DOD PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL

I. Uniform Formulary Review Process

Under 10 U.S.C. § 1074g, as implemented by 32 C.F.R. 199.21, the DoD P&T Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, TMA, on formulary status, pre-authorizations, and the effective date for a drug's change from formulary to non-formulary status receive comments from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director before making a final decision.

II. NEWLY APPROVED DRUGS - Antilipidemic-II Agents (LIP-2) — Fenofibrate acid capsules (Trilipix)

P&T Comments

A. Trilipix— Relative Clinical Effectiveness

Fenofibrate acid (Trilipix) is the choline salt of fenofibrate; the active ingredient is the same as the other fenofibrate formulations (Tricor, Fenoglide, Triglide, etc). The fenofibrates are classified in the Antilipidemic-II (LIP-2) drug class that was reviewed for Uniform Formulary (UF) placement in May 2007. Trilipix is 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 Trilipix clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). There are no comparative clinical trials between Trilipix 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 Trilipix 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 Trilipix reflects that of the other fenofibrate products.

Relative Clinical Effectiveness Conclusion:

The P&T Committee concluded 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 vs. the other fenofibrates. The P&T Committee concluded 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.

COMMITTEE ACTION: The P&T Committee voted to accept the clinical effectiveness conclusion stated above.

B. Trilipix— Relative Cost-Effectiveness

The P&T Committee evaluated the relative cost-effectiveness of 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 Trilipix) relative to other UF LIP-2s. Results from the CMA showed the projected weighted average cost per day for Trilipix is higher than fenofibrate micronized (Lofibra/generics) and fenofibrate meltdose (Fenoglide). The CMA also revealed the projected weighted average cost per day for Trilipix is slightly lower than the non-formulary LIP-2 agent, Tricor. Lofibra/generics and Fenoglide remain the most cost effective LIP-2 agents on the UF compared to Trilipix.

Relative Cost-Effectiveness Conclusion:

The P&T Committee, based upon its collective professional judgment, voted that fenofibrate acid capsules (Trilipix) are not cost effective relative to other formulary LIP-2 agents.

COMMITTEE ACTION: The P&T Committee voted to accept the cost effectiveness conclusion stated above.

C. Trilipix— Uniform Formulary 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 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).

D. Trilipix — Implementation Plan

The P&T Committee voted 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.

III. NEWLY APPROVED DRUGS Antilipidemic-II Agents (LIP-2) — Fenofibrate acid capsules (Trilipix)

BAP Comments

A. Trilipix — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Antilipidemic-II Agents, and other relevant factors, the P&T Committee voted to recommend Trilipix be designated as non-formulary under the UF, based on cost effectiveness.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. Trilipix – Implementation Plan

The P&T Committee voted 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

IV. NEWLY APPROVED DRUGS Overactive Bladder Drugs — Fesoterodine extended release (ER) tablets - (Toviaz)

P&T Comments

A. 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, Toviaz 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 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 Toviaz 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 Toviaz 8 mg was higher than Detrol LA 4 mg in the one indirect active comparator trial available. Product labeling states that Toviaz does not prolong the QT interval.

Relative Clinical Effectiveness Conclusion:
The P&T Committee concluded 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.

COMMITTEE ACTION: The P&T Committee voted to accept the clinical effectiveness conclusion stated above.

B. Toviaz — Relative Cost-Effectiveness

The P&T Committee evaluated the relative cost-effectiveness of 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 Toviaz relative to other UF OABs. Results from the CMA showed the projected weighted average cost per day for Toviaz is higher than other UF OABS.

Relative Cost-Effectiveness Conclusion:
The P&T Committee concluded fesoterodine ER tablets (Toviaz) are not cost effective relative to other formulary OAB agents.

COMMITTEE ACTION: The P&T Committee voted to accept the cost effectiveness conclusion stated above.

C. Toviaz — Uniform Formulary 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 that fesoterodine ER tablets (Toviaz) be designated non-formulary on the UF.

D. Toviaz — Implementation Plan

The P&T Committee voted 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.

V. NEWLY APPROVED DRUGS Overactive Bladder Drugs — Fesoterodine extended release (ER) tablets - (Toviaz)

BAP Comments

A. Toviaz — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Overactive Bladder Drugs, and other relevant factors, the P&T Committee voted to recommend: Toviaz be designated non-formulary on the UF.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. Toviaz – Implementation Plan: The P&T Committee voted 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions

VI. NEWLY APPROVED DRUGS Nasal Allergy Drugs (NADs) — Azelastine with sucralose nasal spray - (Astepro)

P&T Comments

A. 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 $\geq$5 years, and non-allergic rhinitis). The Nasal Allergy Drugs (NADs) were previously reviewed for UF placement in November 2008.

The 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 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.

COMMITTEE ACTION: The P&T Committee voted to accept the clinical effectiveness conclusion stated above.

B. Astepro — Relative Cost-Effectiveness

The P&T Committee evaluated the relative cost-effectiveness of 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 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 Astepro is higher than 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 that Astepro is not cost effective relative to other UF nasal antihistamine subclass agents in the NAD class.

COMMITTEE ACTION: The P&T Committee voted to accept the cost effectiveness conclusion stated above.

C. Astepro — Uniform Formulary 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 that azelastine with sucralose nasal spray (Astepro) be designated non-formulary on the UF.

D. Astepro — Implementation Plan

The P&T Committee voted 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.

VII. NEWLY APPROVED DRUGS - Nasal Allergy Drugs (NADs) — Azelastine with sucralose nasal spray - (Astepro)

BAP Comments

A. Astepro — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Nasal Allergy Drugs, and other relevant factors, the P&T Committee voted to recommend: azelastine with sucralose nasal spray (Astepro) be designated non-formulary on the UF.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. Astepro – Implementation Plan: The P&T Committee voted 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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

VIII. NEWLY APPROVED DRUGS Proton Pump Inhibitors — Dexlansoprazole delayed release capsules - (Kapidex)

P&T Comments

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

Relative Clinical Effectiveness Conclusion:

The P&T Committee concluded 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.

COMMITTEE ACTION: The P&T Committee voted to accept the clinical effectiveness conclusion stated above.

B. Kapidex — Relative Cost-Effectiveness

The P&T Committee evaluated the relative cost-effectiveness of 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 Kapidex relative to selected PPIs, including omeprazole (Prilosec) and esomeprazole (Nexium). Results from the CMA showed the projected weighted average cost per day for Kapidex is higher than all other comparators.

Relative Cost-Effectiveness Conclusion:

The P&T Committee, based upon its collective professional judgment, voted that Kapidex are not cost effective relative to other formulary PPI agents.

COMMITTEE ACTION: The P&T Committee voted to accept the cost effectiveness conclusion stated above.

C. Kapidex — Uniform Formulary 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 that Kapidex be designated non-formulary on the UF.

D. Kapidex — Implementation Plan

The P&T Committee voted 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.

IX. NEWLY APPROVED DRUGS Proton Pump Inhibitors — Dexlansoprazole delayed release capsules - (Kapidex)

BAP Comments

A. Kapidex — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Proton Pump Inhibitors, and other relevant factors, the P&T Committee voted to recommend that Kapidex be designated non-formulary on the UF.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. Kapidex — Implementation Plan: The P&T Committee voted 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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions

X. NEWLY APPROVED DRUGS Antidepressant-1 Agents — Venlafaxine - Extended Release Tablets

P&T Comments

A. Venlafaxine -Extended Release Tablets — 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 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.

COMMITTEE ACTION: The P&T Committee voted to accept the clinical effectiveness conclusion stated above.

B. Venlafaxine -Extended Release Tablets — 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 that Venlafaxine ER Tablets are cost effective relative to other UF SNRI subclass agents in the AD-1 class.

COMMITTEE ACTION: The P&T Committee voted to accept the cost effectiveness conclusion stated above.

C. Venlafaxine -Extended Release Tablets — Uniform Formulary 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 that Venlafaxine ER Tablets remain formulary on the UF.

D. Venlafaxine -Extended Release Tablets — Implementation Plan: Not Applicable

XI. NEWLY APPROVED DRUGS Antidepressant-1 Agents — Venlafaxine Extended Release Tablets

BAP Comments

A. Venlafaxine -Extended Release Tablets — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Antidepressant-1 Agents, and other relevant factors, the P&T Committee voted to recommend that venlafaxine ER Tablets remain formulary on the UF.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. Venlafaxine -Extended Release Tablets — Implementation Plan – Not Applicable

XII. NEWLY APPROVED DRUGS Antiemetics — Granisetron transdermal system (Sancuso)

P&T Comments

A. Sancuso — Relative Clinical Effectiveness

The granisetron transdermal system (TDS), (Sancuso patch) 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.

Sancuso 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 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, Sancuso has shown non-inferiority (but not superiority) to oral Kytril/generics in controlling nausea and vomiting associated with CINV. There is insufficient evidence to determine whether Sancuso 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 Sancuso and 5-HT3 antagonists other than oral Kytril/generics.

Relative Clinical Effectiveness Conclusion:

The P&T Committee concluded although Sancuso is the only newer antiemetic available in a transdermal (patch) 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.

COMMITTEE ACTION: The P&T Committee voted to accept the clinical effectiveness conclusion stated above.

B. Sancuso — Relative Cost-Effectiveness

The P&T Committee evaluated the relative cost- effectiveness of 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 Sancuso relative to Zofran/generics oral and oral dissolving tablets and Kytril/generics tablets. Results from the CMA showed the projected weighted average cost per week for Sancuso is higher than all other comparators.

Relative Cost-Effectiveness Conclusion:

The P&T Committee, based upon its collective professional judgment, voted that Sancuso is not cost effective relative to other antiemetic agents.

COMMITTEE ACTION: The P&T Committee voted to accept the cost effectiveness conclusion stated above.

C. Sancuso — Uniform Formulary 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 Sancuso be designated as non-formulary on the UF.

D. Sancuso — Implementation Plan

The P&T Committee voted 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.

XIII. NEWLY APPROVED DRUGS Antiemetics — Granisetron transdermal system (Sancuso)

BAP Comments

A. Sancuso — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Antiemetics, and other relevant factors, the P&T Committee voted to recommend that Sancuso be designated as non-formulary on the UF.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. Sancuso — Implementation Plan: The P&T Committee voted 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions: