14 August 2009

Executive Summary

UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL COMMENTS
30 July 2009

The Uniform Formulary (UF) Beneficiary Advisory Panel (BAP) commented on the recommendations from the DoD Pharmacy & Therapeutics (P&T) Committee May 2009 meeting.

1. **Antilipidemic-II Agents (Lip-2) – Fenofibrate Acid Capsules (Trilipix):** The P&T Committee recommended the following:

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).

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 0 absent) 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.

Summary of Panel Vote/Comments:

- The Panel voted 7 Concur, 0 Non-Concur regarding the recommendations for formulary and non-formulary agents.
- The Panel voted 7 Concur, 0 Non-Concur regarding the recommended implementation period of 60 days.

Director, TMA:

☑ These comments were taken under consideration prior to my final decision.

Ellen P. Embrey

2. **Overactive Bladder Drugs – Fesoterodine Extended Release Tablets (Toviaz):** The P&T Committee recommended the following:

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.

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 0 absent) 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) program and in the TRICARE Retail Network Pharmacy Program (TRRx), and at the MTFs no later than a 60-day implementation period. The implementation period will begin immediately following the approval by the Director, TMA.

Summary of Panel Vote/Comments:

- The Panel voted 7 Concur, 0 Non-Concur regarding the recommendations for formulary and non-formulary agents.
- The Panel voted 7 Concur, 0 Non-Concur regarding the recommended implementation period of 60 days.

***Director, TMA*:**

☑ These comments were taken under consideration prior to my final decision.

Ellen P. Embrey

3. **Nasal Allergy Drugs – Azelastine With Sucralose Nasal Spray (Astepro):** The P&T Committee recommended the following:

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.

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.

Summary of Panel Vote/Comments:

- The Panel voted 7 Concur, 0 Non-Concur regarding the recommendations for formulary and non-formulary agents.

- The Panel voted 7 Concur, 0 Non-Concur regarding the recommended implementation period of 60 days.

***Director, TMA*:**

☑ These comments were taken under consideration prior to my final decision.

Ellen P. Embrey

4. **Proton Pump Inhibitors– Dexlansoprazole Delayed Release Capsules (Kapidex):** The P&T Committee recommended the following:

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, voted to recommend (13 for, 0 opposed, 0 abstained, 0 absent) that Kapidex be designated non-formulary on the UF.

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.

Summary of Panel Vote/Comments:

- The Panel voted 7 Concur, 0 Non-Concur regarding the recommendations for formulary and non-formulary agents.
- The Panel voted 7 Concur, 0 Non-Concur regarding the recommended implementation period of 60 days.

***Director, TMA*:**

☑ These comments were taken under consideration prior to my final decision.

Ellen P. Embrey

5. **Antidepressant-1 Drugs–Venlafaxine Extended Release Tablets:** The P&T Committee recommended the following:

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.

Summary of Panel Vote/Comments:

- The Panel voted 7 Concur, 0 Non-Concur regarding the recommendations for formulary and non-formulary agents.

Director, TMA:

☑ These comments were taken under consideration prior to my final decision.

Ellen P. Embrey

6. **Antiemetics – Granisetron Transdermal Patch (Sancuso):** The P&T Committee recommended the following:

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.

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.

Summary of Panel Vote/Comments:

- The Panel voted 5 Concur, 2 Non-Concur regarding the recommendations for formulary and non-formulary agents.
- One Panel comment offered was that the agent, being the only patch dosage available, might help someone and shouldn't be placed on the third tier of the Formulary. Another was that the BAP believes that it is important to leave options open for beneficiaries.
- The Panel voted 5 Concur, 2 Non-Concur regarding the recommended implementation period of 60 days.

Director, TMA:

☑ These comments were taken under consideration prior to my final decision.

Ellen P. Embrey

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
July 30, 2009
Washington, D.C.

Panel Members Present:

- Deborah Fryar, National Military Family Association, representing The Military Coalition, Chairperson
- Kathryn Buchta, Medical Professional, Health Net Federal Services
- Barbara Cohoon, National Military Family Association, representing the Military Coalition
- John Crum, Medical Professional, Humana Military Healthcare Services, Inc.
- Rance Hutchings, Medical Professional, Uniformed Services Family Health Plan
- Lisa Le Gette, Medical Professional, Express-Scripts, Inc.
- Marissa Schlaifer, Medical Professional, Academy of Managed Care Pharmacy

The meeting was held at the Naval Heritage Center Theater, 701 Pennsylvania Ave., N.W., Washington, D.C. Lt Col Thomas Bacon, the Designated Federal Officer (DFO), called the proceedings to order at 10:10 A.M.

Lt Col Bacon said the meeting of the Panel has been convened to review and comment on the recommendations of the Department of Defense (DOD) Pharmacy and Therapeutic (P&T) Committee meeting held May 13, 2009 in San Antonio, TX.

Agenda

The agenda for this meeting of the Panel is:

- Opening remarks
- Public citizen comments
- Review and discussion of P&T Committee recommendations of six newly approved drugs: Trilipix, Toviaz, Astepro, Kapidex, venlafaxine ER tablets, and the Sancuso patch.
- Wrap-up comments

Opening Remarks

Lt Col Bacon indicated that Title 10 United States Code (U.S.C.) section 1074g requires the Secretary of Defense to establish a DOD Uniform Formulary (UF) of pharmaceutical agents, review the formulary on a periodic basis and make additional recommendations regarding the formulary as the Committee deems necessary and appropriate.

10 U.S.C. section 1074g (subparagraph d) also requires the Secretary to establish a UF Beneficiary Advisory Panel (BAP) to review and comment on the development of the UF. The Panel includes members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries. Comments of the Panel must be considered by the Director, TRICARE Management Activity (TMA) before implementing changes to the UF. The Panel's meetings are conducted in accordance with the Federal Advisory Committee Act (FACA).

The duties of the Uniform Formulary Beneficiary Advisory Panel are:

- To review and comment on the recommendations of the P&T Committee concerning the establishment of the UF and subsequent recommended changes. Comments to the Director, TMA, regarding recommended formulary status, pre-authorizations, and the effective dates for changing drugs from "formulary" to "non formulary" status must be considered by the Director before making a final decision.
- To hold quarterly meetings in an open forum. The Panel may not hold meetings except at the call of or with the advance approval of the Chairman of the Panel.
- To prepare minutes of the proceedings and prepare comments for the Secretary or his designee regarding the Uniform Formulary or changes to the Formulary. The minutes will be available on the website and comments will be prepared for the Director, TMA.

As guidance to the Panel regarding this meeting, Lt Col Bacon said the role of the BAP is to comment on the UF recommendations made by the P&T Committee at their last meeting. While the Department appreciates that the BAP may be interested in the drug classes selected for review, drugs recommended for the basic core formulary (BCF) or specific pricing data, these topics do not fall under the purview of the BAP.

The P&T Committee met for approximately 20 hours to consider the class review recommendations presented today. Since this meeting is considerably shorter, the Panel will not receive the same extensive information that is presented to the P&T Committee members. However, the BAP will receive an abbreviated version of each presentation and its discussion. The materials provided to the Panel are available on the TRICARE website.

Detailed minutes of this meeting are being prepared. The BAP minutes, the DOD P&T Committee meeting minutes and Ms. Embry's decisions will be available on the TRICARE website in approximately four – six weeks.

Lt Col Bacon next provided the ground rules for conducting the meeting:

- All discussions take place in the open public forum. There is to be no committee discussion outside the room, during breaks or at lunch.

- Audience participation is limited to private citizens who signed up to address the Panel.
- Members of the Pharmacoeconomic Center (PEC) and the P&T Committee are available to answer questions related to the BAP's deliberations. Should a misstatement be made, these individuals may interrupt to ensure that the minutes accurately reflect relevant facts, regulations or policy.

Lt Col Bacon then introduced the individual members and briefly reviewed housekeeping considerations pertaining to the meeting.

Private Citizen Comments

The DFO opened the meeting for private citizen comments. No individuals signed up in advance and there were no individuals present at the meeting who wished to address the Panel.

Chairperson's Opening Remarks

BAP Chair, Deborah Fryar, expressed the Panel's appreciation for the work done in preparation for today's meeting and thanked the individual Panel members for their continued dedication and commitment to the BAP process. She also thanked members of the audience for taking time to attend the meeting.

Presentation of Drug Class Reviews

LTC Spridgen, PEC Director, introduced the presentation of drug class reviews and recommendations from the May meeting of the P&T Committee.

BAP Script – 30 July 2009

(LTC Spridgen): I'm LTC Stacia Spridgen, the PEC Director. Joining me today from the PEC is Dave Meade, a Clinical Pharmacist, retired Air Force Lieutenant Colonel, and Director of Clinical Operations at the DoD Pharmacoeconomic Center. CDR Ellzy, the co-chair of the P&T Committee, will provide the physician perspective and comment on the recommendations made by the Committee.

The DoD Pharmacoeconomic Center (PEC) supports the DoD P&T Committee by conducting the relative (relative meaning in comparison to the other agents defined in the same class) clinical-effectiveness analyses and relative cost-effectiveness analyses of drug classes under review and consideration by the DoD P&T Committee for the Uniform Formulary (UF).

We are here to present an overview of the analyses presented to the DoD P&T Committee. 32 Code of Federal Regulation (C.F.R.) establishes procedures for inclusion of pharmaceutical agents on the Uniform Formulary based upon both relative clinical effectiveness and relative cost effectiveness. The goal of this presentation is not to

provide you with the same in-depth analyses presented to the DoD P&T Committee but a summary of the processes and analyses presented to the DoD P&T Committee. These include:

1) A brief overview of the relative clinical-effectiveness analyses considered by the DoD P&T Committee.
2) A brief general overview of the relative cost-effectiveness analyses. This overview will be general in nature since we are unable to disclose the actual costs used in the economic models. This overview will include the factors used to evaluate the costs of the agents in relation to the safety, effectiveness, and clinical outcomes.
3) The DoD P&T Committee's Uniform Formulary recommendation based upon its collective professional judgment when considering the analyses from both the relative clinical and relative cost-effectiveness evaluations of six newly approved drugs, Trilipix, Toviaz, Astepro, Kapidex, venlafaxine ER tablets, and the Sancuso patch.
4) The DoD P&T Committee's recommendation as to the effective date of the agents being changed from formulary tier to the non-formulary tier of the Uniform Formulary. Based on 32 C.F.R. 199.21, such change will not be longer than 180 days from the final decision date but may be less.

We've given you a handout which includes the Uniform Formulary recommendations for all the drugs discussed today; these are found on pages 2 through 10. There are tables and utilization figures for all the drug classes. We'll be using trade names as much as possible, so you can refer to your handout throughout the presentation.

Dr. Meade will now present the relative clinical and cost effectiveness evaluations for the six newly approved drugs.

ANTILIPIDEMIC-II AGENTS (LIP-2) – FENOFIBRATE ACID CAPSULES (TRILIPIX)

Dr. Meade presented the results if the P&T Committee's review of the newly-approved drug trilipix.

BAP Script – 30 July 2009

Relative Clinical Effectiveness

(Dave Meade) Background: 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, which was reviewed for Uniform Formulary (UF) placement in May 2007. The main differences between the various fenofibrate formulations are in the particle size of the individual components of the tablets or capsules, which allows the dose to be absorbed and last 24 hours.

Table 1 on page 2 of your handout shows Trilipix and the formulary status of the other LIP-2 drugs. Several fenofibrate products are on the UF. Trilipix is FDA-approved for use as monotherapy, and in combination with a statin (Zocor, Lipitor, Pravachol, etc) to lower triglycerides (TGs) and increase high density lipoprotein (HDL) cholesterol in patients with coronary heart disease or coronary heart disease risk equivalent to those who are receiving optimal statin therapy.

Utilization and Expenditures: Figure 1 on page 2 shows the utilization of the LIP-2 drugs. Tricor is the highest utilized LIP-2 drug in the MHS, but will soon be overtaken by Fenoglide. There have been about 4,000 unique users of Trilipix.

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, such as a reduction in myocardial infarction (heart attack) or death. 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.

Trilipix Relative Clinical Effectiveness Conclusion The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) that although 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, fenofibrate.

Relative Cost Effectiveness

(Dave Meade) In considering the relative cost-effectiveness of Trilipix, the P&T Committee evaluated the costs of Trilipix in relation to the efficacy, safety, tolerability, and clinical outcomes of the other agents in the class, specifically 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.

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.

Uniform Formulary Recommendation

(Dave Meade) 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).

Non-Formulary Justification

The P&T Committee recommended that Trilipix be classified as non formulary under the UF. The Committee's recommendation was based on the following:

1. Results of the clinical effectiveness evaluation did not support clinically significant differences between Trilipix and the other fenofibrate products. There are three fenofibrate formulations already available on the Uniform Formulary, Fenoglide, Triglide, and Lofibra. Although Trilipix is the only fenofibrate product specifically labeled for use with a statin drug, it is standard practice to use the other fenofibrate products with a statin.
2. Trilipix was not cost effective relative to those LIP-2 drugs already included on the Uniform Formulary.

Trilipix — Implementation Plan

(Dave Meade) The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 0 absent) 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.

P&T Committee Physician's Perspective

CDR Ellzy presented the BAP with a physician's perspective on the Committee's recommendations. He indicated that even though Trilipix is the only product in this drug class that FDA had approved for use with statins to raise high density lipoprotein (HDL) cholesterol and lower triglycerides (TGs), there was no evidence of a meaningful therapeutic advantage for that use over other fenofibrates already on the UF. As noted by the Committee, it is already standard practice to use fenofibrates in combination with a statin. That plus the drug's lack of relative cost effectiveness led the Committee to recommend non-formulary placement.

Beneficiary Advisory Panel Questions and Discussion

Ms. Cohoon asked why the drug's status as the only FDA-approved agent for use with statins wouldn't make it weigh more heavily in favor of formulary placement. Dave Meade answered that practitioners are already successfully using other fenofibrates in combination with statins even without the specific FDA labeling. Additionally, he indicated that three new combination products are already in the pipeline.

CDR Ellzy agreed that physicians are satisfied with the results obtained by using drugs currently on the formulary in combination with statins and see no need for a new product with no special clinical advantage.

Dr. Crum noted that the special labeling for this product was an unusual thing for FDA to do.

Ms. Fryar asked when Trilipx came on the market. Dr. Meade answered that it has been out quite a while and, even so, usage is low.

Panel Vote on Fenofibratre Acid Capsules (Trilipix)

Uniform Formulary Placement

The Panel Chair, Ms. Fryar, read the P&T Committee's 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 (13 for, 0 opposed, 0 abstained, 0 absent) fenofibrate acid capsules (Trilipix) be designated non-formulary on the UF.

Without further discussion, the BAP voted:

7 concur; 0 non-concur.

Implementation Plan

The chair read the implementation plan recommendations:

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 0 absent) 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

Without further discussion, the BAP voted:

7 concur; 0 non-concur.

OVERACTIVE BLADDER DRUGS – FESOTERODINE EXTENDED RELEASE TABLETS (TOVIAZ)

Dr. Meade also presented the results of the P&T Committee's review of the newly-approved drug Toviaz.

BAP Script – 30 July 2009

Relative Clinical Effectiveness

(Dave Meade) Background: If you turn back to Table 2 on page 3 of your handout, the next newly approved drug that the P&T Committee evaluated was fesoterodine extended release tablets, or Toviaz. Toviaz belongs to the overactive bladder drugs (or OAB) class, which was previously reviewed for UF placement in August 2008 and February 2006. After administration, Toviaz is converted to the same active metabolite as tolterodine (Detrol, Detrol LA). Toviaz tablets are FDA-approved for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and frequency, which are the same indications as the other OAB drugs.

Utilization and Expenditures: Figure 2 on page 3 of your handout shows the utilization of the OAB drugs. Detrol LA by far has the highest utilization in the MHS. Toviaz does not even show up on this graph. So far in the MHS, there have been 102 Toviaz unique utilizers.

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. In the clinical trials used to obtain FDA approval Toviaz caused statistically significant improvements in the endpoints of urinary frequency, urge urinary incontinence, and urinary urgency when compared to placebo. 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, which can lead to problems with the heart's rhythm and potential complications.

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

(Dave Meade) 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 OAB drugs.

Toviaz 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.

Uniform Formulary Recommendation

(Dave Meade) 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

Non-Formulary Justification

(Dave Meade): The P&T Committee recommended that Toviaz be classified as non-formulary under the UF. The Committee's recommendation was based was based on the following:

1. Toviaz is converted to the same active metabolite that is found in Detrol LA and Detrol. There are no head-to-head trials that directly compare the efficacy of Toviaz with the other OAB drugs. The Uniform Formulary currently includes all of the OAB drugs, with the exception of immediate release Detrol, and immediate release Sanctura (trospium).

2. Toviaz was not cost-effective relative to the other OAB drugs included on the UF.

Implementation Plan

(Dave Meade) The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) program and in the TRICARE Retail Network Pharmacy Program (TRRx), and at the MTFs no later than a 60-day implementation period. The implementation period will begin immediately following the approval by the Director, TMA.

P&T Committee Physician's Perspective

CDR Ellzy informed the Panel that there was general agreement among the Committee members that Toviaz did not offer significant advantages over the OAB drugs already available in terms of effectiveness, safety, and clinical outcomes and that the cost-effectiveness analysis didn't make it competitive.

Beneficiary Advisory Panel Questions and Discussion

The BAP asked no questions regarding the Committee's recommendations on this product.

Panel Vote on Festerodine Extended Release Tablets (Toviaz) Recommendations

Uniform Formulary Placement

Ms. Fryar, read the P&T Committee's 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 (13 for, 0 opposed, 0 abstained, 0 absent) that fesoterodine ER tablets (Toviaz) be designated non-formulary on the UF.

Without further discussion, the Panel voted on the recommendation as follows:

7 concur; 0 non-concur.

Implementation Plan

The Chair read the implementation plan recommendations:

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday following a 60-day implementation period in the

TRICARE Mail Order Pharmacy (TMOP) program and in the TRICARE Retail Network Pharmacy Program (TRRx), and at the MTFs no later than a 60-day implementation period. The implementation period will begin immediately following the approval by the Director, TMA.

Without further discussion, the Panel voted as follows:

7 concur; 0 non-concur.

NASAL ALLERGY DRUGS – AZELASTINE WITH SUCRALOSE NASAL SPRAY (ASTEPRO)

Dr. Meade next presented the P&T Committee's analysis and recommendations regarding the nasal allergy drug Astepro.

BAP Script – 30 July 2009

Relative Clinical Effectiveness

(Dr. Meade) Background: The third newly approved drug is the Astepro nasal spray. Astepro is a Nasal Allergy Drug (nasal antihistamine) that contains 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. The Nasal Allergy Drugs (NADs) were previously reviewed for UF placement in November 2008. Table 3 on page 4 shows the Nasal Allergy Drugs, which include the nasal antihistamine and nasal steroid sub-classess. For the nasal antihistamine subclass, Astelin is included on the Uniform Formulary, while Patanase is NF.

Utilization and Expenditures Figures 3 and 4 on page 5 of your handout show the utilization of the Nasal Allergy drugs. Since the nasal steroids are also in the Nasal Allergy drug (or NAD) class, and have utilization, Figure 4 only shows the nasal antihistamines. Astelin has the highest market share of the nasal antihistamines. There have been over 5,200 unique utilizers of Astelin in the MHS.

Astepro is FDA-approved for treating seasonal allergic rhinitis (SAR) in patients 12 years of age and older. Astelin is approved for SAR in patients $\geq$5 years, and has an additional indication to treat non-allergic rhinitis. One unpublished study reported statistically significant improvements in nasal congestion, rhinorrhea (runny nose), 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. The adverse events reported most frequently with Astepro are bitter taste and epistaxis (nose bleeds), which are the same adverse events reported with Astelin.

Relative Clinical Effectiveness Conclusion: The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) azelastine with sucralose nasal spray (Astepro) did 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

(Dave Meade) 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 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: The P&T Committee, based upon its collective professional judgment, voted (12 for, 0 opposed, 0 abstained, 1 absent) that Astepro is not cost effective relative to other UF nasal antihistamine agents in the NAD class.

Uniform Formulary Recommendation

(Dave Meade) 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.

Non-Formulary Justification

(Dave Meade): The P&T Committee recommended that Astepro be classified as non-formulary under the UF. The Committee's recommendation was based was based on the following:

1. Astepro contains the same active ingredient found in Astelin, azelastine. Patients taking Astelin frequently complain about the bitter taste. Although Astepro has the sucralose and sorbitol added to mask the taste, the incidence of bitter taste is about the same with Astepro and Astelin. Astelin has more FDA-approved indications than Astepro, and is approved for children as young as 5 years, while Astepro is approved in children 12 years of age and older.
2. Astepro was not cost-effective relative to the other nasal antihistamine already included on the UF (Astelin nasal spray).

Implementation Plan

(Dave Meade) 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.

P&T Committee Physician's Perspective

CDR Ellzy told the Panel that there was a little bit more discussion on this product. The cost was a little bit closer, so the Committee looked at the clinical effectiveness, particularly the improvement in the taste, which turned out not to be as significant as some had hoped. The one vote that was "opposed" resulted from a member returning from being absent on the previous vote.

BAP Questions and Discussion

Panel members had no questions of the presenters regarding this set of recommendations.

Panel Vote on Azelastine With Sucralose Nasal Spray (Astepro)

Uniform Formulary Placement

Ms. Fryar, read the P&T Committee's formulary recommendation:

In view of 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.

Without further discussion, the Panel voted as follows:

7 Concur; 0 Non-Concur.

Panel Vote on Astepro Implementation Plan

The Chair read the implementation plan recommendation:

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.

Without further discussion, the Panel voted as follows:

7 Concur; 0 Non-Concur.

PROTON PUMP INHIBITORS– DEXLANSOPRAZOLE DELAYED RELEASE CAPSULES (KAPIDEX)

Dr. Meade next presented the results of the Committee's consideration of Kapidex.

BAP Script – 30 July 2009

Relative Clinical Effectiveness

(Dr. Meade) Background: The fourth newly approved drug is the proton pump inhibitor (or PPI) dexlansoprazole (Kapidex). The PPIs were reviewed for UF placement in May 2007 and February 2005. Table 4 on page 6 of the handout shows the UF status of the PPIs. This class has an automated prior authorization (or Step therapy), requiring patients to try Nexium or generic Prilosec first, before receiving the other PPIs. Kapidex is a sustained-release formulation of the R-enantiomer of lansoprazole (Prevacid). Generic formulations of lansoprazole are anticipated in late 2009.

Utilization and Expenditures Figures 5 on page 6 of your handout shows the PPI utilization. Nexium and Prilosec have the highest utilization. There have been about 1,000 unique utilizers of Kapidex in the MHS.

Kapidex capsules are FDA-approved for use in adults for healing of erosive esophagitis, maintenance of healing of erosive esophagitis, and gastroesophageal reflux disease (GERD). 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 (13 for, 0 opposed, 0 abstained, 0 absent) 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

(Dave Meade) 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 (13 for, 0 opposed, 0 abstained, 0 absent) that Kapidex was not cost effective relative to other formulary PPI agents.

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, voted to recommend (13 for, 0 opposed, 0 abstained, 0 absent) that Kapidex be designated non-formulary on the UF.

Non-Formulary Justification

(Dave Meade The P&T Committee recommended that Kapidex be classified as non-formulary under the UF. The Committee's recommendation was based was based on the following:

1. Kapidex is the pure isomer form of Prevacid. Although Kapidex has delayed release capsules which allow for once daily dosing, Prevacid and the other PPIs are also dosed once daily. There are no studies available that directly compare Kapidex with another PPI. The one study that did evaluate Kapidex vs. Prevacid did not use equivalent doses. Prevacid is indicated for more uses by the FDA than Kapidex.
2. Kapidex was not cost-effective relative to generic Prilosec and Nexium.

Implementation Plan

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.

P&T Committee Physician's Perspective

CDR Ellzy said the Committee vote was based on the fact that the product didn't work better than those already available and it cost more.

BAP Questions and Discussion

Ms. Cohoon noted that this drug was released relatively recently – in February 2009 – and asked what the policy would be if tests are done that show that the drug is more effective. Dr. Meade answered that the Committee's experts would bring that matter before the Committee. Ms. Cohoon asked at what point this would happen, and Dr. Meade replied that it would depend on several factors.

Dr. Crum asked about the rationale for developing a new drug with no distinguishing features for a market that already has many products. Dr. Meade answered that it is a pretty lucrative market and that sometimes a PPI is the only product available.

Panel Vote on Dexlansoprazole Delayed Release Capsules (Kapidex)

Uniform Formulary Placement

Ms. Fryar, read the P&T Committee's formulary recommendation:

In view of 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, voted to recommend (13 for, 0 opposed, 0 abstained, 0 absent) that Kapidex be designated non-formulary on the UF.

With no further Panel discussion, the vote was taken. The result was:

7 Concur; 0 Non-Concur.

Implementation Plan

The Chair read the Committee's implementation plan recommendations:

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.

Without further discussion, the Panel voted as follows:

7 Concur; 0 Non-Concur.

ANTIDEPRESSANT-1 DRUGS–VENLAFAXINE EXTENDED RELEASE TABLETS

Dr. Meade presented the results of the Committee's consideration of venlafaxine extended release tablets (VERT).

BAP Script – 30 July 2009

Relative Clinical Effectiveness

(Dr. Meade) Background: Our next drug belongs to the Antidepressant-1 class (or AD-1). The Antidepressant-I (AD-1) drug class was reviewed for UF placement in November 2005. Venlafaxine ER tablets do not have a brand name. I'll refer to the new drug as "VERT" from now one, for simplicity sake. Table 5 on page 7 shows the UF status of the AD-1 drugs, which contains several subclasses of drugs. VERT is sub-classified as an SNRI, or selective norepinephrine reuptake inhibitor. The other SNRIs are Effexor immediate release tablets; Effexor XR extended release capsules, and Pristiq. Pristiq is the only non-formulary SNRI. The AD-1 class also includes the SSRIs (selective serotonin reuptake inhibitors); some popular SSRIs are Celexa, Prozac, and Zoloft.

Utilization and Expenditures: Page 8, Figure 6 has the AD-1 utilization. The VERT tablets barely show up on the bottom of the graph.

VERT contains the same active ingredient as Effexor XR capsule, but the FDA does not consider venlafaxine ER Tablets an AB-rated generic formulation of Effexor XR capsules. VERT 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. VERT has demonstrated bioequivalence with Effexor XR capsules in pharmacokinetic studies.

VERT is FDA-approved for treating Major Depressive Disorder and Social Anxiety Disorder; Effexor XR has additional indications. No clinical trials have been conducted with VERT, because only bioequivalence studies were needed for FDA approval, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. Adverse events with VERT 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

(Dave Meade) The P&T Committee evaluated the relative cost-effectiveness of VERT 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 VERT 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 VERT is higher than both SSRIs reviewed. The CMA also revealed VERT 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.

Uniform Formulary Recommendation

(Dave Meade) 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.

Non-Formulary Justification and Implementation Plan

(Dave Meade): These do not apply, as VERT is recommended to remain UF.

P&T Committee Physician's Perspective

CDR Ellzy commented on the vote opposing the clinical effectiveness recommendation. He said that one of the Committee's pharmacists based his vote on the fact that the FDA doesn't consider the product to be an AB-rated generic formulation of venlafaxine ER capsules and are not considered to be therapeutically interchangeable. The Committee was also influenced by the fact that the product is the most cost-effective agent in the AD-1 class and wanted to keep in on the formulary because of that.

BAP Questions and Discussion

Mr. Hutchings asked if the product would be designated as a generic. Dr. Meade said he thought it would be categorized as a brand-name drug.

Dr. Schlaifer asked if there is only one manufacturer for this drug. The answer was yes.

Panel Vote on venlafaxine Extended Release Tablets (VERT)

Uniform Formulary Placement

Ms. Fryar, read the P&T Committee's formulary recommendation:

In view of 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.

Without further discussion, the Panel voted as follows:

7 Concur; 0 Non-concur.

ANTIEMETICS – GRANISETRON TRANSDERMAL PATCH (SANCUSO)

Dr. Meade presented the results of the Committee's review of this newly-approved drug to the Beneficiary Advisory Panel.

BAP Script – 30 July 2009

Relative Clinical Effectiveness

(Dr. Meade) Background: The last newly approved drug is the antiemetic granisetron, which is formulated as a transdermal system or patch, under the brand name Sancuso. Table 6 on page 9 shows the UF decision for the antiemetics, which were last reviewed in May 2006. Sancuso is sub-classified as a newer antiemetic, along with Kytril, Zofran, and Emend. Sancuso is the only newer antiemetic available in a patch form. Granisetron, under the brand name Kytril, is also available in tablets, an oral solution, and intravenous formulation; these other granisetron formulations are now available as generics. All the different generic formulations of Kytril and Zofran are included on the UF.

Utilization and Expenditures Figure 7 on page 10 of your handout shows the utilization of the newer antiemetics. There have been 115 unique utilizers of Sancuso in the MHS.

Sancuso is FDA-approved for the prevention of nausea and vomiting in adult patients receiving moderately or highly emetogenic chemotherapy regimens (or those regimens with a very high risk of causing nausea and vomiting) lasting for ≤ 5 consecutive days. Other newer antiemetics (generic Kytril and Zofran) have indications in addition to chemotherapy-induced nausea and vomiting (CINV), such as nausea and vomiting caused by radiation therapy or following surgery with anesthesia.

In clinical studies, Sancuso has shown non-inferiority (but not superiority) to oral generic Kytril 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 newer antiemetics. There are no studies evaluating differences in the adverse events between Sancuso and other antiemetics, with the exception of generic oral Kytril.

Relative Clinical Effectiveness Conclusion: The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) 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..

Relative Cost-Effectiveness

(Dave Meade) 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 generic Zofran oral tablets and orally dissolving tablets, and generic Kytril oral 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 (13 for, 0 opposed, 0 abstained, 0 absent) that Sancuso is not cost effective relative to other antiemetic agents.

Uniform Formulary Recommendation

(Dave Meade) — 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.

Non-Formulary Justification

The P&T Committee recommended that Sancuso be classified as non-formulary under the UF. The Committee's recommendation was based was based on the following

1. Sancuso is the only antiemetic formulated as a patch. In clinical trials, Sancuso has not been shown to be superior to generic Kytril preventing CINV; it has not been compared to the other antiemetics.
2. Sancuso was not cost-effective relative to the other newer antiemetics already included on the UF.

Implementation Plan

(Dave Meade) 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.

P&T Committee Physician's Perspective

CDR Ellzy stated that. Clinically, it was difficult to locate the best place in patient therapy for this drug. Antiemetics are already available in oral and intravenous form. Although Sancuso is the only transdermal patch available, tests indicate that it takes twenty-four to forty-eight hours for the drug to take effect. This rules out taking the drug before additional chemotherapy. Additionally, there is no way to get it out of a patient's system quickly – it takes three to five days to clear. Agents with similar or equivalent effectiveness are already available on formulary.

BAP Questions and Discussion

Mr. Hutchings asked whether there was any discussion about using step therapy in connection with this drug. He acknowledged that patients can get it using the Medical Necessity procedure. Dr. Meade replied that there was no discussion of step therapy.

Ms. Cohoon asked about the scopolamine patch, which is already on formulary. Dr. Meade replied that it is available but is an older agent and is not likely to be used. Ms. Cohoon asked whether it wouldn't be a good idea to have at least one patch dosage available as an alternative to the oral dosage to follow-on from the drip.

Ms. Fryar also indicated that she believes it would be better to have a patch form of antiemetic available, even if step therapy is needed to be involved in administering it.

Panel Vote on Granisetron Transdwermal System (Sancuso)

Uniform Formulary Placement

Ms. Fryar, read the P&T Committee's formulary recommendation:

In view of 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.

The Beneficiary Advisory Panel vote on this recommendation was:

5 Concur; 2 Non-concur.

One Panel comment offered was that the agent, being the only patch dosage available, might help someone and shouldn't be placed on the third tier of the Formulary. Another was that the BAP believes that it is important to leave options open for beneficiaries.

Implementation Plan

The Chair read the implementation plan recommendations for Sancuso:

The P&T Committee recommends: 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.

Without further discussion, the Panel; voted on the recommendation with the following result:

5 Concur; 2 Non-concur.

The reasons given for non-concurrence were those offered regarding the vote on formulary placement: the agent should be readily available as an option where needed as it is the only product available in patch form. Also, if it has to be removed, that should be done quickly.

The Chair turned the meeting back to the DFO for closing remarks.

Closing Remarks

Lt Col Bacon thanked the Panel. He also thanked those in the audience who attend the Panel's meetings. He explained that the Panel was smaller than normal for this meeting and that the meeting had been delayed for a month because of changes in the appointment process for FACA Committees. New criteria have been adopted that require TMA to identify replacements for some Panel members. The hope is that the process will move quickly.

The next meeting is scheduled for September 24, 2009.

Lt Col Bacon adjourned the meeting at 11:20.

Brief Listing of Acronyms Used in This Summary

Abbreviated terms are spelled out in full in this summary; when they are first used, the acronym is listed in parentheses immediately following the term. All of the terms used as acronyms are listed below for easy reference. The term "Panel" in this summary refers to the "Uniform Formulary Beneficiary Advisory Panel," the group whose meeting is the subject of this report.

- AD-1 — Antidepressant-1 (a drug class)
- AE — Adverse event
- APR — Automated Profile Review
- BAP — Uniform Formulary Beneficiary Advisory Panel (the "Panel" referred to above)
- BCF — Basic Core Formulary
- BIA — Budget Impact Analysis
- BPA — Blanket Purchase Agreement
- CEA — Cost-effectiveness analysis
- CFC — Chlorofluorocarbon
- C.F.R — Code of Federal Regulations
- CINV — Chemotherapy-induced nausea and vomiting
- CMA — Cost-Minimization Analysis
- CR — Controlled Release (a drug formulation)
- DEA — U.S. Drug Enforcement Administration
- DFO — Designated Federal Officer
- DOD — Department of Defense
- ECF – Extended Core Formulary
- ER — Extended Release (a drug formulation)
- ESI — Express-Scripts, Inc.
- FACA — Federal Advisory Committee Act
- FCP — Federal Ceiling Price
- FDA — U.S. Food and Drug Administration
- HDL — High density lipoprotein
- HMO — Health Maintenance Organization
- IR — Immediate Release (a drug formulation)
- IV — Intravenous
- LIP-2 — Antilipidemic-II (a drug class)
- MHS — Military Health System
- MN — Medical Necessity
- MTF — Military Treatment Facility
- NAD — Nasal allergy drugs
- NF — Non-formulary
- NIH — National Institutes of Health

- NNH — Number Needed to Harm
- NNT — Number Needed to Treat
- OAB — Overactive Bladder (a drug class)
- OTC — Over the counter
- PA — Prior Authorization
- P&T Committee — DOD Pharmacy and Therapeutics Committee
- PDTS — Pharmacy Data Transaction Service
- PEC — DOD Pharmacoeconomic Center
- PPI — Proton pump inhibitor (a drug class)
- POS — Point of Service
- RCTs — Randomized Control Trials
- SAR — Seasonal allergic rhinitis
- SNRI — Selective norepinephrine reuptake inhibitor (a drug sub-class)
- SSRI — Selective serotonin reuptake inhibitor (a drug sub-class)
- TG — Triglycerides
- TMA — TRICARE Management Activity
- TMOP — TRICARE Mail Order Pharmacy
- TRRx — TRICARE Retail Pharmacy Program
- UF — DOD Uniform Formulary
- U.S.C. — United States Code
- VA — U.S. Department of Veterans Affairs
- VARR — Voluntary Agreement on Retail Rebates
- VERT — Venlafaxine Extended Release Tablets (a drug)