

# Department of Defense Pharmacoeconomic Center

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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 Eglund, 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

<b>Non-Preferred Drug</b>	<b>Preferred Alternative</b>
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 Eglund, 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](http://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 hepatotoxicity 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. \$2.16 for 2 mg bid of rosiglitazone, and \$2.94 for 400 mg of troglitazone 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 Eglund 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 Eglan, 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 Eglan 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 Eglan 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 18<sup>th</sup> 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 15<sup>th</sup>.

<signed>

DANIEL D. REMUND  
COL, MS, USA  
Co-chairman

<signed>

TERRANCE EGLAND  
CDR, MC, USN  
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 <sup>1</sup>	2.00% <sup>2</sup>	\$7
Restructured NMOP Formulary	\$587,713 <sup>3</sup>	1.57% <sup>4</sup>	\$30
<b>Net Change</b>	<b>\$416,713</b>	<b>(0.43%) or 22% decrease</b>	<b>\$23</b>

† 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
<b>Total</b>			<b>\$397,030</b>	<b>6849</b>	<b>\$58</b>

† 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.**

	<b>Estimated Annual Cost Avoidance to DoD</b>	<b>Phone Calls Generated as a Percent of Total Rx Filled†</b>	<b>Cost Avoidance per Phone Call</b>
Old NMOP Formulary <sup>1</sup>	\$171,000	2.00%	\$7
Restructured NMOP Formulary <sup>1</sup>	\$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 <sup>2</sup>	1.88% <sup>3</sup>	\$38
<b>Net Change (Old NMOP Formulary as compared to proposed changes)</b>	<b>\$813,743</b>	<b>(0.12%) or 6% decrease</b>	<b>\$31</b>

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)

### Market Share of Extended Release Diltiazem Tablet Purchases

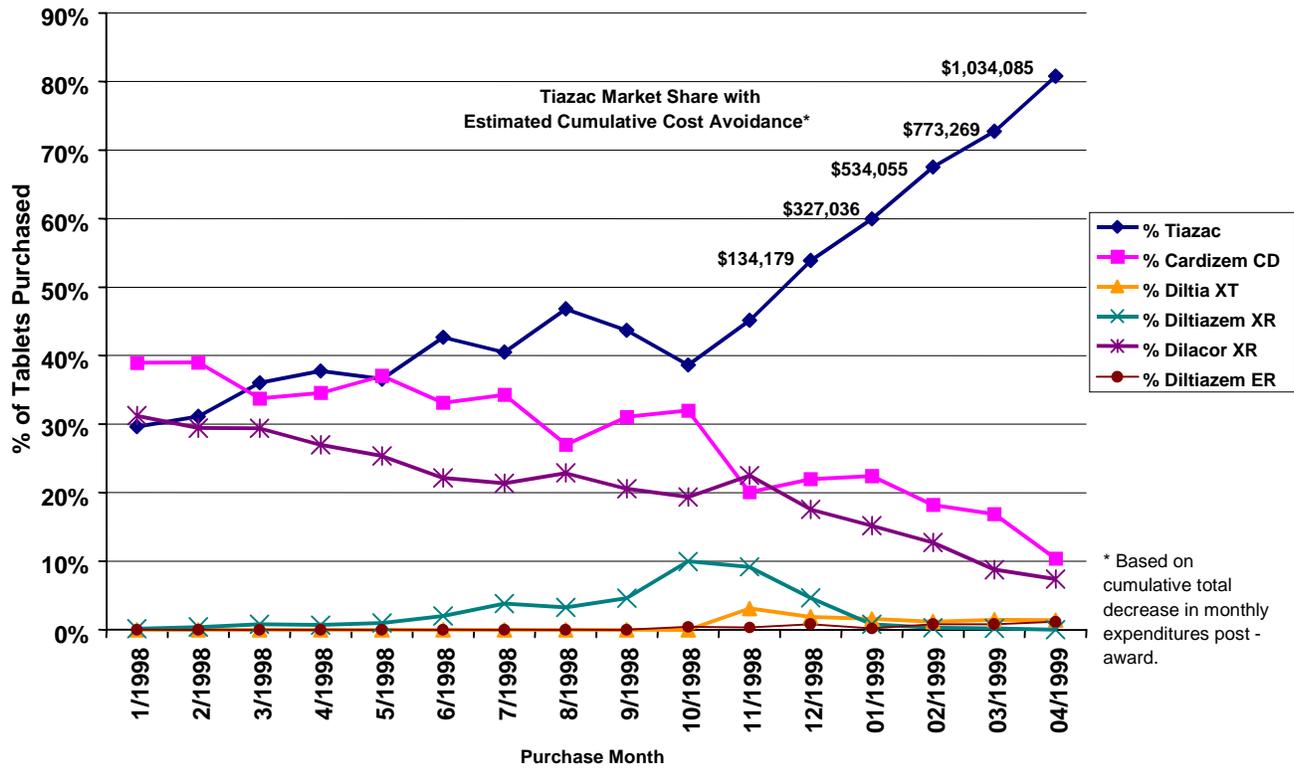


Figure 1: Market Share of Extended Release Diltiazem Tablet Purchases

**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
<b>Antiemetics</b>			
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 regimens 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 regimens 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 regimens 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.
<b>Oral and Nasal Inhalers</b>			
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	

<b>Drug</b>	<b>Previous NMOP Limit</b>	<b>New Quantity Limits</b>	<b>Rationale</b>
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	

<b>Drug</b>	<b>Previous NMOP Limit</b>	<b>New Quantity Limits</b>	<b>Rationale</b>
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	
<b>Antimigraine Drugs</b>			
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. <sup>2,3,4</sup>			
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. <sup>2,3,4</sup>
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. <sup>2,3,4</sup> (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. <sup>2,3,4</sup> (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. <sup>2,3,4</sup>
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. <sup>2,3,4</sup> (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. <sup>2,3,4</sup>
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. <sup>2,3,4</sup>
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. <sup>2,3,4</sup>
<b>Miscellaneous</b>			
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.

<b>Drug</b>	<b>Previous NMOP Limit</b>	<b>New Quantity Limits</b>	<b>Rationale</b>
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. <sup>6</sup>
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. <sup>3</sup> 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 <sup>7</sup> 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	
<b>Antifungals</b>			
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. <sup>8</sup>
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

<b>Drug</b>	<b>Previous NMOP Limit</b>	<b>New Quantity Limits</b>	<b>Rationale</b>
<b>Ophthalmics</b>			
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.
<b>Antibiotics</b>			
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
<b>Fertility and Impotence</b>			
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, 52<sup>nd</sup> 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.<sup>6</sup> 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