21 October 2009

Executive Summary

UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL COMMENTS
24 September 2009

The Uniform Formulary (UF) Beneficiary Advisory Panel (BAP) commented on the recommendations from the DoD Pharmacy & Therapeutics (P&T) Committee 12-13 August 2009 meeting.

1. **Phosphodiesterase Type 5 Inhibitors Drug Class:** 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 against, 0 abstain, and 0 absent that:

1. Vardenafil (Levitra) be classified as formulary on the UF.

2. Sildenafil (Viagra) and tadalafil (Cialis) be designated as non-formulary under the UF, based on cost effectiveness.

The P&T Committee recommended 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 Network Pharmacy Program (TRRx), and in the MTFs, no later than a 60-day implementation period; and 2) There were no changes to the current UF, no beneficiaries should be affected and no notification letters are required. The implementation period will begin immediately following approval by the Director, TMA.

Summary of Panel Vote/Comments:

- The Panel voted 6 Concur, 0 Non-Concur, regarding the recommendations for formulary and non-formulary agents.
- The Panel voted 6 Concur, 0 Non-Concur, regarding the recommended implementation period of 60 days.
- The Panel voted 6 Concur, 0 Non-Concur, regarding the prior authorization changes.
- The Panel asked to have comments included to clarify its view that Levitra is still intended mainly for patients over 50. Also, if possible, TMA should consider adding that use of nitroglycerine in the past six months should be a negative automated PA criterion.

Acting Director, TMA:

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

2. **Targeted Immunomodulator biologics – Golimumab (Simponi injection):** The P&T Committee recommended the following:

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the TIBs, and other relevant factors, the P&T Committee voted to recommend Simponi (golimumab injection) be designated as non-formulary under the UF, based on cost effectiveness.

The Committee's recommendation was based was based on the following

1. Simponi has fewer FDA-approved indications (3) than the UF TIB, Humira (7). There is less clinical efficacy and safety data available for Simponi than the other TIBs (Humira and Enbrel).

2. Simponi was not cost-effective relative to the other TIB already included on the UF (Humira).

The P&T Committee voted (12 for, 0 against, 0 abstain and 1 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.

Summary of Panel Vote/Comments:

- The Panel voted 6 Concur, 0 Non-Concur, regarding the recommendation non-formulary status.
- The Panel voted 6 Concur, 0 Non-Concur, regarding the recommended implementation period of 60days.
- The Panel voted 6 Concur, 0 Non-Concur, regarding the prior authorization criteria.
- Dr. Crum commented that these drugs can be delivered outside the pharmacy benefit and he wanted to bring to the attention of the TMA that today's action covers only a portion of the targeted immunobiologics.

Acting Director, TMA:

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

Ellen P. Embrey

3. **Targeted Immunomodulator Biologics – Certolizumamab (Cimzia Injection):** The P&T Committee recommended the following:

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the TIBs, and other relevant factors, the P&T Committee voted (12 for, 0 against, 0 abstain and 1 absent) to recommend Cimzia (certolizumab injection) be designated as non-formulary under the UF, based on cost effectiveness.

The Committee's recommendation was based was based on the following

1. Cimzia has fewer FDA-approved indications (3) than the UF TIB, Humira (7). There is less clinical efficacy and safety data available for Cimzia than the other TIBs (Humira and Enbrel).

2. Cimzia was not cost-effective relative to the other TIB already included on the UF (Humira).

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.

Summary of Panel Vote/Comments:

- The Panel voted 6 Concur, 0 Non-Concur, regarding the recommendation non-formulary status.
- The Panel voted 6 Concur, 0 Non-Concur, regarding the recommended implementation period of 60days.
- The Panel voted 6 Concur, 0 Non-Concur, regarding the prior authorization criteria.

Acting Director, TMA:

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

4. **Narcolepsy/Attention Defficit Hyperactivity Disorder (ADHD) – Armodafinil (Nuvigil):** 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 (12 for, 0 against, 0 abstain and 1 absent) to recommend that armodafinil tablets (Nuvigil) be designated formulary on the UF.

Nuvigil — Uniform Formulary Implementation Plan – does not apply

Summary of Panel Vote/Comments:

- The Panel voted 5 Concur, 1 Non-Concur, regarding the recommendations for formulary status.
- Dr. Crum added a comment that the release of a new drug just in advance of a generic formulation becoming available has the effect of increasing prices.
- The Panel voted 6 Concur, 0 Non-Concur, regarding the prior authorization criteria.

Acting Director, TMA:

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

5. **Alpha Blockers for Benign Prostatic Hyperplasia (BPH) – Silodosin capsules (Rapaflo):** 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 Rapaflo be designated non-formulary on the UF.

The Committee's recommendation was based was based on the following

1. There are no direct comparative trials between Rapaflo and either Flomax or Uroxatral. Based on indirect comparisons, the efficacy for Rapaflo shows similar changes in urinary flow rates and symptom scores. Also, generic formulations of Flomax are expected in 2010.

2. Rapaflo was not cost-effective relative to the other alpha blocker already included on the UF (Uroxatral).

The P&T Committee voted (13 for, 0 against, 0 abstain and 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.

Summary of Panel Vote/Comments:

- The Panel voted 6Concur, 0 Non-Concur, regarding the recommendations for non-formulary status.
- The Panel voted 6 Concur, 0 Non-Concur, regarding the recommended implementation period of 60days.
- The Panel voted 6 Concur, 0 Non-Concur, regarding the prior authorization criteria.

- Mr. Hutchings asked if the PA form could be changed to add the interactions with Uroxatral. He said he thinks that Flomax has an interaction notation on it, but that may be an old form. Whatever the case, this form should be consistent with the Flomax form.

Acting Director, TMA:

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

Ellen P. Embrey

6. **Prior authorization and Implementation Plan – Modafinil (Provigil):** The P&T Committee recommended the following:

As discussed earlier, Provigil and Nuvigil are very similar. New data published since the original Narcolepsy drug class review in November 2006 was evaluated to determine if the Provigil) PA required updating. The P&T Committee agreed that the evidence for using Provigil for sleepiness associated with Parkinson's disease was not supportable. There is new data for treating fatigue associated with traumatic brain injury (TBI) mentioned in a recent VA/DoD guideline, which was deemed supportable by the P&T Committee. The P&T Committee also recommended updating the criteria used for objectively diagnosing narcolepsy via polysomnogram or mean sleep latency testing (MSLT).

The P&T Committee recommended the following PA criteria should apply to Provigil. Coverage would be approved if a patient met any of the following criteria and would expire in one year. The P&T Committee also recommended an implementation date effective date of the first Wednesday one week after the minutes are signed. The implementation period will begin immediately following approval by the Director, TMA.

a) Narcolepsy associated with persistent and excessive daytime sleepiness as diagnosed by polysomnogram or MSLT objective testing;

b) Obstructive sleep apnea associated with persistent and excessive daytime sleepiness AND continuous positive airway pressure (CPAP) treatment adequately titrated and patient compliant with treatment;

c) Nightshift worker with diagnosis of shift work sleep disorder associated with excessive sleepiness;

d) Multiple sclerosis with excessive fatigue and secondary causes have been addressed;

e) Myotonic dystrophy associated with excessive fatigue;

f) A diagnosis of depression AND primary antidepressant therapy (defined as 4-6 week trial of at least one antidepressant agent) has failed AND the use of other stimulant augmentation (such as methylphenidate products) is contraindicated due to adverse effects, previous failure, or hypersensitivity;

g) Idiopathic hypersomnia diagnosed by a sleep specialist;

h) Fatigue associated with mild traumatic brain injury.

Summary of Panel Vote/Comments:

- The Panel voted 6 Concur, 0 Non-Concur, regarding the new prior authorization criteria.

Acting Director, TMA:

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

Ellen P. Embrey

7. **Implementation of Federal Ceiling Price Regulation:** The P&T Committee recommended the following:

The committee reviewed drugs that were not included on a Department of Defense Retail Refund Pricing Agreement; these drugs are not compliant with 32 C.F.R. 199.21(q)(2), part of the regulation implementing the FY2008 National Defense Authorization Act, Section 703. The regulation provides that if a drug is not covered by a pricing agreement to comply with Federal

Ceiling Prices, the drugs will generally be designated non-formulary (Tier 3) under the Uniform Formulary and will require a pre-authorization prior to use in the retail point of service. These drugs will remain available in the mail order point of service without pre-authorization. Drugs, with and without pricing agreements, were systematically classified based along therapeutic and pharmacologic lines. The classification system was based on the American Hospital Formulary System Classification and First Data Bank classification.

By the August P&T meeting, over 130 manufacturers had submitted executed pricing agreements representing over 94% (approximately 3000 NDCs) of the drugs subject to the Federal Ceiling Price legislation. Out of the 190 drugs reviewed, 169 were recommended by the Committee to move to Tier 3. Since the meeting, that number has decreased to 45. Of those 45, six were already on Tier 3 and 23 have multiple generics. That would result in 16 newly-designated Tier 3 drugs. Ten drugs were recommended to remain on Tier 2 (since the August meeting, that number has decreased to 6) and eleven drugs (now decreased to eight) were tabled for the November meeting pending Pricing Agreements. We anticipate that these numbers will change again as we receive amended/new pricing agreements. At the meeting, unless otherwise recommended by the Committee, all drugs that were on Tier 2 and covered by a pricing agreement were maintained on Tier 2. The Committee considered each drug carefully with the goal of minimizing the impact on beneficiary care. The Committee considered many factors in its recommendations. These included whether a drug was considered "one-of-a-kind", whether there were other brand name products in the same drug class, and whether multiple generics were available in the class. From these considerations, the Committee's rationale was to move drugs to non-formulary (Tier 3) status only if the committee knew there were appropriate therapeutic substitutions within that drug class. Those without appropriate therapeutic substitutes were not

moved and those that the Committee needed additional information on were deferred to the November meeting. Also, the Committee recommended that any drug manufacturer that signs a pricing agreement before 14 October would not have their drug(s) moved to non-formulary (Tier 3). If their drug(s) were already in Tier 3, they would remain as Tier 3 but without an additional pre-authorization. The updated list of drugs is listed in the addendum which was provided as a handout and will be posted on the BAP website. The three (3) lists of drugs that were reviewed are as follows:

A. Drugs that were not on a pricing agreement but should remain on formulary status.
B. Drugs that should be designated or retain the designation of non-formulary on the UF.
C. Drugs that would require re-evaluation at the November meeting.

Information will be provided at the November DoD P&T Committee meeting.

A. The implementation date will not be prior to 1 January 2010 and not later than 180 days after the minutes of this meeting are signed by the Director, TMA.

B. Formulary status of a drug recommended to move from Tier 2 to Tier 3 will stay in Tier 2 if a Price Agreement is received prior to October 14, 2009.

C. Recommend a transition period at MTFs to treat drugs recommended to move from Tier 2 to Tier 3 as if they were still on Tier 2 for purposes of MTF availability until 1 January 2011.

The following drugs, though not on a pricing agreement, should retain their formulary designation on the UF**Corrected Handout Recommendations for Implementation of Federal Ceiling Price Regulation which was voted on by BAP. This list is from August 2009 P&T Committee Meeting.

VANCOCIN HCL	DERMA-SMOOTHE-FS	PANRETIN
ACTIMMUNE	DERMOTIC	RADIOGARDASE
APOKYN	STROMECTOL	
INTAL	THIOLA	

The following drugs should be designated or retain the designation of non-formulary on the UF:

MIRAPEX	SORIATANE CK	EVOXAC
WELCHOL	DAYTRANA	CUTIVATE
LIALDA	FOSRENOL	CYTOMEL
PENTASA	ATROVENT HFA	SAIZEN
ESTRACE	METANX	TRANSDERM-SCOP
MUSE	BREVOXYL-8	PAMINE FQ
EMSAM	NIRAVAM	LACTINOL-E
ENDOMETRIN	CORDRAN	DECLOMYCIN
VIRAMUNE	NEOBENZ MICRO	OBSTETRIX EC
ZONEGRAN	HALOG	LAC-HYDRIN
SEROSTIM	BREVOXL-4	TAPAZOLE

TRANSDERM-SCOP
DYRENIUM
BUPHENYL
INTELENCE
ELIGARD
QUIXIN
CERTROTIDE
RIOMET
APTIVUS
LUVERIS
OXSORALEN
THALITONE
PLETAL
ZAROXOLYN
EURAX
SULFAMYLON
K-PHOS NO. 2
LITHOSTAT
DEGARELIX
ZORBTIVE
ACIPHEX
FLOMAX
PROCRIT
VYVANSE
KADIAN
AZOR
CARBATROL
KAPIDEX
OXISTAT
POTASSIUM CHLORIDE
KDUR
P-TEX
LEVULAN
CYTOXAN
SEDAPAP
HYCODAN
DYNEX 12
DYNEX VR
ANAPROX
SEPTRA
LIMBITROL
MINOCIN
LOCOID
WESTCORT
CHROMAGEN
ATROVENT
MS CONTIN
POLY-TUSSIN DHC
PRECARE PREMIER
CORTISPORIN
CORGARD
ULTRAVATE PAC
TRETIN-X
CHROMAGEN FORTE
ALA-HIST D
PREFERA-OB
AGRYLIN
ALTACE
RESPA A.R.
DEPAKENE
POLY HIST FORTE
PRECARE
EXELDERM
PERCODAN
CATAPRES
ALA-HIST
TENEX
SALAGEN
MOBIC
POLY TAN DM
MICRO-K
PHOSLO
HEMATRON-AF
FLOXIN
GESTICARE
ELESTRIN
VALIUM
KINERET
FIORICET
DERMA-SMOOTHE-FS
SONATA
KENALOG
KLONOPIN
TESTRED
GYNAZOLE-1
CADUET
ANDROID
DIBENZYLINE
VESANOID
TINDAMAX
K-PHOS ORIGINAL
PERSANTINE
TIGAN
TEMOVATE EMOLLIENT
NUZON
PAMINE
LACTINOL
KAON-CL 10
TEMOVATE
OMNICEF
VIROPTIC
HEMATRON
KYTRIL
SEPTRA DS
ELDEPRYL
ANAPROX DS
MYAMBUTOL
POLY HIST PD
NOVASTART
CORTISPORIN
CARNITOR SF
PAMINE FORTE
SILVADENE
ACLOVATE
DYNEX LA
FLEXERIL
BROVEX
PEDIAPRED
BROVEX SR
BROVEX-D
BROVEX CT
PROAMATINE
RESPA-BR
PREMESIS RX
NIFEREX GOLD
POLY TAN D
PRECARE CONCEIVE PCE
OXANDRIN
CARNITOR
DIPENTUM
ULTRAVATE
RHEUMATREX
MONODOX
POLY-TUSSIN DM
POLY HIST DM
NIFEREX-150 FORTE

The following drugs require more information prior to determination of a formulary status:

REBIF	SYNTHROID	
VOLTAREN	GONAL-F	UROCIT-K
ROZEREM	FARESTON	PAREMYD
GONAL-F RFF	GLUCAGEN	ARESTIN

The implementation date will not be prior to January 2010 and not later than 180 days after the minutes of this meeting are signed by the Director, TMA.

Formulary status of a drug recommended to move from Tier 2 to Tier 3 will stay in Tier 2 if a Price Agreement is received prior to October 14, 2009.

Recommend a transition period at MTFs to treat drugs recommended to move from Tier 2 to Tier 3 as if they were still on Tier 2 for purposes of MTF availability until 1 January 2011.

Summary of Panel Vote/Comments:

- The Panel voted 6 Concur, 0 Non-Concur, regarding formulary and non-formulary agents.
- The Panel voted 6 Concur, 0 Non-Concur, regarding drugs requiring more information before determining formulary status.
- The Panel voted 6 Concur, 0 Non-Concur, regarding the implementation date of not being prior to January 2010 and not later than 180 days after the minutes being signed.
- The Panel voted 6 Concur, 0 Non-Concur, (but was not announced) regarding the formulary status of a drug recommended to move from Tier 2 to Tier 3 staying in Tier 2 if a pricing agreement is received prior to October 14, 2009.
- The Panel voted 6 Concur, 0 Non-Concur, regarding a transition period at the MTFs.

Acting Director, TMA:

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

Ellen P. Embrey

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
September 24, 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
- 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 8:15 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 August 12 and 13, 2009 in San Antonio, TX.

Agenda

The agenda for this meeting of the Panel is:

- Welcome and opening remarks
- Public citizen comments
- Review and discussion of P&T Committee recommendations for the following:
  - Phosphodiesterase Type 5 Inhibitors (PDE-5) for Erectile Dysfunction (ED)
  - Designated Newly-Approved Drugs
    - Targeted Immunomodulatory Biologics (TIBs) – Simponi (golimumab)
    - Targeted Immunomodulatory Biologics (TIBs) – Cimzia (certolizumab)
    - Narcolepsy Drug Class Nasal Allergy Drugs – Nuvigil (armodafinil)
    - Alpha-1 Blocker BPH Agents – Rapaflo (silodosin)
  - Changes in Prior Authorization for Provigil (modafinil)
- Formulary status of drugs not in compliance with 32 CFR 199.21(q)(2) (implementing 2008 NDAA Section 703)
- Wrap-up comments

Opening Remarks

Lt Col Bacon began by indicating that Title 10 United States Code (U.S.C.) section 1074g subsection b requires the Secretary of Defense to establish a DOD Uniform Formulary (UF) of pharmaceutical agents, and establishes the P&T Committee to 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 subsection c 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 establishing the UF or 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 reviewed 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. She then turned the meeting over to LTC Spridgen, the PEC Director, to introduce the drug class review presentations.

DRUG CLASS REVIEW PRESENTATIONS

[PEC Script]

(LTC Spridgen): I'm LTC Stacia Spridgen, the PEC Director. Joining me today from the PEC are LCDR Marisol Martinez, who is the Public Health Service clinical pharmacist, and 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 one Uniform Formulary drug class – the Phosphodiesterase Type-5 Inhibitors for erectile dysfunction; four newly approved drugs, Simponi injection, Cimzia injection, Rapaflo and Nuvigil; and a prior authorization update for Provigil.

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, including the Federal Price Ceiling (FCP); these are found on pages 2 through 5. 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.

LCDR Martinez will now start with the relative clinical effectiveness evaluations for the drugs reviewed by the DoD P&T Committee.

I. PHOSPHODIESTERASE TYPE-5 INHIBITORS

RELATIVE CLINICAL EFFECTIVENESS

(LCDR Martinez:)

The P&T Committee evaluated the clinical effectiveness of the Phosphodiesterase Type-5 inhibitors for the treatment of ED, which I'll call the PDE-5s. The drug class was previously reviewed for UF placement in May 2005. Please turn to page 2 of the handout, where you'll see the table of the PDE-5s. The class is comprised of two subclasses, three drugs for erectile dysfunction (ED), which include sildenafil (Viagra), tadalafil (Cialis), and vardenafil (Levitra); and two drugs for pulmonary artery hypertension (PAH): sildenafil (Revatio) and tadalafil (Adcirca). The PDE-5s are also used off-label for a variety of uses.

Figure 1 on page 2 of the handout shows that for all three points of service, Military Treatment Facility (MTF), the TRICARE Mail Order Pharmacy (TMOP) and the TRICARE Retail Network Pharmacy Program (TRRx), Levitra has the highest utilization, followed by Viagra and then Cialis.

Information regarding the safety, effectiveness, and clinical outcomes of the PDE-5s for ED subclass was considered. The clinical review included, but was not limited to, the requirements stated in the UF Rule, 32 CFR 199.21(e)(1).

Relative Clinical Effectiveness Conclusion — The P&T Committee recommended the following clinical effectiveness conclusions regarding PDE-5 inhibitors:

With regard to efficacy, the following conclusions were made:

1. For ED:

    a) There is insufficient evidence to conclude that there are clinically relevant differences in efficacy of PDE-5 inhibitors for ED. There are no head-to head trials comparing the three PDE-5 inhibitors. Although all three PDE-5s are clinically superior to placebo, the variability in study design, demographics, and outcome measures prohibits us from saying that one is clinically superior to the others.

    b) Based on meta-analyses by Agency for Healthcare Research and Quality, the Cochrane reviewers, and BioMed Central, indirect comparisons suggest that there are similar improvements between the three PDE-5 inhibitors in the accepted endpoints for measuring ED. These endpoints are the International Index of Erectile Function (IIEF) domain change score for erectile function; the percentage of patients responding "yes" on the Global Assessment Questionnaire, question one; the percentage of patients with improved erections; and numbers needed to treat for these endpoints.

    c) One Cochrane analysis found that PDE-5 inhibitors improve erections in diabetic patients.

    d) There is insufficient evidence to conclude that daily therapy for ED is superior to on demand therapy.

2. For Pulmonary Arterial Hypertension (or PAH): Sildenafil (under the trade name Revatio), and tadalafil (under the trade name Adcirca) both are approved by the FDA for treating PAH.

3. For preservation/restoration of erectile function after prostatectomy: The P&T Committee agreed that the evidence, based on positive results from published clinical trials, was supportable for daily use of the PDE-5 inhibitors for this off-label indication.

4. For Raynaud's Phenomenon: Although results are conflicting and larger, longer-term trials are needed, benefits have been shown with daily use of PDE-5 inhibitors in terms of improvements in blood flow in the fingers of patients with Raynaud's disease. The P&T Committee agreed that this was a supportable off-label use.

5. For other off-label uses: The P&T Committee agreed that the current published literature is insufficient to support use of PDE-5 inhibitors for the following conditions: female sexual dysfunction, hypertension, esophageal motility disorders, ocular blood flow disorders, Eisenmenger's Syndrome, premature ejaculation, recurrent ischemic priapism, and lower urinary tract symptoms due to benign prostatic hypertrophy (BPH).

6. With regards to safety and tolerability, the P&T Committee agreed that there is insufficient evidence to conclude that there are clinically relevant differences in safety between PDE-5s for ED. The product labeling for the three drugs is similar with regard to contraindications, precautions, and warnings.

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

PHOSPHODIESTERASE TYPE-5 INHIBITORS - RELATIVE COST EFFECTIVENESS

(Dave Meade): Results from the CMA of PDE-5s for ED agents revealed that vardenafil (Levitra) was the most cost effective PDE-5 agent. The potential impact of scenarios with selected PDE-5 was evaluated with a budget impact analysis (BIA). Results from the BIA of PDE-5s for ED revealed that placing vardenafil (Levitra) on the UF in conjunction with a PA requiring a trial of Levitra for new patients was the most cost effective scenario overall. Lowering the age limit for automatic PA approval of the treatment of typical organic erectile dysfunction in males from 50 to 40 years old would add about 3.7% to the cost of each scenario reviewed.

COMMITTEE ACTION: The P&T Committee voted to accept the cost effectiveness conclusion stated above. The vote was 12 for, 0 against, 0 abstain and 1 absent.

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 against, 0 abstain, and 0 absent that:

1. Vardenafil (Levitra) be classified as formulary on the UF.

2. Sildenafil (Viagra) and tadalafil (Cialis) be designated as non-formulary under the UF, based on cost effectiveness.

PDE-5s- NF JUSTIFICATION

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

1. For ED, there are no direct comparative trials between the three PDE-5s. Indirect comparisons show no major differences in efficacy. For the off-label uses, there is no data to directly compare the efficacy of the PDE-5s.

2. Cialis and Viagra were not cost-effective relative to the other PDE-5s already included on the UF, Levitra.

UNIFORM FORMULARY IMPLEMENTATION PLAN

(Dave Meade) The P&T Committee recommended 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 Network Pharmacy Program (TRRx), and in the MTFs, no later than a 60-day implementation period; and 2) There were no changes to the current UF, no beneficiaries should be affected and no notification letters are required. The implementation period will begin immediately following approval by the Director, TMA.

PRIOR AUTHORIZATION CRITERIA AND IMPLEMENTATION PLAN

(Dave Meade) The P&T Committee recommended following PA criteria should apply to PDE-5 inhibitors other than vardenafil (Levitra). Coverage would be approved if a patient met any of the following criteria, and would expire in one year. The PA implementation would be timed to coincide with the UF implementation:

1. Automated PA criteria:

   a) The patient has received a prescription for Viagra, Cialis, or Levitra at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

   b) The patient is a male, aged 40 years or older.

2. PA if automated criteria are not met:

   a) The patient has tried Levitra and has had an inadequate response or was unable to tolerate treatment due to adverse effects.

   b) Treatment with Levitra is contraindicated.

   c) Sildenafil (Viagra or Revatio) or tadalafil (Cialis or Adcirca) is for treatment of Pulmonary Artery Hypertension (PAH).

   d) Use is for preservation/restoration of erectile function after prostatectomy.

   e) Use is for Raynaud's Phenomenon.

(Dave Meade) : CDR Ellzy will now give the physician perspective for the PDE-5s

PHOSPHODIESTERASE TYPE-5 INHIBITORS COMMITTEE PHYSICIAN PERSPECTIVE

(CDR Ellzy)

CDR Ellzy said this was an interesting class to go over, not because of the formulary decisions but because of there are a lot of off-label indications for the medications and what the automated PA criteria were. When the Committee looked at the differences in the drugs themselves, it didn't find a lot of updated information that would require changes to what was and wasn't on the UF. What did change was the indications, particularly the preservation or restoration of erectile function after prostatectomy. There had previously not been enough evidence to support that use when the class was last looked at in 2005. More studies and more information since then convinced the Committee to add that as one of the criteria to be included in the prior authorization. Additionally, the PA was changed to include treatment for Raynaud's Phenomenon. The age limit for an automated PA was also lowered to 40 based on private-sector information and studies concerning who was being treated for erectile dysfunction these days as well as a survey of DoD physicians.

BAP QUESTIONS AND DISCUSSION: PHOSPHODIESTERASE TYPE-5 (PDE-5) INHIBITORS

Ms. Fryar asked for an explanation of a figure included in Table 7 of the handout, specifically the entry "14,524 new users that will hit step" in the column headed "Total Beneficiaries Affected." She asked if that is the number looked at the first time the class was reviewed or something else. Dr. Meade replied that the number represents Prior Authorizations since the first review in 2005.

Ms. Legette noted that page 3 of the background information states that lowering the age limit will add 3.7 percent to the cost and asked why. Dr. Ellzy said that the cost is the increased paperwork and noted that the patients are all getting the drug now because they need it. However, the automated PA will add another step to the process that the pharmacist has to go through.

Ms. LeGette also said that the criteria raise a source of confusion as to whether what is required, a PA or step therapy. Her concern is how to implement the PA criteria operationally. Dr. Meade said that for drugs other than Levitra, step therapy is being implemented. But the PA criteria apply to all three drugs, including Levitra. Mr. Hutchings agreed with Ms. LeGette that criteria (a) and (b) were more like "medical necessity" than PA or step therapy.

Mr. Hutchings asked about criterion "c" -- preservation or restoration of erectile function after prostatectomy. His question was whether we really want and need to include this criterion and whether a one-year PA is the right time period. He agreed that there should be coverage for the condition, but expressed concern about specifying a particular drug. Dr. Meade stressed that the PA is just for erectile dysfunction associated with the prostatectomy.

Mr. Hutchings also asked a question about the wording on the PA form and whether it now needs to be changed. He sees the potential for some unsafe drug interactions for people on nitroglycerine using an ED agent unless a PA is included with step therapy. Mr. Hutchings said that his company does see approved PA forms for people already on nitro -- they do slip through. The system relies on the pharmacist to catch things that might not be in the best interest of the patients and this doesn't always happen. Dr. Schlaifer noted that she, too, isn't clear about what you can and can't do if a patient is on nitroglycerine. She also asked if a beneficiary can challenge a decision not to allow such a prescription. The answer given was that the patient cannot challenge such a decision and Dr. Meade agreed to take another look at the forms.

Dr. Crum asked about people already using Viagra and Cialis shown on Figure 1 of the handout. Dr. Meade said the drugs are already non-formulary, so anyone using them has already gone through one of the processes required to get them and this won't require any changes for them.

BAP VOTE ON FORMULARY RECOMMENDATIONS FOR THE PHOSPHODIESTERASE TYPE-5 (PDE-5) INHIBITORS DRUG CLASS

Ms. Fryar asked the Panel for any further discussion of the recommendations in this drug class. As there was no further discussion, the Chair read the P&T Committee's formulary recommendation for the PDE-5 drug class:
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 that Sildenafil (Viagra) and tadalafil (Cialis) be designated as non-formulary under the UF, based on cost effectiveness.

The BAP vote was:

6 concur, 0 non-concur.

BAP VOTE ON THE IMPLEMENTATION PLAN FOR THE PHOSPHODIESTERASE TYPE-5 (PDE-5) INHIBITORS DRUG CLASS

The Chair read the P&T Committee's implementation plan recommendation:
The P&T Committee voted to recommend 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 Network Pharmacy Program (TRRx), and in the MTFs, no later than a 60-day implementation period. The implementation period will begin immediately following approval by the Director, TMA.

There was no further Panel discussion of this recommendation.

The Panel vote was:

6 concur, 0 non-concur.

BAP VOTE ON PRIOR AUTHORIZATION CRITERIA AND IMPLEMENTATION PLAN FOR THE PHOSPHODIESTERASE TYPE-5 (PDE-5) INHIBITORS DRUG CLASS

Ms. Fryar next read the P&T Committee's PA criteria recommendations for this drug class: The P&T Committee recommended following PA criteria should apply to PDE-5 inhibitors other than vardenafil (Levitra). Coverage would be approved if a patient met any of the following criteria, and would expire in one year. The PA implementation would be timed to coincide with the UF implementation:

1. Automated PA criteria:

   a) The patient has received a prescription for Viagra, Cialis, or Levitra at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

   b) The patient is a male, aged 40 years or older.

2. PA if automated criteria are not met:

   a) The patient has tried Levitra and has had an inadequate response or was unable to tolerate treatment due to adverse effects.

   b) Treatment with Levitra is contraindicated.

   c) Sildenafil (Viagra or Revatio) or tadalafil (Cialis or Adcirca) is for treatment of Pulmonary Artery Hypertension (PAH).

   d) Use is for preservation/restoration of erectile function after prostatectomy.

e) Use is for Raynaud's Phenomenon.

Discussion by the Panel, including Ms. Buchta and Mr. Hutchings, favored adding a comment to the vote to reflect the Panel's concerns about the PA forms.

The Panel vote was:

6 concur; 0 non-concur.

PANEL COMMENTS

The Panel asked to have comments included to clarify its view that Levitra is still intended mainly for patients over 50. Also, if possible, TMA should consider adding that use of nitroglycerine in the past six months should be a negative automated PA criterion.

II. REVIEW OF NEWLY APPROVED DRUGS

Ms. Fryar introduced the next agenda item: the review of newly approved drugs.

1) TARGETED IMMUNOMODULATOR BIOLOGICS– GOLIMUMAB (SIMPONI INJECTION)

[BAP Script]

SIMPONI — RELATIVE CLINICAL EFFECTIVENESS

(LCDR Martinez): Now we will discuss our first newly approved drug.

Golimumab injection (Simponi) is a tumor necrosis factor alpha (TNFα) inhibitor. Simponi is classified in the Targeted Immunomodulatory Biologic, or TIB, drug class, which was reviewed for UF placement in November 2007. The TIBs are shown on Table 2, on page 3 of your handout. Please note that the Raptiva product was voluntarily withdrawn from the market by the manufacturer in June 2009.

Figure 2 on page 3 of the handout shows the utilization of the TIBs. As of Oct 2008, Humira has surpassed Enbrel as being the highest utilized TIB in at all three points of service. There were only 240 Rxs dispensed for Simponi in the MHS, so utilization does not show up on the graph.

Simponi is administered subcutaneously (SQ) once a month. It is FDA-approved for the treatment of moderate to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX), moderate to severely active psoriatic arthritis (PsA) alone or in combination with MTX, and active ankylosing spondylitis (AS) in adults. The other injectable TNFα inhibitors with multiple FDA-approved indications include Humira, Enbrel, and Cimzia.

There is insufficient evidence to determine whether treatment with Simponi would result in greater clinical response than other TNF inhibitors. The safety profile of Simponi reflects that of the other anti-TNF agents currently on the market.

An analysis of Enbrel and Humira by the Pharmacy Outcomes Research Team reported that clinical coverage in the TIB class appears adequate overall. Relatively few patients (17%) switch between Enbrel and Humira in approximately the first 3 years of treatment; and only about 5% discontinue treatment after trying both.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded that although Simponi requires less frequent administration than the other multi-indication TIBs, it did not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other TIBs currently included on the UF.

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

SIMPONI — RELATIVE COST EFFECTIVENESS

(Dave Meade) The P&T Committee evaluated the costs of Simponi in relation to the efficacy, safety, tolerability, and clinical outcomes of the TIBs 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).

Relative Cost-Effectiveness Conclusion: Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded Simponi (golimumab) was not cost-effective compared to other agents currently on the UF. Results of the CMA confirmed that Humira (adalimumab) remains the most cost-effective TIB agent available on the UF.

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

SIMPONI —UNIFORM FORMULARY RECOMMENDATION

(Dave Meade) In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the TIBs, and other relevant factors, the P&T Committee voted to recommend Simponi (golimumab injection) be designated as non-formulary under the UF, based on cost effectiveness.

SIMPONI — NF JUSTIFICATION

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

1. Simponi has fewer FDA-approved indications (3) than the UF TIB, Humira (7). There is less clinical efficacy and safety data available for Simponi than the other TIBs (Humira and Enbrel).

2. Simponi was not cost-effective relative to the other TIB already included on the UF (Humira).

SIMPONI — UNIFORM FORMULARY IMPLEMENTATION PLAN

(Dave Meade) The P&T Committee voted (12 for, 0 against, 0 abstain and 1 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.

SIMPONI — PRIOR AUTHORIZATION CRITERIA AND IMPLEMENTATION PLAN

(Dave Meade) Currently PA requirements apply to etanercept (Enbrel), adalimumab (Humira) and the other TIBs. The P&T Committee agreed that the following PA criteria should apply to golimumab injection, consistent with the FDA-approved labeling and PA requirements for the other TIBs. The implementation plan would be timed to coincide with the UF implementation plan.

1. Coverage would be approved for the treatment of adult patients with moderate to severely active RA in combination with MTX, moderate to severely active PsA alone or in combination with MTX, and active AS in adults.

2. Coverage would not be provided for concomitant use with abatacept (Orencia), adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), infliximab (Remicade), or rituximab (Rituxan).

(Dave Meade): CDR Ellzy will now give the physician perspective for Simponi.

SIMPONI — COMMITTEE PHYSICIAN PERSPECTIVE

CDR Ellzy said the Committee was satisfied that patient needs were being met with the preferred agent Humira and the backup agent Enbrel as evidenced by the fact that only 17% switch between Enbrel and Humira in the first 3 years of treatment and only about 5% discontinue treatment after trying both. Lacking evidence of either a clinical or a cost-effectiveness advantage, the Committee saw no reason to add another agent to the UF.

BAP QUESTIONS AND DISCUSSION: SIMPONI

Mr. Hutchings asked whether patients now on Simponi would need prior authorization. He also asked what the rationale is for having or not having a step therapy procedure in general and, specifically, why the decision was made not to use step in the case of Simponi. Mr. Hutchings said he likes the idea of a PA and finds the PA form useful for letting non-MTF physicians know what the preferred agent is, which can often lead them to change to Humira. CDR Ellzy's reply was that the decision was based on the fact that the Committee was just dealing with the one new drug, not the whole class. When the whole class is reviewed, step therapy will be considered.

BAP VOTE ON UNIFORM FORMULARY RECOMMENDATION — TARGETED IMMUNOMODULATOR BIOLOGICS– GOLIMUMAB (SIMPONI INJECTION)

The Chair read the P&T Committee's uniform formulary recommendation for Simponi:

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the TIBs, and other relevant factors, the P&T Committee voted to recommend Simponi (golimumab injection) be designated as non-formulary under the UF, based on cost effectiveness.

Without further discussion, the BAP voted:

6 concur, 0 non-concur.

BAP VOTE ON IMPLEMENTATION PLAN RECOMMENDATION — TARGETED IMMUNOMODULATOR BIOLOGICS– GOLIMUMAB (SIMPONI INJECTION)

Ms. Fryar next read the implementation plan for Simponi:

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.

There was no further discussion, and the Panel vote was:

6 concur; 0 non-concur.

BAP VOTE ON PRIOR AUTHORIZATION CRITERIA — TARGETED IMMUNOMODULATOR BIOLOGICS– GOLIMUMAB (SIMPONI INJECTION)

The Chair then read the Prior Authorization criteria for Simponi:

The P&T Committee agreed that the following prior authorization criteria should apply to golimumab injection, consistent with the FDA-approved labeling and PA requirements for the other TIBs. The implementation plan would be timed to coincide with the UF implementation plan.

1. Coverage would be approved for the treatment of adult patients with moderate to severely active RA in combination with MTX, moderate to severely active PsA alone or in combination with MTX, and active AS in adults.

2. Coverage would not be provided for concomitant use with abatacept (Orencia),adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), infliximab (Remicade), or rituximab (Rituxan).

Without further discussion, the Panel voted:

6 concur; 0 non-concur.

Dr. Crum commented that these drugs can be delivered outside the pharmacy benefit and he wanted to bring to the attention of the TMA that today's action covers only a portion of the targeted immunobiologics.

Ms. Fryar then called for the presentation on Cimzia.

2. TARGETED IMMUNOMODULATOR BIOLOGICS - CERTOLIZUMUMAB (CIMZIA INJECTION)

CIMZIA — RELATIVE CLINICAL EFFECTIVENESS

[BAP Script]

(LCDR Martinez) The second new drug we have to discuss is also a TIB, certolizumab, or Cimzia. As of last week there were 188 Rxs for Cimzia dispensed at all three points of service.

Cimzia is a TNFα inhibitor that is conjugated to polyethylene glycol, or PEG, which increases the duration of action. Cimzia is available as a lyophilized powder for reconstitution and a solution for SQ injection. It is dosed once monthly for Crohn's disease and every two weeks for RA, but has the option of once monthly dosing. Cimzia is FDA-approved for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients. It is also approved for the treatment of moderate to severely active RA in adults.

There is insufficient evidence to determine whether Cimzia would result in greater response than the other TIBs. Adding PEG did not add benefits in either the efficacy or toxicity profile. The safety profile of Cimzia in general is similar to that of the other TNF α inhibitors.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded that although Cimzia has the potential for less frequent administration than Humira and Enbrel, it did not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other TIBs currently included on the UF.

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

CIMZIA — RELATIVE COST EFFECTIVENESS

(Dave Meade) The P&T Committee evaluated the costs of Cimzia in relation to the efficacy, safety, tolerability, and clinical outcomes of the TIBs 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).

Relative Cost-Effectiveness Conclusion: Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded that Cimzia (certolizumab) was not cost-effective compared to other agents currently on the UF. Results of the CMA confirmed that Humira (adalimumab) remains the most cost-effective TIB agent available on the UF.

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

UNIFORM FORMULARY RECOMMENDATION

(Dave Meade) In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the TIBs, and other relevant factors, the P&T Committee voted (12 for, 0 against, 0 abstain and 1 absent) to recommend Cimzia (certolizumab injection) be designated as non-formulary under the UF, based on cost effectiveness.

CIMZIA — NF JUSTIFICATION

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

1. Cimzia has fewer FDA-approved indications (3) than the UF TIB, Humira (7). There is less clinical efficacy and safety data available for Cimzia than the other TIBs (Humira and Enbrel).

2. Cimzia was not cost-effective relative to the other TIB already included on the UF (Humira).

CIMZIA — UNIFORM FORMULARY IMPLEMENTATION PLAN

(Dave Meade) 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.

CIMZIA — PRIOR AUTHORIZATION CRITERIA AND IMPLEMENTATION PLAN

(Dave Meade) Currently PA requirements apply to etanercept (Enbrel), adalimumab (Humira) and the other TIBs. The P&T Committee agreed that the following PA criteria should apply to certolizumab injection, consistent with the FDA-approved labeling and PA requirements for the other TIBs. The implementation plan would be timed to coincide with the UF implementation plan.

1. Coverage would be approved for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderate to severely active

disease refractory to conventional therapy; and also for the treatment of moderate to severely active RA in adults.

2. Coverage would not be provided for concomitant use with abatacept (Orencia), adalimumab (Humira), anakinra (Kineret), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), or rituximab (Rituxan)

(Dave Meade) : CDR Ellzy will now give the physician perspective for Cimzia.

CIMZIA — COMMITTEE PHYSICIAN PERSPECTIVE

CDR Ellzy presented the physician's perspective on the P&T Committee's actions. He said the discussion of this new drug was similar to that for Simponi, noting that Comzia has only three FDA-approved indications compared with seven for Humira, there is less information available about it and it is not cost effective.

CIMZIA — BAP QUESTIONS AND DISCUSSION

Ms. Fryar asked if the same situation applied to this new drug as to the previous one regarding step therapy, which is that the whole drug class would have to be reviewed to use step therapy. The answer provided was that the situation was the same. Ms. Fryar commented that the systems being put in place for beneficiaries should be transparent to them; they shouldn't be able to see the process. This isn't necessarily true of some of the new procedures that have been implemented over the past year or two. CDR Ellzy replied that they are trying to avoid situations where the beneficiaries go to the pharmacy and then have to come back because of the process. Mr. Hutchings added that the procedures are usually adopted in cases where the drug is very costly. Ms. Fryar said she is increasingly hearing from beneficiaries about the process. CDR Ellzy said that the TRICARE website makes it very transparent what the requirements are.

Dr. Crum noted that the prior authorization criteria re-state the FDA approved indications in regard to RA and he wondered if that might not be too liberal for what TMA is trying to achieve. CDR Ellzy said the Committee tries not to limit an agent if it does as well and keeps it on formulary if it does better. In this case, cost-effectiveness is why it wasn't left on the UF. He noted the Panel's concern, but reiterated that Committee can't put step therapy in place without reviewing the whole class. There was also a brief discussion of the difference between "medical necessity" and "prior authorization." Mr. Hutchings asked whether the PA form had the UF preferred agent listed on it and said that it has been helpful in the past in guiding physicians.

Ms. Legette commented that Raptiva, listed on page three of the handout as a UF product, has been withdrawn from the market.

BAP VOTE ON UNIFORM FORMULARY RECOMMENDATION — TARGETED IMMUNOMODULATOR BIOLOGIC - CERTOLIZUMUMAB (CIMZIA INJECTION)

Ms. Fryar read the P&T Committee's UF recommendation for Cimzia:

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the TIBs, and other relevant factors, the P&T Committee voted to recommend Cimzia (certolizumab injection) be designated as non-formulary under the UF, based on cost effectiveness.

There was no further discussion.

The BAP vote was:

6 concur; 0 non-concur.

BAP VOTE ON CIMZIA IMPLEMENTATION PLAN

Ms. Fryar read the Committee's implementation plan recommendations:

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.

Without further discussion the BAP voted:

6 concur; 0 non-concur.

BAP VOTE ON CIMZIA PRIOR AUTHORIZATION CRITERIA

Ms. Fryar next read the PA criteria for Cimzia:

The P&T Committee agreed that the following PA criteria should apply to golimumab injection, consistent with the FDA-approved labeling and PA requirements for the other TIBs. The implementation plan would be timed to coincide with the UF implementation plan.

1. Coverage would be approved for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderate to severely active disease refractory to conventional therapy; and also for the treatment of moderate to severely active RA in adults.

2. Coverage would not be provided for concomitant use with abatacept (Orencia), adalimumab (Humira), anakinra (Kineret), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), or rituximab (Rituxan)

The Panel vote was:

6 concur, 0 non-concur.

The Chair indicated that the Panel was ready for the next presentation.

3. NARCOLEPSY/ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) — ARMODAFINIL (NUVIGIL)

RELATIVE CLINICAL EFFECTIVENESS

[BAP Script]

(LCDR Martinez) Please turn to page 4 of the handout where Table 3 shows the subset of Narcolepsy drugs. Armodafinil (Nuvigil) is a non-amphetamine wakefulness promoting agent. It is the single R-enantiomer of modafinil (or Provigil), which is a racemic mixture. The R-enantiomer has been shown to have a longer half-life than its S-counterpart; however, the half-lives of Nuvigil and Provigil are similar. The subclass of narcolepsy agents was last reviewed in November 2006 as part of the ADHD and narcolepsy drug class. The other narcolepsy agents on the uniform formulary are Provigil and Xyrem. We will not discuss the ADHD drugs here.

Figure 3 on page 4 of the handout shows the utilization of the narcolepsy drugs. There is a small mark on the graph for the month of May 2009 which shows the Nuvigil utilization. Provigil has the highest utilization. As of last week, there were 1,874 Rxs dispensed for Nuvigil.

Nuvigil is FDA-approved for the treatment of excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift work sleep disorder. These are the same FDA indications as the current UF product Provigil. Generic formulations of Provigil are expected in mid-2010 (which was corrected to 2011) There are no head-to-head trials comparing Nuvigil to Provigil and there is no conclusive data to support that the effects of Nuvigil last longer than Provigil. After review of the clinical literature, Nuvigil does not have compelling clinical advantages over existing narcolepsy agents on the UF.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded there is currently insufficient data to conclude that Nuvigil offers improved efficacy, safety, or tolerability compared to the UF product Provigil.

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

NUVIGIL — RELATIVE COST EFFECTIVENESS

(Dave Meade) The P&T Committee evaluated the relative cost-effectiveness of Nuvigil in relation to efficacy, safety, tolerability, and clinical outcomes of modafinil (Provigil). 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 Nuvigil relative to Provigil. Results from the CMA showed the projected weighted average cost per day for Nuvigil is less than Provigil.

Relative Cost-Effectiveness Conclusion: The P&T Committee concluded armodafinil (Nuvigil) is cost effective relative modafinil (Provigil).

COMMITTEE ACTION: The P&T Committee voted (10 for, 2 against, 0 abstain and 1 absent) to accept the cost effectiveness conclusion stated above.

NUVIGIL — 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, voted (12 for, 0 against, 0 abstain and 1 absent) to recommend that armodafinil tablets (Nuvigil) be designated formulary on the UF.

Nuvigil — Uniform Formulary Implementation Plan – does not apply

NUVIGIL — PRIOR AUTHORIZATION CRITERIA AND IMPLEMENTATION PLAN

(Dave Meade) Taking into consideration the clinical review, the P&T Committee recommended the following PA criteria should apply to armodafinil (Nuvigil). Coverage would be approved if a patient met any of the following criteria and would expire in one year:

1. Narcolepsy associated with persistent and excessive daytime sleepiness as diagnosed by sleep studies (polysomnogram or mean sleep latency time (MSLT));

2. Obstructive sleep apnea associated with persistent and excessive daytime sleepiness. (CPAP (continuous positive airway pressure) treatment adequately titrated and patient compliant with treatment);

3. Nightshift worker with diagnosis of shift work sleep disorder associated with excessive sleepiness.

(Dave Meade) : CDR Ellzy will now give the physician perspective for Nuvigil.

NUVIGIL – COMMITTEE PHYSICIAN PERSPECTIVE

(CDR. Ellzy)

CDR Ellzy said that the Committee noted that Nuvigil tested well and that its cost was comparable to Provigil and it decided to put the agent on the UF.

NUVIGIL — BAP QUESTIONS AND DISCUSSION

Dr. Schlaifer noted that the presentation mentioned that Provigil will be going generic in the near future and asked if that had an effect on the Committee's decision. The answer given was that Provigil would not be available in generic form for almost a year and that the class would be reviewed again when that happens.

Mr. Hutchings asked what basis is used — base dollars or an extrapolated figure — to conduct a cost analysis when, in cases such as this, generic formulations are looming on the horizon. He noted that TMA wouldn't want a situation where they wound up paying twenty times the amount necessary since a generic is released. Dr. Meade said that the cost analyses are based on a three-year calculation but that the entire class would be reviewed in the case of a sudden shift in costs.

Dr. Crum suggested that the system is facilitating an unfortunate process: that of releasing a new drug just before a generic formulation is marketed, which manufacturers do to affect pricing. CDR Ellzy replied that the Committee is aware of the situation and reiterated that the release of a generic formulation would trigger a re-review of the while class.

BAP VOTE ON UNIFORM FORMULARY RECOMMENDATION — NARCOLEPSY/ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) — ARMODAFINIL (NUVIGIL)

With no further discussion of Nuvigil, the Chair read the P&T Committee's UF recommendation:

In view of the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations of the Narcolepsy/ADHD, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted to recommend that Nuvigil be designated formulary on the UF.

The BAP vote was:

5 concur; 1 non-concur.

Comment: Dr. Crum added a comment that the release of a new drug just in advance of a generic formulation becoming available has the effect of increasing prices.

The Chair noted that there was no implementation plan to consider for Nuvigil as it is being placed on the UF.

BAP VOTE ON PRIOR AUTOHORIZATION CRITERIA — NUVIGIL

Ms. Fryar then read the prior authorization criteria recommended for Nuvigil:

Taking into consideration the clinical review, the P&T Committee recommended the following PA criteria should apply to armodafinil (Nuvigil). Coverage would be approved if a patient met any of the following criteria and would expire in one year:

1. Narcolepsy associated with persistent and excessive daytime sleepiness as diagnosed by sleep studies (polysomnogram or mean sleep latency time (MSLT)) objective testing;

2. Obstructive sleep apnea associated with persistent and excessive daytime sleepiness. (CPAP (continuous positive airway pressure) treatment adequately titrated and patient compliant with treatment);

3. Nightshift worker with diagnosis of shift work sleep disorder associated with excessive sleepiness.

Without further discussion, the BAP voted:

6 concur; 0 non-concur.

The Chair then introduced the next newly-approved drug presentation.

4. ALPHA BLOCKERS FOR BENIGN PROSTATIC HYPERPLASIA (BPH) — SILODOSIN CAPSULES (RAPAFLO)

RELATIVE CLINICAL EFFECTIVENESS

(BAP Script)

(LCDR Martinez) Our last newly approved drug is silodosin, or Rapaflo, which is an alpha blocker FDA-approved for treating benign prostatic hypertension (BPH), or enlarged prostate. The alpha blockers for BPH were last reviewed for UF placement in Nov 2007.

Table 4 on page 5 of the handout shows the UF status of the alpha blocker drugs. This class has an automated prior authorization (or step therapy) requiring use of Uroxatral before using Flomax. The utilization of the alpha blockers is shown in Figure 4 on page 5. As of Feb 2009, Uroxatral has the highest utilization in the class, followed by the non-formulary product Flomax. The generic product terazosin (or Hytrin) has the third highest utilization at all three points of service. As of last week there were 1561 Rxs for Rapaflo dispensed in the MHS.

Rapaflo is similar to Flomax in that it is a highly selective antagonist of α1A- receptors in the prostate. Receptor selectivity for the prostrate means that the drug is concentrated in the prostrate, and is less likely to cause adverse events in other tissues (like dry mouth, or low blood pressure). Uroxatral is also a selective antagonist of the α1A- receptors.

There are no direct comparative clinical trials between Rapaflo and the other alpha blockers for BPH. Also, no trials are available that evaluate outcomes other than changes in signs and symptoms of BPH. The clinical trials used to obtain FDA approval reported that Rapaflo is effective at reducing symptoms and increasing maximum urinary flow rate in patients with BPH. Improvements in these parameters are comparable to the changes seen with the other alpha blockers. The safety profile of Rapaflo appears to be comparable to Uroxatral and Flomax.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded Rapaflo does not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other alpha blockers for BPH currently included on the UF.

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

RAPAFLO — RELATIVE COST EFFECTIVENESS

(Dave Meade) Cost minimization analysis (CMA) was used to evaluate the relative cost-effectiveness of Rapaflo relative to other UF alpha blocking agents. Results from the CMA showed the projected weighted average cost per day for Rapaflo is higher than alfuzosin (Uroxatral). The CMA also revealed the projected weighted average cost per day for Rapaflo is lower than the non-formulary alpha blocking agent, Flomax. Uroxatral remains the most cost-effective alpha-blocking agents on the UF.

Relative Cost-Effectiveness Conclusion:

The P&T Committee, based upon its collective professional judgment, voted that silodosin (Rapaflo) are not cost effective relative to alfuzosin (Uroxatral).

COMMITTEE ACTION: The P&T Committee voted (13 for, 0 against, 0 abstain and 0 absent) to accept the cost effectiveness conclusion stated above.

RAPAFLO — 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 Rapaflo be designated non-formulary on the UF. This recommendation was based on the clinical effectiveness conclusion and the determination that alfuzosin (Uroxatral) remains the most cost effective alpha blocker on the UF compared to silodosin (Rapaflo).

RAPAFLO — NON-FORMULARY JUSTIFICATION

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

1. There are no direct comparative trials between Rapaflo and either Flomax or Uroxatral. Based on indirect comparisons, the efficacy for Rapaflo shows similar changes in urinary flow rates and symptom scores. Also, generic formulations of Flomax are expected in 2010.

2. Rapaflo was not cost-effective relative to the other alpha blocker already included on the UF (Uroxatral).

RAPAFLO — UNIFORM FORMULARY IMPLEMENTATION PLAN

(Dave Meade) The P&T Committee voted (13 for, 0 against, 0 abstain and 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.

RAPAFLO — PRIOR AUTHORIZATION CRITERIA AND IMPLEMENTATION PLAN

(Dave Meade) An automated prior authorization (APR) or *step therapy* is currently in effect and requires use of UF alfuzosin (Uroxatral) before other non-formulary alpha blockers for BPH, unless there is therapeutic failure, intolerance, or hypersensitivity. The P&T Committee agreed that the following PA criteria should apply to silodosin capsules (Rapaflo). Coverage would be approved if the patient met any of the following criteria. Implementation would be timed to coincide with that of the UF implementation plan:

1. Automated PA criteria:

    a) The patient has received a prescription for either silodosin (Rapaflo) or alfuzosin (Uroxatral) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

2. PA criteria if automated criteria are not met:

    a) The patient has tried alfuzosin (Uroxatral) and had an inadequate response or was unable to tolerate treatment due to adverse effects.

    b) Treatment with alfuzosin (Uroxatral) is contraindicated.

    c) The patient requires an alpha blocker that can be crushed and sprinkled on food.

(Dave Meade): CDR Ellzy will now give the physician perspective for Rapaflo.

RAPAFLO — PHYSICIAN PERSPECTIVE
(CDR. Ellzy)

CDR Ellzy said that Rapaflo is very similar to what the system already has available on the market. It is neither better nor more cost-effective.

BAP QUESTIONS AND DISCUSSION — RAPAFLO

The BAP asked no questions or offered further discussion of the recommendations concerning Rapaflo.

BAP VOTE ON UNIFORM FORMULARY RECOMMENDATION — ALPHA BLOCKERS FOR BENIGN PROSTATIC HYPERPLASIA (BPH) — SILODOSIN CAPSULES (RAPAFLO)

The Chair read the UF recommendation for Rapaflo:
In view of the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations of the Alpha Blocking Agents, and other relevant factors, the P&T Committee, voted to recommend Rapaflo be designated non-formulary on the UF based on cost effectiveness.

Without further discussion, the BAP voted as follows on the UF recommendation:

6 concur; 0 non-concur.

BAP VOTE ON IMPLEMENTATION PLAN FOR RAPAFLO

Ms. Fryar read the P&T Committee's implementation plan recommendation for Rapaflo:

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.

There was no additional discussion. The vote was:

6 concur; 0 non-concur.

BAP VOTE ON PRIOR AUTHORIZATION CRITERIA AND IMPLEMENTATION PLAN FOR RAPAFLO

The Chair read the Committee's recommendations:

An automated prior authorization (APR) or *step therapy* is currently in effect and requires use of UF alfuzosin (Uroxatral) before other non-formulary alpha blockers for BPH, unless there is therapeutic failure, intolerance, or hypersensitivity. The P&T Committee agreed that the following PA criteria should apply to silodosin capsules (Rapaflo). Coverage would be approved if the patient met any of the following criteria. Implementation would be timed to coincide with that of the UF implementation plan:

1. Automated PA criteria:

    a) The patient has received a prescription for either silodosin (Rapaflo) or alfuzosin (Uroxatral) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

2. PA criteria if automated criteria are not met:

    a) The patient has tried alfuzosin (Uroxatral) and had an inadequate response or was unable to tolerate treatment due to adverse effects.

    b) Treatment with alfuzosin (Uroxatral) is contraindicated.

    c) The patient requires an alpha blocker that can be crushed and sprinkled on food.

Without discussion, the BAP voted as follows:
6 concur; 0 non-concur.

Following the vote, Mr. Hutchings asked if the PA form could be changed to add the interactions with Uroxatral. He said he thinks that Flomax has an interaction notation on it, but that may be an old form. Whatever the case, this form should be consistent with the Flomax form.

The Chair then introduced the Provigil presentation.

5. PRIOR AUTHORIZATION AND IMPLEMENTATION PLAN — MODAFINIL (PROVIGIL)

[BAP Script]

(Dave Meade) We have changes to discuss for the Prior Authorization for modafinil (Provigil), which is the UF narcolepsy drug. As discussed earlier, Provigil and Nuvigil are very similar. New data published since the original Narcolepsy drug class review in November 2006 was evaluated to determine if the Provigil) PA required updating. The P&T Committee agreed that the evidence for using Provigil for sleepiness associated with Parkinson's disease was not supportable. There is new data for treating fatigue associated with traumatic brain injury (TBI) mentioned in a recent VA/DoD guideline, which was deemed supportable by the P&T Committee. The P&T Committee also recommended updating the criteria used for objectively diagnosing narcolepsy via polysomnogram or mean sleep latency testing (MSLT).

The P&T Committee recommended the following PA criteria should apply to Provigil. Coverage would be approved if a patient met any of the following criteria and would expire in one year. The P&T Committee also recommended an implementation date effective date of the first Wednesday one week after the minutes are signed. The implementation period will begin immediately following approval by the Director, TMA.

a) Narcolepsy associated with persistent and excessive daytime sleepiness as diagnosed by polysomnogram or MSLT objective testing;

b) Obstructive sleep apnea associated with persistent and excessive daytime sleepiness AND continuous positive airway pressure (CPAP) treatment adequately titrated and patient compliant with treatment;

c) Nightshift worker with diagnosis of shift work sleep disorder associated with excessive sleepiness;

d) Multiple sclerosis with excessive fatigue and secondary causes have been addressed;

e) Myotonic dystrophy associated with excessive fatigue;

f) A diagnosis of depression AND primary antidepressant therapy (defined as 4-6 week trial of at least one antidepressant agent) has failed AND the use of other stimulant augmentation (such as methylphenidate products) is contraindicated due to adverse effects, previous failure, or hypersensitivity;

g) Idiopathic hypersomnia diagnosed by a sleep specialist;

h) Fatigue associated with mild traumatic brain injury.

(Dave Meade): CDR Ellzy will now give the physician perspective.

PROVIGIL — PHYSICIAN PERSPECTIVE

(CDR. Ellzy)

CDR Ellzy stated that the new data regarding the use of Provigil for the treatment of sleepiness associated with Parkinson's disease and DoD data on fatigue associated with Traumatic Brain Injury led the Committee to recommend new PA criteria for Provigil.

BAP QUESTIONS AND DISCUSSION — PROVIGIL PA

The BAP asked no questions or offered further discussion of the recommendations concerning the new PA criteria and implementation plan for Provigil.

BAP VOTE ON PROVIGIL PRIOR AUTHORIZATION CRITERIA

Ms. Fryar read the P&T Committee's recommendations on PA criteria and implementation plan for Provigil:

The P&T Committee recommended the following PA criteria should apply to Provigil. Coverage would be approved if a patient met any of the following criteria and would expire in one year. The P&T Committee also recommended an implementation date effective date of the first Wednesday one week after the minutes are signed. The implementation period will begin immediately following approval by the Director, TMA.

a) Narcolepsy associated with persistent and excessive daytime sleepiness as diagnosed by polysomnogram or MSLT objective testing;

b) Obstructive sleep apnea associated with persistent and excessive daytime sleepiness AND continuous positive airway pressure (CPAP) treatment adequately titrated and patient compliant with treatment;

c) Nightshift worker with diagnosis of shift work sleep disorder associated with excessive sleepiness;

d) Multiple sclerosis with excessive fatigue and secondary causes have been addressed;

e) Myotonic dystrophy associated with excessive fatigue;

f) A diagnosis of depression AND primary antidepressant therapy (defined as 4-6 week trial of at least one antidepressant agent) has failed AND the use of other stimulant augmentation (such as methylphenidate products) is contraindicated due to adverse effects, previous failure, or hypersensitivity;

g) Idiopathic hypersomnia diagnosed by a sleep specialist;

h) Fatigue associated with mild traumatic brain injury.

Without further discussion the BAP voted as follows:

6 concur; 0 non-concur.

The Chair then introduced the presentation on Federal Ceiling Price (FCP) regulations implementation.

III. IMPLEMENTATION OF FEDERAL CEILING PRICE REGULATION

Before starting the presentation, LTC Spridgen announced an addendum to the previously-available material concerning FCP regulation implementation which was provided to the BAP and made available to attendees.

[BAP Script]

LTC Spridgen

The committee reviewed drugs that were not included on a Department of Defense Retail Refund Pricing Agreement; these drugs are not compliant with 32 C.F.R. 199.21(q)(2), part of the regulation implementing the FY2008 National Defense Authorization Act, Section 703. The regulation provides that if a drug is not covered by a pricing agreement to comply with Federal

Ceiling Prices, the drugs will generally be designated non-formulary (Tier 3) under the Uniform Formulary and will require a pre-authorization prior to use in the retail point of service. These drugs will remain available in the mail order point of service without pre-authorization. Drugs, with and without pricing agreements, were systematically classified based along therapeutic and pharmacologic lines. The classification system was based on the American Hospital Formulary System Classification and First Data Bank classification.

By the August P&T meeting, over 130 manufacturers had submitted executed pricing agreements representing over 94% (approximately 3000 NDCs) of the drugs subject to the Federal Ceiling Price legislation. Out of the 190 drugs reviewed, 169 were recommended by the Committee to move to Tier 3. Since the meeting, that number has decreased to 45. Of those 45, six were already on Tier 3 and 23 have multiple generics. That would result in 16 newly-designated Tier 3 drugs. Ten drugs were recommended to remain on Tier 2 (since the August meeting, that number has decreased to 6) and eleven drugs (now decreased to eight) were tabled for the November meeting pending Pricing Agreements. We anticipate that these numbers will change again as we receive amended/new pricing agreements. At the meeting, unless otherwise recommended by the Committee, all drugs that were on Tier 2 and covered by a pricing agreement were maintained on Tier 2. The Committee considered each drug carefully with the goal of minimizing the impact on beneficiary care. The Committee considered many factors in its recommendations. These included whether a drug was considered "one-of-a-kind", whether there were other brand name products in the same drug class, and whether multiple generics were available in the class. From these considerations, the Committee's rationale was to move drugs to non-formulary (Tier 3) status only if the committee knew there were appropriate therapeutic substitutions within that drug class. Those without appropriate therapeutic substitutes were not moved and those that the Committee needed additional information on were deferred to the November meeting. Also, the Committee recommended that any drug manufacturer that signs a pricing agreement before 14 October would not have their drug(s) moved to non-formulary (Tier 3). If their drug(s) were already in Tier 3, they would remain as Tier 3 but without an additional pre-authorization. The updated list of drugs is listed in the addendum which was provided as a handout and will be posted on the BAP website. The three (3) lists of drugs that were reviewed are as follows:

A. Drugs that were not on a pricing agreement but should remain on formulary status.
B. Drugs that should be designated or retain the designation of non-formulary on the UF.
C. Drugs that would require re-evaluation at the November meeting.

Information will be provided at the November DoD P&T Committee meeting.

A. The implementation date will not be prior to 1 January 2010 and not later than 180 days after the minutes of this meeting are signed by the Director, TMA.

B. Formulary status of a drug recommended to move from Tier 2 to Tier 3 will stay in Tier 2 if a Price Agreement is received prior to October 14, 2009.

C. Recommend a transition period at MTFs to treat drugs recommended to move from Tier 2 to Tier 3 as if they were still on Tier 2 for purposes of MTF availability until 1 January 2011.

BAP QUESTIONS AND DISCUSSION — FEDERAL CEILING PRICE IMPLEMENTATION

There was no Panel discussion of the P&T Committee's recommendations.

BAP VOTE ON FEDERAL CEILING PRICE REGULATION IMPLEMENTATION RECOMMENDATIONS

The following is a list of actions read to panel members as the recommendations of the DoD P&T Committee. :

A. The following drugs, though not on a pricing agreement, should retain their formulary designation on the UF:

ACTIMMUNE
INTAL
PANRETIN
RADIOGARDASE
THIOLA
VANCOCIN HCL

B. The following drugs should be designated or retain the designation of non-formulary on the UF:

ACHIPHEX
ACLOVATE
AGRYLIN
ALTACE
APTIVUS
ATROVENT
ATROVENT HFA
BUPHENYL
CARBATROL
CARNITOR
CARNITOR SF
CATAPRES
CETROTIDE
CORGARD
CORTISPORIN
CUTIVATE
CYTOMEL
CYTOXAN
DEPAKENE
ELESTRIN
ELIGARD
ENDOMETRIN
EURAX
FLOMAX
FOSRENOL
GYNAZOLE-1
HALOG
KADIAN
KAON-CL 10
KINERET
LAC-HYDRIN
LEVULAN
LIMBITROL
LITHOSTAT
LOCOID
LUVERIS
MICRO-K
MINOCIN
MIRAPEX
MOBIC
MONODOX
MS CONTIN
NIRAVAM
OMNICEF
OXISTAT
PAMINE FORTE
PAMINE FQ
PERSANTINE
PHOSLO
PLETAL
PROAMATINE
RHEMATREX
RIOMET
SAIZEN
SALAGEN
SEPTRA
SEPTRA DS

SEROSTIM	THALITONE	VIRAMUNE
SILVADENE	TIGAN	VIROPTIC
SONATA	TINDAMAX	VYVANSE
TAPAZOLE	TRANSDERM-SCOP	WESTCORT
TEMOVATE	TRETIN-X	ZONEGRAN
TEMOVATE EMOLLIENT	ULTRAVATE	ZORBTIVE
	ULTRAVATE PAC	

Ms. Fryer asked the panel for a vote by raising their right hand. TMA Deputy General Counsel (DGC) noted the actions being read were not the full recommendations of the P&T Committee and asked that the full recommendations be read. The vote was not recorded into the minutes.

Upon the advice of the Deputy General Counsel, it was determined that the Panel had voted on an incorrect list and would need to re-do its vote. The correct procedure to be followed is for the Panel to vote on the full list of 169 agents as included in the original handout, then vote on whether the agents needed to get down to 45 should be taken off. The Committee also recommended that if an agreement is received by October 14, that agent will not have to move from Tier 2 to Tier 3. If the BAP agrees with that recommendation, it will automatically take care of the further changes.

The Beneficiary Advisory Panel Chair asked for a motion to rescind its vote on the revised addendum. Dr Crum made a motion which was seconded by Ms. LeGette to rescind the vote on the revised addendum. The chair noted that the revised addendum was intended only for informational purposes. Panel members voted to officially rescind its vote on the addendum. The Chair requested a copy of the correct list from Deputy General Counsel so it could be read into the record. The Chair had the list read by Mr. Hutchings. The Panel then voted on the correct list. The Deputy General Counsel agreed with the approach, also noting that the updated list was intended only for information purposes.

PANEL VOTE ON RECOMMENDATION A: DRUGS RETAINING FORMULARY STATUS

The Chair read the P&T Committee recommendations:

The following drugs, though not on a pricing agreement, should retain their formulary designation on the UF**Corrected Handout Recommendations for Implementation of Federal Ceiling Price Regulation which was voted on by BAP. This list is from August 2009 P&T Committee Meeting.

VANCOCIN HCL	DERMA-SMOOTHE-FS	PANRETIN
ACTIMMUNE	DERMOTIC	RADIOGARDASE
APOKYN	STROMECTOL	
INTAL	THIOLA	

PANEL VOTE ON RECOMMENDATION B: NON-FORMULARY DRUGS

The Chair, assisted by Mr. Hutchings, read the non-formulary drug recommendations:

The following drugs should be designated or retain the designation of non-formulary on the UF:

MIRAPEX
WELCHOL
LIALDA
PENTASA
ESTRACE
MUSE
EMSAM
ENDOMETRIN
VIRAMUNE
ZONEGRAN
SEROSTIM
TRANSDERM-SCOP
DYRENIUM
BUPHENYL
INTELENCE
ELIGARD
QUIXIN
CERTROTIDE
RIOMET
APTIVUS
LUVERIS
OXSORALEN
THALITONE
PLETAL
ZAROXOLYN
EURAX
SULFAMYLON
K-PHOS NO. 2
LITHOSTAT
DEGARELIX
ZORBTIVE
ACIPHEX
FLOMAX
PROCRIT
VYVANSE
KADIAN
AZOR
CARBATROL
KAPIDEX
OXISTAT
POTASSIUM CHLORIDE
KDUR
SORIATANE CK
DAYTRANA
FOSRENOL
ATROVENT HFA
METANX
BREVOXYL-8
NIRAVAM
CORDRAN
NEOBENZ MICRO
HALOG
BREVOXL-4
MS CONTIN
POLY-TUSSIN DHC
PRECARE PREMIER
CORTISPORIN
CORGARD
ULTRAVATE PAC
TRETIN-X
CHROMAGEN FORTE
ALA-HIST D
PREFERA-OB
AGRYLIN
ALTACE
RESPA A.R.
DEPAKENE
POLY HIST FORTE
PRECARE
EXELDERM
PERCODAN
CATAPRES
ALA-HIST
TENEX
SALAGEN
MOBIC
POLY TAN DM
MICRO-K
PHOSLO
HEMATRON-AF
FLOXIN
GESTICARE
ELESTRIN
VALIUM
EVOXAC
CUTIVATE
CYTOMEL
SAIZEN
TRANSDERM-SCOP
PAMINE FQ
LACTINOL-E
DECLOMYCIN
OBSTETRIX EC
LAC-HYDRIN
TAPAZOLE
PERSANTINE
TIGAN
TEMOVATE EMOLLIENT
NUZON
PAMINE
LACTINOL
KAON-CL 10
TEMOVATE
OMNICEF
VIROPTIC
HEMATRON
KYTRIL
SEPTRA DS
ELDEPRYL
ANAPROX DS
MYAMBUTOL
POLY HIST PD
NOVASTART
CORTISPORIN
CARNITOR SF
PAMINE FORTE
SILVADENE
ACLOVATE
DYNEX LA
FLEXERIL
BROVEX
PEDIAPRED
BROVEX SR
BROVEX-D
BROVEX CT
PROAMATINE

P-TEX	KINERET	RESPA-BR
LEVULAN	FIORICET	PREMESIS RX
CYTOXAN	DERMA-SMOOTHE-FS	NIFEREX GOLD
SEDAPAP	SONATA	POLY TAN D
HYCODAN	KENALOG	PRECARE CONCEIVE PCE
DYNEX 12	KLONOPIN	OXANDRIN
DYNEX VR	TESTRED	CARNITOR
ANAPROX	GYNAZOLE-1	DIPENTUM
SEPTRA	CADUET	ULTRAVATE
LIMBITROL	ANDROID	RHEUMATREX
MINOCIN	DIBENZYLINE	MONODOX
LOCOID	VESANOID	POLY-TUSSIN DM
WESTCORT	TINDAMAX	POLY HIST DM
CHROMAGEN	K-PHOS ORIGINAL	NIFEREX-150 FORTE
ATROVENT		

Preauthorization will be determined at the November meeting.

Without further discussion, the BAP voted as follows on the above recommendation:
6 concur; 0 non-concur.

PANEL VOTE ON RECOMMENDATION C: DRUGS REQUIRING MORE INFORMATION BEFORE DETERMINING FORMULARY STATUS

The chair read the recommendation of the P&T Committee concerning this category:

The following drugs require more information prior to determination of a formulary status:

REBIF	SYNTHROID	
VOLTAREN	GONAL-F	UROCIT-K
ROZEREM	FARESTON	PAREMYD
GONAL-F RFF	GLUCAGEN	ARESTIN

Information will be provided at the November DoD P&T Committee meeting.

Without discussion, the BAP voted:

6 concur; 0 non-concur.

PANEL VOTE ON RECOMMENDATION D: IMPLEMENTATION DATE

Ms. Fryar read the Committee's recommendation:

The implementation date will not be prior to January 2010 and not later than 180 days after the minutes of this meeting are signed by the Director, TMA.

Without discussion, the BAP voted:

6 concur; 0 non-concur.

PANEL VOTE ON RECOMMENDATION E: FUTURE PRICE AGREEMENTS

The Chair read the Committee's recommendation:

Formulary status of a drug recommended to move from Tier 2 to Tier 3 will stay in Tier 2 if a Price Agreement is received prior to October 14, 2009.

Ms. Fryar asked if the panel concurred by show of hands. The number that concurred and non-concurred was not announced during the meeting.

PANEL VOTE ON RECOMMENDATION F: TRANSITION PERIOD

Ms. Fryar read the recommendation:

Recommend a transition period at MTFs to treat drugs recommended to move from Tier 2 to Tier 3 as if they were still on Tier 2 for purposes of MTG availability until 1 January 2011.

Without discussion, the BAP voted:
6 concur; 0 non-concur.

The Chair then turned the meeting back over to the DFO.

CLOSING REMARKS

Lt Col Bacon thanked those involved in preparing materials for the meeting, the Panel members for their efforts and manufacturers representatives for coming. He announced that the next meeting of the Panel will be January 14, 2010 and adjourned the meeting at 10:20 AM

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)
- ADHD — Attention Deficit Hyperactivity Disorder
- 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
- BPH — Benign prostatic huperplasis
- CEA — Cost-effectiveness analysis
- C.F.R — Code of Federal Regulations
- 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
- ED — Erectile dysfunction
- 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
- IIEF — International Index of Erectile Function
- IR — Immediate Release (a drug formulation)
- IV — Intravenous
- MHS — Military Health System
- MN — Medical Necessity
- MSLT — Mean sleep latency testing
- MTF — Military Treatment Facility
- NDAA — National Defense Authorization Act
- NF — Non-formulary
- NIH — National Institutes of Health
- NNH — Number Needed to Harm

- NNT — Number Needed to Treat
- OTC — Over the counter
- PA — Prior Authorization
- PAH — Pulmonary arterial hypertension
- P&T Committee — DOD Pharmacy and Therapeutics Committee
- PDE-5 — Phosphodiesterase Type 5 Inhibitors (a drug class)
- PDTS — Pharmacy Data Transaction Service
- PEC — DOD Pharmacoeconomic Center
- POS — Point of Service
- PsA — Psoriatic arthritis
- RA — Rheumatoid arthritis
- RCTs — Randomized Control Trials
- SQ — Subcutaneously
- TBI — Traumatic brain injury
- TIB — Targeted Immunomodulatory Biologics (a drug class)
- TMA — TRICARE Management Activity
- TMOP — TRICARE Mail Order Pharmacy
- TNF — Tumpr necrosis factor
- 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)