# 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

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|---|---|
| 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<br>(For MAJ Travis Watson, MS) | Army |
| Col Mark Nadeau, MC<br>(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

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|---|---|
| Col John R. Downs, MC | Air Force |

**OTHERS PRESENT**

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|---|---|
| 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**<br><br>(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**<br>General rule applies<br><br>**Prior Authorization**<br>None | Not added to the BCF<br><br>**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**<br><br>(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**<br>General rule applies<br><br>**Prior Authorization**<br>Yes. See Paragraph 8C for criteria and further discussion | Not added to the BCF<br><br>**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**<br><br>(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**<br>General rule applies<br><br>**Prior Authorization**<br>None | Not added to the BCF<br><br>**Similar BCF agents**: Another aldosterone antagonist, spironolactone, is on the BCF. |
| **Estradiol / levonorgestrel transdermal system**<br><br>(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**<br>General rule applies<br><br>**Prior Authorization**<br>None | Not added to the BCF<br><br>**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**<br><br>(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**<br>N/A<br><br>**Prior Authorization**<br>N/A | Not added to the BCF<br><br>**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).<br><br>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**<br><br>(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**<br>General rule applies<br><br>**Prior Authorization**<br>None | Not added to the BCF<br><br>**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**<br><br>(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**<br>General rule applies<br><br>**Prior Authorization**<br>None | Not added to the BCF. The BCF listing for fluoxetine was clarified to exclude Symbyax.<br><br>**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**<br><br>(Cialis; Bayer/ GSK) | 21 Nov 03. Approved for the treatment of erectile dysfunction. | Not added to the TMOP formulary | **Quantity Limits**<br><br>*TMOP:* 18 tablets of any combination of the three oral PDE-5 inhibitors per 90 days (collective quantity limit).<br><br>*Retail:* 6 tablets of any combination of the three oral PDE-5 inhibitors per 30 days (collective quantity limit).<br><br>**Prior Authorization**<br>Yes, see notes below. | Not added to the BCF<br><br>**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