Department of Defense
Pharmacoeconomic Center

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MCCS-GPE **13 FEBRUARY 2002**

MEMORANDUM FOR: Executive Director, TRICARE Management Activity (TMA)

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

1. A meeting of the DoD P&T committee convened at 0800 hours on 13 February 2002, at the Non-Commissioned Officers Club, Fort Sam Houston, TX

2. MEMBERS PRESENT

CDR Terrance Egland, MC, USN	DoD P& T Committee Co-chair
Col John R. Downs, MC	Air Force
Col Mark Nadeau, MC (For Col Bill Sykora, MC)	Air Force
LtCol (select) George Jones, BSC	Air Force
CAPT (select) Matt Nutaitis, MC	Navy
CDR Kevin Cook, MSC	Navy
MAJ Brett Kelly	Army
LTC (P) Joel Schmidt, MC	Army
CAPT Robert Rist	Coast Guard
MAJ Mickey Bellemin, BSC	Defense Supply Center Philadelphia
William Hudson	Humana
Gene Lakey	TriWest
Ron McDonald	Sierra Military Health Services
Trevor Rabie	Uniformed Services Family Health Plans (USFHP)
Dick Rooney	Department of Veterans Affairs

MEMBERS ABSENT

COL Daniel D. Remund, MS, USA	DoD P& T Committee Co-chair
COL Rosa Stith, MC	Army
LTC Mike Kieffer, MS	Joint Readiness Clinical Advisory Board
Ray Nan Berry	Health Net Federal Services

OTHERS PRESENT

COL William Davies, MS, USA	DoD Pharmacy Program Director, TMA
Howard Altschwager	Deputy General Counsel, TMA
CAPT Joe Torkildson, MC, USN	DoD Pharmacoeconomic Center
LCDR Ted Briski, MSC, USN	DoD Pharmacoeconomic Center
LCDR Denise Graham, MSC, USN	DoD Pharmacoeconomic Center
LtCol Ed Zastawny, USAF BSC	DoD Pharmacoeconomic Center
LTC Doreen Lounsbery, MC, USA	DoD Pharmacoeconomic Center
Maj Barb Roach, USAF MC	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
David Bretzke	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
SFC Agustin Serrano	DoD Pharmacoeconomic Center
MAJ Cheryl Filby, MS, USA	Defense Supply Center Philadelphia
CDR Brian Kerr, MSC, USN	Defense Supply Center Philadelphia
Paul Vasquez	Defense Supply Center Philadelphia
Vincent Valinotti	Defense Supply Center Philadelphia
David Chicoine	Uniformed Services Family Health Plan
Mark Petruzzi	Merck-Medco
Elizabeth Scaturro	Merck-Medco Managed Care

3. **REVIEW MINUTES OF LAST MEETING / ADMINISTRATIVE ISSUES** – The minutes from the last meeting were accepted as written.

4. **INTERIM DECISIONS** – No interim decisions.

5. **REPORT FROM THE DOD EXECUTIVE COUNCIL MEETING –** CAPT Torkildson reported on the additions to the BCF:

   - Advair (fluticasone/salmeterol) Inhaler: all strengths
   - Prempro (conjugated estrogen and medroxyprogesterone): all strengths.
   - Zithromax (azithromycin) 250 mg tablets; does not require the Z-pak dosage formulation.

6. **IMPLEMENTATION OF PHARMACY BENEFIT PROVISIONS IN THE FY00 AND FY01 NATIONAL DEFENSE AUTHORIZATION ACTS** - COL Davies will present the proposed rules at the next meeting if the document has been published. COL Davies stated that Managed Care Support Contractors have submitted nominations for providers to the DoD P&T Committee.

7. **PPI UTILIZATION IN THE NMOP** – CAPT Torkildson reported on proton pump inhibitor (PPI) use in all three points of service. There was a substantial decrease in the number of PPI prescriptions filled at MTFs during the Thanksgiving and Christmas holiday seasons, which raises questions regarding access. The total number of prescriptions for PPIs filled in the NMOP remains fairly flat while the retail network is showing a gradual growth rate. An analysis of the market share of the various PPIs by point of service reveals an increase in rabeprazole (Aciphex) use in the MTFs,

while the retail network analysis reveals a growing use of esomeprazole (Nexium) and stable use of omeprazole. The market share of omeprazole in the NMOP remains high at around 75% of all PPI prescriptions, with a slight upward trend in esomeprazole use. An analysis of the average cost per unit for PPIs for each point of service shows that the cost has declined by over 50% in MTFs, has remained flat in the retail network, and increased in the NMOP due to an omeprazole price increase. The Committee took no action on this information, but will continue to monitor the class.

8. **GENERIC LOVASTATIN IN THE NMOP** –The impact of the recent approval of a generic formulation of lovastatin on the current statin contract and the potential for creating patient dissatisfaction regarding the current structure of copays was discussed. The situation has been created in which a patient might submit a prescription for lovastatin to the NMOP in order to obtain the $3.00 generic copay, only to be told that they must use the contracted drug simvastatin and pay a $9.00 copay. COL Davies stated that it is not within the purview of this committee to reduce the co-pay for simvastatin to the generic copay since it did not compete directly against generic products. In a closed class contract, medical necessity is required in order to go outside the contract. When presented with a statin prescription other than simvastatin, the NMOP should call the provider and determine if there is a medical necessity for the noncontracted statin. If not, the contract situation should be explained to the provider, and an opportunity presented to switch to simvastatin. If the provider is not willing to change the prescription, the prescription should be returned to the patient and their options explained to them.

9. **BCF AND NATIONAL MAIL ORDER PHARMACY (NMOP) FORMULARY ISSUES** – The Committee determined the NMOP formulary status, NMOP or retail network formulary restrictions (quantity limits or prior authorization), and Basic Core Formulary (BCF) status for 13 new drugs (see Appendix A).

10. **ANTIBIOTIC PROPHYLAXIS FOR ANTHRAX EXPOSURE** – CAPT Torkildson reported that the utilization of doxycycline and ciprofloxacin at the NMOP and in the retail network has returned to baseline levels. The Committee concluded that there is no further need to report on this subject unless subsequent events create the possibility of change.

11. **PRIOR AUTHORIZATIONS**

A. *Cost avoidance from NMOP prior authorizations (PAs)* – Shana Trice (PEC) reported that, for the 1st quarter of FY 02, the NMOP PAs for sildenafil, COX-2 inhibitors, and etanercept resulted in an estimated cost avoidance per new prescription submitted of $51.91 for sildenafil, $15.64 for COX-2 inhibitors, and $276.74 for etanercept. The estimated cost avoidance per new prescription submitted is based on the cost avoidance model outlined in the Aug 00 DoD P&T Committee minutes. Since these estimates are consistent with previous reports, the Committee did not make any changes to these PAs.

B. *Changes to PA criteria for COX-2 inhibitors* – The Committee addressed two issues: 1) a new FDA-approved indication for celecoxib (Celebrex) for acute pain in adults and treatment of primary dysmenorrhea; and 2) the availability of a new COX-2 inhibitor valdecoxib (Bextra). The FDA approved valdecoxib in Nov 01 for treatment of osteoarthritis (OA), adult rheumatoid arthritis (RA), and primary dysmenorrhea.

Existing NMOP PA criteria for COX-2 inhibitors allow use of rofecoxib but not celecoxib for 20 days or less in patients with risk factors for GI adverse events, since celecoxib previously lacked any indication for acute use. The Committee approved the following revised COX-2 inhibitor criteria for all COX-2 inhibitors (celecoxib, rofecoxib, valdecoxib):

- *Benefit coverage NOT provided for:*
    - *Concurrent anti-inflammatory therapy with any NSAID or aspirin at doses > 325 mg per day, or*
    - *The prevention of colon cancer, or*
    - *The prevention or treatment of Alzheimer's disease*
- *Benefit coverage provided for:*
    - *Patient has previously failed an adequate trial with at least two different NSAIDS,*

      OR
    - *COX-2 therapy AND high risk for NSAID-induced gastropathy OR use of a NSAID could result in destabilization or risk. Identified by an of the following:*
        - *Concurrent oral corticosteroids, anticoagulants, antiplatelet agents*
        - *History of PU*
        - *History of NSAID related ulcer*
        - *History of clinically significant GI bleeding*
        - *Hereditary or acquired coagulation defect*
        - *Age 65 years or older*

C. *Criteria for etanercept PA* – The FDA recently approved psoriatic arthritis as a new indication for etanercept (Enbrel). The Committee voted to add this indication to etanercept's PA criteria.

D. *Anakinra (Kineret)* – This is a new IL-1 receptor antagonist product with a mechanism of action similar to the TNF receptor antagonist etanercept. However, it differs from etanercept in its FDA approved indications (see Appendix A), and therefore requires a separate PA. The Committee voted to adopt the Merck Medco criteria currently in place:

1. Coverage provided for the treatment of moderately to severely active rheumatoid arthritis in patients ≥ 18 years of age.
2. Coverage provided in situations where the use of methotrexate and at least one other DMARD have failed to treat the patient's rheumatoid arthritis.
3. Coverage provided in situations where the patient has had an inadequate response to methotrexate, unless the use of methotrexate is contraindicated for the patient.
4. Benefit coverage not provided for use of anakinra in combination with etanercept or infliximab.

The Committee discussed quantity limits for anakinra, given the exiting 6-week quantity limits in the NMOP for etanercept. They felt that, given the similarities between etanercept and anakinra, it would be most appropriate to apply the same quantity limits to both drugs. The

Committee established a 6-week quantity limit was established for anakinra in the NMOP and a 4-week supply in the retail network. The reason for the quantity limit is the same for both etanercept and anakinra: potential for significant unnecessary expense resulting from discontinuation, given the extremely high unit cost of these medications.

12. SUBCOMMITTEE REPORT: PROVISION OF INJECTABLE DRUGS IN THE NMOP OR RETAIL NETWORK PHARMACIES – Tabled until the May DoD P&T Committee meeting

13. CONTROLLED DISTRIBUTION OF PEGINTERFERON ALFA 2B (PEG-INTRON; SCHERING) – LCDR Briski reported that the distribution process has been complicated due to the unexpected demand for Peg-Intron. A formal understanding with Schering has been reached. Currently, any new patients will go onto a waiting list. The wait is expected to be one to two months. All current patients will be provided product to complete their course of therapy. LCDR Briski provided an outline of the current distribution method:

- New patients should be instructed to call the Schering 800 number to get on the waiting list. The patient will be called when it is their turn to move off the list and be instructed to take their prescription to the MTF pharmacy. All new starts, as they move off the wait list, will receive product via a drop-ship to MTF mechanism, which will be billed through Prime Vendor.
- Any current patients should complete their therapy by continuing to use their current mechanism for acquiring the drug. If the patient was enrolled into the "Assured Access" program and assigned an identifying number, they should complete their course using that mechanism. Sites that have been getting the Peg-Intron drop-shipped without registering the patient should continue to do so. As the current patients using assured access identifiers complete their therapy, the need for using the numbers will also go away.
- LCDR Briski is the point of contact for distribution issues. The PEC will provide a monthly report to Schering regarding the number of MTF patients receiving Peg-Intron so Schering can reconcile this with the amount of product shipped. If an imbalance occurs, the PEC will clarify the situation by contacting the MTFs involved directly.

14. ADJOURNMENT – The meeting adjourned at 1200 hours. The next meeting will be held at the Non-Commissioned Officers Club, Fort Sam Houston, TX starting at 0800 on Wednesday, 09 May 2002. All agenda items should be submitted to the co-chairs no later than April 8, 2002.

<signed>
DANIEL D. REMUND
COL, MS, USA
Co-chair

<signed>
TERRANCE EGLAND
CDR, MC, USN
Co-chair

List of Appendices

APPENDIX A: NEWLY APPROVED DRUGS CONSIDERED FOR THE NATIONAL MAIL ORDER PHARMACY FORMULARY AND DOD BASIC CORE FORMULARY

Generic name (Trade name; manufacturer)	**FDA approval date, drug class, FDA-approved indication**	**NMOP Formulary Status**	**NMOP and/or retail network formulary restrictions**	**BCF Status**
Valdecoxib tablets (Bextra; Pharmacia)	19 Nov 01; COX-II inhibitor for treatment of signs and symptoms of osteoarthritis (OA) and adult rheumatoid arthritis (RA), and for the pain associated with menstrual cramping	Added to the NMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization:** Add to (NMOP only) COX-2 inhibitor PA as modified in the Feb 02 DoD P&T Committee minutes. **Rationale for PA:** The COX-II inhibitors celecoxib and rofecoxib require prior authorization in the NMOP. The potential for inappropriate use is substantial.	Not added to the BCF **Similar BCF Drugs:** none
Frovatriptan tablets (Frova; Elan)	09 Nov 01; 5HT agonist ("triptan") for the treatment of migraine with and without aura in adults	Added to the NMOP Formulary	**Quantity Limits** 9 tablets per 30 days; 27 tablets per 90 days; consistent with existing quantity limits for other triptans **Rationale for Quantity Limits:** Clinical appropriateness concerns: potential for overuse and increased likelihood of rebound headaches **Prior Authorization** None	Not added to the BCF **Similar BCF Drugs:** Sumatriptan
Desloratadine tablets Clarinex; Schering-Plough)	21 Dec 01; non-sedating 2nd-generation antihistamine for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and older	Added to the NMOP Formulary **Note**: Closed class contract is in place for 2nd generation NSA (fexofenadine) in the MTFs, but it does not apply to the NMOP. Three other 2nd generation products are currently available through the NMOP.	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF Drugs:** Closed class contract exists for fexofenadine (Allegra) that includes BCF status.

Generic name (Trade name; manufacturer)	**FDA approval date, drug class, FDA-approved indication**	**NMOP Formulary Status**	**NMOP and/or retail network formulary restrictions**	**BCF Status**
Anakinra injection (Kineret; Amgen)	14 Nov 01; interleukin-1 receptor antagonist administered subcutaneously for the reduction in signs and symptoms of moderately to severely active RA in adult patients who have failed one or more disease modifying antirheumatic drugs (DMARDs)	Added to the NMOP Formulary and Covered Injectables List **Note**: Etanercept for RA is included in the NMOP Covered Injectables List, subject to quantity limits and prior authorization	**Quantity Limits:** 6-weeks **Rationale for quantity limits:** Extremely high unit cost increases negative impact of premature discontinuation. **Prior Authorization** Yes, approved use of PA criteria already established by Merck Medco.	Not added to the BCF **Similar BCF Drugs:** none
Comments about anakinra injection: Can be used alone or in combination with DMARDs other than Tumor Necrosis Factor (TNF) blocking agents [etanercept (Enbrel); infliximab (Remicade)]. Potential for serious infections and neutropenia is increased when used in combination with TNF blocking agents; combination use is not authorized in current PA criteria. Injection site problems are very common (71% of patients) upon initiation of therapy.				
Triptorelin pamoate depot injection (Trelstar LA; Debiopharm/ Pharmacia)	Jun 01; injectable leutinizing hormone releasing hormone (LHRH) agonist administered every 3 months for the treatment of advanced stage prostate cancer. Product is extension of previously approved one-month product, Trelstar Depot	Added to the NMOP Formulary and Covered Injectables List **Note**: Other depot LHRH agonists (Lupron and Zoladex) are included on the NMOP Covered Injectables List. Both 1-month and 3-month products added	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF Drugs:** none
Fondaparinux injection (Arixtra; Sanofi/Organon)	11 Dec 01; injectable factor Xa inhibitor (different than a low - molecular-weight heparin [LMWH]) for the prevention of venous thromboembolism following orthopedic surgery (knee replacement, hip replacement, hip fracture repair)	Added to the NMOP Formulary and Covered Injectables List **Note**: Injectable LMWHs are included on the NMOP Covered Injectables List	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF Drugs:** none
Comments about fondaparinux injection: The Committee discussed the fact that the current BCF mandates MTFs to have at one LMWH (enoxaparin, dalteparin, tinzaparin) on their formulary; individual MTFs choose which LMWH to have on formulary. Fondaparinux is not a LMWH and is not yet approved for outpatient treatment of VTE. The Committee determined that fondaparinux would not be considered a suitable substitution for one of the other LMWH products.				

Generic name (Trade name; manufacturer)	**FDA approval date, drug class, FDA-approved indication**	**NMOP Formulary Status**	**NMOP and/or retail network formulary restrictions**	**BCF Status**
Pimecrolimus 1% cream (Elidel; Novartis)	13 Dec 01; treatment of mild to moderate atopic dermatitis in patients aged two years and older	Added to the NMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF Drugs:** See comments
Comments about Pimecrolimus 1% cream: There are no non-steroidal topical immunomodulators (TIMS) currently on the BCF. The BCF does include a medium potency steroid agent (triamcinolone acetonide 0.1% cream; Kenalog) and a high potency steroid agent (fluocinonide 0.05% cream; Lidex).				
Diclofenac sodium topical gel (Solaraze; Sky Pharma)	23 Oct 00; treatment of actinic keratoses; topical NSAID	Added to the NMOP Formulary	**Quantity Limits** General rule applies **Prior Authorization** None	Not added to the BCF **Similar BCF Drugs:** None
Dexmethyl-phenidate tablets (Focalin; Novartis)	13 Nov 01; d-isomer of methylphenidate administered twice daily for the treatment of attention deficit hyperactivity disorder; not an extended or sustained release product	Added to the NMOP Formulary	**Quantity Limits** Standard NMOP rule for Schedule II products for treatment of ADHD applies– up to 90 day supply, no refills **Rationale for Quantity Limits: F**alls under standard rule in NMOP for Schedule II products for treatment of ADHD **Prior Authorization:** None	Not added to the BCF **Similar BCF Drugs:** Methylphenidate, methylphenidate SR and methylphenidate extended release (Concerta)
Comments about dexmethylphenidate tablets: The pharmacokinetic properties of the isomer are sufficiently different such that the FDA considers dexmethylphenidate to be a new drug. Therefore, it should not be considered the same as methylphenidate. There is no evidence that this is a significant advance in therapy for ADHD. A head-to-head trial against other forms of methylphenidate (instead of placebo) would help to clarify its place in therapy. It is specifically excluded from the BCF listing for methylphenidate.				

Generic name (Trade name; manufacturer)	**FDA approval date, drug class, FDA-approved indication**	**NMOP Formulary Status**	**NMOP and/or retail network formulary restrictions**	**BCF Status**
Bosentan tablets (Tracleer; Actelion)	20 Nov 01; non-selective endothelin receptor antagonist for the treatment of pulmonary artery hypertension	NOT Added to the NMOP Formulary **Note**: Not feasible to provide bosentan through the NMOP due to its restricted distribution process	**Quantity Limits** N/A **Prior Authorization** Need to coordinate with TRICARE	Not added to the BCF **Similar BCF Drugs:** none
Comments about bosentan tablets: Although bosentan will be used in only a limited number of patients; it needs to be available to DoD beneficiaries. There are approximately 1,900 patients in the DoD with a diagnosis of PAH, but the severity of disease cannot be determined. Bosentan cannot be added to the NMOP due to the closed distribution system initiated by the manufacturer. The limited distribution system is due to the potential toxicities (hepatic and fetal) of this agent. Bosentan will be made available upon referral from specialty care physicians. When the distribution process is finalized, it will be disseminated via the service pharmacy consultants.				
Lovastatin/niacin tablets (Advicor; KOS)	18 Dec 01; combination of a statin and extended release niacin for the treatment of 1° hypercholesterolemia and mixed dyslipidemia who require additional lipid modification for LDL and HDL cholesterol and triglycerides beyond that achieved by the individual components	NOT Added to the NMOP Formulary	**Quantity Limits** N/A **Prior Authorization** N/A	Not added to the BCF **Similar BCF Drugs:** Closed class contract exists for simvastatin (Zocor)
Comments about lovastatin/niacin tablets: Addition of Advicor to either the BCF or NMOP formulary would be a violation of the simvastatin contract. Advicor should be available through the NMOP only in cases of documented medical necessity.				
Extended phenytoin sodium, 200 mg and 300 mg capsules (Phenytek; Bertek)	6 Dec 01; New branded generic formulation of phenytoin sodium indicated for the treatment of generalized tonic-clonic and complex partial seizures and prevention and treatment of seizures during or following neurosurgery 200 and 300 mg Phenytek capsules are bioequivalent to 2 and 3 Dilantin 100-mg capsules, respectively	Automatic addition to NMOP Formulary as line extension	**Quantity Limits** General rule applies **Prior Authorization** None	Need to clarify whether the current BCF listing for phenytoin oral will include Phenytek. This issue was tabled until pricing and provider input is available.
Brimonidine tartrate ophthalmic solution (Alphagan P; Allergan**)**	Reformulation of brimonidine tartrate ophthalmic solution with a different preservative, a lower concentration of brimonidine, and a modified pH	Added to the NMOP Formulary Conversion from Alphagan 0.2% to Alphagan P 0.15% is expected due to the planned phase out of Alphagan P 0.2%.	**Quantity Limits** General rule applies **Prior Authorization** None	Added to the BCF **Clarification:** The BCF listing will be clarified to identify brimonidine 0.15% (Alphagan P) as the specific agent on the BCF for the reasons outlined in the comments below.
Comments about brimonidine tartrate ophthalmic solution: Alphagan P 0.15% provides comparable IOP-lowering efficacy to Alphagan 0.2% (potentially due to increased bioavailability of the purite formulation as demonstrated in animal studies). No clinically significant differences were found in mean IOP or mean change from baseline in IOP between the two formulations. The incidence rate of allergic conjunctivitis in the Alphagan P 0.15% group was 41% less than in the Alphagan 0.2% group. Both products are used BID 95% of the time vs. the TID package insert recommended dosing. Company plans on phasing out the Alphagan 0.2%.				

APPENDIX B: COMBINED SUMMARY OF FORMULARY CHANGES FROM THE DOD P&T EXECUTIVE COUNCIL MEETING AND THE DOD P&T COMMITTEE MEETING

1. **BCF CHANGES**

   A. *Additions to the BCF*

      1) Advair (fluticasone/salmeterol) Inhaler: all strengths

      2) Prempro (conjugated estrogen and medroxyprogesterone): all strengths.

      3) Zithromax (azithromycin) 250 mg tablets, does not require the Z-pak dosage formulation.

      4) Plavix (clopidogrel) *[NOTE: Clopidogrel added to Appendix B subsequent to the initial release of these minutes on 8 Mar 2002. Please see Section 11 of the Feb 02 DoD P&T Executive Council meeting minutes.]*

   B. *Deletions from the BCF*

      None

   C. *Changes and clarifications to the BCF*

      1) The current BCF listing for brimonidine tartrate ophthalmic solution was clarified to identify the new Alphagan P 0.15% formulation as the specific agent included on the BCF.

2. **NMOP FORMULARY CHANGES**

   A. *Additions to the NMOP Formulary* (See Appendix A for details)

      1) Valdecoxib tablets (Bextra; Pharmacia) – added to NMOP with PA criteria

      2) Frovatriptan tablets (Frova; Elan) – quantity limits apply, see below

      3) Desloratadine tablets (Clarinex; Schering-Plough)

      4) Anakinra injection (Kineret; Amgen) –added to NMOP Covered Injectables List with PA criteria, quantity limits apply, see below

      5) Triptorelin pamoate depot injection (Trelstar LA; Debiopharm/Pharmacia) – added to NMOP Covered Injectables List

      6) Fondaparinux injection (Arixtra; Sanofi/Organon) – added to NMOP Covered Injectables List

      7) Pimecrolimus 1% cream (Elidel; Novartis)

      8) Diclofenac sodium topical gel (Solaraze; Sky Pharma)

      9) Dexmethylphenidate tablets (Focalin; Novartis) – quantity limits apply, see below

      10) Extended phenytoin sodium, 200 mg and 300 mg capsules (Phenytek; Bertek) – automatic line extension

      11) Brimonidine tartrate ophthalmic solution (Alphagan P; Allergan) - with natural attrition from Alphagan 0.2% to Alphagan P 0.15%

   B. *Exclusions from the NMOP Formulary*

      1) *Bosentan (Tracleer; Actelion)* - excluded from the NMOP due to closed distribution system initiated by the manufacturer.

2) *Lovastatin/niacin (Advicor; KOS) sustained release tablets* – lovastatin is currently excluded as a formulary agent due to existing statin contract (simvastatin) that is in effect through Feb 02.

C. Clarifications to the NMOP Formulary

None

3. **QUANTITY LIMIT CHANGES (NMOP AND RETAIL NETWORK)**

A. Quantity limit for frovatriptan tablets: 9 tablets per 30 days; 27 tablets per 90 days; consistent with existing quantity limits for other triptans.

B. Quantity limit for anakinra injection (Kineret; Amgen): NMOP: 6 packs of 7 syringes per 6 weeks; Retail: 4 packs of 7 syringes per 4 weeks.

C. Quantity limit for dexmethylphenidate tablets: Standard NMOP rule for Schedule II controlled products for treatment of ADHD applies – up to 90 days supply, no refills

4. **CHANGES TO THE PRIOR AUTHORIZATION PROGRAM (NMOP AND RETAIL NETWORK)**

A. *Etanercept (Enbrel)* -The FDA recently approved psoriatic arthritis as a new indication for etanercept (Enbrel). The Committee voted to add this indication to etanercept's PA criteria.

B. *COX-2 Inhibitors* - The Committee voted to have the same PA criteria apply to all COX-2 Inhibitors. See Section 11B for revised PA criteria.

C. *Anakinara (Kineret)* - The Committee voted to adopt the Merck Medco criteria currently in place. See Section 11D, of minutes for PA criteria.