Department of Defense
Pharmacoeconomic Center

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MCCS-GPE **6 AUGUST 2003**

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

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

1. A meeting of the DoD P&T Committee convened at 0800 hours on 6 August 2003, at the TRICARE Management Activity (TMA), Falls Church, VA.

2. VOTING MEMBERS PRESENT

CDR Terrance Egland, MC	DoD P& T Committee Co-chair
COL Daniel D. Remund, MS	DoD P& T Committee Co-chair
COL Joel Schmidt, MC	Army
COL Doreen Lounsbery, MC	Army
COL Mike Heath, MS (For MAJ Travis Watson, MS)	Army
LtCol Kimberly May, MC (For Col John R. Downs, MC)	Air Force
Col Bill Sykora, MC	Air Force
LtCol Phil Samples, BSC (For LtCol George Jones, BSC)	Air Force
CAPT Matt Nutaitis, MC	Navy
CDR Mark Richerson, MSC	Navy
CAPT Charles Bruner	Coast Guard
Rance Hutchings, Pharm.D. (For Dr. Trevor Rabie)	Uniformed Services Family Health Plans (USFHP)
Francine Goodman (For Mike Valentino)	Department of Veterans Affairs

VOTING MEMBERS ABSENT

None	

OTHERS PRESENT

COL William Davies, MS	DoD Pharmacy Program Director, TMA
Col Ardis Meier, BSC	Air Force Pharmacy Consultant
CAPT Joe Torkildson, MC, USN	DoD Pharmacoeconomic Center
CDR Denise Graham, MSC, USN	DoD Pharmacoeconomic Center
CDR Ted Briski, MSC, USN	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
LtCol Dave Bennett, USAF, BSC (Via VTC)	DoD Pharmacoeconomic Center
LtCol Barb Roach, USAF, MC (Via VTC)	DoD Pharmacoeconomic Center
CPT Jill Dacus, USA, MC (Via VTC)	DoD Pharmacoeconomic Center
David Bretzke (via VTC)	DoD Pharmacoeconomic Center
Eugene Moore (via VTC)	DoD Pharmacoeconomic Center
Angela Allerman (via VTC)	DoD Pharmacoeconomic Center
Lisa LeGette	Express Scripts
MAJ John Howe, MS	Defense Supply Center Philadelphia
Gene Lakey	TriWest
William Hudson	Humana
Kelly Lenhart	Humana

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

4. **INTERIM DECISIONS**

An interim "email" DoD Executive Council Meeting resulted in the following BCF and TMOP changes:

- Latanoprost (Xalatan) was added to the BCF
- Rosiglitazone (Avandia) was added to the BCF
- Rosiglitazone/metformin (Avandamet) was added to the BCF
- Serevent MDI was removed from the BCF due to market withdrawal. Serevent DPI will be the remaining salmeterol on the BCF.
- Zolmitriptan oral tablets (Zomig) were added to the BCF
- Sumatriptan oral tablets (Imitrex) were removed from the BCF
- Gefitinib (Iressa) was added to the TMOP with quantity limits
- Lovastatin extended release (Altocor) was removed from the TMOP

5. **UNIFORM FORMULARY (UF) PROPOSED RULE**- COL William Davies, DoD Pharmacy Program Director, TMA, stated that the current plan is to implement the Uniform Formulary in conjunction with the TRICARE Retail Pharmacy (TRRx) contract. The TRRx contract is scheduled for implementation in Spring 2004.

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 11 new drugs or formulations (see Appendix A). The PEC also presented brief information on eleven additional new drugs or formulations not requiring action by the Committee (see Appendix B). The Committee agreed that no further review was required.

7. **MAIL ORDER AND RETAIL NETWORK ISSUES**

   A. *TMOP* – Lisa LeGette from Express Scripts provided a TMOP update to the Committee.

   B. *TMOP Prior Authorizations (PAs)* – Shana Trice provided an update on TMOP PAs.

   C. *Change to TMOP PA for Etanercept* - Etanercept (Enbrel) was recently approved for ankylosing spondylitis, a chronic disease involving inflammation of the sacroiliac, intervertebral, and costovertebral joints. Ankylosing spondylitis affects approximately 350,000 patients in the United States. The Committee unanimously added treatment of ankylosing spondylitis to the PA criteria for etanercept. TMOP PA criteria and forms are available on the PEC website at www.pec.ha.osd.mil/TMOP/TMOPhome.htm#2c-PA.

8. **CONTROLLED DISTRIBUTION OF PRESCRIPTION DRUGS** – Enfuvirtide (Fuzeon) 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. Roche Laboratories and Trimeris have contracted the distribution of Fuzeon to the specialty pharmacy operator Chronimed. Fuzeon is available through the TRICARE retail pharmacy benefit through the Fuzeon Progressive Distribution Program established by Chronimed and as described on their website, www.fuzeon.com.

   DoD has made arrangements with Chronimed to make Fuzeon available for MTF pharmacies to purchase and dispense to their patients. The procedure for MTF pharmacies to purchase Fuzeon with their department credit card is outlined on the DoD Fuzeon Procurement Form. The DoD Fuzeon Procurement Form is available for download at the PEC website, http://www.pec.ha.osd.mil/Controlled_Distribution_Drugs.htm, or in the File Library of RxNET, www.dodrxnet.org. Purchases through this mechanism will be billed at federal pricing. Commercial pricing applies to prescriptions filled through the TRICARE retail pharmacy benefit.

   Air Force pharmacies can obtain Fuzeon through the Air Force's High Dollar Program, which is managed out of Wright-Patterson Air Force Base. Air Force facilities wanting to use the High Dollar Program should complete the request forms provided by Wright-Patterson and not the DoD Fuzeon Procurement form described here.

   Questions about the DoD Fuzeon Procurement Form can be directed to David Bretzke or CDR Ted Briski of the DoD Pharmacoeconomic Center at (210) 295-1271.

9. ADJOURNMENT – The meeting adjourned at 1100 hours. The next meeting will be held at Fort Sam Houston, TX at 0800 on Friday, 14 November 2003. All agenda items should be submitted to the co-chairs no later than 06 October 2003.

<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**
Moxifloxacin ophthalmic solution 0.5% (Vigamox; Allergan)	16 Apr 03: Fourth generation quinolone ophthalmic antibiotic indicated for treating bacterial conjunctivitis caused by susceptible strains of aerobic gram positive and aerobic gram negative organisms and Chlamydia.	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization:** None	Not added to the BCF **Similar BCF agents:** None
Oxybutynin transdermal system (Oxytrol; Watson)	10 Mar 03: First transdermal formulation of oxybutynin for treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency. Applied every 3-4 days (twice weekly). The product is packaged in 1 carton containing 8 patches, a 30-day supply.	Added to the TMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF agents:** Oxybutynin oral (immediate release tablets) and tolterodine extended release capsules are on the BCF
Influenza intranasal vaccine (FluMist; Medimmune/Wyeth)	17 Jun 03: First nasally administered live influenza virus vaccine. Approved for active immunization for the prevention of disease caused by influenza A and B viruses in healthy children ages 5-17 and healthy adults ages 18-49. FluMist is not to be administered to asthmatics, immunocompromised patients, or patients taking drugs which compromise the immune system (chemo agents, high dose steroids, etc).	Not added to the TMOP Formulary The product is not intended for self-administration and must remain frozen prior to use.	**Quantity Limits** N/A **Prior Authorization** None	Not added to the BCF **Similar BCF agents**: None
Omalizumab injection (Xolair; Genentech/Novartis)	20 Jun 03: First injectable monoclonal antibody that targets the IgE antibody. Approved for treatment of patients 12 years of age and older with moderate to severe allergy-related asthma that is inadequately controlled with inhaled steroid treatments. Eligible patients must have a positive skin test or *in vitro* reactivity to perennial allergies to confirm the diagnosis of allergy-related asthma.	Not added to the TMOP Formulary	**Quantity Limits** N/A **Prior Authorization** None	Not added to the BCF **Similar BCF agents**: None

Note about Omalizumab: Omalizumab injection will not be available from the TMOP due to the following reasons:

1) The product is not labeled or packaged for patient self-administration. No patient instruction information is enclosed in the package insert.
2) The risk of anaphylaxis and lack of clinical experience with omalizumab does not support its use outside of a controlled environment.
3) Reconstitution and administration requirements make patient preparation difficult. (Omalizumab is a lyophilized powder that takes 15-20 minutes to dissolve. Subcutaneous administration of the viscous liquid takes 5-10 seconds, and multiple injection sites may be needed due to the injection volume.)
4) Commercial distribution is limited to a specialty pharmacy network that supplies medications to physicians' offices.

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
Pravastatin/ buffered aspirin tablets (Pravigard PAC; BMS)	24 Jun 03: This product is not a single tablet formulation, but simply two tablets (pravastatin and buffered aspirin) packaged side-by-side in the same blister pack. Six dosage strengths are available (3 dosages of pravastatin, 20, 40 and 80 mg; with 2 aspirin dosages 81 mg and 325 mg). The product requires a prescription. Indications are to reduce the occurrence of cardiovascular events, including death, MI or stroke in patients who have clinical evidence of cardiovascular and/or cerebrovascular disease. Pravigard PAC is only indicated for secondary prevention of cardiovascular disease; pravastatin is indicated for both primary and secondary prevention.	Not added to the TMOP Formulary	**Quantity Limits** N/A **Prior Authorization** None	Not added to the BCF **Similar BCF agents:** Simvastatin
Notes about Pravigard PAC: • **TMOP**: Pravigard PAC was not added to the TMOP Formulary as it costs a lot more than pravastatin and aspirin that are not packaged together and provides no additional clinical benefit. (Pravigard PAC FSS prices: 20 mg + ASA: $1.84/day; 40 mg +ASA or 80 mg + ASA $2.70/day. Pravastatin FSS prices: 20 mg: $0.75/day; 40 mg: $1.30/day; 80 mg: $1.49/day. Aspirin: Less than $0.01/day.) Pravastatin is available from the TMOP, which will meet the clinical needs of patients with prescriptions for Pravigard PAC. • **BCF & MTF Formularies:** Pravigard PAC was not added to the BCF. The statin contract allows MTFs to have either pravastatin or fluvastatin on their formularies, but not both. MTFs cannot add Pravigard PAC to their local formulary if fluvastatin is on their formulary. MTFs may add Pravigard PAC to their formulary if pravastatin is on their formulary, but MTFs are advised not to add Pravigard PAC to their formulary because it costs too much			
Testosterone buccal system mucoadhesive (Striant; Columbia)	Jun 03: Buccal testosterone mucoadhesive is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone. Schedule III product.	Added to the TMOP, consistent with inclusion of other non-injectable testosterone products	**Quantity Limits** TMOP: 3 cartons per 90 days Note: although there is a 30-day supply limit on most controlled substances dispensed by the TMOP, other topical androgen replacement products have a 90-day supply limit in the TMOP. Retail: 1 carton per 30 days **Prior Authorization** None	Not added to the BCF. **Similar BCF agents:** None.
Note about Testosterone Buccal System Mucoadhesive: This product is supplied in a blister card of 10 buccal systems, with a total of 6 blister cards (60 buccal systems) in each carton. Anticipated retail cost for one month is $149.35 /60 systems= $4.97/day (need 2 systems/day). As of July 15, there was no FSS listing for this formulation.				

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**
Conjugated estrogen / medroxyprogesterone acetate (Prempro 0.3/1.5; Wyeth)	Jun 03: Lower-dose formulation of Prempro contains 0.45 mg of estrogen, and 1.5 mg of progestin (existing Prempro doses include 0.625 / 2.5 mg, and 0.45 mg / 1.5 mg which was approved in April 2003). Approved for both menopausal vasomotor symptoms and osteoporosis.	Added to the TMOP (line extension)	**Quantity Limits** N/A **Prior Authorization** None	BCF listing for conjugated estrogens / medroxy-progesterone oral (Prempro) will include the 0.3/1.5 mg strength
Conjugated estrogen 0.45 mg (Premarin; Wyeth)	Jun 03: Lower-dose formulation of conjugated estrogens approved for both menopausal vasomotor symptoms and osteoporosis.	Added to the TMOP (line extension)	**Quantity Limits** N/A **Prior Authorization** None	BCF listing for conjugated estrogens will include the 0.45 mg strength.
Clonazepam orally disintegrating tablets (Klonopin Wafers; Solvay)	May 03: Rapidly dissolving formulation of clonazepam, available in 0.125, 0.25, 0.5, 1 and 2 mg sizes. There is no FSS price yet for the new formulation, but it is anticipated to be considerably more costly than generic clonazepam tablets, which cost approximately $0.05 per tab. The Committee agreed that the clinical benefit was unlikely to be sufficient to justify the increased cost for the rapidly dissolving formulation.	Added to the TMOP (line extension)	**Quantity Limits** N/A **Prior Authorization** None	The BCF listing for clonazepam 0.5 mg was clarified to exclude clonazepam orally disintegrating tablets.
Risperidone orally disintegrating tablets (Risperdal Redi-tabs; J&J)	May 03: Rapidly dissolving formulation of risperidone, available in 0.5, 1 and 2 mg strengths. Potential candidates may include psychiatric patients on directly observed therapy, or patients with swallowing difficulties. The cost of the orally disintegrating tablets is somewhat higher than the regular tablets, based on either FSS or BPA pricing. Risperidone is not available generically.	Added to the TMOP (line extension)	**Quantity Limits** N/A **Prior Authorization** None	The BCF listing for risperidone was clarified to exclude the orally disintegrating tablets.
Montelukast oral granules (Singulair; Merck)	May 03: New 4 mg oral granule formulation of montelukast. The new formulation is FDA-approved for treating asthma down to 12 months of age, and for treating seasonal allergic rhinitis down to 2 years of age. Previously, the youngest age for which montelukast was indicated was 2 years (4 mg chewable tablets). The oral granules should be mixed with carrots, applesauce, ice cream or rice; they are not to be mixed with liquids. Montelukast is not available generically. The Committee agreed that the new formulation provides an FDA-approved alternative in this age group and is likely to increase the ease of treatment.	Added to the TMOP (line extension)	**Quantity Limits** N/A **Prior Authorization** None	The BCF listing for montelukast oral was clarified to include the oral granules.

APPENDIX B: FORMULARY STATUS OF NEWLY APPROVED DRUGS NOT REQUIRING FORMAL REVIEW BY THE P&T COMMITTEE

Generic name (Trade name; manufacturer)	**Comments**
Omeprazole magnesium delayed release tablets, OTC (Prilosec OTC; Proctor and Gamble))	Indicated for treatment of frequent heartburn symptoms. Therapy should not be continued beyond 14 days. Available as 20.6 mg tablets in the magnesium salt form, which is equivalent to 20 mg of omeprazole. The over-the counter (OTC) product is not AB rated to Rx omeprazole. Prilosec OTC is anticipated to cost $0.80/tablet, but it will be packaged in blister cards of 14, 28, or 42 tablets, which may limit its usefulness to local MTFs considering formulary addition. Prescription omeprazole will remain on the market. Prices for the prescription products: Rx Prilosec: $2.11/cap (FSS); Rx generic omeprazole: $2.89/cap (retail). Prilosec OTC was not considered for addition to the BCF, since it is an OTC product. Currently there are two proton pump inhibitors (PPIs) on the BCF in an open class: rabeprazole and lansoprazole. Prilosec OTC was not added to the TMOP Formulary, since OTC agents are not a covered TRICARE benefit.
Desloratadine orally disintegrating tablets (Clarinex Redi Tabs; Schering)	Automatically added to the TMOP Formulary as a line extension. Not considered for the BCF because desloratadine (Clarinex) is not a BCF item.
Agalsidase beta (Fabrazyme; Genzyme)	Orphan drug for treating Fabry disease. Administered by IV infusion every 2 weeks. Not considered for the TMOP Formulary because it is not intended for self-administration. Not considered for the BCF due to the specialized nature of the medication.
Laronidase (Aldurazyme; Genzyme))	Orphan drug for treating the Hurler and Hurler-Scheile forms of mucopolysaccharidoses I. Administered by IV infusion q week. Not considered for the TMOP Formulary because it is not intended for self-administration. Not considered for the BCF due to the specialized nature of the medication.
Bortezomib (Velcade; Millennium Pharmaceuticals)	Proteasome inhibitor (new class of anti-cancer drugs). Third-line treatment for multiple myeloma. Administered by IV bolus injection twice/week for two weeks, followed by 10 days off therapy. Not considered for the TMOP Formulary because it is not intended for self-administration. Not considered for the BCF due to the specialized nature of the medication.
Tositumomab & I 131 tositumomab (Bexxar; Corixa Corp)	Monoclonal antibody in combination with radiation for non-Hodgkin's lymphoma. Administered by nuclear medicine. Not considered for the TMOP Formulary because it is not intended for self-administration. Not considered for the BCF due to the specialized nature of the medication.
Carbidopa / levodopa / entacapone (Stalevo; Novartis / Orion)	Combination of Anti-Parkinson's agents carbidopa/levodopa with entacapone (Comtan), a catechol-O-methyltransferase [COMT] inhibitor. Entacapone is always given with carbidopa/levodopa, and never administered by itself. The combination product is indicated for treating Parkinson's Disease patients who experience end-of-dose wearing off. Automatically added to the TMOP Formulary as a new combination of drugs already available. Not considered for the BCF since entacapone is not listed on the BCF.
Ondansetron orally disintegrating tablets (Zofran ODT; GSK)	Automatically added to the TMOP Formulary as a line extension. Not considered for the BCF because ondansetron is not listed on the BCF.
Olmesartan medoxomil /HCTZ tablets (Benicar HCT; Forest/Sankyo)	ARB in combination with HCTZ. Automatically added to the TMOP Formulary as a line extension. Not considered for BCF addition as ARB contracting initiative is in progress.
Atazanavir (Reyataz; BMS)	Protease inhibitor approved for use in combination with other antiretroviral agents for HIV. First once daily protease inhibitor. Automatically added to TMOP as an HIV agent. Not considered for the BCF due to the specialized nature of the medication.
Emtricitabine (Emtriva; Gilead)	NNRTI (non-nucleotide reverse transcriptase inhibitor) for HIV. Automatically added to TMOP as an HIV agent. Not considered for the BCF due to the specialized nature of the medication.

APPENDIX C: COMBINED SUMMARY OF FORMULARY CHANGES FROM THE DOD P&T EXECUTIVE COUNCIL MEETING, THE DOD P&T COMMITTEE MEETING, AND THE JULY 2003 INTERIM "E-MAIL" MEETING OF THE DOD P&T EXECUTIVE COUNCIL

1. **BCF CHANGES**

   A. *Additions to the BCF*

      1) Polymycin B Sulfate/Trimethoprim Ophthalmic Solution
      2) Erythromycin Ophthalmic Ointment
      3) Insulin Aspart (Novolog) vials

   Interim Meeting Decisions

      4) Latanoprost (Xalatan)
      5) Rosiglitazone (Avandia)
      6) Rosiglitazone/metformin (Avandamet)
      7) Zolmitriptan oral tablets (Zomig)

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

   Interim Meeting Decisions

      1) Serevent MDI – removed from the BCF due to market withdrawal. The remaining dry powder salmeterol formulation (Serevent Diskus) will be on the BCF.
      2) Sumatriptan oral tablets (Imitrex) – removed from the BCF due to award of the triptan contract.

2. **TMOP FORMULARY CHANGES**

   A. *Additions to the TMOP Formulary*

      1) Moxifloxacin ophthalmic solution 0.5% (Vigamox)
      2) Oxybutynin transdermal system (Oxytrol)
      3) Testosterone buccal system mucoadhesive (Striant) – quantity limits apply, see below

   Interim Meeting Decisions

      4) Gefitinib (Iressa) – quantity limits apply, see below

   B. Exclusions from the TMOP Formulary

      1) Pravastatin/buffered aspirin (Pravigard PAC)
      2) Influenza nasal vaccine (FluMist)

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

   Interim Meeting Decisions

      1) Lovastatin extended release (Altocor) – Interim Meeting Decision

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

A. Quantity limit for testosterone buccal system mucoadhesive (Striant):

- TMOP: day supply limit of 90 days (same exception to usual 30-day supply limit for controlled substances as other topical testosterone products); quantity limit of 3 cartons (180 systems) per 90 days
- Retail: 1 carton (60 systems) per 30 days

B. Quantity limits for gefitinib (Iressa):

- TMOP: day supply limit of 45 days; quantity limit of 45 tablets per 45 days
- Retail: day supply limit of 30 days; quantity limit of 30 tablets per 30 days

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

A. The PA criteria for etanercept (Enbrel) were changed to reflect the recent FDA indication for ankylosing spondylitis. The revised form is available on the PEC website.