Department of Defense
Pharmacoeconomic Center

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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	TERRANCE EGLAND
COL, MS, USA	CDR, MC, USN
Co-chairman	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.