Department of Defense
Pharmacoeconomic Center

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MCCS-GPE 18 November 1999

MEMORANDUM FOR Assistant Secretary of Defense (Health Affairs)

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

1. In accordance with Health Affairs policy 98-025, a meeting of the DoD P&T committee convened at 0800 hours on 18 November 1999, at the DoD Pharmacoeconomic Center (PEC), Fort Sam Houston, TX.

2. MEMBERS PRESENT:

COL Daniel D. Remund, MS	Co-chairman
CDR Terrance Egland, MC	Co-chairman
COL Rosa Stith, MC	Army
LTC Judith O'Connor, MC	Army
Danielle Doyle	Army
CDR Matt Nutaitis, MC	Navy
LCDR Kevin Cook, MSC	Navy
COL (select) Bill Sykora, MC	Air Force
LTC John R. Downs, MC	Air Force
MAJ George Jones, BSC	Air Force
CDR Robert W. Rist	Coast Guard
Ronald L. Mosier	Department of Veterans Affairs (alternate)
COL George Crawford, MS	Joint Readiness Clinical Advisory Board
LTC Steven Humburg, MC	Health Affairs
MAJ Mickey Bellemin, BSC	Defense Supply Center Philadelphia (DSCP)
Trevor Rabie	Uniformed Services Family Health Plans (USFHP)
Ray Nan Berry	Foundation Health
Kirby Davis	Anthem Alliance
William Hudson	Humana, Inc
Gene Lakey	TriWest
Ron McDonald	Sierra Military Health Services

3. OTHERS PRESENT:

CAPT Charlie Hostettler, MSC	DoD Pharmacy Program Director, TMA
Howard Altschwager	Deputy General Counsel, TMA
David Chicoine	Uniformed Services Family Health Plans (USFHP)
COL Jeffery Meffert, MC	BAMC, Dermatology
CDR Mark Brouker, MSC	DoD Pharmacoeconomic Center
LCDR Mark Richerson, MSC	DoD Pharmacoeconomic Center
MAJ Barbara Roach, MC	DoD Pharmacoeconomic Center
MAJ Ed Zastawny, BSC	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
Mark Petruzzi	Merck-Medco
LTC Gary Blamire, BSC	TRICARE Southwest Lead Agent Office

4. ADMINISTRATIVE ISSUES:

A. Introduction of new members and attendees: Trevor Rabie, MD, is a new committee member representing the Uniformed Services Family Health Plans (USFHP). Howard Altschwager is a new attendee as legal counsel for the DoD P&T Committee.

B. The minutes from the 13 Aug 99 meeting were accepted as written.

C. The co-chairs reported an interim decision to temporarily discontinue the 10-tablet quantity limit for zolpidem (Ambien) because almost all NMOP prescriptions were written for more than 10 tablets and many patients complained about the quantity limit. The labeling for zolpidem recommends that therapy should generally be limited to 7 to 10 days of use, but medical literature supports longer-term use of zolpidem for patients with chronic insomnia. The committee decided that zolpidem should be subject to the standard quantity limit of a 30-day supply for controlled substances.

5. OLD BUSINESS

A. Non-preferred/preferred drug pairs in the NMOP

1. CDR Brouker (PEC) reported that the cumulative switch rates from non-preferred to preferred drugs observed from 29 May 99 to 6 November 99 were similar to the switch rates observed from 29 May 99 to 31 July 99. The overall switch rate was 57%. The committee removed Zileuton (Zyflo) from the list of non-preferred drugs because the NMOP received only six prescriptions for the drug in 24 weeks, and only one of those prescriptions was switched to a preferred drug.

2. MAJ Bellemin reported that Merck-Medco has not yet implemented the new non-preferred/preferred drug pairs approved at the August 1999 P&T meeting. Merck-Medco will implement them on 1 Dec 99.

3. CDR Brouker will design a standard report for monitoring processes and outcomes related to non-preferred/preferred drug pairs in the NMOP. The report will include switch rate data, the resulting distribution of prescriptions within the pertinent drug classes, and the estimated cost avoidance. CDR Brouker will submit a draft of the report to the committee co-chairs not later than 17 December 1999. CDR Brouker will submit the finalized version of the report to the committee at the next meeting.

B. Prior authorizations in the NMOP

1. MAJ Bellemin reported that Merck-Medco has implemented prior authorization processes for celecoxib (Celebrex), rofecoxib (Vioxx), etanercept (Enbrel), and sildenafil (Viagra). He will present data concerning the cost-efficiency of prior authorizations at the next meeting.

2. Military treatment facility (MTF) providers are concerned about the amount of time they spend dealing with phone calls and fax forms from Merck-Medco for drugs requiring prior authorization. MTF providers requested that prior authorization fax forms be posted on the PEC website so that they could save time by filling out the form and having the patient submit it along with the prescription to the NMOP. Mark Petruzzi stated that Merck-Medco would concur with the proposal as long as the actual form approved by Merck Medco was posted on the PEC website. He further stated that prescriptions would be filled without calling prescribers if the prescriptions are submitted along with the correct form and meet the prior authorization criteria. The committee directed the PEC to post the prior authorization fax forms (instead of the prior authorization criteria) on the PEC website. Sufficient explanation and directions will be provided on the website to enable prescribers to fill out the fax form correctly and to emphasize that the forms are intended to facilitate sending prescriptions to the NMOP program only, not to the retail network.

C. Report on starter packs—MTFs may accept starter packs from pharmaceutical companies to the extent that the price paid for a drug includes the cost of any starter packs that are supplied by the pharmaceutical company. Present and future contracts (and DAPAs until they are deleted) should be reviewed to ensure they incorporate language to the effect that the prices charged for the drugs shall include the cost of any starter packs which may be distributed to DoD facilities and given to patients. The DOD Pharmacy Board of Directors recommended that MTFs determine local policy for the use of starter packs, with the caveat that starter packs should be dispensed by the pharmacy and not in the physician's office.

D. Report of the formulary management subcommittee—COL Remund reported that the task originally assigned to the subcommittee will be performed by a workgroup formed by TMA to draft regulations pertaining to the pharmacy benefit section of the FY 00 Defense Authorization Act. The subcommittee was dissolved.

E. Report of the fertility drugs subcommittee—This issue was tabled pending resolution of formulary redesign issues.

F. Report of the weight reduction subcommittee—TRICARE policy currently excludes coverage of drug therapy for weight reduction. MAJ Barb Roach (PEC) reported that a review of drug therapy for weight reduction did not reveal a compelling clinical imperative to recommend coverage for such therapy. The committee decided not to recommend any change to the TRICARE policy.

G. Advances in Medical Practice (AMP) funding initiative—A subcommittee was to have developed a list of drugs that could possibly be purchased with AMP funds, but officials responsible for the AMP program needed the list before the subcommittee could meet. The PEC gave the AMP officials a list of newly approved drugs that were categorized as to their relative clinical importance based on the degree of therapeutic advance over other agents, the severity/intractability of the condition, and the availability of other agents. The AMP officials will use this list to help determine which drugs should be obtained with AMP funding.

H. Status of TRICARE/CHAMPUS Policy Manual changes pertaining to pharmacy —CAPT Hostettler reported that Chapter 7 of the TRICARE/CHAMPUS Policy Manual has officially been changed so that quantity limits and prior authorizations apply uniformly to the NMOP and retail pharmacy networks.

6. NEW BUSINESS

A. Quantity Limits—MAJ Bellemin reported on quantity limits issues that were pending from the last meeting:

Blood product/biotech products: The committee decided that quantity limits on antihemophilic factors (e.g., Factor VIII, Factor IX Complex) were unnecessary, given the small number of prescriptions received by the NMOP for these agents. MAJ Bellemin informed the committee that the NMOP has quantity limits for other agents in this category that were not included on the list that the committee approved at the August 1999 meeting.

Topicals: Information regarding the typical quantities dispensed for five high-cost topicals (imiquimod (Aldara); calcipotriene (Dovonex); altitretinoin (Panretin); becaplermin (Regranex); and tazarotene (Tazorac)) is not yet available from Merck-Medco. Mark Petruzzi (Merck-Medco) will supply this information to a subcommittee consisting of Bill Hudson (Humana; subcommittee chair), MAJ George Jones, and all Managed Care Support Contractor (MCSC) pharmacy representatives. The subcommittee will formulate recommendations for quantity limits for these topical agents. An interim report is due to the co-chairs not later than 20 January 2000, and a full report is to be submitted to the committee at the next meeting. MAJ Bellemin informed the committee that the NMOP has quantity limits for other topicals that were not included on the list that the committee approved at the August 1999 meeting.

Antibiotics: MAJ Bellemin reported no problems with the current quantity limits on antibiotics. MAJ Bellemin also informed the committee that the NMOP has quantity limits for other antibiotics that were not included in the list that the committee approved at the August 1999 meeting.

Fertility Agents: MAJ Bellemin reported no problems or patient complaints associated with the 20 ampules per prescription quantity limit on injectable fertility agents.

Ophthalmics: MAJ Bellemin reported no problems with quantity limits on ophthalmics established at the last meeting.

Ondansetron for hyperemesis gravidarum: The quantity limits for ondansetron do not support the use of ondansetron for hyperemesis gravidarum. Ondansetron is Pregnancy Category B and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Consultation with MTF specialists indicated that ondansetron is not widely used or recommended for hyperemesis gravidarum. However, Gene Lakey (TriWest) reported that second level medical review through TriWest concluded that ondansetron is appropriate for hyperemesis gravidarum for some patients. The typical procedure in the retail network is to override the quantity limit if the medical review determines that a larger quantity is medically appropriate. The committee decided not to change the quantity limit for ondansetron in either the NMOP or the retail network because the small number of cases where ondansetron is used for hyperemesis gravidarum can be managed on an exception basis.

Actions: MAJ Bellemin and Mark Petruzzi (Merck-Medco) will supply a list of all NMOP quantity limits to the PEC. The PEC will then update the quantity limits listed on the PEC website. The PEC will submit a comprehensive list of all quantity limits for the NMOP and retail pharmacy networks for the committee to review at the next meeting.

B. Prior authorization for oral antifungal medications (NMOP and retail network)—TMA officials asked the committee to render an opinion about prior authorization criteria that attempt to differentiate between cosmetic and non-cosmetic use of oral terbinafine (Lamisil) for onychomycosis. COL Jeffery Meffert, MC, BAMC Dermatology, assisted the committee as a guest expert. After extensive discussion, the committee reached general agreement on the following points:

- It is difficult to clearly define and accurately differentiate cosmetic use from non-cosmetic use of oral terbinafine.
- Systemic antifungal therapy should not be instituted unless the presence of a fungal infection is clearly established by KOH prep, culture, or PAS stain. Use of systemic antifungal therapy in the absence of a fungal infection unnecessarily exposes the patient to the risk of adverse effects and wastes money.
- The pulse dosing of terbinafine for the treatment of onychomycosis provides the same degree of effectiveness and offers significant economic advantage over daily dosing.
- Even though the initial treatment with oral terbinafine usually eliminates the fungal infection, the nails may remain discolored until they grow out. It is inappropriate to continue oral terbinafine therapy just because the nails are discolored.

- A prior authorization program for oral terbinafine could potentially shift usage to itraconazole, which is even more expensive than terbinafine for onychomycosis.

The committee concluded that oral terbinafine should be subject to prior authorization that focuses on the appropriate diagnosis of onychomycosis and appropriate duration of therapy. The committee co-chairs will finalize the prior authorization criteria for oral terbinafine. The prior authorization program for oral terbinafine will be monitored for a shift in usage to the more expensive agent.

C. The committee considered a number of drugs for addition to the BCF and the NMOP Formulary. See Appendix A for a list of formulary changes.

D. Prior authorization for growth hormone treatment — The committee decided that in light of the costs associated with growth hormone treatment and the potential for inappropriate use, a subcommittee should evaluate the need for prior authorization and recommend appropriate criteria. The subcommittee will be chaired by Bill Hudson (Humana) and includes MAJ George Jones, MAJ Mickey Bellemin, Ray Nan Berry (Foundation Health), Kirby Davis (Anthem Alliance), William Hudson (Humana), Gene Lakey (TriWest), and Ron McDonald (Sierra Military Health Services). The subcommittee will evaluate current utilization in the NMOP and retail networks, formulate potential prior authorization criteria, and estimate potential cost savings associated with a prior authorization program. The subcommittee will submit an interim report to the co-chairs not later than 20 January 2000 and will provide the finalized report and recommendations to the committee at the next meeting.

E. Oral inhaled corticosteroids—On 1 November 1999 the price of the Schering brand of beclomethasone inhaler (Vanceril) increased from $5.75 to $19.27, and the price of the double strength beclomethasone inhaler (Vanceril DS) increased from $6.90 to $27.02. The committee decided to remove beclomethasone and beclomethasone double strength oral inhaler from the BCF because they are now among the most costly inhalers for any given dosage range (see Appendix C).

Although the triamcinolone oral inhaler is now the only oral corticosteroid inhaler remaining on the BCF, that does not mean that MTFs should have only the triamcinolone inhaler on their formularies. MTFs almost certainly need more than one oral corticosteroid to satisfy the clinical needs of patients, but the committee did not want to mandate a specific inhaler by selecting another inhaler for the BCF. Price instability within the drug class, the anticipated introduction of products reformulated without chlorofluorocarbons, and the impending introduction of a new agent make it difficult for the committee to ascertain which inhaler (in addition to triamcinolone) provides the greatest value. The committee recommends that MTFs consider the information provided in Appendix C in selecting agents for MTF formularies.

F. Selective serotonin reuptake inhibitors—The BCF currently specifies that MTFs must have at least one SSRI on their formularies, but the BCF does not identify a specific SSRI. The committee considered two options regarding the status of SSRIs on the BCF:

- Option 1: Add citalopram, fluoxetine, paroxetine, and sertraline to the BCF and provide information that the MTFs and/or TRICARE regions could use to encourage greater use of the more cost-effective agents.

- Option 2: Continue the current status of SSRIs on the BCF and provide information that the MTFs and/or TRICARE regions could use to encourage greater use of the most cost-effective agents.

The committee selected Option 2 because of concern that Option 1 would cause large increases in expenditures for SSRIs at MTFs that currently have only one SSRI on formulary. The BCF will continue to specify that MTFs must have at least one SSRI on their formularies. The committee directed the PEC to provide information about the relative cost-effectiveness of the SSRIs to MTFs and TRICARE regions. The committee strongly encourages MTFs and TRICARE regions to maximize the use of the most cost-effective SSRIs when consistent with the clinical needs of patients.

G. Withdrawal of betaxolol (Betoptic; Alcon) ophthalmic solution—The committee approved a change in the BCF listing for "betaxolol ophthalmic solution" to "betaxolol ophthalmic suspension" as a result of the withdrawal of betaxolol ophthalmic solution from the market. Betaxolol ophthalmic suspension (Betoptic S; Alcon) remains available. Another ophthalmic beta-blocker, timolol, is also on the BCF.

H. Unavailability of propranolol LA —Mel Miller (PEC) informed the committee that Wyeth-Ayerst sent a letter to physicians and patients concerning an anticipated shortage of both Inderal LA and generic propranolol LA, both of which are made by Wyeth-Ayerst. The committee concluded that this is probably not a significant issue for DoD because propranolol LA (brand and generic) accounts for a relatively small proportion of oral beta-blockers used by DoD facilities. Additionally, Wyeth-Ayerst has notified its customers that it will be shipping product by mid-December, so any shortages will be short-lived.

I. Legislation regarding the DoD P&T Committee and DoD formulary management—Capt Hostettler and Mr. Altschwager briefed the committee on the FY00 Defense Authorization Act that amends Chapter 55 of title 10, United States Code, to establish a DoD Pharmacy Benefits Program. The Pharmacy Benefits Program provides for the establishment of a uniform formulary, a DoD P&T Committee, and a Uniform Formulary Beneficiary Advisory Panel that will review and comment on the development of the uniform formulary and subsequent formulary changes.

J. Pharmaceutical contracts awarded since last P&T meeting—COL Remund reported that DoD statin contracts were awarded to Merck for simvastatin (Zocor) and to Bayer for cerivastatin (Baycol). These contracts “close” the statin class on the BCF. A joint DoD-VA contract was awarded to Novo Nordisk for 10 mL vials of human insulin (rDNA) N, R, L, and 70/30. Joint DoD-VA generic contracts were awarded for specific brands of amantadine capsules, amoxicillin capsules, captopril tablets, fluocinolone solution, fluocinonide cream, fluocinonide ointment, fluocinonide solution, nortriptyline capsules, prazosin capsules, and verapamil sustained-release tablets. A summary of national pharmaceutical contracts is provided in Appendix D.

K. DoD P&T Committee involvement in pharmaceutical procurement contracts—Any pharmaceutical contracting initiative that is more complex than the simple selection of a specific brand among AB-rated generics should be sanctioned by the DoD P&T Committee

before a solicitation is issued.

L. Potential contracting initiatives:

1. *Estrogen replacement therapy:* Conjugated estrogen (Premarin) is on the BCF and has more than 90% of the estrogen replacement therapy market in DoD. The current price for Premarin tablets is nearly triple the price that existed when the drug was in the depot system. Alternate drugs are available to compete for market share. For example, a large HMO in the state of Washington achieved significant cost savings by converting more than 14,000 patients from conjugated estrogens to an esterified estrogen product. The committee recommended that DSCP and the PEC continue to explore the potential for a joint VA and DoD contract. The committee also recommended that DSCP explore potential price reductions through DAPA incentive agreements.

2. *Nicotine patches:* The joint DoD/VA clinical practice guideline for smoking cessation includes the use of nicotine patches. Drug therapy for smoking cessation is not a covered benefit in the NMOP and retail pharmacy networks. A nicotine patch is not listed on the BCF, but some MTFs provide nicotine patches as part of smoking cessation programs. The 3-step (21 mg, 14 mg, and 7 mg) nicotine patches account for the vast majority of DoD and VA nicotine patch usage. Four companies market a 3-step nicotine patch, so an opportunity exists for price competition. The committee favors a contracting initiative that will lower the cost of nicotine patches for those MTFs that choose to have a nicotine patch on their formulary. The committee, however, does not want to select a nicotine patch for the BCF and thus mandate that all MTFs have a nicotine patch on their formularies. The committee recommended that VA and DoD seek a joint contract for a single brand of 3-step nicotine patches. The committee recommended that the contract include the following provisions:

   - The contract would not require MTFs to have a nicotine patch on their formularies. If an MTF does have a 3-step nicotine patch on its formulary, it must be the contracted brand. An MTF may not have a non-contracted brand of 3-step nicotine patches on its formulary.

   - The nicotine patch class would remain "open" on the BCF. The contract would not affect the formulary status of other types of nicotine patches (i.e. 1-step (Nicotrol) or 2-step (Prostep) patches). MTFs could choose to have Nicotrol or Prostep patches on their formularies in addition to or instead of the contracted brand of the 3-step nicotine patch.

3. *Non-sedating antihistamines:* DoD expenditures are increasing significantly in this drug class. None of the agents are on the BCF. The following issues affect the potential for a joint contract for VA and DoD in this drug class:

   - Some MTFs oppose a contract that would add a non-sedating antihistamine to the BCF because they do not want to add a non-sedating antihistamine to the MTF formulary.

   - Some MTFs want a contract that adds a non-sedating antihistamine to the BCF in order to obtain significant price reductions.

- Definition of the drug class is problematic. Loratidine (Claritin) and fexofenadine (Allegra) are classified as “non-sedating” antihistamines. Cetirizine (Zyrtec) is considered a “low-sedating” antihistamine since the incidence of sedation in clinical trials with cetirizine is significantly more than with placebo. All three agents appear to be less sedating than conventional antihistamines.

The committee recommended that VA and DoD explore the possibility of a joint contract that would select a non-sedating antihistamine for the BCF and leave the class “open” on the BCF. The committee also recommended that DSCP should seek price reductions through DAPA incentive agreements.

7. ADJOURNMENT: The meeting adjourned at 1500 hours. The next meeting will be held on Thursday, 24 February 2000, at Portsmouth, Virginia. All agenda items should be submitted to the DoD PEC no later than Friday, 28 January 2000.

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

LIST OF APPENDICES:

Appendix A: Formulary Changes

Appendix B: Reports Due to the Committee

Appendix C: Table: Cost per Month for Oral Inhaled Corticosteroids (Adults)

Appendix D: Table: DoD and DoD/VA Pharmaceutical Contracts

Appendix A: Formulary Changes

A. BCF

1. Beclomethasone and beclomethasone double strength oral inhalers were removed from the BCF.

2. The BCF listing for betaxolol ophthalmic solution was changed to betaxolol ophthalmic suspension as a result of the withdrawal of the solution formulation.

B. NMOP

1. Ketotifen fumarate ophthalmic solution (Zaditor; Ciba Vision) —added to NMOP Formulary

2. Pioglitazone (Actos; Takeda) —added to NMOP Formulary

3. Temozolomide (Temodar; Schering) —Bill Hudson (Humana) reported that pharmacies in national chains, which tend to have their own warehouses and distribution systems, have reported some trouble obtaining this drug, since the national chains have not been stocking this in their warehouses. Although the committee agreed that the NMOP is probably not the most efficient or desirable way for patients to acquire this chemotherapy agent, the committee agreed that temozolomide should be available through the NMOP. Added to the NMOP Formulary with a 30-day quantity limit (1 cycle).

4. Zaleplon (Sonata; Wyeth-Ayerst) —added to NMOP Formulary with a 30-day quantity limit due to its status as a Schedule IV drug as well as recommendations in product labeling

5. Doxercalciferol (Hectorol; Bone Care International) —added to NMOP Formulary

6. Cyanocobalamin intranasal gel (Nascobal; Schwarz Pharma) —The current excluded drug listing on the NMOP Formulary reads "Legend vitamins - Please note that legend formulations of folic acid, niacin, and vitamins D, K, and B12 (injection) are covered." The intranasal formulation of cyanocobalamin is an alternative for treatment of B12 deficiency states (in patients who are hematologically stable and do not have nervous system involvement). The committee agreed to change the excluded drug list notation to "Legend vitamins - Please note that legend formulations of folic acid, niacin, and vitamins D, K, and B12 are covered" and notify Merck-Medco that intranasal cyanocobalamin gel is covered.

7. Sermorelin acetate for injection (Geref; Serono) —This agent is growth hormone releasing hormone, indicated for treatment of idiopathic growth hormone deficiency in children with growth failure. It is useful only in children who retain pituitary responsiveness to growth hormone releasing hormone. Other growth hormone products are currently on the NMOP Formulary. Unlike the growth hormones, growth hormone-releasing hormone may be undetectable by current testing for growth hormone use in athletic competitions.

Added to NMOP Formulary only for patients who are 16 years old or younger. Mark Petruzzi (Merck-Medco) will report back to committee co-chairs if there are any problems with implementing the age edit in the NMOP.

8. Levonorgestrel tablets (Plan B; Women's Capital Corporation) —This emergency contraception product was excluded from the NMOP Formulary because it must be used within 72 hours of unprotected intercourse to be effective.

9. Rabeprazole (Aciphex; Eisai/Janssen) —excluded from the NMOP Formulary per contractual requirements of the proton pump inhibitor contract. Like lansoprazole (Prevacid; TAP), rabeprazole will be listed as a "non-contracted drug" on the NMOP Formulary. It will be provided by the NMOP only if medical necessity is substantiated.

10. Entacapone (Comtan; Orion/Novartis) —added to NMOP Formulary

11. Sirolimus solution (Rapamune; Wyeth Ayerst) —added to NMOP Formulary

12. Zileuton (Zyflo; Abbott) was removed from the list of non-preferred drugs.

Appendix B: Reports Due to the Committee

1. Growth hormone subcommittee (Bill Hudson (chair); MAJ George Jones; MAJ Mickey Bellemin; Ray Nan Berry (Foundation Health); Kirby Davis (Anthem Alliance); William Hudson (Humana); Gene Lakey (TriWest); Ron McDonald (Sierra Military Health Services)) — An interim report is due to the co-chairs not later than 20 January 2000, and a full report with recommendations is due at the next meeting of the P&T committee.

2. Listing of quantity limits on the PEC website — MAJ Bellemin and Mark Petruzzi (Merck-Medco) will supply a list of all NMOP quantity limits to the PEC. The PEC will then update its website to accurately reflect quantity limits for blood products/biotech products, antibiotics, topicals and other categories as necessary. The PEC will submit a complete report of all quantity limits for the NMOP and retail pharmacy networks for the committee to review at the next meeting.

3. Quantity limits for topicals — A subcommittee consisting of Bill Hudson (chair); MAJ George Jones; MAJ Mickey Bellemin; Ray Nan Berry (Foundation Health); Kirby Davis (Anthem Alliance); William Hudson (Humana); Gene Lakey (TriWest); and Ron McDonald (Sierra Military Health Services) will formulate recommendations for quantity limits on five high-cost topicals: imiquimod (Aldara); calcipotriene (Dovonex); altitretinoin (Panretin); becaplermin (Regranex); and tazarotene (Tazorac).

4. Non-preferred/preferred drug pairs standard report (see Paragraph 5A3) — CDR Brouker (PEC) will submit a draft of a standard report to the co-chairs not later than 17 December 1999. CDR Brouker will submit the finalized version of the report to the committee at the next meeting.

5. Prior authorization for oral antifungals — CDR Terry Egland, COL Dan Remund will report the status of the prior authorization for oral terbinafine at the next meeting.

Appendix C: Cost per month for oral inhaled corticosteroids (adults)

						Number of puffs per day and approximate cost per month		
NDC	**Generic Name**	**Trade Name**	**Pkg sz**	**# Inh per unit**	**DAPA 10/99***	**Low dose****	**Medium dose****	**High dose****
173046900	Beclomethasone 42mcg/puff	Beclovent (Glaxo) MDI	6.7 GM	80	8.00	4 - 12 puffs $12.00 - $36.00	12 - 20 puffs $36.00 - $60.00	20 or more puffs $60.00 +
173031288	Beclomethasone 42mcg/puff	Beclovent (Glaxo) MDI	16.8 GM	200	19.07	4 - 12 puffs $11.44 - $34.33	12 - 20 puffs $34.33- $57.21	20 or more puffs $57.21 +
85111201	Beclomethasone 84mcg/Actuat	Vanceril-DS (Schering) MDI	12.2 GM	120	27.02	2 - 6 puffs $13.51 - $40.53	6 - 10 puffs $40.53 - $67.55	10 or more puffs $67.55 +
85073604	Beclomethasone 42mcg/puff	Vanceril (Schering) MDI	17 GM	200	19.27	4 - 12 puffs $11.56 - $34.69	12 - 20 puffs $34.69- $57.81	20 or more puffs $57.81+
186091542	Budesonide 200mcg/Inhl	Pulmicort (Astra) DPI	0.4 GM	200	67.42	1 - 2 puffs $10.11 - 20.23	2 - 3 puffs $20.23 - $30.34	3 - 4 or more puffs $30.34 - 40.45 +
456067099	Flunisolide 250mcg/puff Menthol	Aerobid-M (Forest) MDI	7 GM	100	2.79	2 - 4 puffs $1.67- $3.35	4 - 8 puffs $3.35 - $6.70	8 or more puffs $6.70 +
456067299	Flunisolide 250mcg/puff	Aerobid (Forest) MDI	7 GM	100	2.79	2 - 4 puffs $1.67- $3.35	4 - 8 puffs $3.35 - $6.70	8 or more puffs $6.70 +
173049700	Fluticasone 44mcg/puff	Flovent (Glaxo) MDI	7.9 GM	60	19.64	2 - 6 puffs $19.64- $58.92		
173049100	Fluticasone 44mcg/puff	Flovent (Glaxo) MDI	13 GM	120	13.78	2 - 6 puffs $6.89 - $20.67		
173049800	Fluticasone 110mcg/puff	Flovent (Glaxo) MDI	7.9 GM	60	24.57	2 puffs $24.57	2 - 6 puffs $24.57 - $73.71	6 - 8 puffs $73.71- $98.28
173049400	Fluticasone 110mcg/puff	Flovent (Glaxo) MDI	13 GM	120	21.95	2 puffs $10.98	2 - 6 puffs $10.98 - $32.93	6 - 8 puffs $32.93 - $43.90
173049900	Fluticasone 220mcg/puff	Flovent (Glaxo) MDI	7.9 GM	60	38.53			3 - 4 puffs $57.80 - $77.06
173049500	Fluticasone 220mcg/puff	Flovent (Glaxo) MDI	13 GM	120	45.97			3 - 4 puffs $34.48 - $45.97
173051100	Fluticasone 50 Mcg/Inhalation	Flovent Rotadisk (Glaxo) DPI	1.5 GM	60	12.95	2 - 6 puffs $12.95 - $38.85		
173050900	Fluticasone 100 Mcg/Inhalation	Flovent Rotadisk (Glaxo) DPI	1.5 GM	60	14.5		3 - 6 puffs $21.75 - $43.50	6 - 10 puffs $43.50- $72.50
173050400	Fluticasone 250 Mcg/Inhalation	Flovent Rotadisk (Glaxo) DPI	1.5 GM	60	34.73			2 - 4 puffs $34.73- $69.46
75006037	Triamcinolone 100mcg/puff	Azmacort (RPR) MDI	20 GM	240	9.6	4 - 8 puffs $4.80 - $9.60	8 - 12 puffs $9.60 - $14.40	12 - 16 puffs $14.40 - $19.20

* DAPA price for a 30-day supply as of 10/1/99 plus Schering price increases effective 11/1/99

** Dose in puffs or inhalations/day, derived from NHLBI Asthma Guidelines--Expert Panel 2 Report Figure 3-5b, page 88

Appendix D: DoD and DoD/VA Pharmaceutical Contracts

Drug	Manufacturer	Strength	NDC	Package Size	Package Cost	Tablet or Capsule Cost	Contract Base Period*	Potential Annual Cost Avoidance
Albuterol inhaler	Warrick	0.09 mg/ inh	59930-1560-01	17 gm	$1.75	NA	11/98-11/99	$568,000
Amantadine capsules	Invamed	100 mg	62269-0211-24 62269-0211-29	100 500	$5.50 $26.00	$0.0550 $0.0520	8/99-8/00	$16,000†
Amoxicillin capsules	Apothecon	250 mg	00003-0101-50 00003-0101-60	100 500	$2.65 $10.87	$0.0260 $0.0220	8/99-8/00	$69,121
		500 mg	00003-0109-55 00003-0109-60	100 500	$4.50 $18.99	$0.0450 $0.0380		
Captopril tablets	Apothecon	12.5 mg	59772-7045-01 59772-7045-03	100 1000	$1.17 $9.24	$0.0117 $0.0092	10/99-10/00	$230,000
		25 mg	59772-7046-01 59772-7046-03	100 1000	$1.25 $10.77	$0.0125 $0.0108		
		50 mg	59772-7047-01 59772-7047-03	100 1000	$2.10 $16.50	$0.0210 $0.0165		
		100 mg	59772-7048-01	100	$5.14	$0.0514		
Cerivastatin	Bayer	0.2 mg	00026-2883-51	100	$30.00	$0.3000	8/99-8/00	See Simvastatin
		0.3 mg	00026-2884-51	100	$30.00	$0.3000		
		0.4 mg	00026-2885-69 00026-2885-51	30 100	$9.00 $30.00	$0.3000 $0.3000		
Cimetidine	Sidmak	300 mg	50111-550-01 50111-550-02 50111-550-03	100 500 1000	$3.12 $14.20 $27.56	$0.0312 $0.0284 $0.0276	11/98-11/99	$300,000‡
		400 mg	50111-551-04 50111-551-01 50111-551-02 50111-551-03	60 100 500 1000	$2.72 $4.04 $18.40 $34.40	$0.0453 $0.0404 $0.0368 $0.0344		
		800 mg	50111-552-10 50111-552-01 50111-552-02	30 100 500	$2.68 $8.90 $42.25	$0.0893 $0.0890 $0.0845		
Diltiazem extended release tablets	Forest	120 mg	00456-2612-00 00456-2612-30 00456-2612-90	1000 30 90	$270.00 $8.10 $24.30	$0.2700 $0.2700 $0.2700	12/98-12/99	$5.7 million
		180 mg	00456-2613-00 00456-2613-30 00456-2613-90	1000 30 90	$270.00 $8.10 $24.30	$0.2700 $0.2700 $0.2700		
		240 mg	00456-2614-00 00456-2614-30 00456-2614-90	1000 30 90	$270.00 $8.10 $24.30	$0.2700 $0.2700 $0.2700		
		300 mg	00456-2615-00 00456-2615-30 00456-2615-90	1000 30 90	$430.00 $12.90 $38.70	$0.4300 $0.4300 $0.4300		
		360 mg	00456-2616-00 00456-2616-30 00456-2616-90	1000 30 90	$430.00 $12.90 $38.70	$0.4300 $0.4300 $0.4300		
Fluocinolone solution	Bausch & Lomb	0.01%	24208-0465-63 24208-0465-67	20 ml 60 ml	$1.72 $2.12	NA	9/99-9/00	Not significant
Fluocinonide cream	Teva	0.05%	00093-0262-15 00093-0262-30 00093-0262-92	15 gm 30 gm 60 gm	$1.00 $1.50 $2.25	NA	9/99-9/00	$288,000
Fluocinonide ointment	Teva	0.05%	00093-0264-15 00093-0264-30 00093-0264-92	15 gm 30 gm 60 gm	$3.50 $5.50 $7.25	NA		
Fluocinonide soln	Teva	0.05%	00093-0266-39	60 ml	$5.50	NA		
Lisinopril tablets	Zeneca	2.5 mg	00310-0135-10	100	$14.00	$0.1400	8/99-8/00	$7.6 million
		5 mg	00310-0130-39 00310-0130-10 00310-0130-34	100 UD 100 1000	$14.00 $14.00 $140.00	$0.1400 $0.1400 $0.1400		
		10 mg	00310-0131-39 00310-0131-10 00310-0131-34 00310-0131-73	100 UD 100 1000 3000	$14.00 $14.00 $140.00 $420.00	$0.1400 $0.1400 $0.1400 $0.1400		
		20 mg	00310-0132-39 00310-0132-10 00310-0132-34 00310-0132-73	100 UD 100 1000 3000	$14.00 $14.00 $140.00 $420.00	$0.1400 $0.1400 $0.1400 $0.1400		
		40 mg	00310-0134-10	100	$14.00	$0.1400		

* Most contracts have options for renewal periods
† Estimate ranges from $15,500 to $17,500 depending on purchased package size mix
‡ Estimate ranges from $233,000 to $364,000

Appendix D (continued): DoD and DoD/VA Pharmaceutical Contracts

Drug	Manufacturer	Strength	NDC	Package Size	Package Cost	Tablet or Capsule Cost	Contract Base Period*	Potential Annual Cost Avoidance
Insulin, Human (rDNA)	Novo Nordisk	Novolin N	00169-1834-11	10 ML	$4.49	NA	11/99-11/00	$820,000
		Novolin R	00169-1833-11	10 ML	$4.49			
		Novolin L	00169-1835-11	10 ML	$4.49			
		Novolin 70/30	00169-1837-11	10 ML	$4.49			
Nortriptyline capsules	Teva	10 mg	00093-0810-01	100	$1.83	$0.0183	10/99-10/00	$179,000
			00093-0810-05	500	$8.69	$0.0174		
		25 mg	00093-0811-01	100	$2.46	$0.0246		
			00093-0811-05	500	$11.07	$0.0221		
		50 mg	00093-0812-01	100	$3.31	$0.0331		
			00093-0812-05	500	$15.72	$0.0314		
		75 mg	00093-0813-01	100	$4.21	$0.0421		
Omeprazole capsules	Astra	10 mg	00186-0606-28	100 UD	$140.00	$1.4000	10/99-10/00	$11.6 million
			00186-0606-31	30	$42.00	$1.4000		
			00186-0606-68	100	$75.93	$0.7593		
			61113-0606-82	1000	$$1,400.00	$1.4000		
		20 mg	61113-0742-28	100 UD	$140.00	$1.4000		
			00186-0742-31	30	$42.00	$1.4000		
			00186-0742-82	1000	$1,400.00	$1.4000		
		40 mg	61113-0743-28	100 UD	$140.00	$1.4000		
			61113-0743-31	30	$42.00	$1.4000		
			61113-0743-68	100	$140.00	$1.4000		
			61113-0743-82	1000	$1,400.00	$1.4000		
Prazosin capsules	Zenith Goldline	1 mg	00172-4067-60	100	$1.90	$0.0190	11/99-11/00	$53,000
			00172-4067-80	1000	$19.00	$0.0190		
		2 mg	00172-4068-60	100	$2.50	$0.0250		
			00172-4068-80	1000	$25.00	$0.0250		
		5 mg	00172-4069-60	100	$4.02	$0.0402		
			00172-4069-70	500	$21.20			
Ranitidine tablets	Geneva	150 mg	00781-1883-60	60	$1.93	$0.0320	12/98-12/99	$4,493,000§
			00781-1883-05	500	$13.57	$0.0270		
			00781-1883-10	1000	$26.72	$0.0270		
		300 mg	00781-1884-31	30	$2.28	$0.0760		
			00781-1884-25	250	$16.48	$0.0660		
Simvastatin tablets	Merck	5 mg	00006-0726-61	60	$27.00	$0.4500	8/99-8/00	$22.2 million in combination with Cerivastatin
			00006-0726-54	90	$40.50	$0.4500		
			00006-0726-28	100 UD	$45.00	$0.4500		
		10 mg	00006-0735-61	60	$39.60	$0.6600		
			00006-0735-54	90	$59.40	$0.6600		
			00006-0735-28	100 UD	$66.00	$0.6600		
			00006-0735-82	1000	$660.00	$0.6600		
			00006-0735-87	10,000	$6,600.00	$0.6600		
		20 mg	00006-0740-61	60	$64.20	$1.0700		
			00006-0740-28	100 UD	$107.00	$1.0700		
			00006-0740-82	1000	$1,070.00	$1.0700		
			00006-0740-87	10,000	$10,700.00	$1.0700		
		40 mg	00006-0749-61	60	$64.20	$1.0700		
		80 mg	00006-0543-61	60	$64.20	$1.0700		
Verapamil sustained-release tablets	Zenith Goldline°	120 mg	00172-4285-60	100	$12.99	$0.1299	12/99-11/00	To be determined
		180 mg	00172-4286-60	100	$5.97	$0.0597		
		240 mg	00172-4280-60	100	$5.97	$0.0597		
			00172-4280-70	500	$29.00	$0.0580		

* Most contracts have options for renewal periods

§ Estimated cost avoidance for ranitidine ranges from $765,000 (based on lowest available DAPA price at time of award) to $7,321,000 (based on actual purchases for FY98). The $4,493,000 estimate is based on the DAPA price of the Geneva brand that existed prior to the award of the contract.

° Contract was previously awarded to G.D.Searle, with a base contract performance period of 8/20/99-8/19/00. After the contract was awarded, G.D. Searle stated that they had made a mistake on the price of the 240 mg 500s ($9.50/bottle of 500). The contract will be terminated on 12/1/99. A settlement has been reached concerning the price of the 240mg bottle of 500 during the period of time the contract was in effect.

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MCCS-GPE 30 August 1999

MEMORANDUM FOR Assistant Secretary of Defense (Health Affairs)

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

1. In accordance with Health Affairs policy 98-025, a meeting of the DoD P&T committee convened at 0800 hours on 13 August 1999, at the DoD Pharmacoeconomic Center (PEC), Fort Sam Houston, TX.

2. MEMBERS PRESENT:

COL Daniel D. Remund, MS	Co-chairman
CDR Terrance Egland, MC	Co-chairman
COL Rosa Stith, MC	Army
LTC Judith O'Connor, MC	Army
Danielle Doyle	Army
CDR Matt Nutaitis, MC	Navy
LCDR Kevin Cook	Navy
LTC John R. Downs, MC	Air Force
MAJ George Jones, BSC	Air Force
CDR Robert W. Rist	Coast Guard
Ronald L. Mosier	Department of Veterans Affairs (alternate)
LTC (P) George Crawford, MS	Joint Readiness Clinical Advisory Board
LTC Steven Humburg, MC	Health Affairs
MAJ Mickey Bellemin BSC	Defense Supply Center Philadelphia (DSCP)
C. Andrew Bergman	Uniformed Services Family Health Plans (USFHP)
Ray Nan Berry	Foundation Health
Kirby Davis	Anthem Alliance
William Hudson	Humana, Inc
Gene Lakey	TriWest
Ron McDonald	Sierra Military Health Services

3. OTHERS PRESENT:

CAPT Charlie Hostettler, MSC	DoD Pharmacy Program Director, TMA
CDR Mark Brouker, MSC	DoD Pharmacoeconomic Center
MAJ Donald DeGroff	DoD Pharmacoeconomic Center
LCDR Mark Richerson	DoD Pharmacoeconomic Center
MAJ Barbara Roach	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
Tom Kellenberger	Merck-Medco
Mark Petruzzi	Merck-Medco
Shelby Tanner, Jr.	Staff Judge Advocate, Fort Sam Houston
David Chicoine	Uniformed Services Family Health Plans (USFHP)

4. ADMINISTRATIVE ISSUES:

A. Financial disclosure reports were distributed to voting members of the committee and alternates. Voting members and alternates are to return the reports to COL Remund not later than the next meeting.

B. Introduction of new members and attendees: LCDR Kevin Cook replaced LCDR Denise Graham as a Navy representative. C. Andrew Bergman, MD, Johns Hopkins Medical Services Corporation is a new committee member representing the Uniformed Services Family Health Plans (USFHP). David Chicoine, Administrative Director, Brighton Marine Health Center also attended the meeting on behalf of the USFHP. The USFHP is a Department of Defense-sponsored managed healthcare option currently providing care to nearly 100,000 eligible family members of active duty personnel, retirees and their families in seven areas of the country.

C. The minutes from the 14 May 99 meeting were accepted as written.

5. OLD BUSINESS:

A. CDR Mark Brouker, Deputy Director of the Pharmacoeconomic Center (PEC), compared the estimated cost avoidance and phone call workload for the old NMOP preferred drug list (PDL) to the current non-preferred/preferred drugs on the restructured NMOP formulary. Based on data for a 10-week period (see Table 1, Appendix A), each phone call requesting a change from a non-preferred agent to a preferred alternative under the restructured NMOP formulary results in a $30 cost avoidance, compared to only $7 under the old NMOP PDL. DoD annual cost avoidance is projected to increase from $171,000 to $588,000. Phone calls to request switches have decreased from 2% to 1.6% of total prescriptions filled.

The Committee approved a PEC proposal to add four pairs of non-preferred/preferred drugs to the NMOP formulary (see table below). These non-preferred/preferred drugs are projected to yield an average cost avoidance of $58 per phone call and $397,000 in annual cost avoidance (see Table 2, Appendix A). A summary of the cost avoidance and phone call workload estimates is provided in Table 3, Appendix A.

Additional Non-Preferred/Preferred Drugs on NMOP Formulary

Non-Preferred Drug	**Preferred Alternative**
famotidine (Pepcid)	ranitidine (Geneva brand generic*)
nizatidine (Axid)	ranitidine (Geneva brand generic*)
enalapril (Vasotec)	lisinopril (Zestril* brand)
nitroglycerin patches (Minitran, Transderm Nitro, Nitrodisc, and generics)	nitroglycerin patches (Nitro-Dur)
	* national contracts specify the brands of these preferred alternative drugs

The Committee removed astemizole (Hismanal) from the non-preferred/preferred alternative list due to its withdrawal from the market. Cartia XT (Andrx's generic equivalent for Cardizem CD) was added to the non-preferred listing for diltiazem extended-release.

B. CDR Brouker reported that the NMOP implemented prior authorization procedures for celecoxib (Celebrex) on 2 August 1999. Prior authorization procedures for etanercept (Enbrel) are being implemented as of 13 August 1999. Prior authorization procedures for sildenafil (Viagra), which is currently available through the NMOP, will be implemented no later than 24 Sep 99.

A subcommittee will attempt to quantify the value of the NMOP prior authorization program in terms of clinical, economic, and humanistic outcomes. Members of the subcommittee are: CDR Mark Brouker (PEC); MAJ Mickey Bellemin (DSCP), Tom Kellenberger and Mark Petruzzi (Merck-Medco). The subcommittee will report on its measurement efforts at the next meeting.

C. At the May 14 meeting, the committee voted to add over-the-counter (OTC) forms of niacin prescribed for antilipemic therapy to the list of OTC items that are covered by the NMOP. Implementation of this decision was contingent on a TMA policy review. TMA legal opinion is that this decision represents an improper application of discretionary authority because it waives a policy provision for a class of cases rather than for an individual case. Based on the TMA legal opinion, OTC forms of niacin will not be available through the NMOP. Prescription forms of niacin remain available through the NMOP.

D. MAJ Bellemin reported on the current status of disposable insulin syringes, alcohol swabs, blood glucose test strips, lancets, and disposable syringes for non-insulin injectable medications on the NMOP formulary:

1) Disposable Insulin Syringes and Alcohol Swabs are dispensed on one prescription number and require only one co-pay. A quantity of alcohol swabs equal to or rounded up to the nearest 100 of the quantity of syringes prescribed is automatically dispensed whenever a prescription for insulin syringes is received.

2) Blood glucose test strips and lancets are dispensed on one prescription number and require only one co-pay. A quantity of lancets equal to or rounded up to the nearest 100 of the quantity of blood test strips prescribed is automatically dispensed whenever a prescription for blood test strips is received.

3) Syringes will be provided through the NMOP if they are prescribed in conjunction with a prescription for an injectable medication. A separate prescription should be written for the syringes, and the prescription should specify the type of syringe. A quantity of alcohol swabs equal to or rounded up to the nearest 100 of the quantity of the corresponding syringes will be automatically dispensed. A co-pay will be required for the syringes/alcohol swabs in addition to the co-pay for the injectable medication.

E. The committee reviewed the current status of oral corticosteroid inhalers on the BCF. There have been no substantial price increases in this class since the last meeting. The committee agreed that there does not appear to be any reason to make changes to the BCF agents at this time. Vanceril, Vanceril DS, and Azmacort will remain on the BCF. The PEC will continue to monitor price changes in this class and will bring the issue back to the P&T committee if it needs to be revisited.

F. Instead of pursuing a sole source contract for warfarin sodium, the committee advised the Defense Supply Center Philadelphia to accept a DAPA incentive agreement that reduces the price of the Coumadin brand of warfarin sodium. The DAPA incentive agreement will yield approximately $700,000 annually in cost avoidance for DoD based on current DoD usage data for the Coumadin brand of warfarin. The DAPA incentive agreement will obviate the need for a formal contracting initiative, so DSCP can focus its efforts on drug classes with greater economic implications to DoD. The DAPA incentive agreement does not affect the BCF listing for warfarin. The BCF will continue to list warfarin with no brand name specified. MTFs may select any brand of warfarin for their local formularies. All currently marketed brands of warfarin are AB rated to the DuPont product.

6. NEW BUSINESS:

A. Contracting update

1. *Diltiazem extended release* – The DoD/VA contract awarded to Forest Pharmaceuticals for Tiazac as the mandatory sole source product for extended-release diltiazem was effective 15 Dec 98. COL Remund reported on the success of the contract implementation for Tiazac (see Appendix B). By the end of April 99, the last month for which complete prime vendor data is available, market share for Tiazac had exceeded 80%. The cumulative cost avoidance attributable to the contract was over $1 million through April 99. The annual cost avoidance to DoD from this contract is estimated to be $5.5 million dollars.

2. *Lisinopril* – A DoD contract awarded to Zeneca Pharmaceuticals for the Zestril brand of lisinopril took effect 1 Aug 99. All MTFs and the NMOP must use only the Zestril brand of Lisinopril. The contract does not close the ACE inhibitor class. The contract has no effect on the BCF status or MTF formulary status of ACE inhibitors other than lisinopril. The Zestril brand of lisinopril is now flat-priced at $0.14 per tablet for all strengths and package sizes. An annual cost avoidance of $7.5 million is projected for the lisinopril contract.

3. *Proton pump inhibitors (PPIs)* – A DoD contract for proton pump inhibitors was awarded to Astra Pharmaceuticals for omeprazole (Prilosec) on 6 August 99. The contract takes effect on 1 Oct 99 and closes the PPI class on the BCF. Omeprazole must be on all MTF formularies. No other PPI is permitted on any MTF formulary. PPIs other than omeprazole will not be available at MTF pharmacies or the NMOP, unless a medical necessity requires the use of a PPI other than omeprazole for an individual patient. An implementation plan for the PPI contract was sent out to all MTFs. The price per capsule for omeprazole decreased from $1.72 for most strengths to the contract price of $1.40 for all strengths and all package sizes except the 100-count bottles of omeprazole 10 mg. The 100-count package size of omeprazole 10-mg remains at its previous DAPA price of $0.76 per capsule due to federal ceiling price regulations. The price reductions are projected to yield $11.6 million annually in cost avoidance to DoD.

4. *Insulin* – LTC Rick Downs reported that the DoD/VA contract solicitation for insulin was issued 26 July 99 and closes 25 August 99.

5. *Statins* – COL Remund reported that the General Accounting Office (GAO) was expected to rule on two protests concerning the DoD contract solicitation for HMG-CoA reductase inhibitors (statins) no later than 18 August 99. If the GAO decides in favor of DoD, a contract award announcement may be made shortly thereafter.

B. CAPT Hostettler informed committee members about portions of the pending FY 2000 National Defense Authorization Bill that pertain to the DoD P&T Committee and formulary

management.

C. The committee approved a recommendation that a subcommittee be established to draft a set of principles to guide formulary management decisions. Subcommittee members are CDR Egland, MAJ George Jones, COL Remund, Bill Hudson, and Tom Kellenberger. A draft set of principles is to be presented at the next P&T committee meeting.

D. Per guidance from higher authority, the committee tabled a decision on the proposal to select one SSRI for the BCF while leaving the class open.

E. The committee approved the addition of spironolactone to the BCF. This decision was primarily in response to results from the RALES (Randomized Aldactone Evaluation Study) trial in patients with severe congestive heart failure. The trial was discontinued early because an interim analysis showed that the addition of low doses of spironolactone to standard therapy in patients with severe CHF was associated with a 30 percent reduction in mortality, a 30 percent reduction in cardiac hospitalizations, and significant improvements in New York Heart Association (NYHA) class. The results of the RALES trial are available in their entirety on the Internet at www.nejm.org, and will be published in the 2 Sep 99 issue of the *New England Journal of Medicine.*

   Spironolactone 25 mg is generically available from several manufacturers at DAPA prices ranging from $0.02 per tablet for the lowest priced generic to $0.25 per tablet for the brand-name product (Aldactone; Searle). At the lowest generic price, a year of therapy with spironolactone 25 mg daily would cost $8.00. The FDA recently approved a generic version of spironolactone 50- and 100-mg tablets.

F. Due to a substantial DAPA price increase, the committee removed beclomethasone 42mcg/spray (Vancenase Pockethaler) from the BCF at the May meeting. The committee modified the BCF listing to state that each facility must have at least one nasal corticosteroid on its formulary. The committee also indicated its intention to review the corticosteroid nasal inhalers at the next meeting to see if a specific inhaler should be selected for the BCF in order to standardize availability across the MHS.

   The committee reviewed information on corticosteroid inhalers presented by LCDR Richerson and unanimously decided to add fluticasone nasal spray (Flonase) to the BCF. The class remains open on the BCF. Based on current DAPA prices and the number of puffs per day required for maintenance therapy in adults, fluticasone is 20% less expensive than flunisolide (Nasalide) 25 mcg/spray (see Appendix C). Allergy/immunology specialists reviewed the dosing, which was based on package labeling for each product. The specialists expressed the opinion that fluticasone would be a good selection as a “workhorse” nasal corticosteroid on the BCF based on their clinical experience, the information in Appendix C, and the fact that fluticasone is approved for use in patients as young as 4 years old.

G. Agents considered for BCF and NMOP formulary status:

1. *Rofecoxib (Vioxx; Merck)*: The committee did not add rofecoxib to the BCF, but approved the addition of rofecoxib to the NMOP formulary subject to prior authorization. Although committee members expressed concern that Merck Medco's prior authorization criteria allow prescriptions to be filled for short-term use for pain, the committee elected to adopt the existing Merck Medco prior authorization criteria for rofecoxib because criteria customized for DoD could take at least 90 days to implement. The percentage of prescriptions for rofecoxib that will be written for short-term therapy is unknown. The same subcommittee that was tasked to quantify the value of the NMOP prior authorization program was also tasked to quantify the usage of rofecoxib for short-term therapy.

   Rofecoxib was approved by the FDA on 20 May 99 for the treatment of osteoarthritis (OA), acute pain, and primary dysmenorrhea. Like celecoxib (Celebrex; Searle/Pfizer) rofecoxib is an NSAID that is highly selective for cyclooxygenase-2 and is commonly known as a COX-2 inhibitor. Unlike celecoxib, rofecoxib is not indicated for rheumatoid arthritis, although trials are underway. Celecoxib currently lacks indications for acute pain and primary dysmenorrhea. The use of rofecoxib for pain for more than 5 days has not studied. Rofecoxib, unlike celecoxib, is not a sulfonamide and is not contraindicated for patients allergic to sulfa drugs. Like celecoxib, rofecoxib is significantly more costly than other NSAIDs. Rofecoxib appears to be no more effective than other NSAIDs, including celecoxib, in relieving pain and inflammation; the potential benefit of the COX-2 inhibitors is primarily related to a potential reduction in the incidence of GI adverse events. Data on actual outcomes is yet not available for either celecoxib or rofecoxib. There does not appear to be any advantage in using the selective COX-2 inhibitors short-term for pain as compared to other NSAIDs, given the extreme rarity of GI events after short-term therapy.

2. *Rosiglitazone (Avandia; SmithKline Beecham)*: The committee added rosiglitazone to the NMOP formulary and did not add it to the BCF. Rosiglitazone was approved by the FDA on 25 May 99 as an adjunct to diet and exercise to lower blood glucose in patients with Type 2 diabetes mellitus, both as monotherapy and in combination with metformin (Glucophage; Bristol-Myers Squibb). Rosiglitazone has been studied in combination with sulfonylureas and insulin, although these combinations are not yet FDA approved. Rosiglitazone is a thiazolidinedione antidiabetic agent that acts primarily as an insulin sensitizer. There are currently three thiazolidinediones on the market: rosiglitazone, troglitazone (Rezulin; Parke-Davis), and pioglitazone (Actos; Takeda). Pioglitazone was approved by the FDA in mid-July and has not yet come up for P&T committee review.

   The primary difference between troglitazone and rosiglitazone appears to be the reported incidence of hepatotoxicity. LTC Rick Downs reported on the comparative safety, tolerability, effectiveness, and price of the two agents. The FDA recently withdrew the monotherapy indication for troglitazone and tightened requirements for monitoring liver enzymes in light of reports of 28 deaths and 40 liver transplants associated with a denominator of approximately a million patients exposed to the drug—an incidence of between 3-4 events per 100,000 patients. There have been no indications of

hepatotoxicity with rosiglitazone in clinical trials involving approximately 4000 patient-years of follow-up. However, according to the FDA, in order to have a 95% chance of discovering side effects that occur at an incidence of greater than 1 in 1000, a patient population of at least 3000-4000 patients is required. Because liver failure and death clearly occur much less frequently than 1 in 1000, there is insufficient evidence to draw firm conclusions about the risk of hepatotoxicity associated with rosiglitazone. There are some pharmacokinetic differences between the two drugs that are consistent with a hypothesis of less hepatoxicity with rosiglitazone than troglitazone.

Effectiveness may be considered to be a function of compliance and efficacy. Compliance with the two drugs is expected to be about the same, since both are dosed qd to bid. The actual reduction in HbA1C is modest, with 200 mg of troglitazone lowering HbA1c about as much as 2 mg bid of rosiglitazone and 400 mg of troglitazone about as efficacious as 4 mg bid of rosiglitazone. At this dose equivalence, rosiglitazone appears to cost somewhat more than troglitazone, since 4 mg once daily does not appear to work as well as 2 mg bid: $1.85 for 200 mg troglitazone *vs*. $2.l6 for 2 mg bid of rosiglitazone, and $2.94 for 400 mg of troglitazone 400 mg *vs*. $2.98 for 4 mg bid of rosiglitazone. LTC Downs proposed that rosiglitazone be retained in a pending category until the next meeting in order to more clearly define the risk of hepatotoxicity associated with the drug.

After extensive discussion, the committee concluded that there is no evidence that rosiglitazone offers a safety, efficacy, or cost advantage compared to other drugs on the market. However, leaving the drug in the "pending review" category on the NMOP formulary would likely just cause patients to obtain the drug through retail network pharmacies at a higher cost. The committee decided to add rosiglitazone to the NMOP formulary since delaying its availability through the NMOP is not likely to affect overall utilization of the drug. The committee will review this class of drugs again at the next meeting.

3. *Cilostazol (Pletal; Pharmacia & Upjohn)*: The committee added cilostazol to the NMOP formulary as a non-preferred drug, with pentoxifylline as the preferred alternative for this indication. Cilostazol was not added to the BCF.

   Cilostazol was approved by the FDA on 15 Jan 99 for the treatment of intermittent claudication, a condition that affects an estimated 18,000 to 30,000 patients in DoD. The only other drug that is currently indicated for intermittent claudication is pentoxifylline. Cilostazol is a PDE III inhibitor, a class of drugs that has been associated with increased mortality in cardiac patients. Cilostazol was approved by the FDA with a black box warning stating that it is not to be used in patients with CHF of any severity (about 10-15% of patients with intermittent claudication have CHF). In addition, the FDA was concerned about the lack of data on the use of cilostazol concurrently with clopidogrel (Plavix). Phase IV trials to more clearly define the safety of this drug are currently either in the planning stages or underway. Cilostazol costs approximately $1.78/day, compared to about $0.44/day for generic pentoxifylline, but may prove to be more efficacious.

After 24 weeks, cilostazol increased pain-free walking distances of intermittent claudication patients by about 107 meters (117 yards), compared to 65 meters (71 yards) with pentoxifylline.

The committee designated cilostazol as a non-preferred drug, with pentoxifylline as the preferred alternative on the NMOP formulary because of the safety issue as well as comparative costs. The committee will review any available information concerning safety, the volume of calls being made, and comparative costs at the next meeting.

4. *Zanamivir (Relenza; GlaxoWellcome)*: The committee excluded zanamivir from the NMOP formulary and it was not added to the BCF. Zanamivir was approved by the FDA 27 July 99. Zanamivir is an orally inhaled neuraminidase inhibitor given twice daily for 5 days for the treatment of uncomplicated acute illness due to influenza in adults and adolescents older than 12 years of age who have been symptomatic for no more than 2 days. It decreases flu symptoms and shortens the duration of symptoms by approximately 1 to 1.5 days. Although zanamivir was primarily tested in influenza A, it also appears to be active against influenza B. There is evidence that zanamivir is also effective in prevention. MAJ Barbara Roach (PEC) reported that use of the drug is likely to be limited in DoD due to the widespread administration of flu shots. In addition, other drugs with influenza A activity (e.g., amantadine, rimantadine) are available both as chemoprophylaxis and treatment, although they may cause CNS side effects. Zanamivir may cause bronchospasm in susceptible patients and has not been studied in children under 12 or in a large number of elderly patients with comorbid disease. The DAPA price for zanamivir is likely to be about $28.00 for a 5-day regimen, compared to approximately $1.20 - $13.60 for 10 days of treatment with amantadine or rimantadine, respectively. Use of zanamivir is likely to be most rational during outbreaks of the flu and then only for individuals who cannot tolerate the antiviral drugs. Another potential use may be during outbreaks of influenza B. The NMOP is not an appropriate source for zanamivir because the NMOP could not provide the medication quickly enough for it to be effective for patients.

H. At the May meeting a subcommittee was appointed to investigate the issue of fertility drugs in greater detail, obtain input from individuals outside of the P&T Committee if necessary, and recommend actions to make the coverage of fertility drugs consistent in the NMOP and the retail pharmacy networks. CDR Egland reported that the subcommittee has reviewed applicable law and federal regulations pertaining to fertility drugs and is working on a plan to make the coverage of fertility drugs consistent in the NMOP and the retail pharmacy networks. The plan will be brought back to the committee, which may then decide whether to submit the plan to TMA with its recommendations and/or requests for changes in current policy. The subcommittee will provide an interim report at the next meeting.

I. Although follitropin alfa (Gonal-F, Serono) and follitropin beta (Follistim, Organon) were not explicitly listed on the previous NMOP preferred drug list (PDL), prescriptions for both agents have been being filled through the NMOP on an ongoing basis. Because these agents were not on the PDL, they were not picked up for the Covered Injectables list during the

restructuring of the NMOP Formulary. Follitropin alfa and beta are fertility agents similar to others on the Covered Injectables list. Both can be given subcutaneously. The committee decided to add follitropin alfa (Gonal-F) and follitropin beta (Follistim) to the NMOP Covered Injectables List.

J. The committee discussed current policies regarding drug therapy for weight reduction, in light of the recent FDA approval of orlistat (Xenical), a non-systemic lipase inhibitor that reduces the absorption of dietary fat. After consideration of the policies governing dispensing of drugs through the NMOP, the committee agreed that orlistat could not be added to the NMOP Formulary since drug therapy for weight reduction is not a covered benefit. The committee also agreed that orlistat is not appropriate for the BCF.

   Further discussion centered on the necessity for alignment of policy with the current philosophy of prevention and the move from a fee-for-service system to managed healthcare. The committee agreed that it should formulate an opinion on the issue of weight reduction that could be passed along to other venues for consideration. The committee appointed a subcommittee to formulate a statement regarding weight reduction policy for the committee to consider at the next meeting. Subcommittee members include MAJ Barbara Roach, LTC Rick Downs, COL Humberg, CAPT Hostettler. COL Humberg will report recommendations and proposed policy changes (if appropriate) to TMA.

K. The committee discussed pending changes in the TRICARE/CHAMPUS Policy Manual that will apply quantity limits and prior authorization requirements to the retail network. The quantity limits and prior authorization requirements will be consistent with those in the NMOP
   .

L. The Quantity Limits Subcommittee [MAJ Bellemin, Danielle Doyle, Ray Nan Berry (Foundation Health), Eugene Moore (PEC)] submitted a proposed list of quantity limits to the committee. The quantity limits will also apply to the retail network pharmacies when changes to Chapter 7, Section 7.1 of the TRICARE/CHAMPUS policy manual are finalized. After considerable discussion and modification of some quantity limits, the committee approved the list of quantity limits shown in Appendix D. Specific matters of discussion for which reports are due to the committee are listed below:

   - *Zolpidem (Ambien)*—The committee approved the proposed limit of 10 tablets in 30 days for mail order proposed by the subcommittee, but requested that MAJ Bellemin report back to the committee at the next meeting concerning the number of prescriptions returned to the patient because of exceeding the maximum daily dose. This concern was based on literature support for use of zolpidem in psychiatric disorders more frequently than once per day. Tom Kellenberger from Merck-Medco explained that the usual procedure for prescriptions that exceed the maximum daily dose is to call the physician and obtain an affidavit that the physician understands the maximum and accepts responsibility. If the physician cannot be contacted, the prescription is returned to the patient.

- *Blood products/biotech products*— The committee discussed the difficulty of determining actual quantity limits for these medications, which tend to be very dependent on patient-specific factors. Quantity limits are easier to administer if they are expressed as the maximum amount of medication provided per copayment or period of time. However, it is difficult to decide where to set the maximum amount, since prescriptions may be written "as directed." Options discussed included increasing the current "30-days supply" limit to 45 days, increasing the limit to 90 days, or eliminating quantity limits for this category. The committee agreed that some control is desirable due to the high cost of these agents and the possibility that the patient might experience side effects necessitating discontinuation, might no longer require, or might not respond to the drug. The committee requested that Merck-Medco report back to the committee with the customary dose, supply, and refill quantity of blood products and biotech drugs being dispensed by Merck-Medco.
- *Topicals:* The committee was unable to reach consensus on the six topical agents selected for the quantity limits list. Merck-Medco was asked to report back to the committee with the customary dose, supply, and refill quantity of these agents in order to better quantify reasonable quantity limits. Bill Hudson (Humana) will also report on utilization through managed care.
- *Antibiotic quantity limits* – MAJ Bellemin will report at the next meeting concerning any issues with the current limits and report on utilization.
- *Injectable fertility agents:* The committee requested that MAJ Bellemin report back at the next meeting concerning utilization of injectable fertility agents to determine whether the current 20 amp per prescription limit is adequate (since the quantity may increase with each cycle). MAJ Bellemin will also report on current prior authorization policies and issues concerning fertility treatment.

The quantity limit for etanercept injection (Enbrel) was increased to a 6-week supply (3 cartons of 4 injections) in the NMOP. This will decrease the likelihood that patients would run out of medication between refills, and it increases the incentive for filling prescriptions for the drug through the NMOP as compared to the retail network pharmacies.

M. Anthem Alliance requested that the P&T Committee review a proposed utilization program for non-sedating antihistamines. The request was referred to the P&T committee by TMA-West in order to ensure proper coordination and support for the goal of having the MCSC, NMOP, and MTFs provide the same equitable, consistent, and cost-effective benefit. The request led to a general discussion about coordinating national contracting efforts, DAPA incentive agreements, DoD P&T formulary decisions, regional/MTF formulary decisions, and managed care contractor utilization programs. The committee did not endorse the Anthem Alliance proposal because:

- Utilization programs should ideally be applied consistently across the retail pharmacy networks for all TRICARE regions. A decision to apply should a program across all regions would require more in depth analysis and extensive coordination to obtain agreement by all MCSC.

- ♦ The PEC plans to review the non-sedating antihistamine drug class for the BCF and the NMOP formulary. The drug class may be appropriate for a contacting initiative or DAPA incentive agreement. Anthem Alliance may want to ensure that its utilization management program is in agreement with BCF and NMOP formulary decisions.

N. The Advances in Medical Practice (AMP) funding initiative will provide additional funding to the Defense Health Program in FY 00 and beyond. This funding initiative is designed to support the adoption of technological advances in medical care. The Surgeons General have identified funding for pharmacy—specifically new drug technologies—as one of the areas where this money could be utilized. The committee empowered a subcommittee to make recommendations and decisions concerning the use of these funds. Subcommittee members include: COL Rosa Stith, CDR Mark Brouker, LCDR Mark Richerson, CDR Terry Egland, MAJ Mickey Bellemin.

O. Pharmaceutical manufacturers typically distribute "starter packs" for free in the private sector. MTF pharmacies cannot accept free goods unless they comply with cumbersome regulations governing the acceptance of gifts by the government. CDR Egland suggested that MTFs could buy starter packs in bulk for a minimal fee in order to facilitate initial therapy. CAPT Hostettler agreed to address this issue with DSCP and will report back to the committee at the next meeting.

P. The committee discussed the procedure for interim committee decisions. CDR Egland stated that while ideally he would prefer to present proposals for discussion via electronic connections, sometimes the co-chairs will have to decide issues on an interim basis. The committee agreed that interim decisions should be communicated to the committee via e-mail. A standing report of all interim decisions will be placed as one of the first items on the agenda at each meeting.

7. ADJOURNMENT: The meeting adjourned at 1400 hours. The next meeting will be held on Thursday, November 18th at the DoD Pharmacoeconomic Center, Fort Sam Houston, Texas, beginning at 0800 hours. All agenda items are to be submitted to the DoD PEC no later than Friday, October 15th.

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

Appendix A: Non-Preferred Drugs/Preferred Alternatives in the NMOP

Table 1. Annual cost avoidance to DoD and workload impact on Merck-Medco: Old PDL NMOP Formulary as compared to restructured NMOP Formulary

	Estimated Annual Cost Avoidance to DOD	Phone Calls Generated as a Percent of Total Rx's Filled†	Cost Avoidance Per Phone Call
Old NMOP Formulary	$171,000[1]	2.00%[2]	$7
Restructured NMOP Formulary	$587,713[3]	1.57%[4]	$30
Net Change	**$416,713**	**(0.43%) or 22% decrease**	**$23**

† Actual phone calls generated by Merck-Medco during report period divided by actual prescriptions filled by Merck-Medco during same report period.

1. The vast majority of 'mapped drugs' used previous to the May 1999 DoD P&T committee by Merck-Medco resulted in saving to DoD of less than $1,000/year. In fact, some of the mapping requests actually resulted in cost increases to DoD. Assuming that each of the estimated 342 previously mapped drugs saved DoD $500/year, we estimate that the cost savings from the previous list of mapped drugs was $171,000/year (342 x $500).
2. Phone calls generated by Merck-Medco during report period of 21 November 1998 through 27 March 1999 (8142) divided by actual prescriptions filled by Merck-Medco during same reporting period (406,040).
3. Estimated, based on switch rate data (29 May 1999 -31 July 1999), current DAPA prices and CY98 NMOP usage data.
4. Phone calls generated by Merck-Medco during report period of 29 May 1999 through 31 July 1999 (3720) divided by actual prescriptions filled by Merck-Medco during same reporting period (237,346).

Table 2. Phone calls generated for Merck-Medco and projected cost avoidance to DoD if Pepcid, Axid, Vasotec and nitroglycerin patches are included as non-preferred drugs on the NMOP Formulary

Non-Preferred Drug	Preferred Drug	Switch Rate	Annual Cost Avoidance to DoD†	Phone calls (per year) generated for Merck Medco††	Cost Avoidance Per Phone Call
Minitran Deponit Transderm Nitro Nitrodisc, NTG patch generics	Nitrodur	74%*	$20,647	334	$62
Pepcid	Generic ranitidine	50%**	$152,919	2015	$76
Axid	Generic ranitidine	50%**	$40,389	915	$44
Vasotec	Lisinopril (Zestril)	52%*	$183,075	3585	$51
Total			**$397,030**	**6849**	**$58**

† Estimated, based on CY1998 NMOP usage data, current DAPA prices and estimated/actual switch rates.

†† From Merck-Medco. Represents number of new prescriptions filled for the non-preferred drug(s) in CY98. Assumes phone calls are made only on new prescriptions.

* Based on switch rates for specific non-preferred/preferred drug pair as provided by Merck-Medco.

** Switch rate data not available - switch rate assumed to be 50%.

Table 3. Annual cost avoidance to DoD and workload impact on Merck-Medco: Old PDL NMOP Formulary as compared to restructured NMOP Formulary plus Axid, Pepcid, Vasotec and nitroglycerine patches added as non-preferred drugs to the NMOP Formulary.

	Estimated Annual Cost Avoidance to DoD	Phone Calls Generated as a Percent of Total Rx Filled†	Cost Avoidance per Phone Call
Old NMOP Formulary[1]	$171,000	2.00%	$7
Restructured NMOP Formulary[1]	$587,713	1.57%	$30
Restructured NMOP Formulary plus Axid, Pepcid, Vasotec and nitroglycerine patches added as non-preferred drugs to the NMOP Formulary	$984,743[2]	1.88%[3]	$38
Net Change (Old NMOP Formulary as compared to proposed changes)	**$813,743**	**(0.12%) or 6% decrease**	**$31**

1. From Table 1.
2. Totals from Tables 1 and 2.
3. Estimated number of phone calls generated by Merck-Medco in the next 12 months (26,193) divided by projected number of prescriptions filled by Merck-Medco in the next 12 months [total prescriptions filled in May 1999, June 1999, July 1999 = 347,960 multiplied by 4 = 1,391,840]

Appendix B: Contract Implementation Results for Diltiazem (Tiazac)

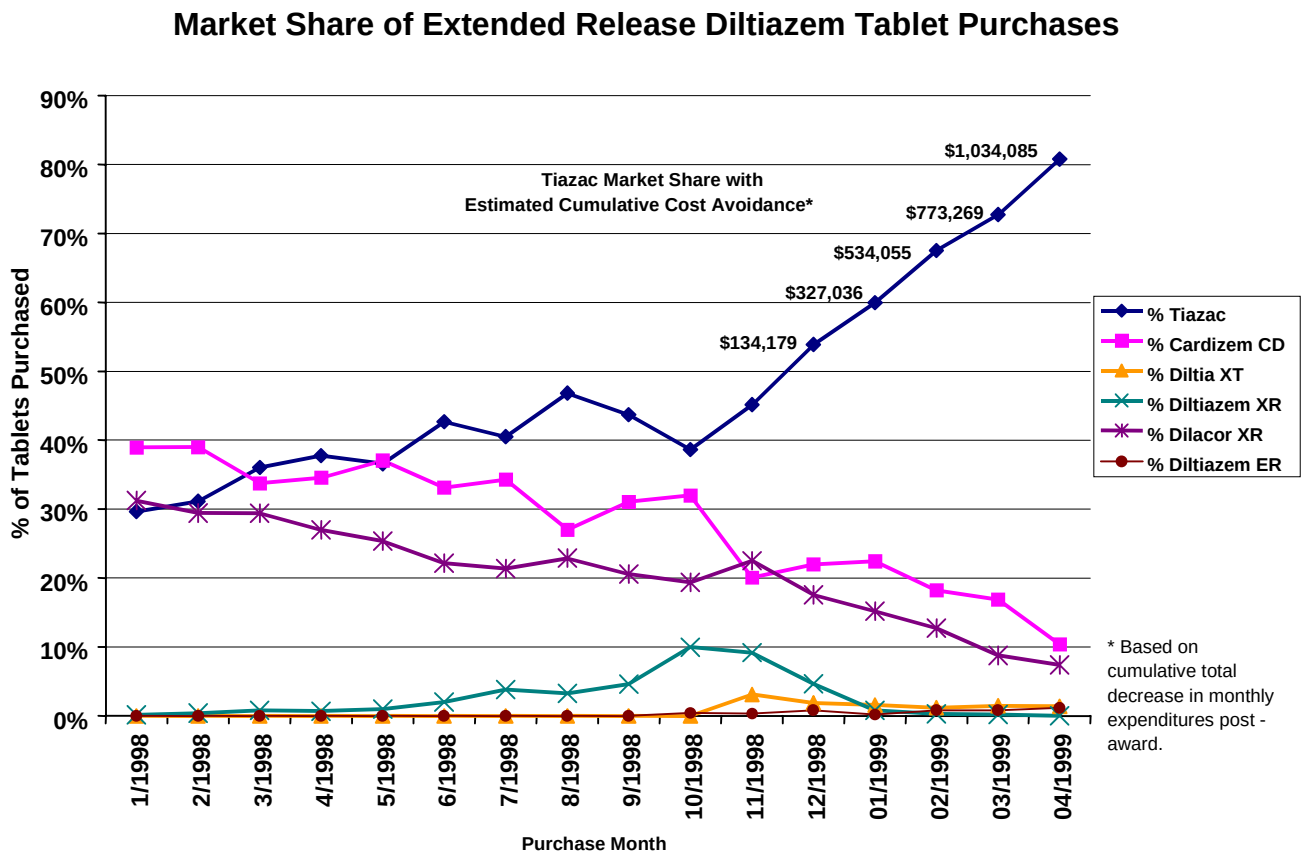

Figure 1: Market Share of Extended Release Diltiazem Tablet Purchases

Table 1: Impact of Diltiazem (Tiazac) Contract Over Time

(Contract Start Date: 12/15/98)

Month	Total Purchased	Total Cost	Cost per Tablet	Cumulative Cost Avoidance*
Jan 98	1,416,730	$919,553	0.649	0
Feb 98	1,261,430	$817,966	0.649	0
Mar 98	1,429,710	$911,019	0.634	0
Apr 98	1,568,720	$994,208	0.639	0
May 98	1,345,110	$860,270	0.628	0
Jun 98	1,401,220	$880,033	0.629	0
Jul 98	1,452,630	$913,433	0.601	0
Aug 98	1,383,700	$831,405	0.625	0
Sep 98	1,801,750	$1,125,832	0.582	0
Oct 98	1,472,300	$856,906	0.582	0
Nov 98	1,255,470	$655,365	0.522	0
Dec 98	1,481,370	$801,344	0.547	$134,179
Jan 99	1,461,310	$732,871	0.501	$327,036
Feb 99	1,404,200	$639,490	0.455	$534,055
Mar 99	1,510,620	$676,970	0.448	$773,269
Apr 99	1,482,210	$593,330	0.40	$1,034,085

* Where applicable, cumulative cost avoidance calculated as follows:

a. Total units purchased for each drug and strength were multiplied times the prices in effect prior to the contract award.

b. Total units purchased for each drug and strength were multiplied times the prices in effect after the contract award.

c. Results of b. above were subtracted from a. above.

Appendix C: Nasal Corticosteroid Cost Analysis

Trade Name	Generic Name	Manufacturer	Sprays Per Unit	Average Price Paid Calendar Year 1998	Current Unit Cost (based on DAPA prices as of 1 Aug 99)	Change in Unit Cost	Dosing Frequency	Maintenance Puffs per Day (Adult)	Maintenance Cost / Month	Age range
Flonase	fluticasone 50mcg/spray	Glaxo	120	$10.68	$11.12	4%	QD	2	$5.56	4 to adult
Nasalide	flunisolide 25 mcg/spray	Dura	200	$11.24	$11.65	4%	BID	4	$6.99	6 to adult
Vancenase Pockethaler*	beclomethasone 42mcg/spray	Schering	200	$3.76	$9.25	146%	TID	6	$8.33	6 to adult
Vancenase AQ DS	beclomethasone 84mcg/spray	Schering	120	$10.75	$18.96	76%	QD	2	$9.48	6 to adult
Nasacort AQ	triamcinolone 55mcg/spray	RPR	120	$7.74	$18.96	145%	QD	2	$9.48	6 to adult
Nasonex	mometasone 50 mcg/spray	Schering	120	$8.87	$10.49	18%	QD	4	$10.49	12 to adult
Nasacort*	triamcinolone 55mcg/spray	RPR	100	$8.28	$18.22	120%	QD	2	$10.93	6 to adult
Nasarel	flunisolide 25 mcg/spray	Dura	200	$7.18	$18.73	161%	BID	4	$11.24	6 to adult
Rhinocort*	budesonide 32mcg/spray	Astra	200	$12.46	$19.00	52%	BID	4	$11.40	6 to adult
Vancenase AQ	beclomethasone 42mcg/spray	Schering	200	$9.07	$19.50	115%	BID	4	$11.70	6 to adult
Beconase AQ	beclomethasone 42mcg/spray	Glaxo	200	$18.53	$20.96	13%	BID	4	$12.58	6 to adult
Beconase*	beclomethasone 42mcg/spray	Glaxo	200	$12.36	$14.68	19%	TID	6	$13.21	6 to adult
Beconase*	beclomethasone 42mcg/spray	Glaxo	80	$5.85	$8.21	40%	TID	6	$18.47	6 to adult
Vancenase*	beclomethasone 42mcg/spray	Schering	80	$15.89	$14.06	-12%	TID	6	$31.64	6 to adult

*** Metered Dose Inhaler**

Appendix D: Quantity Limits for NMOP and Retail Pharmacy Network

The quantity of medication dispensed is generally limited to a 90-day supply in the National Mail Order Pharmacy (NMOP) and a 30-day supply in retail network pharmacies. If a patient obtains more than a 30-day supply at a retail pharmacy, the patient must pay an additional co-pay for each additional 30-day supply increment, up to a 90-day supply (3 co-pays).

A subcommittee of the DoD P & T Committee and Pharmacoeconomic Center (PEC) staff members developed proposed quantity limits that either (1) deviate from the general 30- or 90-day limits, or (2) specify the quantity that is associated with a specific time period. The following table shows the proposed quantity limits and the rationale for these limits. If a specific rationale is not stated, the quantity limit was calculated by multiplying the maximum daily dose times the days supply limit.

A quantity limit represents the maximum allowable quantity that may be dispensed for a given time period. Maximum quantities to be dispensed are determined by directions for use or the proposed quantity limits below, whichever is less.

Drug	Previous NMOP Limit	New Quantity Limits	Rationale
Antiemetics			
Granisetron 1mg tablet (Kytril)	None	Retail: 8 per 30 days Mail: 24 per 90 days	Indication is for 1 tablet (1 mg) twice daily on days that chemotherapy is given. Most chemotherapy regimes are for 4 or 5 days per cycle. However, Drug Facts & Comparisons lists several chemo regimens (e.g., COPP for lymphoma) that require oral therapy with highly emetogenic drugs for periods ranging from 8 to 14 days per cycle.
Ondansetron 4mg and 8mg (Zofran)	45 tablets or 90 days, whichever is less	Retail: 15 per 30 days Mail: 45 per 90 days	Indication is for 1 tablet (4 or 8 mg) twice daily on days that chemotherapy is given, and for 1 or two days after regimen is finished. Most chemotherapy regimes are for 4 or 5 days per cycle. However, Drug Facts & Comparisons lists several chemo regimens (e.g., COPP for lymphoma) that require oral therapy with highly emetogenic drugs for periods ranging from 8 to 14 days per cycle.
Dolasetron 50mg and 100 mg (Anzemet)	None	Retail: 5 per 30 days Mail: 15 per 90 days	Indication is for 1 tablet (50 or 100 mg) prior to chemotherapy. Most chemotherapy regimes are for 4 or 5 days per cycle. However, Drug Facts & Comparisons lists several chemo regimens (e.g., COPP for lymphoma) that require oral therapy with highly emetogenic drugs for periods ranging from 8 to 14 days per cycle.
Oral and Nasal Inhalers			
Albuterol Inh Soln 20ml (0.5%)	9 units (180ml) or 90 days, whichever is less	Retail: 3 units per 30 days Mail: 9 units per 90 days	
Albuterol Inhaler	5 units or 90 days, whichever is less	Retail: 2 units per 30 days Mail: 6 units per 90 days	
Beclomethasone AQ Nasal Spray 19gm (Beconase)	3 units or 90 days, whichever is less	Retail: 1 units per 30 days Mail: 3 units per 90 days	
Beclomethasone Inhaler 16.8 gm	9 units or 90 days, whichever is less	Retail: 3 units per 30 days Mail: 9 units per 90 days	
Beclomethasone Nasal Inhaler (Beconase, Vancenase)	4 units or 90 days, whichever is less	Retail: 2 units per 30 days Mail: 6 units per 90 days	
Bitolterol Inhaler 15cc (Tornalate)	4 units or 90 days, whichever is less	Retail: 2 units per 30 days Mail: 6 units per 90 days	

Drug	Previous NMOP Limit	New Quantity Limits	Rationale
Budesonide (Pulmicort)	None	Retail: 2 units per 30 days Mail: 6 units per 90 days	
Budesonide Nasal Inhaler 7gm (Rhinocort)	4 units or 90 days, whichever is less	Retail: 2 units per 30 days Mail: 6 units per 90 days	
Cromolyn Sodium Inhaler 112 Puff (Intal)	6 units or 90 days, whichever is less	Retail: 3 units per 30 days Mail: 9 units per 90 days	
Cromolyn Sodium Inhaler 200 Puff (Intal)	4 units or 90 days, whichever is less	Retail: 2 units per 30 days Mail: 6 units per 90 days	
Cromolyn Sodium Nebulizing Soln (20mg)	360 units or days, whichever is less	Retail: 150 units per 30 days Mail: 450 units per 90 days	
Flunisolide Inhaler (Aerobid, Aerobid-M)	7 units or 90 days, whichever is less	Retail: 3 per 30 days Mail: 9 per 90 days	
Flunisolide Nasal Soln (.025%)	7 units or 90 days, whichever is less	Retail: 3 units per 30 days Mail: 9 units per 90 days	
Fluticasone 110mcg (Flovent)	6 units or 90 days, whichever is less	Retail: 2 units per 30 days Mail: 6 units per 90 days	
Fluticasone 220mcg (Flovent)	6 units or 90 days, whichever is less	Retail: 2 units per 30 days Mail: 6 units per 90 days	
Fluticasone 44mcg (Flovent)	None	Retail: 2 units per 30 days Mail: 6 units per 90 days	
Fluticasone Nasal Spray (Flonase)	3 units or 90 days, whichever is less	Retail: 1 units per 30 days Mail: 3 units per 90 days	
Ipratropium 0.03% Nasal Spray 30ml (Atrovent)	3 units or 90 days, whichever is less	Retail: 1 unit per 30 days Mail: 3units per 90 days	
Ipratropium 0.06% Nasal Spray 15ml	4 units or 90 days, whichever is less	Retail: 2 units per 30 days Mail: 6 units per 90 days	Indicated for rhinorrhea associated with the common cold. 16 Sprays per day maximum. 165 sprays per container. Appropriate, because a common cold is a self-limiting illness.
Ipratropium Inhalant Soln 2.5ml (.02%)	360 units or 90 days, whichever is less	Retail: 150 units per 30 days Mail: 450 units per 90 days	
Ipratropium Inhaler	6 units or 90 days, whichever is less	Retail: 2 units per 30 days Mail: 6 units per 90 days	
Metaproterenol Inhalant Soln (0.6%)	None	Retail: 150 units per 30 days Mail: 450 units per 90 days	
Metaproterenol Inhaler (Alupent)	6 units or 90 days, whichever is less	Retail: 3 units per 30 days Mail: 9 units per 90 days	
Triamcinolone Aqueous Nasal Spray (16.5gm) (Nasacort)	6 units or 90 days, whichever is less	Retail: 2 units per 30 days Mail: 6 units per 90 days	
Nedocromil Inhaler (Tilade)	6 units	Retail: 3 units per 30 days Mail: 9 units per 90 days	
Pirebutolol Inhaler 300 puff (Maxair) Inh	4 units or 90 days, whichever is less	Retail: 2 units per 30 days Mail: 6 units per 90 days	
Pirebutolol Autohaler 400 inh	3 units or 90 days, whichever is less	Retail: 1 unit per 30 days Mail: 3 units per 90 days	

Drug	Previous NMOP Limit	New Quantity Limits	Rationale
Salmeterol (Serevent)	6 inhalers or 90 days, whichever is less	Retail: 1 inh per 30 days Mail: 3 inh per 90 days	
Triamcinolone oral Inhaler (Azmacort)	6 units or 90 days, whichever is less	Retail: 2 units per 30 days Mail: 6 units per 90 days	
Antimigraine Drugs			
Note on dosing of 5HT-1 receptor antagonists for treatment of migraine. Generally for an acute migraine attack, the 5HT-1 antagonists are given once, and the dose is repeated in 4 hours if the headache returns or is still present. This is expected to successfully abort a classical migraine attack in 68% to 86% of patients. Subsequent doses may be given at 4-hour intervals, up to the maximum amount specified in a 24-hour period. Safety of treating more than 4 headaches in a 30-day period has not been established. [2,3,4]			
Dihydroergotamine Nasal Spray (Migranal)	None	Retail: 8 units per 30 days Mail: 24units per 90 days	Safety of using more than 3mg/24 hour or 4mg in a 7-day period has not been established.[2,3,4]
Naratriptan 1mg (Amerge)	8 tablets or 30 days, whichever is less	Retail: 9 tabs per 30 days Mail: 27 tabs per 90days	Two tablets per headache, 4 headaches per month. If more than 8 tablets are required, patient should be receiving 2.5 mg tablets.[2,3,4] (Tablets packaged in 9's)
Naratriptan 2.5mg Tablet (Amerge)	8 tablets or 30 days, whichever is less	Retail: 9 tabs per 30 days Mail: 27 tabs per 90 days	Two tablets per headache, 4 headaches per month. Max of 5mg in 24 hours.[2,3,4] (Tablets packaged in 9's)
Rizatriptan 5mg, 10mg Tablet, MLT-5mg, 10mg Tablet 16.8 gm (Maxalt)	None	Retail: 12 tabs or 30 days Mail: 36 tabs or 90 days	Two tablets per headache, 4 headaches per month. Max of 30mg in 24 hours. If more than 12 of the 5mg tablets are needed, patient should be changed to 10mg tablets.[2,3,4]
Sumatriptan 25mg Tablet (Imitrex)	48 tablets or 30 days, whichever is less	Retail: 18 tabs or 30 days Mail: 54 tabs or 90 days	Max of 200 mg (8 tablets) in 24 hours, 4 headaches per month. If more than 18 25-mg tablets are needed in 30 days, patient should move to the 50-mg tablet.[2,3,4] (AWP is the same for both strengths)
Sumatriptan 50mg Tablet (Imitrex)	48 tablets or 30 days, whichever is less	Retail: 18 tabs or 30 days Mail: 54 tabs or 90 days	Max of 200mg (4 tablets) in 24 hours, 4 headaches per month.[2,3,4]
Sumatriptan Injection (Imitrex)	8 injections (4ml) or 30 days, whichever is less	Retail: 8 units per 30 days Mail: 24 units per 90 days	2 injections per 24 hours, maximum recommended. 4 headaches per month.
Sumatriptan Nasal Spray 5mg/unit, 20mg/unit (Imitrex)	None	Retail: 6 units per 30 days Mail: 18 units per 90 days	Packaged in 6's. Maximum of 40 mg/24 hours. If more than 6 units of 5 mg required, should consider 20 mg.[2,3,4]
Zolmitripan 2.5mg and 5mg Tablet (Zomig)	None	Retail: 8 tabs or 30 days Mail: 24 tabs or 90 days	Two tablets per headache, 4 headaches per month. If more than 8 of the 2.5mg tablets are needed, patient should be changed to 5mg tablets.[2,3,4]
Miscellaneous			
Alcohol Swabs	1 swab per syringe	1 swab per syringe rounded up to nearest 100	
Blood/Urine Test Strips	90 days supply or 400 units, whichever is less	90 days supply or 400 units, whichever is less	
Butorphanol NS (Stadol)	4 units or 30 days, whichever is less	Retail: 4 units per 30 days Mail: 4 units per 30 days	Indicated for acute, severe pain. Maximum 4 mg (sprays)/day. 14 sprays/unit.

Drug	Previous NMOP Limit	New Quantity Limits	Rationale
Dornase Alpha (Pulmozyme)	60 ampules or 30 days, whichever is less	Retail: 30-day supply or 120 amps, whichever is less Mail: 90-day supply or 360 amps, whichever is less	Recommended daily dose is 1 amp per day, some patients may benefit from 1 amp BID. However, some patients receive 4 amps BID, two weeks on - two weeks off.[6]
Etanercept injection (Enbrel)	None	Retail: 8 injections (2 cartons of 4 injections) (4 weeks supply) Mail: 12 injections (3 cartons of 4 injections) (6 weeks supply)	Indicated use is for one injection twice weekly. Patients must meet prior authorization criteria for etanercept.
Insulin Syringes & Needles	90 days supply or 400 units, whichever is less	90 days supply or 400 units, whichever is less	
Ketorolac 10mg Tablet (Toradol)	None	Retail: 20 tabs per 5 days Mail: 20 tabs per 5 days	Safety.[3] There were deaths from renal toxicity associated with this drug. Boxed warning is for acute treatment of pain, 4 tablets per day, for 5 days maximum per treatment episode.
Schedule III, IV, V Drugs for non-active duty only	Up to a max of 30 day supply and 5 refills	Retail: max of 30-day supply and 5 refills Mail: max of 30-day supply and 5 refills	Federal and State laws
Phenobarbital, Pemoline, other ADHD drugs	Up to a max of a 90 day supply and 1 refill	Retail: max of 90-day supply and 1 refill Mail: max of 90-day supply and 1 refill	Exception to above laws when used for seizure disorder and ADHD
Tramadol 50 mg (Ultram)	None	Retail: 240 tabs per 30 days Mail: 720 tabs per 90 days	FDB limit[7] There was toxicity and deaths associated with this drug. Boxed warning is for no more than 8 tablets per day.
Zolpidem 10mg Tablet (Ambien)	None	Retail: 10 tabs per 30 days Mail: 10 tabs per 30 days	
Antifungals			
Fluconazole 150mg (Diflucan)	1 tablet/90 days	Retail: 1 tablet per 30 days Mail: 3 tablets per 90 days	One tablet a month of the 150 mg strength is indicated for prophylaxis in 5% of patients.[8]
Oral Antifungals	None	Retail: 30 days supply maximum Mail 90 days supply maximum	While medically indicated for onychomycosis, lifestyle changes are also important.
Terconazole Vaginal Cream (Terazol-3)	1 box (20gm) or 30 days	Retail: 1 box (20 gm) per 30 days Mail: 1 box (20 gm) per 30 days	Short term med
Terconazole Vaginal Cream (Terazole-7)	1 box (45gm) or 30 days	Retail: 1 box (45gm) per 30 days Mail: 1 box (45gm) per 30 days	Short term med
Terconazole Vaginal Suppositories (Terazole-3)	1 box (3 units) or 30 days	Retail: 1 box (3 units) per 30 days Mail: 1 box (3 units) per 30 days	Short term med

Drug	Previous NMOP Limit	New Quantity Limits	Rationale
Ophthalmics			
Antibiotic Ophthalmics	None	Retail: 1 unit per 15 days Mail: 1 unit per 15 days	Short term med, not appropriate for mail order
Antiviral Ophthalmics	None	Retail: 1 unit per 15 days Mail: 1 unit per 15 days	Short term med, not appropriate for mail order
Ketorolac Opth (Acular) 3,5,10ml	None	Retail: 2 units per 30 days Mail: 6 units per 90 days	Two units of the 10ml would accommodate the maintenance dose. Smaller package sizes are appropriate for short-term indications.
Latanoprost (Xalatan) 2.5 ml	None	Retail: 2 units/30 days Mail: 6 units/90 days	Usual in most plans
NSAID ophthalmics Ocufen, Profenal, Voltaren	None	Retail: 1 unit per 15 days Mail: 1 unit per 15 days	Short term med, not appropriate for mail order
Olopatadine Hcl (Patanol) 5 ml	None	Retail: 2 units per month Mail: 2 unit per month	Usual in most plans.
Antibiotics			
Zithromax 250mg	6 tablets or 90 days, whichever is less	Retail: 6 tabs per 30 days Mail: 6 tabs per 30 days	Antibiotic, inappropriate for mail order
Zithromax 600mg	6 tablets or 90 days, whichever is less	Retail: 8 tabs per 30 days Mail: 24 tabs per 90 days	Prophylaxis of MAC at a dose of 2 tablets/week in HIV infected individuals
Fertility and Impotence			
Oral Fertility Agents (except clomiphene)	30 day supply	Retail: 30 day supply Mail: 30 day supply	
Injectable Fertility Agents	20 units or 30 days, whichever is less -no refills allowed.	Retail: 20 units per 30 days - no refills allowed Mail: 20 units per 30 days -no refills allowed	
Clomiphene citrate (e.g., Clomid)	10 tablets or 30 days, whichever is less	Retail: 10 tablets per 30 days Mail: 10 tablets per 30 days	
Alprostadil injection (Caverject, Edex)	6 injections or 30 days, whichever is less	Retail: 6 injections per 30 days Mail: 18 injections per 90 days	Health Affairs policy
Alprostadil intraurethral pellet (Muse)	6 pellets or 30 days, whichever is less	Retail: 6 pellets per 30 days Mail: 18 pellets per 90 days	Health Affairs policy
Sildenafil (Viagra)	6 tablets or 30 days, whichever is less	Retail: 6 tablets per 30 days Mail: 18 tablets per 90 days	Health Affairs policy

Notes/References:

1. Current TRICARE policy allows for patients to receive up to a 90-day supply at retail for most medications. Patients pay a co-payment for each month received.
2. Prescribing information. *Physician's Desk Reference, 52nd ed,* Medical Economics, Inc., Montvale, NJ, 1998.
3. *Drug Facts & Comparisons*, Facts & Comparisons, St. Louis, MO, 1999.
4. The average duration of headaches is 1-2 days, according to *Harrison's Principles of Internal Medicine*, 12ed., pp. 110-4. The typical migraine patient will experience an average of 3 attacks per month.[6] A range of 18 to 24 of the 50mg tablets monthly should be sufficient.
5. Hu XH, Markson LE, *et al.* Burden of Migraine in the United States: Disability and Economic Costs. *Arch Internal Med.* 1999;159(8):813-8.
6. Recommended daily dose, however, some patients receive 4 amps BID, two weeks on - two weeks off.
7. Safety information. First Data Bank, Indianapolis, IN, 1999.
8. *AHFS© Drug Information 1998.* American Society of Health System Pharmacists. Bethesda MD

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MCCS-GPE 17 May 1999

MEMORANDUM FOR Assistant Secretary of Defense (Health Affairs)

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

1. In accordance with Health Affairs policy 98-025, a meeting of the DoD P&T committee convened at 0800 hours on 14 May 1999, at the DoD Pharmacoeconomic Center (PEC), Fort Sam Houston, TX.

2. MEMBERS PRESENT:

COL Daniel D. Remund, MS	Co-chairman
CDR Terrance Egland, MC	Co-chairman
COL Rosa Stith, MC	Army
LTC Judith O'Connor, MC	Army
Danielle Doyle	Army
CDR Matt Nutaitis, MC	Navy
LCDR Denise Graham, MSC	Navy
LtCol John R. Downs, MC	Air Force
LtCol William Sykora, MC	Air Force
MAJ George Jones, BSC	Air Force
CDR Robert W. Rist	Coast Guard
LTC (P) George Crawford, MS	Joint Readiness Clinical Advisory Board
MAJ Steven Humburg, MC	Health Affairs
MAJ Mickey Bellemin BSC	Defense Supply Center Philadelphia (DSCP)
Ronald L. Mosier	Department of Veterans Affairs (alternate)
Ray Nan Berry	Foundation Health
William Hudson	Humana, Inc
Ron McDonald	Sierra Military Health Service
Gene Lakey	TriWest

3. OTHERS PRESENT:

CAPT Charlie Hostettler, MSC	DoD Pharmacy Program Director, TMA
CDR Mark Brouker, MSC	DoD Pharmacoeconomic Center
Lt Col Gary Blamire, BSC	Tricare Southwest Lead Agent
Lt Col (sel) Greg Russie, BSC	Air Force (alternate representative)
Tom Kellenberger	Merck-Medco Representative
Shelby Tanner, Jr.	Staff Judge Advocate, Fort Sam Houston
Shana Trice	DoD Pharmacoeconomic Center

4. ADMINISTRATIVE ISSUES:

   A. The minutes from the 5 February 1999 meeting were accepted as written.

   B. Committee membership: MAJ George Jones replaced Lt Col (sel) Greg Russie as the Air Force pharmacist committee member. Lt Col (sel) Russie will serve as the alternate Air Force pharmacist committee member. LCDR Denise Graham will enter a Duty Under Instruction (DUINS) Program. A Navy pharmacist has not yet been named to replace LCDR Graham on the committee. LTC Joel Schmidt, Walter Reed Army Medical Center, is the alternate Army physician member. LTC Kent Maneval, Walter Reed Army Medical Center, is the alternate Army pharmacist committee member.

5. OLD BUSINESS: Issues pending from previous meetings were addressed under new business because the committee needed to address the proposal to restructure the National Mail Order Pharmacy (NMOP) formulary as its first item of business.

6. NEW BUSINESS: Proposal to restructure the NMOP formulary.

   A. The committee approved a PEC proposal to replace the NMOP Preferred Drug List (PDL) with a restructured NMOP formulary. The restructured NMOP formulary is designed to:

      - Enable patients and providers to more easily and accurately determine the availability of medications in the NMOP.
      - Increase the use of medications that offer significant clinical or economic advantages compared to other medications.
      - Support compliance with DoD and joint VA/DoD pharmaceutical contracts.

   B. The NMOP Preferred Drug List (PDL) will be replaced by an NMOP formulary that includes specific injectable drugs and all non-injectable prescription drugs with the following exceptions or limitations:

- *Excluded drugs and drug classes:* Some drugs or classes of drugs are excluded from the NMOP formulary due to TRICARE policy or DoD P&T Committee decisions. These drugs are not available through the NMOP.
- *Drugs subject to prescribing guidelines or prior authorization:* These drugs must be dispensed in accordance with prescribing guidelines or prior authorization criteria that are established by the DoD P&T Committee.
- *Non-preferred drugs and preferred alternatives:* If the prescriber agrees that a preferred drug is clinically appropriate, a prescription for a non-preferred drug will be changed to a preferred alternative drug.
- *Covered injectable drugs:* The formulary includes selected injectable drugs that are intended for self-administration or are commonly administered in the home setting
- *Covered over-the-counter (OTC) drugs/products*: The formulary includes selected OTC drugs and products.
- *Drugs pending P&T committee review:* Drugs newly approved by the Food & Drug Administration (FDA) that are pending P&T Committee review will not be available through the NMOP until the P&T Committee completes the review and assigns the drug to the appropriate category on the NMOP formulary.

C. Appendix A identifies the drugs that are included in each formulary category in the initial edition of the NMOP formulary.

7. NEW BUSINESS: Agents considered for Basic Core Formulary and NMOP formulary status.

A. Celecoxib (Celebrex), commonly known as a COX-2 inhibitor, is indicated for relief of the symptoms of osteoarthritis and adult rheumatoid arthritis. A summary of efficacy, safety, and cost issues associated with celecoxib is provided at Appendix B. Committee decision: **Do not add to the BCF. Add to the NMOP formulary subject to a prescribing guideline/prior authorization.** Celecoxib is significantly more expensive than other non-steroidal anti-inflammatory drugs, so the prescribing guideline will be designed to target the use of celecoxib to patients who are at high risk for adverse gastrointestinal events. The committee discussed a draft prescribing guideline and provided precepts for the PEC to finalize the guideline. Celecoxib will be available through the NMOP when DSCP and Merck Medco have established procedures for implementing the prescribing guideline.

B. Brand name NSAIDS are 2 to 20 times more expensive than generic NSAIDs based on current DAPA prices. Generic NSAIDs, rather than brand name NSAIDs, should be used to the maximum extent consistent with patients' clinical needs. Committee decision: **The brand name NSAIDs listed below are designated as non-preferred drugs. The preferred alternatives are listed in Appendix 1.**

- nabumetone (Relafen)
- oxaprozin (Daypro)

- etodolac extended release (Lodine XL)
- diclofenac extended release (Voltaren XR)
- naproxen sodium extended release (Napralen)

C. Etanercept (Enbrel) is a new biotech inhibitor of tumor necrosis factor for use in patients with moderate to severe rheumatoid arthritis who have failed other agents. Discussion of a draft prescribing guideline centered on the number and identity of disease-modifying anti-rheumatoid drugs (DMARDS) that a patient must fail before receiving etanercept. The committee was also concerned that the prescribing guideline should take into account an apparent increased risk of serious infections that was recently detected through post-marketing surveillance of patients taking etanercept. The increased risk of serious infections prompted the FDA to revise the warnings section of the package insert for etanercept. The DAPA price for etanercept if $81.93 per dose, which equates to $655.44 per month of therapy. Committee decision: **Do not add to the BCF. Add to the NMOP formulary subject to prescribing guideline/prior authorization.** The committee provided precepts for the PEC to finalize the prescribing guideline. Etanercept will be available through the NMOP when DSCP and Merck Medco have established procedures for implementing the prescribing guideline. To limit the financial waste that occurs when patients discontinue the medication, the NMOP will dispense no more than a 30-day supply of etanercept (2 cartons of 4 injections).

D. Sevelamer hydrochloride (Renagel) is indicated for the reduction of serum phosphorus in patients with end-stage renal disease. It is a nonabsorbable hydrogel polymer that avoids the problems that are associated with phosphate binders containing aluminum or calcium. Aluminum-containing phosphate binders may cause aluminum toxicity resulting in osteomalacia, anemia, and dementia. Systemic absorption of calcium-containing phosphate binders may cause hypercalcemia and increased risk of metastatic calcification. Committee decision: **Do not add to BCF. Add to the NMOP formulary.**

E. Modafinil (Provigil) is used to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy. In clinical trials modafinil showed significant improvement on objective and subjective measures of excessive daytime sleepiness compared to placebo. Direct comparisons of the efficacy of modafinil to other agents are not available. The National Transportation Safety Board has requested that the manufacturer conduct trials using modafinil in long-haul truckers to promote wakefulness. The committee expressed concern about the potential for inappropriate use of modafinil to increase alertness among patients who do not have narcolepsy. Committee decision: **Do not add to BCF. Add to the NMOP formulary and monitor usage patterns for evidence of inappropriate use.** (Note: the manufacturer estimates that only about 125,000 people suffer from narcolepsy in the United States, so usage of this drug should be minimal.)

F. Polyethylene glycol (Miralax) is an osmotic agent that is used as a laxative. Committee decision: **Do not add to the BCF. Add to the NMOP formulary.**

G. Corticosteroid oral inhalers: At the Feb 99 meeting the committee tabled action on a proposal to remove triamcinolone (Azmacort) inhaler from the BCF due to an announced DAPA price increase from $7.95 to $12.90 per inhaler. The DAPA price for Azmacort was subsequently reduced to $9.60 per inhaler. The DAPA price for beclomethasone (Vanceril) inhaler was recently increased from $3.45 to $5.75 per inhaler and Vanceril-DS inhaler went from $5.16 to $6.90 per inhaler. The cost per day for Vanceril, Vanceril-DS, and Azmacort inhalers is still less than the cost per day for other corticosteroids for oral inhalation. Committee decision: **Do not change the corticosteroid oral inhalers on the BCF, but continue to monitor price changes in this drug class. Vanceril, Vanceril-DS, and Azmacort remain on the BCF.**

H. Corticosteroid nasal inhalers: Beclomethasone 42mcg/spray (Vancenase Pockethaler) has been the only corticosteroid nasal inhaler on the BCF. The DAPA price for the Vancenase Pockethaler recently increased from $3.76 to $9.25 per inhaler. A PEC estimate of the monthly maintenance costs for various corticosteroid nasal inhalers (based on the dosing frequency and the number of sprays/puffs available in each on the inhalers) showed that the Vancenase Pockethaler no longer offers an economic advantage compared to other inhalers. Committee decision: **Remove beclomethasone 42mcg/spray (Vancenase Pockethaler) from the BCF. The BCF will state that the MTF must have a corticosteroid nasal inhaler on its formulary, but the MTF can select which one to have on its formulary.** The committee intends to review the corticosteroid nasal inhalers at the next meeting to see if a specific inhaler should be selected for the BCF in order to standardize availability across the Military Health System. (OPEN)

I. Premarin vs Ogen vaginal cream: Conjugated estrogen (Premarin) vaginal cream is currently on the BCF. An MTF requested a BCF modification that would allow the MTF to preferentially use estropipate (Ogen) vaginal cream instead of Premarin. There are no apparent differences in efficacy or safety between Premarin and Ogen vaginal creams. The DAPA price for Premarin vaginal cream is almost twice that of Ogen vaginal cream. Committee decision: **Change the BCF listing from conjugated estrogen vaginal cream to "estrogenic vaginal cream." All MTFs must include an estrogenic vaginal cream on their formularies, but the MTFs will select the specific brand.**

8. NEW BUSINESS: Other issues:

A. Fertility drugs: The TRICARE policy manual classifies noncoital reproductive technologies (artificial insemination, in vitro fertilization, gamete intrafallopian transfer, etc.) as noncovered treatments and specifies that services and supplies directly related to a noncovered procedure are not covered. Based on this policy, managed care support contractors in some TRICARE regions use prior authorization procedures to deny coverage at retail network pharmacies for fertility drugs when they are prescribed for use with noncoital reproductive technologies. Currently, the NMOP does not perform prior authorization procedures for fertility drugs. In some cases, the NMOP dispenses fertility drugs to patients who were previously denied coverage through a retail network pharmacy because the drugs were prescribed for use with noncoital reproductive technologies. The

committee concluded that this issue was too complex to be solved at the meeting. A subcommittee was appointed to investigate this issue in greater detail, obtain input from individuals outside of the P&T Committee if necessary, and recommend actions to make the coverage of fertility drugs consistent in the NMOP and the retail pharmacy networks. (OPEN)

B. Sildenafil (Viagra): The prescribing guideline that the PEC prepared for Merck Medco to fax to prescribers is still not used. The committee discussed the stipulation in the prescribing guideline that sildenafil will only be used for organic erectile dysfunction and hypothesized that provisions in the TRICARE policy manual are the basis for this stipulation. The committee reaffirmed that sildenafil should only be dispensed by the NMOP in accordance with the prescribing guideline.

C. Migraine drug usage in the NMOP: MAJ Bellemin reported that the NMOP receives very few complaints regarding the quantity limits for migraine drug therapy. Several committee members commented that the NMOP quantity limits are quite generous compared to quantity limits at MTFs or in other managed care settings. A subcommittee was appointed to review quantity limits for migraine drugs and submit recommendations to the P&T committee at the next meeting. (OPEN)

D. Niacin for antilipemic therapy: The committee reaffirmed its position that the NMOP should provide niacin (in both OTC and prescription forms) for antilipemic therapy. The committee does not intend that niacin should be provided for vitamin supplementation. A basis for the provision of OTC form of niacin may exist in the TRICARE final rule that established requirements and procedures for implementation of the TRICARE program. The TRICARE final rule allows the establishment of "other procedures for the effective operation of the pharmacy programs" to include drug formularies. While drug formularies are often viewed as a means to limit the availability of medications, the NMOP formulary could also be used to expand the availability of medications to include OTC forms of niacin for antilipemic therapy. The restructured NMOP formulary automatically includes prescription forms of niacin. Committee decision: **Add over-the-counter (OTC) forms of niacin prescribed for antilipemic therapy to the list of OTC items that are covered by the NMOP. Implementation is contingent on TMA West policy review.**

E. The discussion of OTC niacin led to a suggestion that needles, syringes, alcohol pads, and lancet should also be provided through the NMOP. Some committee members expressed concern that when co-pays and dispensing fees are taken into account, the beneficiaries would obtain very little benefit and the government would incur a substantial increase in cost. Other members suggested that costs to the government or the managed care support contractor are much higher if the beneficiary obtains such supplies through home health providers. Committee decision: **The NMOP should supply needles, syringes, and alcohol pads when a medication is dispensed for home injection. The NMOP should also supply alcohol pads and lancets for diabetic patients.** The provision of these items through the NMOP is contingent upon the ability of the NMOP COTR and

contracting officer identify methods by which these items can be provided at a reasonable cost.

F. Handling of high dollar items in the NMOP: The committee tabled this issue at the last meeting and asked the NMOP COTR, the PEC, and the MCS contractors to work out a draft design of an NMOP prior authorization process that the committee could review. This issue is resolved by the restructuring of the NMOP formulary, which includes a category of drugs that are subject to prescribing guidelines/prior authorization.

G. NMOP quantity limitations for ophthalmics and topicals (specifically urea 40% cream): The subcommittee that was appointed to review quantity limitations for migraine drugs will also develop recommendations for the P&T committee regarding quantity limitations for ophthalmics and topicals. (OPEN)

9. NEW BUSINESS: Contracting update

A. Insulin: Pre-solicitation conferences with the pharmaceutical companies are scheduled for 18 and 20 May 99. The solicitation will probably be issued within a week to 10 days after pre-solicitation conferences are completed. This is a joint VA/DoD contracting initiative.

B. Statins: DSCP recently completed discussions with the offerors. The deadline for final proposal revisions is 21 May 99. Target date for awarding the contract is 11 Jun 99.

C. Proton pump inhibitors: The solicitation was issued on 7 May 99 and closes on 10 Jun 99.

D. Lisinopril: The solicitation closes on 21 May 99.

E. Blood glucose test strips: The PEC recommends discontinuation of the current contracting initiative to select a single blood glucose test strip for a closed class on the BCF. Contracting initiatives are taking much longer to complete than originally anticipated. Some MTFs are reluctant to adopt the test strip that is currently on the BCF (Precision QID) because they do not want to switch patients twice in the event that a contract is awarded for a different test strip. Given the number of contracting initiatives that DSCP is already working on, a contract for blood glucose test strips would very likely take 8 to 12 months to complete. It is unreasonable to hold up MTF formulary decisions for that length of time. Committee decision: **Discontinue the current blood glucose test strip contracting initiative. Precision QID remains as the blood glucose test strip in an open class on the BCF.**

F. Selective serotonin reuptake inhibitors (SSRIs): At the Nov 98 meeting the committee concurred with a proposal to select one SSRI for an open class on the BCF. It was anticipated that blanket purchase agreements or DAPA incentive agreements would be established to facilitate the selection of an SSRI for an open class on the BCF, but such

agreements have not been established. The committee intends to select one SSRI for an open class on the BCF at the Aug 99 meeting.

G. Warfarin: At the Nov 98 meeting the committee removed the Coumadin brand only designation from the BCF with the intent of pursuing a sole source contract for a single brand of warfarin. Price competition appears to be increasing in the warfarin market. Increased price competition may diminish the need to pursue a sole source contract.

10. ADJOURNMENT: The meeting adjourned at 1400 hours. The next meeting will be held on 13 August 1999 at the DoD Pharmacoeconomic Center, Fort Sam Houston, Texas, beginning at 0800 hours. All agenda items are to be submitted to the DoD PEC no later than 16 July 1999.

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

Appendix A: NMOP Formulary

Drugs that are covered:

- All non-injectable prescription drugs that are *not* excluded. (Excluded drugs are listed in the Excluded Drugs category.)
- Injectable drugs listed in the Covered Injectable Drugs category
- Non-prescription drugs or products listed in the Covered OTC Drugs/Products category

Excluded Drugs

Drug Classes Excluded for Active Duty Members Only:
- Amphetamines
- CNS stimulants
- Controlled substances in Schedules II, III, IV, V

Excluded Drug Classes:
- Anabolic steroids
- Contraceptive creams, foams, implants, injections, jellies
- Immune globulins
- Immunizations
- Injectable drugs (unless listed in the Covered Injectable Drug category)
- Legend prenatal vitamins for males, and females age 46 and over
- Legend vitamins
- Over-the-counter (OTC) drugs (unless listed in the Covered OTC Drugs/Products category)
- Smoking deterrents
- Vaccines

Exclusions by Drug Use:
- Drugs for cosmetic use as a result of the aging process (e.g., tretinoin cream (Renova)) or whose sole use is to stimulate hair growth [e.g., topical minoxidil (Rogaine), finasteride (Propecia)].
- Drugs for investigational use
- Drugs for obesity and/or weight reduction

Specific Drug Exclusions:
- Clozapine (Clozaril)
- Enoxaparin (Lovenox)
- Quinine
- Thalidomide (Thalomid)
- Tretinoin (Retin-A) age 36 and over

New FDA-approved drugs:
- Excluded until reviewed by the DoD P&T Committee (will be listed in the Drugs Pending P&T Committee review category—to be updated as new drugs are approved by the FDA)

Drugs Pending P&T Committee Review

- Cilostazol (Pletal)

Covered Injectable Drugs*

- Alprostadil (Caverject, Muse) intracavernosal injection
- Antihemophilic Factor VIII
- Antihemophilic Factor IX Complex
- Calcitonin salmon injection
- Cyanocobalamin injection
- Epoetin alfa, recombinant (Epogen, Procrit)
- Filgrastim (Neupogen) injection
- Glatiramer acetate (Copaxone) injection
- Glucagon
- Goserelin acetate (Zoladex) implant syringe
- Insect Sting Treatment Kit
- Insulin
- Insulin analog (Humalog) injection
- Interferon Alpha (Infergen, Roferon-A, Intron A, Rebetron)
- Interferon Beta (Avonex, Betaseron)
- Interferon Gamma-1b (Actimmune)
- Leuprolide (Lupron) depot and subcutaneous injections
- Menotropins (Repronex) injection
- Octreotide (Sandostatin) injection
- Sargramostim (Leukine) injection
- Somatrem (Protropin)
- Somatropin (Humatrope)
- Sumatriptan (Imitrex) injection
- Urofollitropin (Fertinex) injection

**** many of these agents currently have quantity restrictions***

Covered OTC Drugs/Products

- Glucose Test Strips
- Insulin and Insulin syringes
- Lancets
- Niacin (for antilipemic therapy)
- Alcohol swabs, needles and syringes (for injectable drugs dispensed for home injection only)

Drugs Subject to Practice Guidelines/Prior Authorization
• Celecoxib (Celebrex) • Etanercept (Enbrel) • Sildenafil (Viagra)

Non-Preferred Drugs and Preferred Alternatives	
Non-Preferred	**Preferred**
Astemizole (Hismanal)	➢ **Cetirizine (Zyrtec)** **Fexofenadine (Allegra)** **Loratadine (Claritin)**
Diclofenac extended release (ER) (Voltaren XR)	➢ **Diclofenac (generic)** **Naproxen (generic)** **Ibuprofen (generic)** **Salsalate (generic)** **Piroxicam (generic)**
Diltiazem ER (Cardizem CD) Diltiazem ER (Dilacor XR) Diltiazem ER (Diltia XT) Diltiazem ER (Diltiazem XR)	➢ **Diltiazem ER (Tiazac)**
Etodolac ER (Lodine XL)	➢ **Etodolac (generic)** **Ibuprofen (generic)** **Naproxen (generic)** **Sulindac (generic)** **Piroxicam (generic)**
Famciclovir (Famvir)	➢ **Acyclovir (generic)**
Nabumetone (Relafen)	➢ **Salsalate (generic)** **Naproxen (generic)** **Ibuprofen (generic)** **Sulindac (generic)** **Piroxicam (generic)**
Naproxen sodium ER (Naprelan)	➢ **Naproxen (generic)** **Ibuprofen (generic)** **Salsalate (generic)** **Sulindac (generic)** **Piroxicam (generic)**
Nifedipine ER (Procardia XL)	➢ **Nifedipine ER (Adalat CC)**
Oxaprozin (Daypro)	➢ **Salsalate (generic)** **Naproxen (generic)** **Ibuprofen (generic)** **Sulindac (generic)** **Piroxicam (generic)**
Oxybutynin ER (Ditropan XL)	➢ **Oxybutynin (generic)**
Tolterodine (Detrol)	➢ **Oxybutynin (generic)**
Valacyclovir (Valtrex)	➢ **Acyclovir (generic)**
Zileuton (Zyflo)	➢ **Montelukast (Singulair)**

	Zafirlukast (Accolate)

Appendix B: Summary of efficacy, safety and cost issues associated with celecoxib (Celebrex; Searle/Pfizer)

1. Celecoxib does not appear to be any more or any less effective than other non-steroidal anti-inflammatory drugs (NSAIDs) in treating the symptoms of osteoarthritis (OA) or rheumatoid arthritis (RA).
2. The potential benefit of a cyclooxygenase-2 (COX-2) inhibitor such as celecoxib is primarily due to the lack of inhibition of cyclooxygenase-1 (COX-1) at therapeutic doses. Lack of COX-1 inhibition is mechanistically related to a potential decrease in the risk of GI adverse events (ulceration, bleeding, and perforation). Celecoxib lacks the platelet effects associated with other NSAIDs. Celecoxib does not appear to differ from other NSAIDs in terms of renal adverse effects or use during pregnancy.
3. Labeling for celecoxib includes the same warnings about increased risk of adverse gastrointestinal (GI) events as other NSAIDs. During its first three months on the market, 10 deaths and 11 serious gastrointestinal events (bleeding or ulcer) were reported in patients receiving celecoxib. This must be considered in the context of the number of patients who have been exposed to celecoxib during this period, as well as the expected background rate of adverse GI events in patients not exposed to NSAIDs.
4. Trials with celecoxib have shown a significant reduction in the incidence of endoscopically detected ulcerations compared to other NSAIDs. The correlation between endoscopic ulcers and actual GI adverse events is unclear. Premarketing trials with celecoxib were not designed to collect outcomes data on actual events, and no firm conclusions can be drawn from these results.
5. Overall, about 10% of patients (20.7 million) in the U.S. have OA; about 1% (2.1 million) have RA. Patients with RA are at greater risk for NSAID-induced adverse events because they are older, receive higher NSAID doses, and are more likely to be receiving other medications that increase risk.
6. For patients with rheumatoid arthritis (RA), the annual rate of GI hospitalizations is about 1.46% in patients taking NSAIDs compared to 0.27% in patients not taking NSAIDs. Number-needed-to-harm (NNH) = 84. For patients with osteoarthritis (OA), the annual rate of GI hospitalizations is about 0.73% in patients taking NSAIDs compared to 0.29% in patients not taking NSAIDs. NNH = 227.
7. *If the assumption is made that the rate of GI adverse events in patients receiving celecoxib is equal to the rate in patients not receiving NSAIDs,* 84 RA patients or 227 OA patients (or an even greater number of patients in the general patient population) would have to be treated with celecoxib for 1 year in order to avert 1 GI hospitalization. Treating 84 RA patients with celecoxib would increase annual drug costs by approximately $41,403 compared to treatment with conventional NSAIDs. Treating 227 OA patients with celecoxib would increase annual drug costs by approximately $111,888 compared to treatment with conventional NSAIDs. (Note: these estimates are based on the mean daily cost for NSAIDs in the National Mail Order Pharmacy (NMOP) program during calendar year 1998 (about $0.71) and an estimated daily cost for celecoxib of $2.06. Facilities with a lower mean daily cost for NSAIDs would experience greater increases in drug costs if patients were switched from current NSAID therapy to celecoxib.)
8. Use of COX-2 inhibitors such as celecoxib may decrease costs by reducing the number of patients who require concomitant treatment with misoprostol, H2 blockers, or proton pump inhibitors (PPIs). It is difficult to quantify the number of patients who could successfully be taken off H2 blockers or PPIs, since patients may require treatment with such agents for conditions that are independent of NSAID use.
9. Risk factors for increased risk of NSAID-induced GI adverse events include previous history of GI complications, age, concomitant use of corticosteroids and anticoagulants, high doses of NSAIDs, and general health status.
10. A prescribing guideline designed to target the use of celecoxib to patients at high risk for a GI adverse event would minimize the number of patients who must be treated to avert such an event and maximize the *potential* safety benefit associated with celecoxib. It must be noted that an actual reduction in the rate of GI adverse events with celecoxib has not yet been demonstrated in clinical trials. Outcomes studies to address this question are currently in progress.

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MCCS-GPE 5 February 1999

MEMORANDUM FOR Assistant Secretary of Defense (Health Affairs)

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

1. In accordance with Health Affairs policy 98-025, a meeting of the DoD P&T committee convened at 0800 hours on 5 February 1999, at the Skyline office complex in Falls Church, Virginia.

2. MEMBERS PRESENT:

COL William D. Strampel, MC	Co-chairman
COL Daniel D. Remund, MS	Co-chairman
COL Rosa Stith, MC	Army Representative
LTC Judith O'Connor, MC	Army Representative
Ms. Danielle Doyle, DAC	Army Representative
CDR Terrance Egland, MC	Navy Representative
LCDR Denise Graham, MSC	Navy Representative
LCDR John Tourtelot, MC	Navy Representative (alternate)
LtCol John R. Downs, MC	Air Force Representative
LtCol William Sykora, MC	Air Force Representative
LtCol (Sel) Greg Russie, BSC	Air Force Representative
LCDR Pamela Stewart-Kuhn	Coast Guard Representative (alternate)
Capt Debra Parrish, BSC	DSCP Representative
Mr. John Lowe	VA Representative
Mr. Kirby Davis	Anthem Alliance Representative
Ms. Ray Nan Berry	Foundation Health Representative
Mr. William Hudson	Humana, Inc., Representative
Mr. Ron McDonald	Sierra Military Health Service Representative
Mr. Gene Lakey	TriWest Representative

3. OTHERS PRESENT:

CAPT (Sel) Charlie Hostettler	DoD Pharmacy Program Director
MAJ Mickey Bellemin, BSC	DSCP
Mr. Tom Kellenberger	Merck-Medco Representative
Ms. Shana Trice, DAC	Army

4. ADMINISTRATIVE ISSUES:

A. New attendees were introduced:

(1) CAPT (Sel) Charlie Hostettler - DoD Pharmacy Program Director
(2) LCDR John Tourtelot - Pharmacist/Endocrinologist, Bethesda Naval Medical Center

B. COL Strampel stated that this is his last duty day and that he is relinquishing his co-chair duties. MAJ Steve Humburg, MC, USAF, will replace COL Strampel as the physican representative from the TRICARE Management Activity (TMA) to the DoD P&T Committee.

C. The DoD P&T committee charter states that the physician co-chair is to be selected from within the membership. The committee selected CDR Terry Egland as the physician co-chair.

D. An audio recording of the committee meeting is being made to assist in preparation of the minutes. The tape will be destroyed after the minutes are written.

5. OLD BUSINESS:

A. The committee reviewed the minutes from the 13 November 1998 meeting and accepted them as written.

B. All financial disclosure statements have been submitted.

C. Alternate P&T members have still not been identified for the Army. (OPEN)

D. Potential limitations on fertility drugs in the NMOP: The PEC reviewed the medical literature and found studies showing modest reductions in the success rate with fertility drugs as the number of treatment cycles increased. However, there is no precipitous drop in the success rate that would provide a definitive clinical rationale for limiting treatment to a specific number of cycles. Guidelines and criteria developed by Merck-Medco for other health plans suggest continuation of drug therapy for up to six months. Continuation of therapy beyond six months is typically handled on a prior authorization basis. The NMOP contract does not currently provide a mechanism for prior authorization.

The committee decided that more information is needed about fertility drug usage in the NMOP before the committee is willing to explore the establishment of a prior authorization process. The NMOP is to provide information about the number of patients treated, the distribution of those patients according to number of treatment cycles, and the drug therapy costs. (OPEN)

E. Migraine therapy: The clinical practice guideline group confirmed that it does not plan to develop a guideline for migraine therapy. Capt Parrish stated that the NMOP already has migraine product quantity limits that are similar to what Merck-Medco recommends for other health care plans. These quantity limits have not engendered large numbers of patient complaints. Some committee members commented that the NMOP quantity limits are more generous than the quantity limits typically established at MTF pharmacies. Capt Parrish remarked that patient complaints more frequently involve prescriptions for unapproved uses of the drugs (e.g. sumatriptan 50 mg twice daily for a 90-day supply).

   The committee concluded that it is unclear whether a problem actually exists regarding migraine therapy in the NMOP. The NMOP is to provide drug usage data for migraine therapy and include, if possible, an assessment of the extent to which patients obtain migraine medications simultaneously from the NMOP, retail network and MTF pharmacies. (OPEN)

F. Sildenafil (Viagra) policy: COL Strampel stated that a change in the policy or publication of an implementation plan to address flaws in the policy are unlikely to occur. The PEC developed a one-page guideline sheet for Merck-Medco to fax to prescribers so that they can certify that the clinical guideline has been met before Viagra is dispensed. The NMOP has not started to use the guideline sheet. The delay in implementation is presumed to be due to an ongoing legal review of the document by Merck-Medco.

G. Oral contraceptives: Capt Parrish stated that more companies have agreed to offer the same prices for different size packs of oral contraceptives (e.g., 21-, 28-day packs). Sufficient progress has been made to close out this issue.

H. Impact of worldwide flu shots: This item was in reference to a paper that appeared just prior to the last meeting indicating that a push to immunize children against the flu might yield even more benefit than that realized from immunizing older people. This issue is not within the purview of the committee.

6. NEW BUSINESS: FDA priority review drugs—automatic consideration for the BCF and NMOP

   A. **None of the drugs discussed below were added to the BCF** because they are not essential for every MTF to have on their formulary to meet the primary care needs of patients. Committee members were reminded of the four categories that a drug may occupy regarding availability through the NMOP:

(1) **Drug is on the NMOP preferred drug list (PDL)**.

(2) **Drug is not on the NMOP PDL but is "mapped" to one or more drugs that are on the NMOP PDL.** Prescriptions for drugs in this category are filled by the NMOP when none of the drugs on the NMOP PDL can satisfy the clinical needs of the patient. Mapping associates a drug that is not on the NMOP PDL with one or more drugs that are on the NMOP PDL. When a prescription is received for a drug in this category, the NMOP will contact the prescriber to attempt to change the prescription to a drug that it is mapped to on the NMOP PDL. If the prescriber determines that none of the drugs on the NMOP PDL will meet the clinical needs of the patient, the prescription will be filled as originally written.

(3) **Drug is not on the NMOP PDL and is not mapped to a drug on the NMOP PDL, but prescriptions are filled by the NMOP.** Very few drugs will be included in this category. These drugs are deemed to be inappropriate for designation as "preferred" drugs, and they cannot be mapped to acceptable substitutes on the NMOP PDL. Nevertheless, these drugs may be beneficial for some patients and do not appear to present unacceptable safety risks. Prescriptions for drugs in this category will be filled without contacting the prescriber. Papaverine is an example of a drug in this category (see discussion in paragraph 8G).

(4) **Drug is excluded from the NMOP.** Prescriptions will not be filled for drugs that are excluded from the NMOP. The statement of work for the NMOP contract identifies a number of drugs that are excluded from the NMOP. The DoD P&T Committee may also exclude drugs from the NMOP. All newly approved drugs are automatically excluded from the NMOP unless and until the DoD P&T Committee places the drug in one of the three preceding categories.

B. Valrubicin (Valstar) solution is a chemotherapeutic agent that is instilled into the urinary bladder once a week for treatment of urinary carcinoma. **Exclude valrubicin from the NMOP** because it requires special handling as a cytotoxic agent and must be administered using aseptic technique and under the supervision of a physician experienced in the use of intravesical chemotherapeutic agents.

C. The discussion of valrubicin led to a discussion about the status of leuprolide depot (Lupron) injection, which is on the NMOP PDL, and leuprolide acetate for subcutaneous injection, which is not on the NMOP PDL. The leuprolide depot injection is known to be given at home. The committee decided to retain leuprolide depot injection on the NMOP PDL and **add leuprolide subcutaneous injection to the NMOP PDL.**

D. Octreotide acetate depot injection (Sandostatin LAR) is a long-acting intramuscular injection for the reduction of growth hormone and IGF-1 in acromegaly; the suppression of severe diarrhea and flushing associated with malignant carcinoid syndrome; and the

treatment of profuse watery diarrhea associated with VIPomas (vasoactive intestinal peptide secreting tumors). Octreotide subcutaneous injection is listed on the NMOP PDL. **Exclude Sandostatin LAR from the NMOP** because it is an intragluteal injection that is not designed for self-administration.

E. Lamivudine (Epivir-HBV) tablets and oral solution are indicated for the treatment of adults with chronic hepatitis B associated with evidence of hepatitis B viral replication and active liver inflammation. Epivir-HBV should not be used in HIV-infected patients because it contains a lower dose of lamivudine than is required for treatment of HIV infection. Testing for HIV is advised prior to beginning treatment with the drug and periodically during treatment. **Add Epivir-HBV to the NMOP PDL** because of its clinical effectiveness for the treatment of hepatitis B and because other dosage forms of lamivudine are on the NMOP PDL.

F. Abacavir (Ziagen) is a nucleoside analogue reverse transcriptase inhibitor for combination treatment of HIV_1 infection in adults and pediatric patients older than 3 months of age. Prescriptions for abacavir are already being filled through the NMOP based on the committee's previous decision that HIV antiretrovirals would automatically be added to the NMOP PDL. A question arose about whether the "automatic addition" policy for antiretrovirals meant that the NMOP should start filling prescriptions for the drug even before the committee formally approved the addition of the drug to the NMOP PDL. The committee confirmed the **addition of abacavir to the NMOP PDL** and decided that in the future a committee co-chair should give the NMOP interim approval to fill prescriptions for antiretrovirals until the committee formally approves the addition of the drug to the NMOP PDL.

G. Celecoxib (Celebrex), commonly known as a COX-2 inhibitor, is indicated for relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis. At least one other COX-2 inhibitor is expected to enter the market in the near future. Celecoxib does not appear to be any more effective than NSAIDs for osteoarthritis and adult rheumatoid arthritis. Clinical trials comparing celecoxib to naproxen or ibuprofen show that celecoxib is associated with a lower incidence of endoscopically determined ulcerations. However, definitive evidence that celecoxib reduces the incidence of clinically relevant gastrointestinal events is not yet available. The official labeling for celecoxib includes warnings against gastrointestinal side effects similar to those for NSAIDs. Celecoxib is similar in cost to brand name NSAIDs, but is many time more expensive than generic NSAIDs. Prescribing guidelines will likely be required to target usage of COX-2 inhibitors for patients requiring chronic NSAID therapy who are at increased risk for gastrointestinal problems. The minimal amount of available information concerning the actual clinical benefit of celecoxib makes it difficult to develop prescribing guidelines. The committee concluded that there is not a clear imperative to make celecoxib immediately available through the NMOP. The committee **tabled consideration of celecoxib until the next meeting** when more information will hopefully be available to more clearly quantify the clinical benefit that this agent potentially offers. **In the interim, celecoxib is**

excluded from the NMOP. The committee also suggested that MTFs might want to provide this drug through the special order process rather than add it to their formularies at this time. (OPEN)

H. The discussion of celecoxib led to a discussion about the presence of brand name NSAIDs on the NMOP PDL. The NMOP began in October 1997 with a closed formulary that did not include brand name NSAIDs. Brand name NSAIDs were added to the closed NMOP formulary because it was thought that many patients would obtain brand name NSAIDs through the retail network pharmacies at a higher cost to the government if they were not included on the NMOP formulary. The closed NMOP formulary changed to the NMOP PDL in April 1998 and brand name NSAIDs remained on the NMOP PDL. It was suggested that brand name NSAIDs should now be removed from the NMOP PDL and mapped to the generic NSAIDs because brand name NSAIDs do not offer incremental clinical benefits that are commensurate with their high cost compared to generic NSAIDs. The committee tabled this issue until the next meeting in order to consider the brand name NSAIDs and COX-2 inhibitors in an integrated fashion. (OPEN)

7. NEW BUSINESS: BCF Issues

A. Oxybutynin extended release (Ditropan XL): Oxybutynin oral is listed on the BCF, so Ditropan XL would automatically be included on the BCF unless it is specifically excluded. The committee decided to **exclude Ditropan XL from the BCF** because it is unlikely that the incremental clinical benefit will counterbalance the fact that it is more than four times more costly than the immediate release form of oxybutynin. The committee also decided to **map Ditropan XL to immediate release oxybutynin on the NMOP**, which is the same decision that was made at the last meeting for tolterodine (Detrol).

B. Timolol maleate gel (Timoptic XE): Timolol ophthalmic solution is listed on the BCF. The committee decided to **exclude Timoptic XE from the BCF** because it is unlikely to offer sufficient incremental clinical benefit to offset the fact that it is seven to nine times more costly than timolol ophthalmic solution.

C. Triamcinolone oral inhaler (Azmacort): A recent substantial increase in the DAPA price for Azmacort (raised from $7.95 to $12.90 per inhaler) caused the committee to consider the removal of Azmacort from the BCF. The PEC was recently informed that the manufacturer will reduce the price to $9.60 per inhaler effective 1 Mar 99. The committee voted to **table this issue**. The committee wants to be more certain about the price and also wants to ensure that the BCF adequately supports the asthma/COPD treatment guideline that is being developed by the DoD/VA Clinical Practice Guideline Workgroup. (OPEN)

D. Verapamil dosage forms: Verapamil oral is currently listed on the BCF. The committee decided to specify that the BCF listing for verapamil oral includes only the dosage forms

for which generic equivalent products are available. Generic equivalent products are available for the immediate release tablets (e.g. Calan, Isoptin, and others) and the sustained release tablets (e.g. Calan SR, Isoptin SR and others). All other forms of verapamil are excluded from the BCF (such as Verelan, Verelan PM and Covera HS).

E. "Brand Name Only" items: "A" rated generics are available for phenytoin and carbamazepine, but these drugs are still designated as "brand name only" on the BCF. The committee supports the position of the FDA that an "A" rated generic drug is both bioequivalent and therapeutically equivalent to the innovator (brand name) drug. The committee voted to **remove the brand name only designation for phenytoin and carbamazepine on the BCF**. The committee further stipulated that only "A" rated generic equivalent products should be substituted for the brand name products. The NMOP must comply with state laws and regulations that govern the substitutability of generic drugs, so the committee cannot necessarily apply the same policy to the NMOP. Capt Parrish stated that the NMOP operates under New Jersey regulations that currently do not allow generic substitution for phenytoin and carbamazepine.

F. Montelukast (Singulair): Portsmouth Naval Medical Center requested the addition of montelukast to the BCF and NMOP PDL. The BCF does not include any leukotriene receptor antagonists. Zafirlukast (Accolate) is on the NMOP PDL. Montelukast is not on the NMOP PDL but is mapped to zafirlukast. Montelukast is indicated for use in patients as young as six years of age while zafirlukast is only approved for patients aged 12 years and older. Montelukast may also cause less diarrhea, can be given without regard to meals, and is a once-daily agent. The committee **did not add montelukast to the BCF** because it is not an agent that every MTF should be required to have on its formulary. The committee noted that excluding montelukast from the BCF does not preclude any MTF from having montelukast on its formulary. The committee **added montelukast to the NMOP PDL** because it offers clinical advantages commensurate with the higher cost ($1.39 per day for montelukast versus $1.07 per day for zafirlukast). Additionally, Capt Parrish reported that the switch rate for monelukast prescriptions in the NMOP is low, and that the NMOP fills more prescriptions for montelukast than anyother agent not listed on the NMOP PDL.

8. NEW BUSINESS: Other NMOP Issues

A. Report on top "mapped" items: Capt Parrish identified the ten mapped agents for which the NMOP received the most prescriptions. Each time a prescription is received for a mapped agent, the NMOP calls the prescriber to request a change to an agent that is on the NMOP PDL. The "switch rates" identified below refer to the percentage of prescriptions that are switched to agents that are on the NMOP PDL and the number of prescriptions were received over a 6-month period. The committee changed the NMOP status of the various drugs as described below. [Note: In order to make more informed decisions about the NMOP PDL, the committee requested that more data be provided in the future about what prescriptions are being switched to and the relative efficacy, cost

and safety of the various agents.]

(1) Montelukast (Singulair): decision already made to **add to NMOP PDL**.

(2) Glimepiride (Amaryl): Received 912 prescriptions and attained a 15% switch rate. Information on the agents these prescriptions were switched to is not available (i.e. whether a change was made to Glucotrol XL or to generic sulfonylureas). The committee **added glimepiride to the NMOP PDL** on the supposition that glimeperide prescriptions received by the NMOP would most likely be switched to Glucotrol XL, which is more expensive than glimeperide.

(3) Loratadine and pseudoephedrine (Claritin-D 12-Hour and Claritin-D 24-Hour) tablets: The NMOP PDL currently includes fexofenadine (Allegra) and loratadine (Claritin), but does not include the dosage forms that combine these agents with pseudoephedrine. The committee **added Claritin-D 12-Hour, Claritin-D 24-Hour, and Allegra-D tablets to the NMOP PDL** because they cost the same or only slightly more than the plain loratadine or fexofenadine dosage forms.

The committee also considered a request from Walter Reed Army Medical Center (WRAMC) to add cetirizine (Zyrtec) to the NMOP PDL to support WRAMC's new guidelines which may increase the number of cetirizine prescriptions that are submitted to the NMOP. WRAMC is implementing a rhinitis clinical practice guideline that identifies cetirizine as the lead antihistamine. WRAMC submitted documentation indicating that cetirizine (1) is slightly less expensive than other "non sedating" antihistamines and less than half as expensive if tablets are broken in half, (2) has a pediatric indication down to age 2 and is nonsedating at the 5 mg dose in the under 12 age group, and (3) enables WRAMC to comply with the new Joint Task Force Practice Parameters on Diagnosis and Management of Rhinitis. The **committee added cetirizine to the NMOP PDL**. The committee also decided that astemizole (Hismanal) should remain mapped, and that the mapping should be expanded to include the newly added agents.

(4) Tamsulosin (Flomax): **Leave tamsulosin mapped to other alpha-1-adrenergic blockers**.

(5) Norgestimate and ethinyl estradiol (Ortho Tri-Cyclen): Received 754 prescriptions. **Add Ortho Tri-Cyclen to the NMOP PDL**.

(6) Torsemide (Demadex): Received 736 prescriptions and attained a 22% switch rate. The committee decided to leave **torsemide mapped to other diuretics** since most of the switches were probably to a generic furosemide at significantly lower cost.

(7) Mometasone nasal spray (Nasonex): Received 404 prescriptions and attained an 81% switch rate. The committee **tabled consideration of this agent** until prices for agents in this category are known with greater certainty. (OPEN)

(8) Irbesartan (Avapro): Attained a 55% switch rate. **Leave irbesartan mapped** to other angiotensin II receptor antagonists.

(9) Bisoprolol/hydrochlorothiazide (Ziac): Received 628 prescriptions and attained a 12% switch rate. It was not clear to which drugs the prescriptions were being switched. The difficulty in recommending an alternative for a combination product such as Ziac was discussed. The committee voted to **add Ziac to the NMOP PDL**.

(10) Insulin analog injection (Humalog): Received 362 prescriptions with a 0% switch rate. The committee voted to **add Humalog to the NMOP PDL**.

B. Handling of high-dollar items in NMOP: The committee considered a proposal to establish an NMOP prior authorization process that is accomplished by the entity (MTF or MCS contractor) that is at financial risk for the prescription. The committee asked the NMOP COTR, the PEC, and the MCS contractors to work out a draft design of an NMOP prior authorization process that the committee could review prior to forwarding any recommendations to TMA or Health Affairs. (Open)

C. Quantity limits on eye drops: The NMOP computer system allows large quantities of ophthalmic drops for allergic conditions to be dispensed based on the maximum possible doses per day. Until the computer system can be modified to alleviate this problem, Capt Parrish sought guidance from the committee on reasonable quantity limitations. The committee decided to limit quantities for ophthalmic drops for allergic conditions to a maximum of two bottles per month or six bottles per three months. The committee asked the NMOP COTR to provide a list of the agents that will be subject to this limitation. The NMOP COTR will also identify any other ophthalmic agents that should be considered for quantity limitations. (OPEN)

D. Leflunomide (Arava): A decision on leflunomide was tabled at the last meeting. The NMOP PDL includes six other disease-modifying antirheumatic drugs (DMARDs): methotrexate, sulfasalazine, hydroxychlorquine, auranofin, penicillamine, and azathioprine. Drug acquisition cost for one year of therapy with leflunomide would be about $1900. Other DMARDs are less expensive, but mapping leflunomide to other DMARDs would likely result in few switches to agents on the NMOP PDL. Leflunomide appears to represent a therapeutic advance in a relatively well defined population of patients and may serve as an alternative to methotrexate. The committee voted to **add leflunomide to the NMOP PDL**. **Leflunomide was not added to the BCF**.

E. Urea 40% topical (Carmol-40 and others): This is a topical agent used as a moisturizing agent for severely dry skin or under an occlusive dressing to remove diseased nails. The committee **approved addition of this agent to the NMOP PDL**. The committee did not specify a quantity limitation, but the NMOP contracting

officer's technical representative (COTR) is to assess the need for a quantity limitation and report back to the committee. (Open)

F. Quinine: Quinine has historically been used to treat night leg cramps, although this has never been an approved indication. In 1994 the FDA ordered a halt to the marketing of over-the-counter (OTC) quinine sulfate for night leg cramps based on its serious risks. In 1995 the FDA ordered a halt to the marketing of prescription quinine for this use because, even under a physician's care, the risks outweigh any possible benefits. Quinine is now available only as a prescription drug for the second line treatment of malaria. The committee voted to **exclude quinine from the NMOP** in order to preclude inappropriate use of the drug for night leg cramps. The relatively small number of patients who require quinine for second line treatment of malaria can obtain the medication through MTF pharmacies or retail network pharmacies. No new prescriptions will be filled at the NMOP, but existing refills will be honored.

G. Papaverine: Papaverine is a pre-1962 drug that is classified as probably effective for the relief of cerebral and peripheral ischemia associated with arterial spasm and myocardial ischemia complicated by arrhythmias. Given the limited evidence of clinical effectiveness, the committee does not want to list papaverine on the NMOP PDL. Mapping papaverine to other agents is not practical because there is not a specific agent to suggest as an alternative to papaverine. The committee decided that **papaverine will not be on the NMOP PDL and will not be mapped, but prescriptions for papaverine will continue to be filled by the NMOP.**

H. Tobramycin nebulizer solution (TOBI): This is the only nebulizer solution available for treatment of pseudomonas infection in cystic fibrosis patients. A number of other nebulizer solutions are currently supplied by the NMOP. The committee voted to **add TOBI to the NMOP PDL**.

I. Ofloxacin (Floxin) and grepafloxacin (Raxar) package sizes: Capt Parrish reported that special dose packs has recently been introduced for these agents. The prices of these dose packs are very high in relation to simply dispensing the equivalent number of tablets. In contrast, the Zithromax "Z-pak" is less expensive for the NMOP to dispense than 6 tablets. The committee decided to **exclude the ofloxacin and grepafloxacin dose packs from the NMOP.** The NMOP is to offer to fill prescriptions for ofloxacin and grepafloxacin dose packs with the equivalent number of tablets from traditional packaging.

The committee also authorized the NMOP to routinely exclude other more expensive special packaging from coverage through the NMOP when the special packaging does not offer sufficient incremental benefit to justify a higher cost. The general rule is that the substitution must be less expensive than the special packaging and result in no difference in the education or the therapy received by the patient. For example, it would not be feasible to substitute for something like a Medrol dose-pak because it

would be difficult to explain the dosing regimen to patients. The NMOP COTR will routinely report such exclusions to the committee for its concurrence.

J. Nitroglycerin patches: A review of DAPA prices revealed that Nitrodur is significantly less expensive at $.26 per patch than other brands of nitroglycerin patches. The Nitrodur brand offers an extensive array of patch strengths. The committee voted to **specifically list only the Nitrodur brand of nitroglycerin patch on the NMOP PDL. All other brands of nitroglycerin patches will be mapped to the Nitrodur brand**.

K. Antivirals for herpes: Acyclovir and valacyclovir (Valtrex) are currently listed on the NMOP PDL, while Famvir (famciclovir) is mapped to these agents. All three agents are indicated for the treatment of herpes zoster (shingles), recurrent genital herpes (herpes simplex), and suppression of recurrent genital herpes. Famciclovir is indicated for cold sores in HIV patients. Acyclovir is indicated for the treatment of varicella (chicken pox). Depending on the indication, famciclovir and valacyclovir range from three to seventeen times more expensive than acyclovir. The substantially greater cost of famciclovir and valacyclovir appears to outweigh any incremental clinical benefit they might offer over acyclovir. The committee voted to **remove valacyclovir (Valtrex) from the NMOP PDL and to map both valacyclovir and famciclovir to acyclovir** as the more cost-effective alternative. Merck-Medco will place calls to physicians to encourage the use of acyclovir when new prescriptions are submitted for famciclovir or valacyclovir. Existing refills for valacyclovir and famciclovir will be honored. The rate of switching from these agents to generic acyclovir will be monitored by the NMOP.

L. Enbrel (Etanercept): Etanercept is indicated for reduction in signs and symptoms of moderately to severely active rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). Etanercept can be used in combination with methotrexate when patients have an inadequate response to methotrexate alone. Etanercept is given via subcutaneous injection twice weekly and is designed and packaged with necessary supplies for self-administration. It has been shown to be effective for rheumatoid arthritis; however, little evidence is available on long-term use and symptoms return promptly after discontinuation. The drug cost for one year of therapy is approximately $8,500.

Given the extremely high cost of etanercept, it may be important to establish a prescribing guideline to ensure that it is used only for patients for whom it is clearly indicated. Information is also needed regarding the manufacturer's shipping policies and the necessity for shipping the drug on dry ice. The committee agreed to **table a decision on etanercept** to allow some time to explore the development of a prescribing guideline and to clarify the logistical issues associated with mailing the drug. **In the interim, etanercept is excluded from the NMOP.** (OPEN)

M. Urine glucose test strips and urine ketone test strips: The committee did not think these agents should be added to the NMOP PDL. Mapping urine glucose test strips and urine ketone test strips to other agents would be nonsensical. The committee decided that **urine glucose test strips and urine ketone test strips will not be added to the NMOP PDL and will not be mapped, but prescriptions for these agents will be filled by the NMOP.**

N. Niacin for antilipemic therapy: Various barriers work against the provision of niacin through the NMOP. The NMOP does not provide over-the-counter (OTC) items except for insulin and insulin syringes. The NMOP is also prohibited from providing OTC or prescription vitamins, with the exception of prescription multivitamins with folic acid for women ≤ 45 years of age. Capt Parrish stated that the NMOP is not permitted to dispense a niacin product that requires a prescription if the same dosage form and strength is also available OTC. Prescription dosage forms and strengths of niacin are generally also available as OTC products. The majority of the committee members agreed that niacin for antilipemic therapy should be available through the NMOP. The committee tabled this issue to allow consultation with TMA officials about how niacin can be made available for antilipemic therapy through the NMOP. (Open)

9. NEW BUSINESS: Other Issues

A. A managed care support contractor representative asked the committee to consider two proposals: 1) that the NMOP supply blood glucose testing devices and syringes for covered injections, and 2) that the NMOP waive additional co-pays for supplies when dispensed with a covered injection. These proposals are apparently related to a pending managed care support contract modification that specifies waiving of the co-pay for supplies when dispensed with the covered injection.

1. The NMOP statement of work limits authorized supplies to "insulin and related supplies limited to disposable insulin syringes and consumable products intended for home testing for glucose in the blood or urine." Syringes for covered injections other than insulin are not included in the NMOP statement of work. Blood glucose meters are not consumable products, so they are not included in the NMOP statement of work. The committee does not have the authority to unilaterally alter the NMOP statement of work.

2. The committee does not have the authority to waive the co-pays that are established in the NMOP statement of work.

B. BCF limitations on glucose test strips: Brooke Army Medical Center and Wilford Hall Air Force Medical Center (BAMC/WHMC) requested that the committee reconsider the BCF limits on glucose test strips. The BCF limits glucose test strips to a maximum of 100 per 90 days for non-insulin dependent diabetics and 400 strips per 90 days for diabetics who use insulin. The BCF does not limit quantities for any BCF agents other

than glucose test strips. BAMC/WHMC presented concerns about pregnant patients or patients using an insulin pump, who may use up to 7 strips per day, and patients on oral medications who may want or need to test more often than once per day. It was pointed out that it should be possible for facilities to have patients bring in their monitors, download, see what they are using, and supply appropriate amounts. The committee agreed that individual MTFs should be able to establish their own quantity limitations. The committee voted to **remove the quantity limitations on blood glucose test strips from the BCF**. No change was made to the quantity limits for the NMOP.

C. Application of quantity limits in NMOP to prescriptions filled in retail network pharmacies: This issue requires action by TMA and/or Health Affairs and is beyond the purview of the committee.

D. Contracting issues: Contracting issues were not addressed at this meeting.

10. ADJOURNMENT: The meeting adjourned at 1210 hours. The next meeting will be held on 14 May 1999 at the DoD Pharmacoeconomic Center, Fort Sam Houston, Texas, beginning at 0800 hours. All agenda items are to be submitted to the DoD PEC no later than 14 April 1999.

11. A summary of changes to the BCF and NMOP PDL is attached to these minutes.

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

Summary of BCF Changes

1. Blood glucose test strips: Remove the BCF quantity limitations. MTFs may establish their own quantity limitations.

2. Carbamazepine oral: Remove the "Tegretol brand only" designation

3. Oxybutynin oral: Does not include extended release (Ditropan XL)

4. Phenytoin oral: Remove the "Dilantin brand only" designation

5. Timolol ophthalmic solution: Does not include timolol maleate gel (Timoptic XE)

6. Verapamil oral: Includes only the immediate release dosage forms (Calan, Isoptin, or equivalent) and sustained release dosage forms (Calan SR, Isoptin SR, or equivalent) for which generic equivalent products are available. Verapamil oral does not include other forms of verapamil for which generic equivalent products are not available (such as Verelan, Verelan-PM and Covera-HS).

Summary of NMOP Changes

1. **Added to the NMOP PDL:**
   Abacavir (Ziagen)
   Bisoprolol and hydrochlorothiazide (Ziac)
   Leuprolide (Lupron) subcutaneous injection
   Cetirizine (Zyrtec)
   Fexofenadine and pseudoephedrine (Allegra-D)
   Glimepiride (Amaryl)
   Insulin analog injection (Humalog)
   Lamivudine (Epivir-HBV)
   Leflunomide (Arava)
   Loratidine and pseudoephedrine (Claritin-D 12-Hour and Claritin-D 24-Hour)
   Montelukast (Singulair)
   Norgestimate and ethinyl estradiol (Ortho Tri-Cyclen)
   Tobramycin nebublizer solution (TOBI)
   Urea 40% topical (Carmol-40 and others)

2. **Deleted from the NMOP PDL:**
   Nitroglycerin patches: All brands of nitroglycerin patches other than Nitrodur
   Valacyclovir (Valtrex)

3. **Mapped to other agents on the NMOP PDL:**
   Oxybutynin extended release (Ditropan XL)

Nitroglycerin patches: All brands other than Nitrodur are mapped to Nitrodur
Valacyclovir (Valtrex)

4. **Not on NMOP PDL and not mapped, but prescriptions are filled by NMOP:**
   Papaverine oral
   Urine glucose and urine ketone test strips

5. **Excluded from the NMOP:**
   Celecoxib (Celebrex)
   Etanercept (Enbrel)
   Grepafloxacin dose pack
   Octreotide acetate depot injection (Sandostatin LAR)
   Ofloxacin dose pack
   Quinine
   Valrubicin (Valstar) solution

6. **Other changes/notes:**

   Limit ophthalmic drops for allergic conditions to a maximum of two bottles per month or six bottles per three months.
   Nitrodur is the only brand of nitroglycerin patch listed on the NMOP PDL.