

Department of Defense Pharmacoeconomic Center

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MCCS-GPE

21 NOVEMBER 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 21 November 2002, at the Uniformed Services University of the Health Sciences, Bethesda, Maryland.

2. VOTING MEMBERS PRESENT

CDR Terrance Egland, MC	DoD P& T Committee Co-chair
COL Daniel D. Remund, MS	DoD P& T Committee Co-chair
COL Joel Schmidt, MC	Army
MAJ Travis Watson, MS	Army
COL John R. Downs, MC (via VTC)	Air Force
COL Bill Sykora, MC	Air Force
LtCol George Jones, BSC	Air Force
CAPT Matt Nutaitis, MC	Navy
CDR Kevin Cook, MSC	Navy
CAPT Robert Rist	Coast Guard
Kathy Tortorice (Representing Dick Rooney)	Department of Veterans Affairs
Dr. Trevor Rabie	Uniformed Services Family Health Plan

VOTING MEMBERS ABSENT

Physician	Army
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OTHERS PRESENT

LTC Marc Caouette, MS	Joint Readiness Clinical Advisory Board
Howard Altschwager	Deputy General Counsel, TMA
CAPT Joe Torkildson, MC, USN	DoD Pharmacoeconomic Center
LtCol Dave Bennett, USAF, BSC (via VTC)	DoD Pharmacoeconomic Center
CDR Denise Graham, MSC, USN	DoD Pharmacoeconomic Center
Maj Barb Roach, USAF, MC (via VTC)	DoD Pharmacoeconomic Center
CDR (sel) Ted Briski, MSC, USN	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
David Bretzke (via VTC)	DoD Pharmacoeconomic Center
Eugene Moore (via VTC)	DoD Pharmacoeconomic Center
Angela Allerman (via VTC)	DoD Pharmacoeconomic Center
LT Chad McKenzie (via VTC)	DoD Pharmacoeconomic Center, Idaho State PharmD Internship
MAJ Mickey Bellemin, BSC	Defense Supply Center Philadelphia
MAJ John Howe, MS	Defense Supply Center Philadelphia
Paul Vasquez	Defense Supply Center Philadelphia
Vincent Valinotti	Defense Supply Center Philadelphia
Mark Petruzzi	Medco Health
Elizabeth Scaturro	Medco Health
Victor Diaz, MD, MPH	Humana
William Hudson	Humana
Gene Lakey	TriWest
Ray Nan Berry	Health Net Federal Services
Lisa LeGette	DoD Tricare Information Center
LTC Emery Spaar	U.S. Army Officer resident at AMCP

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

4. INTERIM/ ADMINISTRATIVE DECISIONS –

- A. *Membership*: Currently the DoD P&T Committee has 13 voting members. All other members are listed as other attendees. COL Remund will send out a copy of the existing charter to all members and recommendations for changes to the charter regarding membership should be sent to the chairs prior to the March meeting. The Council will decide at that time whether changes need to be made to the charter.
- B. *Venlafaxine extended release capsules (Effexor XR) Blanket Purchase Agreement (BPA)*: At the August 2002 meeting, the Council voted to add venlafaxine extended release 37.5, 75, and 150 mg capsules to the BCF, contingent on the signing of a BPA between Wyeth-Ayerst and DSCP. The BPA was recently signed, so Effexor XR is now on the BCF and facilities are required to include it on their formularies.

- 5. UNIFORM FORMULARY (UF) PROPOSED RULE-** Howard Altschwager, TMA Deputy General Counsel, briefed the Committee on the status of the UF proposed rule. The TMA Pharmacy Program Office is currently in the process of formulating responses to comments submitted by the public.
- 6. 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 or formulations (see Appendix A). The PEC also presented brief information on six additional new drugs or formulations not requiring a complete review by the Committee. The Committee agreed that no further review was required (see Appendix B for comments).
- 7. NMOP AND RETAIL NETWORK ISSUES**

A. Review of the NMOP and retail network quantity limits for antiemetics – A review of the quantity limits established for oral 5-HT₃ receptor agonists, used for the treatment of chemotherapy-induced nausea and vomiting, was initiated based on an inquiry received from a customer service representative at TMA West. A complaint was filed with this individual by a retired beneficiary, who stated that the quantity limit that currently exists was insufficient to meet the clinical needs of his wife, who was receiving treatment for cancer. CAPT Torkildson (PEC) performed the analysis and reported to the Committee.

There currently are three 5-HT₃ receptor antagonists available in the U.S. for prophylaxis or treatment of chemotherapy-induced nausea or emesis: ondansetron (Zofran), granisetron (Kytril), and dolasetron (Anzemet). The P&T Committee established the following quantity limits for these products at their August 1999 meeting. These quantity limits apply both to the NMOP and the retail network:

Table 1: Quantity Limits for 5-HT₃ Receptor Antagonists

Drug	30-day quantity limit	90-day quantity limit
Ondansetron tablets and orally disintegrating tablets	15	45
Granisetron tablets	8	24
Dolasetron tablets	5	15

In each case the quantity limit was established based on the drug's use for the FDA-approved indication: the prevention or treatment of chemotherapy induced nausea or vomiting. The first step of the analysis was to determine if additional FDA-approved indications had been added for one or more of these drugs that would materially change the number of tablets needed during a 30- or 90-day period. Since the quantity limits were initially established, the FDA has approved both ondansetron and granisetron for use in the prevention or treatment of nausea and vomiting associated with radiation therapy. Additionally, ondansetron and dolasetron were approved for treatment of postoperative nausea and vomiting. While the latter indication requires no modification in the quantity limit, the former could be associated with the use of a substantially greater number of tablets than specified by the current quantity limits. Based on the doses recommended for prevention or treatment of radiation-induced nausea and vomiting,

as many as 80 tablets of ondansetron or 40 tablets of granisetron could be required in a 30-day period, well above the current 30-day quantity limits for both products.

The second step of the analysis involved determining the actual number of tablets dispensed per prescription from each point of service and comparing these figures to the established quantity limits. In FY02, 29,645 oral 5-HT3 tablet prescriptions were filled in the MHS. Of these, 53% were filled at MTFs, 45% at retail network pharmacies, and 2% at the NMOP. Table 1 provides information regarding the number and percentage of prescriptions filled in each venue that exceed the currently established 30-day and 90-day quantity limits. No standard quantity limits exist at the MTFs; these figures are provided solely for comparison. It is notable that 13%-18% of prescriptions in the retail network exceed the established 30-day quantity limits. The representatives from each of the MCSC pharmacy benefit managers indicated that this was done only after a review was performed to ensure clinical appropriateness. A small number of prescriptions filled in the NMOP exceeded the 90-day quantity limit; Maj Bellemin indicated that this occurred only after a similar review process had taken been performed by him.

Table 2: Number (percentage) of Prescriptions Filled in FY 02 that Exceed Current NMOP and Retail Quantity Limits

Drug	Qty Limit	Point of Service		
		MTF	Retail	NMOP
Ondansetron 4 mg	> 15	1708 (52.2)	404 (13.2)	N/A
	> 45	427 (13)	63 (2.1)	1 (1.3)
Ondansetron 8 mg	>15	2897 (32.1)	812 (10.2)	N/A
	> 45	647 (7.2)	159 (2.0)	8 (3.1)
Granisetron 1 mg	> 8	468 (14.4)	196 (18.3)	N/A
	> 24	101 (3.1)	43 (4)	2 (4.1)
Dolasetron 50 mg	> 5	1 (100)	1 (5.6)	N/A
	> 15	1 (100)	0 (0)	0 (0)
Dolasetron 100 mg	> 5	37 (19.3)	177 (13.2)	N/A
	> 15	13 (6.8)	37 (2.8)	3 (5.6)

The conclusion reached by the PEC was that the current quantity limits are not sufficient to meet the clinical needs of patients undergoing radiation therapy. However, it does not appear that this creates a significant problem for patients. This is most likely due to two factors: 1) the low number of patients requiring treatment with antiemetics during their radiation therapy. Studies have suggested that only patients receiving higher dose abdominal radiation and some patients receiving radiation therapy to the head and neck will require antiemetic therapy. 2) a fair and effective review process for approval of prescriptions that exceed the established quantity limits. This is supported by the fact that only one complaint has been forwarded to the PEC in the three years since the quantity limits were established. Given the growing number of 5-HT3 receptor antagonist prescriptions being written for off-label indications such as hyperemesis gravidarum, the committee felt it would not be prudent to increase the quantity limits above the current levels, as these prescriptions should all be reviewed for clinical appropriateness. The PEC will monitor the situation and report back if the need arises.

8. **CONTROLLED DISTRIBUTION OF PRESCRIPTION DRUGS** – Gamma hydroxy butyrate solution (Xyrem) has been approved by the FDA with distribution limited to a single pharmacy, Express Scripts’ Specialty Distribution Services. Since Express Script’s Specialty Distribution Services may not be a member of each MCSC network, patients will likely have to file out-of-network claims to get reimbursed for this drug. The MCSC Pharmacy Directors will look into enrolling Express Scripts into their networks so only a copay will be required.
9. **ADJOURNMENT** – The meeting adjourned at 1130 hours. The next meeting will be held at Fort Sam Houston, TX at 0800 on Thursday, 6 March 2003. All agenda items should be submitted to the co-chairs no later than 14 February 2003.

<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 (NMOP) FORMULARY AND THE BASIC CORE FORMULARY (BCF)**
- APPENDIX B: NEWLY APPROVED DRUGS NOT REVIEWED BY THE PEC FOR THE P&T COMMITTEE**
- APPENDIX C: DRUGS ADDED TO THE BCF AND NMOP FORMULARY AT THE DOD P&T EXECUTIVE COUNCIL MEETING AND THE DOD P&T COMMITTEE MEETING**

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
<p>Amoxicillin clavulanate extended release tablets</p> <p>(Augmentin XR; GSK)</p>	<p>2 Oct 02: Treatment of community acquired pneumonia (CAP) or acute bacterial sinusitis caused by beta-lactamase-producing bacteria or <i>Strep. pneumoniae</i> with reduced susceptibility to penicillin (e.g., penicillin MICs = 2 mcg/ml).</p> <p>Not indicated for treating infections due to <i>S. pneumoniae</i> with penicillin MIC \geq 4 mcg/ml, due to only limited data.</p> <p>This formulation has 62.5 mg of clavulanate, instead of 125 mg found in other Augmentin preparations. The dose cannot be duplicated with existing Augmentin preparations. Augmentin XR still requires twice daily dosing; the controlled release mechanism appears to provide higher sustained blood levels of amoxicillin.</p>	<p>Added to the NMOP Formulary</p>	<p>Quantity Limits</p> <p>General Rule applies</p> <p>Prior Authorization: None</p>	<p>Not added to the BCF The BCF listing for amoxicillin/ clavulanate acid oral was clarified to exclude Augmentin XR</p> <p>Similar BCF agents: Amoxicillin/ clavulanate is listed on the BCF. The listing includes the pediatric suspension Augmentin ES-600. A generic version of Augmentin is now available.</p>
<p>Tazarotene 0.1% topical cream</p> <p>(Avage; Allergan)</p>	<p>2-Oct 02: Tazarotene is a retinoid prodrug. As Avage, it is indicated for palliation of facial fine wrinkling, hyper- and hypo-pigmentation, and benign facial lentiginosities in patients using skin care and sunlight avoidance programs.</p> <p>The same active ingredient (0.1% tazarotene) is marketed in a gel formulation under the trade name Tazorac, with indications for the treatment of psoriasis and acne vulgaris.</p>	<p>The Avage brand of tazarotene was specifically excluded from the NMOP Formulary, since its use is limited to cosmetic applications; other drugs intended solely for cosmetic use as a result of the aging process have been determined to be excluded from coverage by TRICARE rule.</p> <p>Tazorac usage will be monitored for any changes in age distribution.</p>	<p>Quantity Limits</p> <p>General rule applies.</p> <p>Prior Authorization None</p>	<p>Not added to the BCF.</p> <p>Similar BCF agents: Tretinoin 0.05% and 0.025% topical cream is listed on the BCF; the listing excludes Renova, a product that is only indicated for wrinkles.</p>
<p>Clindamycin 1% / benzoyl peroxide 5% topical gel</p> <p>(Duac; Steifel Labs)</p>	<p>26 Aug 02: Topical treatment of inflammatory acne vulgaris.</p> <p>This is the second clindamycin 1% / benzoyl peroxide 5% combination product to become available. The other product (BenzaClin; Aventis) is available in 25 and 50-gram jars that require reconstitution prior to dispensing. The Duac product does not require reconstitution; it is available in a 45-gram tube.</p>	<p>Added to the NMOP Formulary</p>	<p>Quantity Limits</p> <p>General rule applies</p> <p>Prior Authorization None</p>	<p>Not added to the BCF</p> <p>Similar BCF agents: Clindamycin 1% solution</p>

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
Glipizide / metformin tablets (Metaglip; BMS)	<p>21 Oct 02: Initial therapy in type 2 diabetics who are not achieving adequate glycemic control with diet and exercise alone.</p> <p>Also approved for second-line therapy in patients with type 2 diabetes who are not achieving adequate glycemic control with diet, exercise, and initial treatment with metformin or a sulfonylurea.</p>	Added to the NMOP Formulary	<p>Quantity Limits</p> <p>General rule applies</p> <hr/> <p>Prior Authorization</p> <p>None</p>	<p>Not added to the BCF</p> <p>Similar BCF agents: Metformin is listed on the BCF; a mandatory source contract is in effect.</p> <p>Glipizide immediate release is also listed on the BCF</p>
Rosiglitazone / metformin tablets (Avandamet; GSK)	<p>10 Oct 02: Use as an adjunct to diet and exercise in type 2 diabetics who are already receiving rosiglitazone and metformin as separate tablets, or who are not adequately controlled with metformin alone (second line therapy).</p> <p>Avandamet is not labeled for use as initial therapy in type 2 diabetics.</p>	Added to the NMOP Formulary	<p>Quantity Limits</p> <p>General rule applies</p> <hr/> <p>Prior Authorization</p> <p>None</p>	<p>Not added to the BCF</p> <p>Similar BCF agents: Metformin is listed on the BCF; a mandatory source contract is in effect.</p> <p>The DoD P&T committee has recommended addition of a TZD to the BCF; a contracting solicitation is in progress.</p>
Dutasteride tablets (Avodart; GSK)	<p>9 Oct 02: Treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate to include:</p> <p>Symptom reduction of BPH</p> <p>Reduction of the risk of urinary retention associated with BPH</p> <p>Reduction of the risk of BPH-related surgery</p>	Added to the NMOP Formulary	<p>Quantity Limits</p> <p>General rule applies</p> <hr/> <p>Prior Authorization</p> <p>None</p>	<p>Not added to the BCF</p> <p>Similar BCF agents: None. The alpha-blockers terazosin and prazosin are BCF items</p>
Ethinyl estradiol 25 mcg / norgestimate tablets (Ortho Tri-Cyclen Lo; Ortho McNeil)	<p>22 Aug 02. Prevention of pregnancy.</p> <p>Oral tri-phasic contraceptive containing 25 mcg of ethinyl estradiol, and three different doses of norgestimate, a low androgenic-potential progestin.</p> <p>Ortho Tri-Cyclen Lo is not indicated for acne.</p>	Added to the NMOP Formulary	<p>Quantity Limits</p> <p>General rule applies</p> <hr/> <p>Prior Authorization</p> <p>None</p>	<p>Not added to the BCF</p> <p>Similar BCF agents: No low estrogen triphasic OCPs are listed on the BCF. A low-dose monophasic preparation (20 mcg ethinyl estradiol / 1 mg norethindrone / 75 mg ferrous fumarate (Loestrin FE or its generic equivalent) was added to the BCF at this meeting.</p>

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
<p>Alosetron tablets (Lotronex; GSK)</p>	<p>7 Jun 02; treatment of severe diarrhea-predominant irritable bowel syndrome in women who have failed to respond to conventional therapy.</p> <p>Alosetron is not expected to be available until Dec 2002. A controlled distribution program is in place that requires physician self-certification and stickers to be placed on all prescriptions. More information is available on the FDA web site at http://www.fda.gov/cder/drug/infopage/lotronex/lotronex.htm.</p> <p>Alosetron was originally pulled off the market in Jun 2000 due to cases of GI toxicity (ischemic colitis and constipation resulting in 2 deaths). The new indication is narrower than the original labeling, and the dosage is now 1 mg qd instead of 1 mg bid.</p>	<p>Added to the NMOP Formulary. The controlled distribution program requirements can be met through the NMOP, however faxed prescriptions cannot be accepted.</p>	<p>Quantity Limits</p> <p>General rule applies; however, the controlled distribution program will necessitate dispensing in pre-packaged quantities. The NMOP will fill Rx's with the amount of tablets that is as close as possible to the original Rx.</p> <p>Prior Authorization None</p>	<p>Not added to the BCF</p> <p>Similar BCF agents: None</p>
<p>Tegaserod tablets (Zelnorm; Novartis)</p>	<p>6 Aug 02: short-term treatment of constipation-predominant irritable bowel syndrome.</p>	<p>Added to the NMOP Formulary</p>	<p>Quantity Limits</p> <p>General rule applies</p> <p>Prior Authorization None</p>	<p>Not added to the BCF</p> <p>Similar BCF agents: None</p>
<p>Adefovir tablets (Hepsera; Gilead)</p>	<p>20 Sep 02 (priority review): treatment of chronic hepatitis B in adults with evidence of active viral replication and either elevations in ALT or AST, or histologically active disease. Labeling has evidence of efficacy for lamivudine-resistant hepatitis B.</p>	<p>Added to the NMOP Formulary</p>	<p>Quantity Limits</p> <p>General rule applies</p> <p>Prior Authorization None</p>	<p>Not added to the BCF</p> <p>Similar BCF agents: None</p>
<p>PEG interferon alfa-2a injection (Pegasys; Roche)</p>	<p>16 Oct 02: treatment of adults with chronic hepatitis C who have compensated liver disease and have not been previously treated with interferon alfa</p>	<p>Added to the NMOP Covered Injectables List</p>	<p>Quantity Limits</p> <p>General rule applies</p> <p>Prior Authorization None</p>	<p>Not added to the BCF. Re-examine potential BCF addition in 3-6 months.</p> <p>Similar BCF agents: None</p>
<p>Comments regarding pegylated interferon alfa products for hepatitis C: PEG interferon alfa-2a (Pegasys) is not associated with a patient enrollment program; supplies are expected to be sufficient to meet demand. Schering's peg interferon alfa-2b product (PEG-Intron) previously had a patient enrollment program, but it was recently discontinued. The P&T Committee decided to readdress the potential BCF addition of a pegylated interferon alfa product for hepatitis C in 3-6 months.</p>				

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
<p>Ezetimibe tablets (Zetia; Merck)</p>	<p>25 Oct 02: Treatment of: Primary Hypercholesterolemia: Monotherapy – as an adjunct to diet to reduce TC, LDL-C, and Apo B Combination therapy – when administered with a statin as an adjunct to diet to reduce TC, LDL-C, and Apo B Homozygous familial hypercholesterolemia: when used in combination with atorvastatin or simvastatin Homozygous sitosterolemia: as an adjunct to diet</p>	<p>Added to the NMOP Formulary</p>	<p>Quantity Limits General rule applies</p> <hr/> <p>Prior Authorization None</p>	<p>Not added to the BCF. The P&T Committee voted to reconsider BCF addition of ezetimibe in 6 months</p> <p>Similar BCF agents: None</p>
<p>Guaifenesin extended release tablets (Mucinex; Adams Labs)</p>	<p>As of 12 Jul 2002, Mucinex (Adams Labs) became the first single ingredient guaifenesin extended release product to be 1) approved as safe and effective under a New Drug Application (NDA) and 2) to be approved as an over-the-counter (OTC) product.</p> <p>As a consequence of approval, the FDA has sent warning letters to manufacturers of guaifenesin extended release products explaining that currently marketed single ingredient guaifenesin extended release products without an approved application are considered misbranded and in violation of section 505(a) of the Food, Drug, and Cosmetic Act (FDCA). In addition, provisions of the Durham-Humphrey amendment (products cannot be marketed as both Rx and OTC products) effectively mean all single ingredient extended release will be OTC products.</p> <p>At least one affected manufacturer is known to be petitioning this action, but it is not known if any single ingredient guaifenesin extended release product other than Mucinex will continue to be available in the near future.</p>	<p>Since single ingredient guaifenesin extended release products are now OTC products, they will no longer be available from the NMOP and will not be included on the NMOP Formulary.</p> <p>Prescription extended release guaifenesin products will be dispensed by the NMOP as long as current supplies permit.</p>	<p>Quantity Limits N/A</p> <hr/> <p>Prior Authorization None</p>	<p>The DoD P&T Executive Council removed the BCF listing for guaifenesin 600 mg extended release. MTFs may decide whether to retain the product on their formularies or not. See minutes of the DoD P&T Executive Council meeting for more information.</p>

APPENDIX B: NEWLY APPROVED DRUGS NOT REQUIRING FULL REVIEW BY THE P&T COMMITTEE

Generic (Trade name; manufacturer)	Indication	Comments
Oxaliplatin injection (Eloxatin; Sanofi)	Treatment of metastatic colon/rectal CA in combination with 5-FU and leucovorin.	Not considered for the NMOP Formulary since the injection is not designed for self-administration. Not considered for the BCF due to the specialized nature of the indication.
Rasburicase injection (Elitek; Sanofi)	Orphan drug for the management of uric acid levels in pediatric patients receiving chemotherapy.	Not considered for the NMOP Formulary since the injection is not designed for self-administration. Not considered for the BCF due to the specialized nature of the indication.
Urokinase injection (Abbokinase; Abbott)	Treatment of thrombolysis of acute PE. Indication for catheter clearance is underway. Re-introduced 10 Oct 02, following market withdrawal in 1999 due to manufacturing problems.	Not considered for the NMOP Formulary since the injection is not designed for self-administration and because of the emergent nature of the indication. Not considered for the BCF due to the specialized nature of the indication and the emergent nature of the indication.
Buprenorphine / naloxone; buprenorphine tablets (Suboxone; Subutex; Schering Plough)	Treatment of opioid dependence. Patients can be treated in MD offices outside of methadone maintenance programs. Controlled distribution program is in effect.	Not considered for the NMOP Formulary because a legal interpretation is needed to determine if treatment of opioid dependence outside of a methadone maintenance program is a covered Tricare benefit. It is not known if requirements of the controlled distribution program could be met in the NMOP. Not considered for the BCF due to the specialized nature of the indication.
Sodium oxybate (gamma hydroxy butyrate) solution (Xyrem; Orphan Medical)	Treatment of cataplexy related to narcolepsy	Not considered for the NMOP Formulary because availability from the NMOP is not feasible; the restricted distribution program for this product is limited to a single pharmacy (see Paragraph 8 in these minutes). Not considered for the BCF due to the specialized nature of the indication.

APPENDIX C: 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) Tolterodine extended release capsules (Detrol LA)
- 2) Timolol maleate, solution, gel-forming 0.25%, 0.5% (Timoptic XE; Merck brand only - mandatory source contract)
- 3) Norethindrone/EE/ferrous fumarate 1/0.02 mg (Loestrin FE or its generic equivalent [Microgestin FE])
- 4) Niacin extended release tablets (Niaspan)
- 5) Venlafaxine extended release capsules (Effexor XR)

B. Deletions from the BCF

- 1) Niacin immediate release oral
- 2) Guaifenesin 600 mg extended (sustained) release tablets

C. Changes and clarifications to the BCF - None

D. Exclusions from the BCF

- 1) Paroxetine controlled release (Paxil CR) was excluded from the BCF listing for paroxetine
- 2) Amoxicillin/clavulanate extended release tablets (Augmentin XR) were excluded from the BCF listing for augmentin/clavulanate acid oral

2. NMOP FORMULARY CHANGES

A. Additions to the NMOP Formulary

- 1) Augmentin/clavulanate acid extended release tablets (Augmentin XR; GSK)
- 2) Clindamycin 1%/benzoyl peroxide 5% topical gel (Duac; Steifel Labs)
- 3) Glipizide / metformin tablets (Metaglip; BMS)
- 4) Rosiglitazone/metformin tablets (Avandamet; GSK)
- 5) Dutasteride tablets (Avodart; GSK)
- 6) Ethinyl estradiol 25 mcg/norgestimate (varying doses) tablets (Ortho Tri-Cyclen Lo; Ortho McNeil)
- 7) Alosetron tablets (Lotronex; GSK) – The controlled distribution program requirements can be met through the NMOP, however faxed prescriptions cannot be accepted.
- 8) Tegaserod tablets (Zelnorm; Novartis)
- 9) Adefovir tablets (Hepsera; Gilead)
- 10) PEG interferon alfa-2a injection (Pegasys; Roche) – added to the NMOP Covered Injectables List
- 11) Ezetimibe tablets (Zetia; Merck)

B. Exclusions from the NMOP Formulary

- 1) Avage brand of tazarotene 0.1% topical cream (Allergan) – specifically excluded from the NMOP Formulary, since its use is limited to cosmetic applications; other drugs intended solely for cosmetic use as a result of the aging process are not available from the NMOP.

C. Removed from the NMOP Formulary; no longer available from the NMOP

- 1) Single ingredient guaifenesin extended release tablets – approved as an OTC product 12 July 02

D. Clarifications to the NMOP Formulary - None

3. **QUANTITY LIMIT CHANGES (NMOP AND RETAIL NETWORK) - None**
4. **CHANGES TO THE PRIOR AUTHORIZATION PROGRAM (NMOP AND RETAIL NETWORK) - None**