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