduled controlled substance (limited to a 30-day supply and a maximum of 5 refills in a 6-month period).

3. QUANTITY LIMIT CHANGES (RETAIL NETWORK AND TMOP)

A. Quantity limit for zolmitriptan (Zomig) nasal spray:

- TMOP: 36 units (6 boxes) per 90 days
- Retail: 12 units (2 boxes) per 30 days

B. Quantity limits for salmeterol dry powder inhaler (Serevent Diskus):

- TMOP: 3 inhalers per 90 days
- Retail: 1 inhaler per 30 days

C. 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 PROGRAM**

- A. Vardenafil will be subject to the same prior authorization process as sildenafil, consistent with guidelines in the Health Affairs Sildenafil Policy.