DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
May 2009

1) CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened a web conference at 10:00 on May 13, 2009.

2) ATTENDANCE

The attendance roster is found in Appendix A.

3) REVIEW MINUTES OF LAST MEETINGS

A. Revisions to the minutes—Revisions to the February 2009 minutes will be reviewed at the August 2009 DoD P&T Committee meeting.

B. Approval of February minutes—Ms. Ellen P. Embrey, performing the duties of the Assistant Secretary of Defense, Health Affairs, approved the minutes of the November 2008 DoD P&T Committee meeting on May 12, 2009.

4) REVIEW OF RECENTLY FDA-APPROVED AGENTS

A. Antilipidemic-II Agents (LIP-2)—Fenofibrate acid capsules (Trilipix)

Relative Clinical Effectiveness—Fenofibrate acid (Trilipix) is the choline salt of fenofibrate; the active moiety is the same as the other fenofibrate formulations. The fenofibrates are classified in the Antilipidemic-II (LIP-2) drug class that was reviewed for Uniform Formulary (UF) placement in May 2007. Fenofibrate acid is Food and Drug Administration (FDA)-approved for use as monotherapy, and in combination with a statin to lower triglycerides (TGs) and increase high density lipoprotein (HDL) cholesterol in patients with coronary heart disease (CHD) or CHD risk equivalent to those who are receiving optimal statin therapy.

The fenofibrate acid (Trilipix) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, Title 32, Code of Federal Regulations (CFR), Section 199.21(e)(1). There are no comparative clinical trials between fenofibrate acid and the other LIP-2 drugs, and no trials evaluating outcomes other than changes in lipid parameters. The clinical trials used to obtain FDA approval reported fenofibrate acid combined with either a low-dose or moderate-dose statin resulted in additive effects on raising HDL cholesterol and lowering TGs, compared to the statin administered alone. The safety profile of fenofibrate acid reflects that of the other fenofibrate products.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) that although fenofibrate acid (Trilipix) is the only fenofibrate drug specifically approved by the FDA for use in combination with a statin, there was insufficient evidence to compare its safety in combination with a statin versus the other fenofibrates. The P&T Committee concluded fenofibrate acid (Trilipix) did not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other fenofibrate formulations currently included on the UF because they all contain the same active ingredient.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of fenofibrate acid capsules (Trilipix) in relation to efficacy, safety, tolerability, and clinical outcomes of other agents in the class, particularly to the following LIP-2 medications: micronized fenofibrate (Lofibra/generic), fenofibrate meltdose (Fenoglide), and nanomicronized fenofibrate (Tricor). Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

Cost minimization analysis (CMA) was used to evaluate the relative cost-effectiveness of fenofibrate acid capsules (Trilipix) relative to other UF LIP-2s. Results from the CMA showed the projected weighted average cost per day for fenofibrate acid capsules (Trilipix) is higher than fenofibrate micronized (Lofibra/generics) and fenofibrate meltdose (Fenoglide). The CMA also revealed the projected weighted average cost per day for fenofibrate acid capsules (Trilipix) is slightly lower than the non-formulary LIP-2 agent, nanomicronized fenofibrate (Tricor). Micronized fenofibrate (Lofibra/generic) and fenofibrate meltdose (Fenoglide) remain the most cost effective LIP-2 agents on the UF compared to fenofibrate acid capsules (Trilipix).

Relative Cost-Effectiveness Conclusion—The P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 0 absent) that fenofibrate acid capsules (Trilipix) are not cost effective relative to other formulary LIP-2 agents.

1) ***COMMITTEE ACTION: UF RECOMMENDATION***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (13 for, 0 opposed, 0 abstained, 0 absent) fenofibrate acid capsules (Trilipix) be designated non-formulary on the UF. This

recommendation was based on the clinical effectiveness conclusion and the determination that micronized fenofibrate (Lofibra/generic) and fenofibrate meltdose (Fenoglide) remain the most cost effective LIP-2 agents on the UF compared to fenofibrate acid capsules (Trilipix).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

2) ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluation of fenofibrate acid capsules (Trilipix) and the conditions for establishing medical necessity (MN) of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (13 for, 0 opposed, 0 abstained, 0 absent) MN criteria for fenofibrate acid capsules (Trilipix). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

3) ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (TRRx), and at military treatment facilities (MTFs) no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval by the Director, TMA.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

B. Overactive Bladder Drugs—Fesoterodine extended release (ER) tablets (Toviaz)

Relative Clinical Effectiveness—The muscarinic antagonist fesoterodine (Toviaz) is a prodrug that undergoes conversion by plasma esterases to the same active metabolite as tolterodine (Detrol, Detrol LA). Like the other OAB

drugs, fesoterodine extended release (ER) tablets are FDA-approved for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency. The OAB drug class was previously reviewed for UF placement in August 2008 and February 2006.

The fesoterodine ER tablets (Toviaz) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). There are no direct comparative clinical trials between fesoterodine ER and the other OAB drugs. Statistically significant improvements in the endpoints of urinary frequency, urge urinary incontinence, and urinary urgency vs. placebo were noted in the clinical trials used to obtain FDA approval. The incidence of dry mouth and constipation reported with fesoterodine ER 8 milligrams (mg) was higher than tolterodine ER (Detrol LA) 4 mg in the one indirect active comparator trial available. Product labeling states that fesoterodine does not prolong the QT interval.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) fesoterodine ER tablets (Toviaz) did not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other OAB drugs currently included on the UF.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of fesoterodine ER tablets (Toviaz) in relation to efficacy, safety, tolerability, and clinical outcomes of other agents in the class, particularly to oxybutynin XL (Detrol XL/generics), tolterodine LA (Detrol LA), solifenacin (Vesicare), and darifenacin (Enablex). Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

CMA was used to evaluate the relative cost-effectiveness of fesoterodine (Toviaz) relative to other UF OABs. Results from the CMA showed the projected weighted average cost per day for fesoterodine (Toviaz) is higher than other UF OABS.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) fesoterodine ER tablets (Toviaz) are not cost effective relative to other formulary OAB agents.

1) ***COMMITTEE ACTION: UF RECOMMENDATION***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (13 for, 0 opposed, 0 abstained, 0 absent) that fesoterodine ER tablets (Toviaz) be designated non-formulary on the UF.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

2) ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluation of fesoterodine ER tablets (Toviaz) and the conditions for establishing medical necessity of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (13 for, 0 opposed, 0 abstained, 0 absent) MN criteria for fesoterodine extended release (ER) tablets (Toviaz). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

3) ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (TRRx), and at MTFs no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval by the Director, TMA.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

C. Nasal Allergy Drugs (NADs)—Azelastine with sucralose nasal spray (Astepro)

Relative Clinical Effectiveness—Azelastine with sucralose nasal spray (Astepro) is a Nasal Allergy Drug (nasal antihistamine) containing the same active ingredient (azelastine) and dosage strength as Astelin nasal spray. Sucralose and sorbitol have been added to the Astepro formulation to help mask the bitter taste reported with Astelin. Astepro is FDA-approved for treating seasonal allergic rhinitis (SAR) in patients 12 years of age and older. Astelin has additional indications (SAR in patients ≥5 years, and non-allergic rhinitis). The Nasal Allergy Drugs (NADs) were previously reviewed for UF placement in November 2008.

The azelastine with sucralose nasal spray (Astepro) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). One unpublished study reported statistically significant improvements in nasal congestion, rhinorrhea, sneezing, and nasal itching with both Astepro and Astelin, compared to the placebo vehicle. The improvements in nasal symptoms were similar with Astepro and Astelin. Bitter taste and epistaxis are the adverse events reported most frequently with Astepro.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) azelastine with sucralose nasal spray (Astepro) does not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other NADs currently included on the UF.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of azelastine with sucralose nasal spray (Astepro) in relation to efficacy, safety, tolerability, and clinical outcomes of the other nasal antihistamine subclass agents in the NAD class, particularly to azelastine (Astelin) and olopatadine (Patanase). Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

CMA was used to evaluate the relative cost-effectiveness of azelastine with sucralose nasal spray (Astepro) relative to other nasal antihistamine subclass agents in the NAD class. Results from the CMA showed the projected weighted average cost per day for azelastine with sucralose nasal spray (Astepro) is higher than azelastine (Astelin) but less than olopatadine (Patanase), which is a non-formulary medication.

Relative Cost-Effectiveness Conclusion–P&T Committee, based upon its collective professional judgment, voted (12 for, 0 opposed, 0 abstained, 1 absent) that azelastine with sucralose nasal spray (Astepro) is not cost effective relative to other UF nasal antihistamine subclass agents in the NAD class.

1) ***COMMITTEE ACTION: UF RECOMMENDATION***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (12 for, 1 opposed, 0 abstained, 0 absent) that azelastine with sucralose nasal spray (Astepro) be designated non-formulary on the UF.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

2) ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluation of azelastine with sucralose nasal spray (Astepro) and the conditions for establishing medical necessity of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (13 for, 0 opposed, 0 abstained, 0 absent) MN criteria for azelastine with sucralose nasal spray (Astepro). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

3) ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (TRRx), and at MTFs no later than a 60-day implementation period; and

2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval by the Director, TMA.

Acting Director, TMA, Decision: ☑Approved ☐ Disapproved

Approved, but modified as follows:

D. Proton Pump Inhibitors—Dexlansoprazole delayed release capsules (Kapidex)

Relative Clinical Effectiveness—The Proton Pump Inhibitor (PPI) dexlansoprazole (Kapidex) is a sustained-release formulation of the R-enantiomer of lansoprazole (Prevacid). Generic formulations of lansoprazole are anticipated in late 2009. The PPIs were reviewed for UF placement in May 2007 and February 2005.

The dexlansoprazole delayed release (DR) capsules (Kapidex) evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). Dexlansoprazole DR capsules are FDA-approved for use in adults for healing of erosive esophagitis (EE), maintenance of EE healing, and gastroesophageal reflux disease. Lansoprazole (Prevacid) has additional FDA-approved indications. The clinical studies used to obtain FDA-approval compared dexlansoprazole DR 60 mg capsules with lansoprazole 30 mg capsules or with placebo; there are no studies directly comparing the drug with other PPIs. The most common adverse events with dexlansoprazole DR capsules are diarrhea, nausea, and abdominal pain, which are similar to the other PPIs.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) dexlansoprazole DR capsules (Kapidex) did not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other PPI drugs currently included on the UF.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of dexlansoprazole DR capsules (Kapidex) in relation to efficacy, safety, tolerability, and clinical outcomes of selected UF agents in the PPI class. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

CMA was used to evaluate the cost-effectiveness of dexlansoprazole DR capsules (Kapidex) relative to selected PPIs, including omeprazole (Prilosec) and esomeprazole (Nexium). Results from the CMA showed the projected weighted average cost per day for dexlansoprazole DR capsules (Kapidex) is higher than all other comparators.

Relative Cost-Effectiveness Conclusion—The P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 0 absent) that dexlansoprazole DR capsules (Kapidex) are not cost effective relative to other formulary PPI agents.

1) ***COMMITTEE ACTION: UF RECOMMENDATION***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (13 for, 0 opposed, 0 abstained, 0 absent) that dexlansoprazole DR capsules (Kapidex) be designated non-formulary on the UF.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

2) ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluation of dexlansoprazole DR capsules (Kapidex) and the conditions for establishing medical necessity of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (13 for, 0 opposed, 0 abstained, 0 absent) MN criteria for dexlansoprazole DR capsules (Kapidex). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

3) ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend 1) an effective date of the first Wednesday 1 week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (TRRx), and at MTFs no later than a 60-day implementation period; and 2)

TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval by the Director, TMA.

Acting Director, TMA, Decision: ☑Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

E. Antidepressant-1 Agents—Venlafaxine Extended Release Tablets

Relative Clinical Effectiveness—Relative Clinical Effectiveness—Venlafaxine is a serotonin norepinephrine reuptake inhibitor (SNRI) antidepressant. The Antidepressant-I (AD-1) drug class was reviewed for UF placement in November 2005. Venlafaxine Extended Release (ER) Tablets (brand name) contain the same active ingredient as venlafaxine ER capsules (Effexor XR), but employ a different mechanism to extend the dosing interval. The FDA does not consider Venlafaxine ER Tablets an AB-rated generic formulation of Effexor XR capsules. Venlafaxine ER Tablets and Effexor XR capsules are not considered therapeutically interchangeable by the FDA due to the different marketed dosage formulations (i.e., capsule vs. tablet). AB-rated generic formulations of Effexor XR capsules are expected in 2010–2011. Venlafaxine ER Tablets have demonstrated bioequivalence with Effexor XR capsules in pharmacokinetic studies.

The Venlafaxine ER Tablets clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). Venlafaxine ER Tablets are FDA-approved for treating Major Depressive Disorder and Social Anxiety Disorder; Effexor XR has additional indications. No clinical trials have been conducted with Venlafaxine ER Tablets. Venlafaxine ER Tablets were FDA-approved under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, based on demonstrated bioequivalence with Effexor XR. Adverse events with Venlafaxine ER Tablets reflect those contained in the Effexor XR product labeling.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (12 for, 1 opposed, 0 abstained, 0 absent) there was no evidence to suggest there are clinically relevant differences in the efficacy, safety, and clinical outcomes of Venlafaxine ER Tablets compared to Effexor XR capsules because both products contain the same active ingredient.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of Venlafaxine ER Tablets in relation to efficacy, safety,

tolerability, and clinical outcomes of selected formulary SSRIs and other SNRI subclass agents in the AD-1 class. Information considered by the P&T Committee included, but was not limited to sources of information listed in 32 CFR 199.21 (e) (2).

CMA was used to evaluate the relative cost-effectiveness of Venlafaxine ER Tablets relative to selected SSRIs, particularly to sertraline (Zoloft/generics) citalopram (Celexa/generics), and other SNRI subclass agents in the AD-1 class. The SNRIs reviewed in the CMA were venlafaxine ER capsules (Effexor XR), duloxetine (Cymbalta), and desvenlafaxine (Pristiq). Results from the CMA showed the projected weighted average cost per day for Venlafaxine ER Tablets is higher than both SSRIs reviewed. The CMA also revealed Venlafaxine ER Tablets are the most cost-effective agent in the SNRI subclass.

Relative Cost-Effectiveness Conclusion—The P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 0 absent) that Venlafaxine ER Tablets are cost effective relative to other UF SNRI subclass agents in the AD-1 class.

1) ***COMMITTEE ACTION: UF RECOMMENDATION***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (13 for, 0 opposed, 0 abstained, 0 absent) that Venlafaxine ER Tablets remain formulary on the UF.

Acting Director, TMA, Decision ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

2) ***COMMITTEE ACTION: BCF RECOMMENDATION***—Based on the results of the clinical and economic evaluations presented, the P&T Committee voted (13 for, 0 opposed, 0 abstained, and 0 absent) to recommend Venlafaxine ER Tablets not be added to the BCF.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

F. Antiemetics—Granisetron transdermal system (Sancuso)

Relative Clinical Effectiveness—The granisetron transdermal system (TDS) (Sancuso) is a serotonin subtype-3 (5-HT3) receptor antagonist. It is the only newer antiemetic available in a transdermal dosage form. Granisetron (Kytril, generics) is also available in tablets, an oral solution, and intravenous formulation. The newer antiemetics were evaluated for UF placement in May 2006.

Granisetron TDS is FDA-approved for the prevention of nausea and vomiting in adult patients receiving moderately or highly emetogenic chemotherapy regimens lasting for ≤5 consecutive days. Other newer antiemetics (granisetron and ondansetron [Zofran, generics]) have indications in addition to chemotherapy-induced nausea and vomiting (CINV).

The granisetron TDS (Sancuso) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). In clinical studies, granisetron TDS has shown non-inferiority (but not superiority) to oral granisetron in controlling nausea and vomiting associated with CINV. There is insufficient evidence to determine whether granisetron TDS would control nausea and vomiting to a greater extent than the other 5-HT3 antagonists. There are no studies evaluating differences in the adverse events between granisetron TDS and 5-HT3 antagonists other than oral granisetron.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) although granisetron TDS (Sancuso) is the only newer antiemetic available in a transdermal formulation, it does not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other newer antiemetics currently included on the UF.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of granisetron TDS (Sancuso) in relation to efficacy, safety, tolerability, and clinical outcomes of selected UF agents in the antiemetic class. Information considered by the P&T Committee included, but was not limited to sources of information listed in 32 CFR 199.21 (e) (2).

CMA was used to evaluate the relative cost-effectiveness of granisetron TDS (Sancuso) relative to ondansetron (Zofran/generics) oral and oral dissolving tablets and granisetron (Kytril/generics) tablets. Results from the CMA showed the projected weighted average cost per week for granisetron TDS (Sancuso) is higher than all other comparators.

Relative Cost-Effectiveness Conclusion—The P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 0 absent) that granisetron TDS (Sancuso) is not cost effective relative to other antiemetic agents.

1) ***COMMITTEE ACTION: UF RECOMMENDATION***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (13 for, 0 opposed, 0 abstained, 0 absent) granisetron TDS (Sancuso) be designated as non-formulary on the UF.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

2) ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluation of granisetron TDS (Sancuso) and the conditions for establishing medical necessity of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (13 for, 0 opposed, 0 abstained, 0 absent) MN criteria for granisetron TDS (Sancuso). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

*3) **COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee voted (11 for, 0 opposed, 0 abstained, 2 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (TRRx), and at MTFs no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval by the Director, TMA.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P Embrey

5) UTILIZATION MANAGEMENT—PRIOR AUTHORIZATIONS (PA) / Quantity Limits (QL) / MEDICAL NECESSITY (MN)

A. PPI—Prior Authorization / Medical Necessity Criteria (MN): The P&T Committee reviewed current published literature, national guidelines/expert consensus statements, and FDA guidance related to reports of a drug interaction between clopidogrel (Plavix) and PPIs, and the corresponding potential for decreased antiplatelet effect and adverse cardiovascular outcomes. An automated prior authorization (APR) or *step therapy* is currently in effect and requires use of UF generic omeprazole or esomeprazole (Nexium) before other non-formulary PPIs, unless there is therapeutic failure, intolerance, or hypersensitivity. MN criteria also applies to non-formulary PPIs. The P&T Committee concluded the evidence was not sufficient at this time to recommend a change in the current PA/MN criteria, but agreed with continued monitoring of the literature for possible changes to the PA/MN criteria.

1) ***COMMITTEE ACTION:*** The Committee voted (12 for, 0 opposed, 1 abstained, 0 absent) to recommend no change to the existing PPI PA/MN criteria.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. QL Updates: In anticipation of the forthcoming TPHARM contract implementation, the P&T Committee updated the quantity limits (QLs) for several drugs. See Appendix C.

1) ***COMMITTEE ACTION:*** The P&T Committee voted (11 for, 0 opposed, 0 abstained, 2 absent) to recommend the QLs for ondansetron (Zofran), dasatinib (Sprycel), budesonide nebulizer solution (Pulmicort Respules), cromolyn inhaler (Intal), azelastine nasal spray (Astelin), azelastine with sucralose nasal spray (Astepro), metaproterenol nebulizer solution (Alupent, generics), ipratropium/albuterol inhaler (Combivent), methylnaltrexone subcutaneous injection (Relistor), as outlined in Appendix C.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

C. **Extended Core Formulary (ECF) Clarification**—The P&T Committee was briefed in August 2008 on efforts to implement electronic prescribing in the Military Health System (MHS). As part of the ongoing plan to systematically review drugs represented on the Basic Core Formulary (BCF)/Extended Core Formulary (ECF), the P&T Committee periodically reviews recommendations for changes to the BCF/ECF. At this meeting, the ECF was reviewed because greater specificity in the drug listings is required to assist with e-prescribing efforts. Appendix D outlines drugs currently designated as ECF.

1) ***COMMITTEE ACTION:*** The P&T Committee voted (11 for, 0 opposed, 1 abstained, 1 absent) to recommend the listing of the ECF drugs, as outlined in Appendix D.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

D. **Oral Fentanyl Citrate Automated PA**—The P&T Committee was briefed on an analysis examining MHS utilization of oral fentanyl citrate buccal lozenges (Actiq) and buccal tablets (Fentora) among opioid-naïve patients (i.e., those without prior opioid exposure). Both Actiq and Fentora are indicated for breakthrough pain in combination with long-acting opioids in opioid-tolerant patients. A total of 1,217 TRICARE beneficiaries received prescriptions for oral fentanyl citrate during the 5-month observation period from November 1, 2009 to May 31, 2009. The oral fentanyl prescriptions were dispensed in majority (89 percent) from the TRRx. Forty percent of patients (492/1,217) were identified as new oral fentanyl citrate users. A total of 375 (76 percent) new users received an opioid prescription within the last 60-days of their first oral fentanyl citrate prescription; 81 percent of new users had prior exposure to a strong opioid. In total, 10 percent (117/1,217) of all oral fentanyl citrate users were opioid-naïve. Sensitivity analysis showed results to be dependent on length of look-back period.

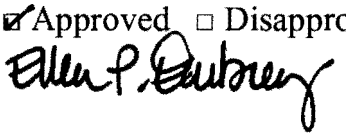
Due to potential patient safety and inappropriate prescribing concerns, the P&T Committee recommended inclusion of oral fentanyl citrate products (Actiq and Fentora) in the current Automated Profile Review (APR) for transdermal fentanyl. The APR is available at retail and mail order points of service and allows pharmacists to override the requirement for evidence of a previous opioid prescription in the 60-day look- back period with intervention and outcome codes (to avoid disrupting chronic therapy). The fentanyl APR

process differs from other PAs that require review by ESI (Express Scripts, Inc., DoD contractor for retail and mail order), have more stringent criteria to allow overrides, and take longer to resolve. The Pharmacy Program Office has requested and will begin testing a similar function in the Composite Health Care System for the MTF pharmacies.

1) ***COMMITTEE ACTION:*** The P&T Committee voted (11 for, 0 opposed, 0 abstained, 2 absent) to recommend addition of the oral formulations of fentanyl citrate, Actiq and Fentora be added to the automated PA.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:



6) FUTURE UF DRUG CLASS REVIEWS

A drug class overview for the Phosphodiesterase type-5 inhibitors (PDE-5s) was presented to the P&T Committee. The P&T Committee provided expert opinion regarding those clinical outcomes considered most important for the Pharmacoeconomic Center to use in completing the clinical effectiveness reviews and developing appropriate cost-effectiveness models. The clinical and economic analyses of this drug class will be completed for August 2009 P&T Committee meeting.

7) ITEMS FOR INFORMATION

A. **National Defense Authorization Act (NDAA) Section 703—Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals Update**—The Office of General Counsel (OGC) updated the P&T Committee on the litigation and status of the final rule that will implement Section 703 of the 2008 NDAA. The judge has not rendered a decision regarding the current litigation. The final rule is at the Office of Management and Budget (OMB). Key members from the TMA Pharmacy Operations Department and OGC have met with OMB personnel. The timetable for approval and impact on the DoD P&T Committee process are not known.

8) ADJOURNMENT

The meeting adjourned at 3:00 on March 13, 2009. The next meeting will be in August 2009.

Appendix A—Attendance
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Quantity Limits
Appendix D—Table of Extended Core Formulary Clarification
Appendix E—Table of Implementation Status of UF Recommendations/Decisions
Appendix F—Table of Abbreviations

SUBMITTED BY:

17 Aug 09

COL John Kugler, MC, USA
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Acting Director, TMA, decisions are as annotated above.

Ellen P. Embrey
Performing the Duties of the
Assistant Secretary of Defense,
Health Affairs

08/17/09
(Date)

Appendix A — Attendance

Voting Members Present	
COL John Kugler, MC	DoD P&T Committee Chair
LTC Stacia Spridgen, MSC	DoD P &T Committee Recorder
COL Doreen Lounsbery , MC	Army, Internal Medicine Physician, Alternate
COL Peter Bulatao *for Col Isiah Harper, MSC*	Army, Pharmacy Officer, Alternate
CAPT Stephanie Simon, MSC	Navy, Pharmacy Officer
CAPT Vernon Lew	Coast Guard, Pharmacy Officer
LTC Bruce Lovins	Army, Family Practice Physician, Alternate
CDR Walter Downs, MC	Navy, Internal Medicine Physician, Alternate
CDR David Tanen, MC	Navy, Physician at Large
Lt Col Thomas Bacon, BSC *for Col Everett McAllister*	Chief, Pharmaceutical Operations Directorate
Lt Col Michael Lee, BSC *for Col Mark Butler*	Consultant to the AF/SG
Lt Col Brian Crownover, MC	Air Force, Physician at Large
Major Jeremy King, MC	Air Force, OB/GYN Physician
Voting Members Absent	
COL Carole Labadie, MS	Army, Pharmacy Officer
COL Ted Cieslak, MC	Army, Physician at Large
Mr. Joe Canzolino	Department of Veterans Affairs
Nonvoting Members Present	
CDR James Ellzy	DoD P&T Vice Chairman
Mr. David Hurt	Deputy General Counsel, TMA
Nonvoting Members Absent	
COL Kent Maneval, MS	Defense Medical Standardization Board
Mr. William Davies	TRRx/TMOP COR
Maj Peter Trang	Defense Supply Center Philadelphia
Guests	
LCDR Tracie Patten *for CDR Robert Hayes*	Indian Health Service
Others Present	
CDR Matthew Carlberg	DoD Pharmacoeconomic Center
Lt Col James McCrary, MC	DoD Pharmacoeconomic Center
MAJ Misty Carlson, MC	DoD Pharmacoeconomic Center
LCDR Joe Lawrence	DoD Pharmacoeconomic Center

Appendix A — Attendance — (continued)

Others Present	
Maj Joshua Devine, BSC	DoD Pharmacoeconomic Center
LCDR Marisol Martinez	DoD Pharmacoeconomic Center
Dr. Shana Trice	DoD Pharmacoeconomic Center
Dr. Eugene Moore	DoD Pharmacoeconomic Center
Dr. Angela Allerman	DoD Pharmacoeconomic Center
Dr. David Meade	DoD Pharmacoeconomic Center
Dr. Teresa Anekwe	DoD Pharmacoeconomic Center
Dr. Jeremy Briggs	DoD Pharmacoeconomic Center
Dr. Brian Beck	DoD Pharmacy Operations Center contractor
Dr. Dean Valibhai	DoD Pharmacy Operations Center contractor
Dr. Carl R. Summers	DoD Pharmacy Outcomes Research Team contractor
Dr. Esmond Nwokeji	DoD Pharmacy Outcomes Research Team contractor
Dr. Roger Potyk	DoD Pharmacy Outcomes Research Team contractor
Mr. Stephen Yarger	DoD Pharmacy Outcomes Research Team contractor
Ms. Deborah Garcia	DoD Pharmacy Outcomes Research Team contractor

Appendix B — Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Azelastine with sucralose nasal spray (Astepro) **Nasal Allergy Drugs (NADs)**	• Use of formulary alternatives is contraindicated
Dexlansoprazole delayed release capsules (Kapidex) **Proton Pump Inhibitors (PPIs)**	• Use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from formulary alternatives.
Fenofibrate acid delayed release capsules (Trilipix) **Antilipidemic-II Drugs (LIP-2s)**	• Use of formulary alternatives is contraindicated
Fesoterodine extended release tablets (Toviaz) **Overactive Bladder Drugs (OABs)**	• Use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from formulary alternatives.
Granisetron transdermal system (Sancuso) **Antiemetics**	• Use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from formulary alternatives. • Formulary agents have resulted in therapeutic failure. • The patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk.

Appendix C — Quantity Limit Updates

Drug	TMOP QL	TRRx QL	Comments
Ondansetron (Zofran) 24 mg tablets	3 tabs/Rx	1 tab/Rx	-Indicated for single dose highly emetogenic chemo; -Not studied in multiple-day regimens -Other strengths of ondansetron are available for delayed nausea and vomiting
Dasatinib (Sprycel) 100 mg tablets	90 tabs/45 days	60 caps / 30 days	-Starting dose is 100mg/d -Max dose is 200mg/d in advanced phase CML -Therapy is continued until disease worsens or patient can't tolerate
Budesonide (Pulmicort Respules) nebulizer soln 1 mg/ml	180 ml (90 ampules) / 90 days	60 ml (30 ampules) / 30 days	Max dose is 1 mg (2ml) per day
Cromolyn (Intal) inhaler 8.1 gm	9 inhalers / 90 days	3 inhalers / 30 days	112 puffs/inhaler, max 240 inhalations/month
Azelastine (Astelin) nasal spray	6 bottles / 90 days	2 bottles / 30 days	Clarified TMOP quantity for consistency
Azelastine with sucralose (Astepro) nasal spray	6 bottles / 90 days	2 bottles/30 days	New product in already reviewed class
Metaproterenol nebulizer solution	600 amps / 90 days	200 amps/30 days	Max dose based on labeling
Ipratropium /albuterol (Combivent) inhaler 14.7 gm	6 inhalers / 90 days	2 inhalers/30 days	Max dose based on labeling
Methylnaltrexone SQ Injection (Relistor)	No Refills	No Refills	Intended for palliative care

Appendix D — Extended Core Formulary Clarification

Therapeutic Category	Generic Name	Brand Name	Dosage	Dosage Form	P&T Meeting
ANTIARTHRITICS	ADALIMUMAB	HUMIRA	40 MG/0.8ML	KIT	Nov 2007 & Feb 2008
AUTONOMIC DRUGS	DONEPEZIL HCL	ARICEPT	10 MG	TABLET	Nov 2005
AUTONOMIC DRUGS	DONEPEZIL HCL	ARICEPT	5 MG	TABLET	Nov 2005
UNCLASSIFIED DRUG PRODUCTS	INTERFERON BETA-1A	AVONEX	30 MCG/.5ML	KIT	May 2005
PSYCHOTHERAPEUTIC DRUGS	PHENELZINE SULFATE	NARDIL	15 MG	TABLET	Feb 2007
HORMONES	SOMATROPIN	NORDITROPIN	5 MG/1.5ML	CARTRIDGE	Aug 2007
HORMONES	SOMATROPIN	NORDITROPIN NORDIFLEX	5 MG/1.5ML	PEN INJCTR	Aug 2007
HORMONES	SOMATROPIN	NORDITROPIN NORDIFLEX	10 MG/1.5ML	PEN INJCTR	Aug 2007
HORMONES	SOMATROPIN	NORDITROPIN	15 MG/1.5ML	CARTRIDGE	Aug 2007
HORMONES	SOMATROPIN	NORDITROPIN NORDIFLEX	15 MG/1.5ML	PEN INJCTR	Aug 2007
UNCLASSIFIED DRUG PRODUCTS	VARDENAFIL HCL	LEVITRA	5 MG	TABLET	May 2005
UNCLASSIFIED DRUG PRODUCTS	VARDENAFIL HCL	LEVITRA	10 MG	TABLET	May 2005
UNCLASSIFIED DRUG PRODUCTS	VARDENAFIL HCL	LEVITRA	20 MG	TABLET	May 2005

Appendix E — Implementation Status of UF Class Review Recommendations / Decisions

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
May 09 (update; reviewed Jun 08; original review May 07)	Antilipidemic Agents-II	**Recommended for non-formulary status May 09; no change to non-formulary status in Jun 08** ▪ fenofibrate acid (Trilipix)	BCF	No changes to BCF recommendation May 09	pending approval	pending approval
Jun 08 (update; reviewed May 07)	Antilipidemic - Agents II	No changes to NF recommended Jun 08	BCF	**Recommended for addition to BCF Jun 08** ▪ fenofibrate meltdose (Fenoglide), to replace fenofibrate IDD-P (Triglide) (Note: fenofibrate IDD-P (Triglide) removed from BCF but still UF)	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
Jun 08 (update; reviewed May 07)	Antilipidemic Agents II	To remain NF ▪ fenofibrate nanocrystallized (Tricor) ▪ fenofibrate micronized (Antara) ▪ omega-3 fatty acids (Omacor) ▪ colesevelam (Welchol)	BCF	Currently BCF ▪ gemfibrozil	24 July 07	21 Nov 07 (120 days)
May 09 update; reviewed Aug 08; Feb 06 original review)	Overactive Bladder Drugs	**Recommended for non-formulary status May 09; no change to non-formulary status in Aug 08** ▪ fesoterodine (Toviaz)	BCF	No changes to BCF recommendation May 09	pending approval	pending approval
Aug 08 (re-review; Feb 06 original review)	Overactive Bladder (OAB) Agents	▪ tolterodine IR (Detrol) ▪ trospium IR (Sanctura)	BCF	▪ tolterodine ER (Detrol LA) ▪ oxybutynin ER (Ditropan XL, generics) (Note: oxybutynin IR [generic Ditropan] removed from BCF, but still UF)	24 Oct 08	4 Feb 09 (90 days)
May 09 (update; reviewed Nov 08)	Nasal Allergy Drugs	**Recommended for non-formulary status May 09; no change to non-formulary status in Nov 08** ▪ azelastine with sucralose (Astepro)	BCF	No changes to BCF recommendation May 09	pending approval	pending approval

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	**Decision Date** (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	**Effective Date for Non-Formulary Medications** (Implementation period)
Nov 08 (update to include nasal antihistamines; nasal steroids reviewed Nov 05 & Aug 07 for Veramyst)	Nasal Allergy Drugs	▪ olopatadine (Patanase) ▪ ciclesonide (Omnaris) ▪ fluticasone furoate (Veramyst) ▪ beclomethasone (Beconase AQ) ▪ budesonide (Rhinocort Aqua) ▪ triamcinolone (Nasacort AQ)	BCF	▪ Fluticasone propionate (generic Flonase) ▪ Azelastine (Astelin)	10 Feb 09	8 Apr 09 (60 days)
May 09 (update; reviewed May 07& Feb 05)	Proton Pump Inhibitors	**Recommended for non-formulary status May 09 no change to non-formulary status in May 07** ▪ Dexlansoprazole (Kapidex)	BCF	No changes to BCF recommendation May 09	pending approval	pending approval
May 07 re-review (Feb 05 original)	PPIs	▪ lansoprazole (Prevacid) ▪ omeprazole/sodium bicarbonate (Zegerid) ▪ pantoprazole (Protonix) ▪ rabeprazole (Aciphex) Automated PA requiring trial of omeprazole OR esomeprazole (Nexium) applies to new users of non-formulary PPIs (no use of PPIs in last 180 days)	BCF	▪ generic omeprazole 10 mg and 20 mg (excludes Prilosec 40 mg) ▪ esomeprazole (Nexium)	24 July 07	24 Oct 07 (90 days)
May 09 (update; reviewed May 06)	Antiemetics	**Recommended for non-formulary status May 09; no change to non-formulary status in** ▪ granisetron transdermal system (Sancuso)	BCF	No changes to BCF recommendation May 09	pending approval	pending approval
May 06	Antiemetics	▪ dolasetron (Anzemet)	BCF	▪ promethazine (oral and rectal)	26 Jul 06	27 Sep 06 (60 days)
Feb 09	Inhaled Corticosteroids	▪ Beclomethasone HFA MDI (Qvar) ▪ Budesonide MFA MDI (Pulmicort Flexhaler) ▪ Ciclesonide HFA MDI (Alvesco) ▪ Flunisolide CFC MDI (Aerobid, Aerobid M) ▪ Triamcinolone CFC MDI (Azmacort)	BCF	▪ Fluticasone DPI (Flovent Diskus) ▪ Fluticasone HFA MDA (Flovent HFA)	12 May 2009	16 Sep 09 (120 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	**Decision Date** (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	**Effective Date for Non-Formulary Medications** (Implementation period)
Feb 09	Long-Acting Beta Agonists	▪ formoterol inhalation solution (Perforomist)	BCF	▪ Salmeterol DPI (Serevent Diskus)	12 May 2009	16 Sep 09 (120 days)
Feb 09	Inhaled Corticosteroids / Long-Acting Beta Agonist Combinations	(No ICS/LABA combinations recommended for NF placement Feb 09)	BCF	▪ Fluticasone/salmeterol DPI (Advair Diskus) ▪ Fluticasone/salmeterol HFA MDI (Advair HFA)	12 May 2009	16 Sep 09 (120 days)
Nov 08	Short-Acting Beta Agonists	▪ albuterol chlorofluorocarbon (CFC) metered dose inhaler (MDI) (no longer manufactured) ▪ metaproterenol (Alupent) CFC MDI (no longer marketed) ▪ metaproterenol inhalation solution ▪ pirbuterol (Maxair) MDI	BCF	▪ Ventolin HFA (albuterol hydrofluoroalkane (HFA) MDI ▪ Albuterol inhalation solution; Note – does not include the following: Accuneb 0.021% [0.63 mg/mL] Accuneb 0.042% [1.25 mg/3mL] Albuterol 0.5% [2.5 mg/0.5 mL in 0.5 unit dose vial]	10 Feb 09	8 Apr 09 (60 days)
Nov 08 (update to include nasal antihistamines; nasal steroids reviewed Nov 05 & Aug 07 for Veramyst)	Nasal Allergy Drugs	▪ olopatadine (Patanase) ▪ ciclesonide (Omnaris) ▪ fluticasone furoate (Veramyst) ▪ beclomethasone (Beconase AQ) ▪ budesonide (Rhinocort Aqua) ▪ triamcinolone (Nasacort AQ)	BCF	▪ Fluticasone propionate (generic Flonase) ▪ Azelastine (Astelin)	10 Feb 09	8 Apr 09 (60 days)
Nov 08 & Aug 08 (update; reviewed Nov 05)	Antidepressants I	**Recommended for non-formulary status Aug 08; no change to non-formulary status in Nov 08** ▪ desvenlafaxine (Pristiq)	BCF	No changes to BCF recommended Aug 08	10 Feb 09; original signing date 24 Oct 08	7 Jan 09 (60 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
Aug 08 (update; reviewed Nov 05)	Antidepressants I	To remain NF ▪ paroxetine HCl CR (Paxil) ▪ fluoxetine 90 mg weekly admin. (Prozac Weekly) ▪ fluoxetine in special packaging for PMDD (Sarafem) ▪ escitalopram (Lexapro) ▪ duloxetine (Cymbalta) ▪ bupropion extended release (Wellbutrin XL)	BCF	Currently BCF ▪ citalopram ▪ fluoxetine (excluding weekly regimen & special packaging for PMDD) ▪ sertraline (Zoloft) ▪ trazodone ▪ bupropion sustained release	19 Jan 06	19 Jul 06 (180 days)
Nov 08	ACE inhibitors – Renin Angiotensin Antihypertensives	Previously non-formulary, recommended for UF status Nov 08 ▪ ramipril (Altace generic)	BCF	▪ No changes recommended to BCF at Nov 08 meeting; ramipril removed from Non-formulary status and designated as Uniform Formulary immediately upon signing of the minutes	10 Feb 09	N/A
Oct 08 (interim teleconference meeting) & Jun 08	Triptans	▪ almotriptan (Axert) ▪ frovatriptan (Frova) ▪ naratriptan (Amerge)	BCF	▪ rizatriptan (Maxalt), immediate upon signing of the minutes ▪ sumatriptan oral and one injectable formulation, when multi-source generics are available	24 Oct 08;; original signing date: 27 Aug 08	26 Nov 08 (90 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
Aug 08	Self-Monitoring Blood Glucose Systems (SMBGS) test strips	▪ OneTouch Ultra 2 strips (for OneTouch Ultra 2, Ultra Mini, and Ultra Smart meters) ▪ TrueTrack strips (for TrueTrack meter) ▪ Accu-chek Comfort Curve strips (for Accu-chek Advantage meter) ▪ Accu-chek Compact Plus drum (for Accu-check Compact Plus meter) ▪ Accu-chek Simplicity, Ascensia Autodisk, Ascensia Breeze 2, Ascensia Elite, Assure, Assure 3, Assure II, Assure Pro, Bd Test Strips, Chemstrip Bg, Control AST, Dextrostix Reagent, Easygluco, Easypro, Fast Take, Freestyle test strips (other than Freestyle Lite), Glucofilm, Glucolab, Glucometer Dex, Glucometer Elite, Glucose Test Strip, Glucostix, Optium, Precision Pcx, Precision Pcx Plus, Precision Q-I-D, Precision Sof-Tact, Prestige Smart System, Prodigy, Quicktek, Sidekick, Sof-Tact, Surestep, Surestep Pro, Test Strip, Relion Ultima, Uni-Check ▪ Plus all other store/private label brand strips not included on the UF (see BCF/ECF column)	BCF	**Basic Core Formulary SMBGS test strips** ▪ Precision Xtra strips (for Precision Xtra meter) **Uniform Formulary SMBGS test strips** ▪ Accu-chek Aviva (for Accu-chek Aviva meter) ▪ Ascensia Contour (for Ascensia Contour meter) ▪ Freestyle Lite (for Freestyle Freedom Lite and Freestyle Lite meters)	24 Oct 08	17 Mar 09 (120 days)
Aug 08 (**re-review**; Feb 06 original review)	Overactive Bladder (OAB) Agents	▪ tolterodine IR (Detrol) ▪ trospium IR (Sanctura)	BCF	▪ tolterodine ER (Detrol LA) ▪ oxybutynin ER (Ditropan XL, generics) (Note: oxybutynin IR [generic Ditropan] removed from BCF, but still UF)	24 Oct 08	4 Feb 09 (90 days)
Aug 08 (update; reviewed Aug 05; also updated Nov 07)	Calcium Channel Blockers	**Recommended for non-formulary status Aug 08** ▪ nisoldipine geomatrix (Sular geomatrix)	BCF	No changes to BCF recommended Aug 08	24 Oct 08	7 Jan 09 (60 days)
		Previously non-formulary, recommended for UF status Nov 07 ▪ amlodipine besylate (Norvasc generic)		Recommended for addition to BCF Nov 07 ▪ amlodipine besylate tablets	13 Feb 08	13 Feb 08
		To Remain Non-Formulary ▪ isradipine IR, ER (Dynacirc; Dynacirc CR) ▪ nicardipine IR (Cardene, generics) ▪ nicardipine SR (Cardene SR) ▪ verapamil ER (Verelan) ▪ verapamil ER HS dosing (Verelan PM, Covera HS) ▪ diltiazem ER for bedtime dosing (Cardizem LA)		Currently BCF ▪ amlodipine besylate (Norvasc, generics) (Recommended at Nov 07 meeting) ▪ nifedipine ER (Adalat CC, generics) ▪ verapamil SR ▪ diltiazem ER (Tiazac, generics)	13 Oct 05	15 Mar 06 (150 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
Jun 08	Osteoporosis Agents	▪ calcitonin salmon nasal spray (Miacalcin)	BCF	▪ alendronate (Fosamax) ▪ ibandronate (Boniva) (Note: raloxifene (Evista) removed from BCF, but still UF)	27 Aug 08	26 Nov 08 (90 days)
Jun 08 (update; reviewed May 07)	Antilipidemic Agents II	No changes to NF recommended Jun 08	BCF	**Recommended for addition to BCF Jun 08** ▪ fenofibrate meltdose (Fenoglide), to replace fenofibrate IDD-P (Triglide) (Note: fenofibrate IDD-P (Triglide) removed from BCF but still UF)	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
Jun 08 (update; reviewed May 07)	Antilipidemic Agents II	To remain NF ▪ fenofibrate nanocrystallized (Tricor) ▪ fenofibrate micronized (Antara) ▪ omega-3 fatty acids (Omacor) ▪ colesevelam (Welchol)	BCF	Currently BCF ▪ gemfibrozil	24 July 07	21 Nov 07 (120 days)
Jun 08 (update; reviewed Nov 07)	Adrenergic Blocking Agents	**Recommended for non-formulary status Jun 08** ▪ nebivolol (Bystolic)	BCF	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		(No ABAs selected for NF placement at Nov 07 meeting)		Currently BCF ▪ atenolol tablets ▪ metoprolol tartrate IR tablets ▪ carvedilol IR tablets ▪ metoprolol succinate ER tablets	13 Feb 08	-
Jun 08 (update; reviewed Aug 07	Newer Antihistamines	**Recommended for non-formulary status Jun 08** ▪ levocetirizine (Xyzal)	BCF	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		To remain NF ▪ desloratadine (Clarinex) ▪ desloratadine/pseudoephedrine (Clarinex D)		▪ MTFs required to carry at least one single ingredient agent from the newer antihistamine class (loratadine, cetirizine, or fexofenadine) on their local formulary, including at least one dosage form suitable for pediatric use	17 Oct 07	16 Jan 08 (90 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
Jun 08 (update; reviewed Aug 07)	Leukotriene Modifiers	**Recommended for non-formulary status Jun 08** ▪ Zileuton ER (Zyflo CR)	BCF	No changes to BCF rec Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		To remain NF ▪ zileuton (Zyflo)		Currently BCF ▪ montelukast (Singulair)	17 Oct 07	16 Jan 08 (90 days)
Jun 08 (update) Original reviews ▪ ACE inhibitors: Aug 05 ▪ Miscellaneous antihypertensives, including ACE/CCB combos. Feb 06 ▪ ARBs: May 07 ▪ Renin inhibitors. Aug 07 ▪ CCB/ARB combos Nov 07 update	Renin Angiotensin Antihypertensives	**Recommended for non-formulary status Jun 08** ▪ olmesartan/amlodipine (Azor)	BCF	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		To remain NF ▪ valsartan amlodipine (Exforge)		No change to BCF recommended Nov 07	13 Feb 08	16 Apr 08 (60 days)
		To remain NF ACE inhibitors ▪ Moexipril +/- HCTZ (Univasc; Uniretic) ▪ perindopril (Aceon) ▪ ramipril (Altace) ACE/CCB combos ▪ felodipine/enalapril (Lexxel) (D/C'd from market) ▪ verapamil/trandolapril (Tarka) ARBs ▪ eprosartan +/- HCTZ (Teveten; Teveten HCT) ▪ irbesartan+/- HCTZ (Avapro, Avalide) ▪ olmesartan +/- HCTZ (Benicar; Benicar HCT) ▪ valsartan +/- (Diovan; Diovan HCT)		Currently on the BCF ACE inhibitors ▪ captopril ▪ lisinopril ▪ lisinopril / HCTZ ACE/CCB combos ▪ amlodipine/benazepril (Lotrel, generics) ARBs ▪ telmisartan (Micardis) ▪ telmisartan HCTZ (Micardis HCT)	ACE inhibitors ▪ 13 Oct 05 ACE/CCB combos ▪ 26 Apr 06 ARBs ▪ 24 July 07	ACE inhibitors ▪ 15 Feb 06 ACE/CCB combos ▪ 26 Jul 06 ARBs ▪ 21 Nov 07
Nov 07	Targeted Immunomodulatory Biologics	▪ etanercept (Enbrel) ▪ anakinra (Kineret)	ECF	▪ adalimumab (Humira) injection	13 Feb 08	18 Jun 08 (120 days)
Nov 07 re-review (Aug 05 original)	BPH Alpha Blockers	▪ tamsulosin (Flomax) Automated PA requiring trial of alfuzosin (Uroxatral) applies to new users of tamsulosin (no use of uroselective alpha blockers in last 180 days)	BCF	▪ terazosin tablets or capsules ▪ alfuzosin tablets (Uroxatral)	13 Feb 08	16 Apr 08 (60 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
Nov 07 (update, original review Nov 06)	ADHD / Narcolepsy Agents	**Recommended for non-formulary status Nov 07** ▪ lisdexamfetamine (Vyvanse)	BCF	No change to BCF recommended Nov 07	13 Feb 08	16 Apr 08 (60 days)
		To remain NF ▪ dexmethylphenidate IR (Focalin) ▪ dexmethylphenidate SODAS (Focalin XR) ▪ methylphenidate transdermal system (Daytrana)		Currently on the BCF ▪ methylphenidate OROS (Concerta) ▪ mixed amphetamine salts ER (Adderall XR) ▪ methylphenidate IR (Ritalin)	17 Jan 07	18 Apr 07
Nov 07 (update, original review May 06)	Contraceptives	**Recommended for non-formulary status Nov 07** ▪ EE 20 mcg/levonorgestrel 0.09 mg in special packaging for continuous use (Lybrel)	BCF	No change to BCF recommended Nov 07	13 Feb 08	16 Apr 08 (60 days)
		To remain NF ▪ EE 30 mcg / levonorgestrel 0.15 mg in special packaging for extended use (Seasonale) ▪ EE 25 mcg / norethindrone 0.4 mg (Ovcon 35) ▪ EE 50 mcg / norethindrone 1 mg (Ovcon 50) ▪ EE 20/30/35 mcg / noreth. 1 mg (Estrostep Fe)		Currently on the BCF ▪ EE 20 mcg / 3 mg drospirenone (Yaz) ▪ EE 20 mcg / 0.1 mg levonorgestrel (Lutera, Sronyx, or equivalent) ▪ EE 30 mcg / 3 mg drospirenone (Yasmin) ▪ EE 30 mcg / 0.15 mg levonorgestrel (Nordette or equivalent / excludes Seasonale)	26 Jul 06	24 Jan 07
		▪ EE 30/10 mcg / 0.15 mg levonorgestrel in special packaging for extended use (Seasonique) ▪ EE 20 mcg / 1 mg norethindrone (Loestrin 24 Fe)		▪ EE 35 mcg / 1 mg norethindrone (Ortho-Novum 1/35 or equivalent) ▪ EE 35 mcg / 0.25 mg norgestimate (Ortho-Cyclen or equivalent) ▪ EE 25 mcg / 0.18/0.215/0.25 mg norgestimate (Ortho Tri-Cyclen Lo) ▪ EE 35 mcg / 0.18/0.215/0.25 mg norgestimate (Ortho Tri-Cyclen or equivalent) ▪ 0.35 mg norethindrone (Nor-QD, Ortho Micronor, or equivalent)	17 Jan 07	18 Mar 07
Aug 07	Growth Stimulating Agents	▪ somatropin (Genotropin, Genotropin Miniquick) ▪ somatropin (Humatrope) ▪ somatropin (Omnitrope) ▪ somatropin (Saizen)	ECF	▪ somatropin (Norditropin)	17 Oct 07	19 Dec 07 (60 days)
May 07 re-review (Feb 05 original)	PPIs	▪ lansoprazole (Prevacid) ▪ omeprazole/sodium bicarbonate (Zegerid) ▪ pantoprazole (Protonix) ▪ rabeprazole (Aciphex) Automated PA requiring trial of omeprazole OR esomeprazole (Nexium) applies to new users of non-formulary PPIs (no use of PPIs in last 180 days)	BCF	▪ generic omeprazole 10 mg and 20 mg (excludes Prilosec 40 mg) ▪ esomeprazole (Nexium)	24 July 07	24 Oct 07 (90 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
May 07 re-review (Feb 05 original)	ARBs	▪ eprosartan +/- HCTZ (Teveten; Teveten HCT) ▪ irbesartan +/-HCTZ (Avapro; Avalide) ▪ olmesartan +/- HCTZ (Benicar; Benicar HCT) ▪ valsartan +/- HCTZ (Diovan; Diovan HCT)	BCF	▪ telmisartan (Micardis) ▪ telmisartan HCTZ (Micardis HCT)	24 July 07	21 Nov 07 (120 days)
May 07	5-Alpha Reductase Inhibitors	▪ dutasteride (Avodart)	BCF	▪ finasteride	24 July 07	24 Oct 07 (90 days)
Feb 07	Newer Sedative Hypnotics	▪ zolpidem ER (Ambien CR) ▪ zaleplon (Sonata) ▪ ramelteon (Rozerem) Automated PA requiring trial of zolpidem IR applies to new users of eszopiclone (Lunesta), ramelteon (Rozerem), zaleplon (Sonata), or zolpidem ER (Ambien CR) (new users = no use of newer sedative hypnotics in last 180 days)	BCF	▪ zolpidem IR (Ambien)	02 May 07	01 Aug 07 (90 days)
Feb 07	Monoamine Oxidase Inhibitors	▪ selegiline transdermal patch (Emsam)	ECF	▪ phenelzine (Nardil)	02 May 07	01 Aug 07 (90 days)
Feb 07	Narcotic Analgesics	▪ tramadol ER (Ultram ER)	BCF	▪ morphine sulfate IR 15 mg, 30 mg ▪ morphine sulfate 12-hour ER (MS Contin or equivalent) 15, 30, 60 mg ▪ oxycodone/APAP 5/325 mg ▪ hydrocodone/APAP 5/500 mg ▪ codeine/APAP 30/300 mg ▪ codeine/APAP elixir 12/120 mg/5 mL ▪ tramadol IR	02 May 07	01 Aug 07 (90 days)
Feb 07	Ophthalmic Glaucoma Agents	▪ travoprost (Travatan, Travatan Z) ▪ timolol maleate for once daily dosing (Istalol) ▪ timolol hemihydrate (Betimol) ▪ brinzolamide (Azopt)	BCF	▪ latanoprost (Xalatan) ▪ brimonidine (Alphagan P); excludes 0.1% ▪ timolol maleate ▪ timolol maleate gel-forming solution ▪ pilocarpine	02 May 07	01 Aug 07 (90 days)
Nov 06	Older Sedative Hypnotics	-	BCF	▪ temazepam 15 and 30 mg	17 Jan 07	-
Nov 06 (update; reviewed Nov 06)	Dermatologic Topical Antifungals*	**Recommended for non-formulary status Nov 06:** 0.25% miconazole / 15% zinc oxide / 81.35% white petrolatum ointment (Vusion)	BCF	No change to BCF recommended Nov 06	14 Jul 05	17 Aug 05 (30 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
		▪ econazole ▪ ciclopirox ▪ oxiconazole (Oxistat) ▪ sertaconazole (Ertaczo) ▪ sulconazole (Exelderm)		▪ nystatin ▪ clotrimazole	17 Jan 07	18 Mar 07 (60 days)
Aug 06	H2 Antagonists / GI protectants	-	BCF	▪ ranitidine (Zantac) – excludes gelcaps and effervescent tablets	23 Oct 06	-
Aug 06	Antilipidemic Agents I	▪ rosuvastatin (Crestor) ▪ atorvastatin / amlodipine (Caduet)	BCF	▪ simvastatin (Zocor) ▪ pravastatin ▪ simvastatin / ezetimibe (Vytorin) ▪ niacin extended release (Niaspan)	23 Oct 06	1 Feb 07 (90 days)
May 06	Antiemetics	▪ dolasetron (Anzemet)	BCF	▪ promethazine (oral and rectal)	26 Jul 06	27 Sep 06 (60 days)
Feb 06 (re-classified Aug 07; and updated Jun 08; see above)	Misc Antihypertensive Agents (ACE/CCB combos now part of RAAs class)	(ACE/CCB combos now part of RAAs class) ▪ felodipine/enalapril (Lexxel) ▪ verapamil/trandolapril (Tarka)	BCF	(ACE/CCB combos now part of RAAs class) ▪ amlodipine/benazepril (Lotrel) ▪ hydralazine ▪ clonidine tablets	26 Apr 06	26 Jul 06 (90 days)
Feb 06	GABA-analogs	▪ pregabalin (Lyrica)	BCF	▪ gabapentin	26 Apr 06	28 Jun 06 (60 days)
Nov 05	Alzheimer's Drugs	▪ tacrine (Cognex)	ECF	▪ donepezil (Aricept)	19 Jan 06	19 Apr 06 (90 days)
Nov 05	Macrolide/ Ketolide Antibiotics	▪ azithromycin 2 gm (Zmax) ▪ telithromycin (Ketek)	BCF	▪ azithromycin (Z-Pak) ▪ erythromycin salts and bases	19 Jan 06	22 Mar 06 (60 days)
May 05	PDE5 Inhibitors	▪ sildenafil (Viagra) ▪ tadalafil (Cialis)	ECF	▪ vardenafil (Levitra)	14 Jul 05	12 Oct 05 (90 days)
May 05	MS-DMDs	-	ECF	▪ interferon beta-1a intramuscular injection (Avonex)	14 Jul 05	-

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	**Decision Date** (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	**Effective Date for Non-Formulary Medications** (Implementation period)
BCF = Basic Core Formulary; ECF = Extended Core Formulary; MN = Medical Necessity; TMOP = TRICARE Mail Order Pharmacy; TRRx = TRICARE Retail Pharmacy program; UF = Uniform Formulary CFC = chlorofluorocarbon; ER = extended release; HFA = hydrofluoroalkane; IR = immediate release; SR = sustained release; IDD-P = insoluble drug delivery-microParticle; AD-1s: Antidepressant-1 Drugs; ADHD = Attention Deficit Hyperactivity Disorder; ARBs = Angiotensin Receptor Blockers; ACE Inhibitors = Angiotensin Converting Enzyme Inhibitors; BPH = Benign Prostatic Hyperplasia; CCBs = Calcium Channel Blockers; EE = ethinyl estradiol; GI = gastrointestinal; GABA = gamma-aminobutyric acid; H2 = Histamine-2 receptor; HCTZ = hydrochlorothiazide; LIP-1 = Antihyperlipidemic-1 Drugs; LIP-2 = Antihyperlipidemic-2 Drugs; MDIs = metered dose inhalers; MOAIs = Monoamine Oxidase Inhibitor Drugs; MS-DMDs = Multiple Sclerosis Disease-Modifying Drugs; NADs = Nasal Allergy Drugs; OABs = Overactive Bladder Medications; PDE5 Inhibitors = Phosphodiesterase- type 5 inhibitors; PPIs = Proton Pump Inhibitors; RAAs = Renin Angiotensin Antihypertensives Drugs; SABAs = Short-Acting Beta Agonists; SMBGS: Self-Monitoring Blood Glucose Systems; TIBs = Targeted Immunomodulatory Biologics; TZDs= Thiazolidinediones *The Dermatologic Topical Antifungal drug class excludes vaginal products and products for onychomycosis (e.g., ciclopirox topical solution [Penlac])						

Appendix F — Table of Abbreviations

5-HT3	serotonin subtype 3
AE	adverse event
APR	Automated profile review
AD-1	Antidepressant-I drug class
BAP	Beneficiary Advisory Panel
BCF	Basic Core Formulary
BIA	budget impact analysis
CEA	Cost-effectiveness analysis
CFR	Code of Federal Regulations
CHCS	Composite Health Care System
CHD	coronary heart disease
CINV	chemotherapy induced nausea and vomiting
CMA	cost minimization analysis
DoD	Department of Defense
DR	delayed release
ECF	Extended Core Formulary
EE	erosive esophagitis
ESI	Express Scripts, Inc
ER	extended release
FCP	Federal Ceiling Price
FDA	Food and Drug Administration
FSS	Federal Supply Schedule Price
FY	fiscal year
HA	Health Affairs
HDL	high density lipoprotein
LIP-2	Antilipidemic-II drug class
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NAD	Nasal Allergy drug class
NDAA	National Defense Authorization Act
OAB	Overactive Bladder drug class
OMB	Office of Management and Budget
P&T	Pharmacy and Therapeutics
PA	prior authorization
PEC	Pharmacoeconomic Center
PORT	Pharmaceutical Outcomes Research Team
PPI	Proton Pump Inhibitor drug class
PDE-5	Phosphodiesterase-type 5 inhibitor drug class
QL	quantity limit
SAR	seasonal allergic rhinitis
SNRI	serotonin norepinephrine reuptake inhibitor
TDS	transdermal system
TFL	TRICARE for life beneficiary
TG	triglyceride
TMA	TRICARE Management Activity
TMOP	TRICARE Mail Order Pharmacy
TRRx	TRICARE Retail Pharmacy Network
UF VARR	Uniform Formulary Voluntary Agreement for Retail Refunds