26 January 2012

Executive Summary

UNIFORM FORUMARY BENEFICIARY ADVISORY PANEL COMMENTS
12 January 2012

The Uniform Formulary (UF) Beneficiary Advisory Panel (BAP) commented on the recommendations from the DoD Pharmacy & Therapeutics (P&T) Committee November 2012 meeting.

UF CLASS REVIEWS: DEPRESSION AND NON-OPOID PAIN SYNDROMES:

1. Depression and Non-Opoid Pain Syndromes – UF Recommendations

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 the following:

Drugs designated with formulary status on UF	For	Opposed	Abstain	Absent
SSRIs: citalopram fluoxetine fluvoxamine paroxetine HCl IR paroxetine HCl CR paroxetine mesylate sertraline *SNRIs:* venlafaxine IR venlafaxine ER venlafaxine ER tablets *SARIs:* nefazodone trazodone *NDRIs:* bupropion HCl IR bupropion HCl SR bupropion HCl ER	17	0	1	0

TCAs: amitriptyline desipramine doxepin imipramine HCl imipramine pamoate nortriptyline protriptyline *A2RAs:* mirtazapine tablets mirtazapine ODT				
GABA analogs: gabapentin	16	1	1	0

Drug Designated with NF status on UPC	For	Oppose	Abstain	Absent
SNRIs: desvenlafaxine (Pristiq)[1] *SARIs:* trazodone ER (Oleptro) *NDRIs:* bupropion HBr (Aplenzin)	17	0	1	0
SNRIs: duloxetine (Cymbalta)[2] milnacipran (Savella)[3] *GABA analogs:* pregabalin (Lyrica)[4] *SPARIs:* vilazodone (Viibryd)	16	1	1	0

Summary of Panel Vote/Comments

The Chair opened the floor to questions and comment from BAP members. Dr. Cohoon asked whether the medications in this class that are going generic would require a PA when they go on the formulary or just remain on the formulary. Dr. Selvester replied that the drugs would automatically go on the formulary when they become cost-effective, noting that there is a little bit of lead time required for that when a drug goes generic. Dr. Cohoon also asked whether the four drugs being made non-formulary were always non step-preferred. The answer was that there was no step preferred requirement for this class, including the four drugs recommended for NF status. Dr. Cohoon then asked what the reason was for adding the step. Dr. Selvester said it was to drive more appropriate prior therapy and get patients to try

more cost-effective agents that have better clinical efficacy. Dr. Meade said that step therapy is particularly difficult for retail and mail order patients and the motivation is to drive these patients to the most appropriate agent.

Ms. LeGette asked whether current users of the four drugs would be grandfathered. Dr. Meade said they would be.

Ms. Fryar asked whether her understanding is correct that this drug class is $490 million annually. Dr. Meade said that is correct.

Ms. Fryar also asked for a definition of "new user." Dr. Selvester said it is someone who did not have any use of drugs in this class during the previous 180 days. He noted that the manual criteria always have an option that would allow patients to establish that they were prior users of the NF drugs. She also asked about using MN criteria as the basis for manual PA criteria. Dr. Selvester replied that MN criteria were previously developed for all four of the NF-recommended drugs. The specific wording of the PA criteria match these MN criteria almost word for word and are absolutely consistent. Ms. Fryar asked if the PA criteria were still to be developed. Dr. Selvester said that they are developed and that they are planning to handle the implementation administratively with explanatory language rather than go back to the P&T Committee again.

Dr. Cohoon noted that there will be increased usage for some of these NF medications, particularly those for chronic back pain. She said the number one complaint from patients coming back from theater is muscle skeletal and these agents are intended primarily for retail sale.

Mr. Chavez noted that returning Iraq-Afghanistan veterans are managed in such a way that the requirements won't be a problem.

- **Without further discussion, the Panel voted on the UF recommendations as follows:**

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

2. **Drugs approved to move from Non-formulary status to Formulary status on the UF, once cost-effective generic formulations become available.**

Drugs approved to move from NF status to Formulary status on UF, once cost-effective generic formulations become available.	For	Opposed	Abstain	Absent
escitalopram (Lexapro) fluoxetine in special packaging (Sarafem) fluoxetine weekly (Prozac weekly)	17	0	1	0

The precedence for moving drugs from NF to UF status once cost-effective generic formulations are available was established at the May 2007 P&T Committee meeting.

Summary of Panel Vote/Comments:

There were no Panel comments regarding this set of recommendations.

- **Without further discussion, the Panel voted on the Dugs approved to move from NF status to Formulary status on UF, once cost-effective generic formulations become available. The recommendations as follows:**

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

3. Depression and Non-Opioid Pain Syndromes – PA Criteria

- ***PRISTIQ PA CRITERIA:*** The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) that desvenlafaxine (Pristiq) be designated step non-preferred, requiring a trial of venlafaxine in new users. Coverage would be approved if the patient met any of the following step therapy/PA criteria:

a. Automated PA criteria:

(1) The patient has filled a prescription for any venlafaxine product at any MHS pharmacy point of service [Military Treatment Facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.

b. Manual (paper) PA criteria, if automated criteria are not met: PA criteria will be developed from existing MN criteria. The existing MN criteria are as follows:

(1) The patient requires treatment with an SNRI due to failure of another formulary depression agent or has experienced adverse events from the other formulary antidepressant.

(2) The patient has a contraindication to venlafaxine or failed therapy with venlafaxine, which is not expected to occur with desvenlafaxine (Pristiq).

(3) The patient has experienced adverse events with venlafaxine which is not expected to occur with desvenlafaxine (Pristiq).

(4) The patient has previously responded to desvenlafaxine (Pristiq) and changing to a formulary depression agent would incur unacceptable risk.

Summary of Panel Vote/Comments:

There were no Panel comments regarding this set of recommendations.

- **Without further discussion, the Panel voted on the PA Criteria recommendations as follows:**

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

- ***LYRICA PA CRITERIA***: The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) that pregabalin (Lyrica) be designated non-step-preferred, requiring a trial of gabapentin in new users. Coverage would be approved if the patient met any of the following step therapy/PA criteria:

  a) Automated PA criteria:

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

  b) Manual (paper) PA criteria, if automated criteria are not met: PA criteria will be developed from existing MN criteria. The existing MN criteria are as follows:

     (1) The patient has failed therapy with gabapentin or the formulary non-opioid pain syndrome agents.

     (2) The patient has a contraindication to gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with pregabalin (Lyrica).

     (3) The patient has experienced adverse events with gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with pregabalin (Lyrica).

     (4) The patient has previously responded to pregabalin (Lyrica).and changing to a formulary non-opioid pain syndrome agent would incur unacceptable risk.

Summary of Panel Vote/Comments:

There were no Panel comments regarding this set of recommendations.

- **Without further discussion, the Panel voted on the PA Criteria recommendations as follows:**

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

- ***CYMBALTA PA CRITERIA***: The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) that duloxetine (Cymbalta) be designated non-step-preferred, requiring a trial of any antidepressant [Group B drug—SSRI, SNRI (except milnacipran), TCA, mirtazapine, bupropion, SARI, or MAOI] or non-opioid pain syndrome agent [Group C drug—SNRI including milnacipran, TCA, cyclobenzaprine, gabapentin or pregabalin] in new users. Coverage would be approved if the patient met any of the following step therapy/PA criteria:

  a) Automated PA criteria:

     (1) The patient has filled a prescription for any antidepressant (Group B) or non-opioid pain medicine (Group C) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

  b) Manual (paper) PA criteria, if automated criteria are not met: PA will be developed from existing MN criteria. The existing MN criteria are as follows:

     (1) The patient has failed therapy with the formulary depression/non-opioid pain syndrome agents, which is not expected to occur with duloxetine (Cymbalta).

     (2) The patient has a contraindication to the formulary depression/non-opioid pain syndrome agents which is not expected to occur with duloxetine (Cymbalta).

     (3) The patient has experienced adverse events with the formulary depression/non-opioid pain syndrome agents, which is not expected to occur with duloxetine (Cymbalta).

     (4) The patient has previously responded to duloxetine (Cymbalta).and changing to a formulary depression/non-opioid pain syndrome agent would incur unacceptable risk.

Summary of Panel Vote/Comments:

There were no Panel comments regarding this set of recommendations.

- **Without further discussion, the Panel voted on the PA Criteria recommendations as follows:**

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

- ***SAVELLA PA CRITERIA***: The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) that milnacipran (Savella) be designated non-step-preferred requiring a trial of any non-opioid pain syndrome agent [Group C drug—SNRI, including milnacipran, TCA, cyclobenzaprine, gabapentin or pregabalin] in new users. Coverage would be approved if the patient met any of the following criteria:

  a) Automated PA criteria:

  (1) The patient has filled a prescription for any non-opioid pain syndrome agent (Group C) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

  b) Manual (paper) PA criteria, if automated criteria are not met: PA criteria will be developed from existing MN criteria. The existing MN criteria are as follows:

  (1) Use of the formulary non-opioid pain syndrome agents is contraindicated.

  (2) The patient has experienced adverse effects from the formulary non-opioid pain syndrome agents.

  (3) Use of the formulary non-opioid pain syndrome agents has resulted in therapeutic failure.

  (4) The patient has previously responded to milnacipran (Savella) and changing to a formulary non-opioid pain syndrome agent would incur unacceptable risk.

Summary of Panel Vote/Comments:

There were no Panel comments regarding this set of recommendations.

- **Without further discussion, the Panel voted on the PA Criteria recommendations as follows:**

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

4. Depression and Non-Opioid Pain Syndrome Agents —UF Implementation Plan

P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service, and 2) TMA send a letter to beneficiaries affected by this UF decision.

Summary of Panel Vote/Comments:

There were no Panel comments regarding this set of recommendations.

- **Without further discussion, the Panel voted on the implementation plan recommendations as follows:**

  Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA: ☑ These comments were taken under consideration prior to my final decision.

UF CLASS REVIEWS—SHORT ACTING BETA AGONISTS (SABAs)

1. Short Acting Beta Agonists – UF Recommendations

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: albuterol HFA (Ventolin HFA, Proventil HFA, ProAir HFA), levalbuterol HFA (Xopenex HFA), albuterol inhlation solution (Accuneb, generics), and levalbuterol inhalation solution (Xopenex) remain formulary on the UF. The P&T Committee recommended that pirbuterol CFC inhaler (Maxair) be designated NF on the UF.

Summary of Panel Vote/Comments:

The BAP had no questions or comments of the presenters regarding the recommendations in this drug class.

- **Without further discussion, the Panel voted on the UF recommendations as follows:**

  Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA: ☑ These comments were taken under consideration prior to my final decision.

UF CLASS REVIEW - PHOSPHODIESTERASE-5 (PDE-5) INHIBITORS

1. Phosphodiesterase-5 (PDE-5) Inhibitors

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:

1. Sildenafil (Viagra 25 mg, 50 mg, and 100 mg) be designated with formulary status on the UF.

2. Tadalafil (Cialis 2.5 mg, 5 mg, 10 mg, and 20 mg) and vardenafil (Levitra 2.5 mg, 5 mg, 10 mg, and 20 mg; Staxyn 10 mg) be designated NF on the UF, based on cost-effectiveness.

Summary of Panel Vote/Comments:

The Chair asked the BAP members if they had any questions of the presenters. Dr. Crum noted that two-thirds of the volume of patients currently covered are receiving Levitra and asked whether these Levitra users would be grandfathered in. Dr. Meade said there will be no grandfathering; the Levitra users will have to switch. Dr. Crum then asked for clarification of the automated PA criteria, which states that: "Coverage approved for treatment of ED if the patient has received a prescription for ... Levitra." Dr. Meade said they would have to work on the wording because there is no grandfathering in this class.

Later in the discussion of this class, Dr. Meade noted that the switch from Levitra to Viagra would not be required for retail network beneficiaries. The joint contract with VA does not apply to the retail network and for those users Levitra is actually the most cost-effective agent.

Dr. Cohoon asked for an explanation of the BPH criterion number 4, "The Prior Authorization will expire after 1 year from input date." Specifically, she asked what is meant by the "input date." Dr. Meade answered that it refers to the date that the prescription was entered into the automated tracking system. Dr. Cohoon also commented that she appreciates the fact that the Committee added the non-ED applications after hearing from beneficiaries during the last meeting.

Ms. LeGette asked about the effect on several PA procedures that her organization has in place today. Dr. Meade indicated there will be no impact on those procedures.

- **Without further discussion, the Panel voted on the UF recommendations as follows:**

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

2. PDE-5 Inhibitors —Panel Vote on UF Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service, and 2) TMA send a letter to beneficiaries affected by this UF decision.

Summary of Panel Vote/Comments:

Regarding the implementation plan, it was noted that there are a lot of users (450,000) affected by this switch. Dr. Meade noted that the big switch will be in the MTFs and they are

confident that they will be able to live with the 60-day timeframe.

Prior to the Panel vote, Dr. Meade interrupted Ms. Fryar and stated that he had a correction to the questions about grandfathering in the retail network. He indicated that Dr. Crum was correct. Levitra will stay available in the retail network. The reason is because grandfathering Levitra is the most cost effective scenario in the retail network. There were no additional bids in the retail network. While it is non-formulary, patients are already on it and we will not make them switch. You can't start new people but if they are already on it, they can stay on it. To clarify, Ms. Fryar asked if grandfathering was in effect in accordance with the way that it was actually written. Dr. Mead responded, in the retail network.

Dr. Cohoon thank Dr. Meade for making the correction because she, as well as Dr. Salom, had concerns about whether the 60 days was adequate.

Dr. Meade: Commented about the fact that the big switch would be at the MTF where Viagra is currently non-formulary. To clarify, Ms. Fryar asked if 60 days was adequate in the MTF?

- **Without further discussion, the Panel voted on the implementation plan recommendations as follows:**

  Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

3. **PDE-5 Inhibitors for ED—Panel Vote on Step Therapy and PA Criteria**

The P&T Committee recommended that step therapy apply to the PDE-5 inhibitors for the treatment of ED. For all new users of PDE-5 inhibitors, the following criteria apply:

1. Automated Criteria:

   Coverage approved for treatment of ED if:
   a) The patient has received a prescription for sildenafil (Viagra), tadalafil (Cialis), or vardenafil (Levitra and Staxyn) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days, AND
   b) The patient is a male aged 40 years or older.

2. Manual Criteria:

   Coverage approved if:

   a) Patient has tried sildenafil (Viagra) and has had an inadequate response or was unable to tolerate treatment due to adverse effects.

   b) Treatment with sildenafil (Viagra) is contraindicated.

c) Patient is less than 40 years of age and is being treated for ED of organic or mixed organic/psychogenic origin. [Must try sildenafil (Viagra) first or indicate inability to due to reasons stated above in 2) (a) or 2) (b)].

d) Patient is less than 40 years of age and is being treated for drug-induced ED where the causative drug cannot be altered or discontinued. [Must try sildenafil (Viagra) first or indicate inability to due to reasons stated above in 2) (a) or 2) (b)].

Coverage approved for the following non-ED uses requiring daily therapy:

a) Use of tadalafil (Cialis or Adcirca) for Pulmonary Arterial Hypertension (PAH)

b) Use of any PDE-5 inhibitor for preservation/restoration of erectile function after prostatectomy

c) Use of any PDE-5 inhibitor for Raynaud's Phenomenon

d) Use of Cialis 5 mg for treatment of benign prostatic hyperplasia (BPH)

Summary of Panel Vote/Comments:

There were no Panel comments regarding this set of recommendations.

- **Without further discussion, the Panel voted on the step therapy and PA Criteria recommendations as follows:**

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

4. PDE-5 Inhibitors for ED —Panel Vote on PA Implementation Plan

The P&T Committee voted to recommend the PA implementation plan be timed to coincide with that established for the UF decision for tadalafil and vardenafil.

There was a brief discussion as to whether the wording tying the PA criteria implementation to the UF decision meant "60 days" as that was the UF recommendation. Dr. Meade replied that it did.

Summary of Panel Vote/Comments:

There were no Panel comments regarding this set of recommendations.

- **Without further discussion, the Panel voted on the implementation plan recommendations as follows:**

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

5. PDE-5 Inhibitors for BPH Cialis (Tadalafil)—Panel Vote on Cialis PA Criteria

The P&T Committee recommended in addition to the existing PDE-5 inhibitors automated and manual PA criteria, the following PA criteria should also apply to the tadalafil when used for BPH.

1. Manual PA criteria:
   a) Patient is being treated for benign prostatic hyperplasia (BPH) and the dosing regimen prescribed is tadalafil 5 mg once daily AND

      (1) The patient has tried tamsulosin or alfuzosin and had an inadequate response;
      OR

      (2) The patient has tried tamsulosin or alfuzosin and was unable to tolerate them due to adverse effects;
      OR

      (3) Treatment with tamsulosin or alfuzosin is contraindicated.

      (4) Prior authorization for the BPH indication will expire after 1 year from input date.

Summary of Panel Vote/Comments:

There were no Panel comments regarding this set of recommendations.

- **Without further discussion, the Panel voted on the PA Criteria recommendations as follows:**

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

6. PDE-5 Inhibitors for BPH—Panel Vote on Cialis PA Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service.

Summary of Panel Vote/Comments:

There were no Panel comments regarding this set of recommendations.

- **Without further discussion, the Panel voted on the implementation plan**

recommendations as follows:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

1. Osteoporosis Drugs —Risedronate Delayed Release (ATELVIA) – UF Recommendations

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 risedronate DR (Atelvia) be designated non-formulary (NF).

Summary of Panel Vote/Comments:

Dr. Salom asked how much of this product is dispensed each year. The answer was not readily available. Dr. Meade said he would get an answer for Dr. Salom later.

Dr. Cohoon asked whether it would be a viable option to put the drug on the UF and require a PA and whether the Committee had thought about that. The answer given was that patients who require a product that could be taken without food could get the drug using the Medical Necessity (MN) criteria, which specifically address this situation. The main factors in the UF recommendation were the prohibitive cost of this drug for very little benefit and the fact that generics are coming along soon.

- **Without further discussion, the Panel voted on the UF recommendations as follows:**

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

2. Osteoporosis Drugs —Risedronate Delayed Release (ATELVIA) –Implementation Plan Recommendations

The P&T Committee recommended an effective date of the first Wednesday after a 60-day

implementation period in all points of service.

Summary of Panel Vote/Comments:

The Panel had no comments regarding this set of recommendations.

- **Without further discussion, the Panel voted on the implementation plan recommendations as follows:**

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

UTILIZATION MANAGEMENT

a. ABATACEPT (ORENCIA)—PA

The P&T Committee recommended that the following PA criteria should apply to Orencia, consistent with the FDA-approved labeling and PA requirements for the other TIBs.

a. Coverage would be approved for the treatment of adult patients with moderate to severely active rheumatoid arthritis.

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

Summary of Panel Vote/Comments:

The BAP members had no questions or comments regarding the Orencia PA recommendation.

- **Without further discussion, the Panel voted on the UF recommendations as follows:**

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

No further comments from the Panel.

Director, TMA:

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

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
January 12, 2012
Washington, D.C.

Panel Members Present:

- Deborah Fryar, National Military Family Association, representing The Military Coalition, Chairperson
- Kathryn Buchta, Medical Professional, Health Net Federal Services
- Barbara Cohoon, National Military Family Association, representing The Military Coalition
- Santiago Chavez, Association of Military Surgeons of the United States, representing The Military Coalition
- John Crum, Medical Professional, Humana Military Healthcare Services, Inc.
- Lisa Le Gette, Medical Professional, Express-Scripts, Inc.
- Katherine O'Neill-Tracy, Military Officers Association of America, representing The Military Coalition
- Ira Salom, Medical Professional, Indian Health Service

The meeting was held at the Naval Heritage Center Theater, 701 Pennsylvania Ave., N.W., Washington, D.C. CDR Joseph Lawrence, the Designated Federal Officer (DFO), called the proceedings to order at 9:00 A.M. CDR Lawrence indicated the Panel has been convened to review and comment on the therapeutic drug class recommendations resulting from the Department of Defense (DoD) Pharmacy and Therapeutic (P&T) Committee meeting held November 2011 in San Antonio, TX.

Agenda

The agenda for this meeting of the Panel is:

- Welcome and opening remarks
- Public citizen comments
- Review and Panel discussion of P&T Committee recommendations for the following therapeutic drug classes:

  - *Drug Class Reviews*
    - Depression and Non-Opioid Pain Syndrome Agents
    - Short-Acting Beta Agonists (SABAs)
    - Phosphodiesterase-5 Inhibitor (PDE-5) for Erectile Dysfunction (Cost Effectiveness and Uniform Formulary/Prior Authorization)

  - *Designated Newly Approved Drugs*

    - Osteoporosis Agents — Risedronate delayed release tablets (Atelvia)

- *Utilization Management*
    - Tadalafil (Cialis) for Benign Prostatic Hypertrophy (BPH) Prior Authorization

Opening Remarks

The DFO 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 determines necessary and appropriate.

In addition, 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 include:

- 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, TMA 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 DFO in consultation with the Chairperson 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, CDR Lawrence 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 conducting its reviews of the drug class 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 the Director's decisions will be available on the TRICARE website in approximately four to six weeks.

The DFO 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 the minutes accurately reflect relevant facts, regulations or policy.

Private Citizen Comments

The DFO opened the meeting for private citizen comments but there were none.

CDR Lawrence then introduced the individual Panel members (see list above), noted housekeeping considerations, then turned the meeting over to the Panel Chairperson, Ms. Deborah Fryar.

Chairperson's Opening Remarks

The Chair welcomed the audience and thanked everyone for coming. She reminded the Panel that its function is to represent the beneficiaries by reviewing the P&T Committee's recommendations, asking questions, offering input, voting to concur or not and making comments as appropriate; however the Panel cannot make recommendations on its own. Those must come from the P&T Committee.

Ms. Fryar then turned the meeting over to Dr. Meade of the Pharmacoeconomic Center (PEC) to begin the drug class presentations.

DRUG CLASS REVIEW PRESENTATIONS

(PEC Script)

(Dr. Meade): I'm Dave Meade, Director of Clinical Operations at the Pharmacoeconomic Center. Joining me today from the PEC is LCDR Robert Selvester, our Navy physician consultant. Also joining us today is Lt Col William Hannah, one of the DoD P&T Committee members who will provide the physician perspective and comment on the recommendations made by the P&T Committee. Dr John Kugler, the chairman of the P&T Committee and a retired Army Colonel and physician, is also here. Joining us from the TMA is CAPT Nita Sood, the TMA Chief of Staff of the Pharmaceutical Operations Directorate.

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 is based upon its collective professional judgment when considering the analyses from both the relative clinical and relative cost-effectiveness evaluations. The Committee reviewed two Uniform Formulary drug classes – the Depression and Non-Opioid Pain Syndrome Drugs and the inhaled Short-Acting Beta Agonists (SABAs). Additionally, we'll present the cost and Uniform Formulary recommendations review for the Phosphodiesterase-5 Inhibitors – the clinical effectiveness was presented at a previous meeting. The one newly approved drug that was reviewed was Atelvia.
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. 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.

The first drug class we will review is Depression and Non-Opioid Pain Syndrome Agents, which will be presented by Dr. Selvester.

I. UF CLASS REVIEWS—DEPRESSION AND NON-OPIOID PAIN SYNDROMES

DEPRESSION AND NON-OPIOID PAIN SYNDROMES DRUG CLASS RELATIVE CLINICAL EFFECTIVENESS

(PEC Script)

(Dr. Selvester): *Background Relative Clinical Effectiveness*— The P&T Committee evaluated the relative clinical effectiveness of the Depression and Non-Opioid Pain Syndrome Drug Class. By "non-opioid pain syndromes" we mean "pain syndromes typically targeted for non-opioid-based therapy." The subclasses and individual drug members of the class are listed in Table 1 of the Handout. Military Health System (MHS) expenditures for the Depression and Non-Opioid Pain Syndrome Drug Class exceed $490 million annually.

The class as a whole has not been previously reviewed; however, the Antidepressant agents (AD-1s) were reviewed in November 2005, and the GABA analogs (Lyrica and gabapentin) were reviewed in February 2006.

The two newest entrants to the class are Oleptro and Viibryd. Two new gabapentin formulations, Gralise and Horizant, will be reviewed at an upcoming DoD P&T Committee meeting.

Figure 1 of the handout shows the utilization of the various subclasses. The SSRIs are used most frequently, followed by the GABA analogs and SNRIs. Figure 2 shows that for the SNRIs, Cymbalta has the highest usage, followed by generic Effexor XR. The SSRIs are shown in Figure 3 – generic Zoloft has the highest usage, followed by generic Celexa. Figure 4 shows the GABA analogs and some of the other drugs. Generic Neurontin (gabapentin) has the highest use here.

For the clinical and cost effectiveness reviews, the Depression and Non-Opioid Pain Syndrome drugs were also evaluated in relation to the skeletal muscle relaxant cyclobenzaprine (generic Flexeril, for example), and the monoamine oxidase inhibitors (MAOIs), when appropriate. The review included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(1).

In order to support the clinical and cost-effectiveness evaluations in this complex class, the Pharmacy Outcomes Research Team (PORT) analyzed prior use of agents in this class among DoD beneficiaries initiating treatment with Pristiq, Cymbalta, Savella, or Lyrica between April 1, 2011, and June 30, 2011. Details of the analysis are available on pages 2-4 of the Background Information.

Briefly:

Drugs in the class were divided into three groups (with some overlap):

- Group A (the four study medications): Pristiq, Cymbalta, Savella, and Lyrica;
- Group B (medications used for depression): SSRIs, SNRIs (except Savella), TCAs, and others.
- Group C (medications used for non-opioid pain syndromes): SNRIs including Savella, TCAs, cyclobenzaprine, and GABA analogs (Lyrica and generic Neurontin).

For purposes of estimating the potential impact of step therapy programs for each of these agents, "step-preferred" agents, that is medications that must be tried prior to receiving the non-preferred agent, were defined based on clinical considerations, available alternatives, and patterns of prior use.

- Pristiq is the active metabolite of generic Effexor. For greater than 90% of patients, it offers no clinical advantage compared to the parent compound. Among new users, 73-90% of patients did not have evidence of use of generic Effexor in the previous 6-24 months and about 25% did not have evidence of use of any other antidepressant.

- Cymbalta is an SNRI used both for depression and non-opioid pain syndromes, including fibromyalgia. 36% of all new Cymbalta users did not have evidence of use of any other Group B or C medication in the 6 months prior to receiving Cymbalta.

- Savella is an SNRI indicated only for fibromylgia. Acccordingly, Savella was compared to the Group C medications. 42% of new Savella users did not have evidence of use of any other Group C medication in the 6 months prior to receiving Savella.

- Lyrica is a GABA analog similar to generic Neorontin. Both are used for neuropathic pain syndromes and there is little clinical evidence to support a substantial difference in efficacy or safety between the two. 76% of new Lyrica users did not have evidence of having used generic Neurontin in the 6 months prior to receiving Lyrica.

Moving back to the P&T conclusions:

The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 1 absent) upon the following conclusions regarding drugs used for depression, anxiety and other related disorders (Table 1 of the Handout):

There are no compelling differences in efficacy to clearly differentiate one agent over the others.

High non-responder rates in major depressive disorder (MDD) and anxiety disorders for each of the agents necessitate including a variety of agents on the UF.

Generic Prozac (and others), and possibly Lexapro, are the only agents found to have a favorable risk to benefit profile in the treatment of MDD in children and adolescents.

Trials with Cymbalta show no differences in efficacy with the comparator agents (generic Prozac (and others), generic Paxil (and others), and generic Effexor), despite maximal doses of Cymbalta and submaximal doses of the comparators.

Viibryd is efficacious versus placebo for the treatment of MDD. Its unique mix of receptors may be beneficial to some patients. There are no head-to-head trials comparing Viibryd efficacy to other antidepressant agents and long-term data is limited.

Oleptro is efficacious versus placebo for the treatment of MDD. The effect appears to be heavily influenced by its sedating properties.

Beyond the FDA-indications, there is insufficient evidence to draw conclusions regarding the comparative efficacy of the antidepressants with respect to generalized anxiety disorder, obsessive-compulsive disorder, panic disorder, or post-traumatic stress disorder.

There is a high degree of therapeutic interchangeability for the majority of the antidepressants, when used for MDD.

Discontinuation rates due to adverse events (AEs) are similar between agents.

There is wide variation in the specific AE profiles of the antidepressant agents, which is due to their differences in receptor binding properties.

Factors including activation/sedation properties, weight changes, sexual dysfunction, drug interactions (most commonly based on protein-binding, cytochrome P-450 CYP isoenzyme induction/inhibition), or therapeutic duplication may guide treatment decisions in individual patients.

Rare serious AEs for generic Remeron, nefazodone, and generic Desyrel typically limit these drugs to second-line status.

Minor differences in other factors including different salt forms (HCl versus HBr), delivery mechanisms (IR versus ER), or active metabolites of the parent compound (Pristiq versus generic Effexor) may reduce the number of drugs with the same active ingredient that are required for inclusion on the UF.

The P&T Committee agreed (18 for, 0 opposed, 0 abstained, 0 absent) upon the following conclusions regarding drugs used for non-opioid pain syndromes.

The TCAs (particularly Elavil) and generic Flexeril have substantial data supporting their use, at low doses, in several pain syndromes, and are supported as first-line therapy by many clinical practice guidelines.

Definitive statements about comparative clinical effectiveness between Cymbalta and Lyrica are difficult to make given the lack of head-to-head studies.

Fibromyalgia:

A meta-analysis published in JAMA 2009 concluded the following:

> There is strong evidence for the efficacy of antidepressants (TCAs, SNRIs, SSRIs, MAOIs) in the treatment of FM.
>
> Antidepressants were shown to decrease pain, sleep disturbance and depressed mood and improve health-related quality of life (HRQoL) but not fatigue. TCAs have the largest effect sizes followed by SNRIs, SSRIs, and MAOIs.

A systematic review from the Drug Effectiveness Review Project (DERP) showed the

following:

> Cymbalta was not effective in reducing pain in male, nonwhite, and older patients.
>
> Generic Elavil was similar to Cymbalta, Savella, and Lyrica on outcomes of relieving pain and fatigue. There was insufficient data on other outcomes (changes in patient rating scales) to compare the drugs.
>
> Savella was inferior to Cymbalta on outcomes of pain, depressed mood, and health-related quality of life (HRQoL), and inferior to both Cymbalta and Lyrica on improving sleep disturbance.

In one meta-analysis, only one quarter of patients with FM taking Lyrica at higher doses (450mg–600mg) obtained at least 50% pain relief based on the patient global impression of change rating scale compared to 14 and 15% in the placebo group.

Post-Herpetic Neuralgia: According to another systematic review, there is evidence of analgesic efficacy (number needed to treat < 5.0) in PHN for TCAs, opioids, generic Neurontin, generic Ultram, and Lyrica.

Chronic Low Back Pain (CLBP):

Cymbalta has received an indication for chronic musculoskeletal pain based on studies in CLBP and osteoarthritis of the knee. Cymbalta should not be used first line for CLBP. Acetaminophen, NSAIDs, and a trial of a TCA should be used prior to use of Cymbalta for this indication.

In the clinical trials used to obtain FDA approval for CLBP, ~50% of the patients treated with Cymbalta achieved at least a 30% improvement in pain, which is statistically significant but not clinically significant. There is a significant placebo response (~ 40%) compared to Cymbalta when used for CLBP.

Treating 5–8 patients with Cymbalta resulted in modest improvement in pain (a minimally perceptible difference) in one patient treated for 13 weeks.

Phantom Limb Pain

Only limited information is available. Current VA/DoD guidelines recommend Lyrica, generic Neurontin, and antidepressants (e.g., SSRIs, or TCAs).

Two small trials (<45 patients) reported in the DERP review showed a moderate benefit with generic Neurontin compared to placebo.

There is no published data with Lyrica, and a clinical trial with Cymbalta was terminated early.

Safety and Tolerability

Cymbalta: An additional safety warning exists regarding use in patients with hepatic impairment. Withdrawals due to AEs occurred more often with Cymbalta (15%) than placebo (8%). Cymbalta is more likely to cause nausea, somnolence, constipation, and decreased appetite versus placebo.

Lyrica is similar to generic Neurontin (and others) in AEs, although more peripheral edema and weight gain are likely with Lyrica compared to generic Neurontin (and

others).

Titration and tapering is required with all three of the agents.

Other factors that differentiate the drugs: Cymbalta is dosed once daily and its patent is expected to expire December 2013; Lyrica is dosed three times daily and is a controlled medication. All agents must be dose-adjusted in patients with kidney and/or liver impairment. Most pharmacy benefit managers have some form of restriction in place for Cymbalta, Savella and Lyrica.

The P&T Committee agreed (18 for, 0 opposed, 0 abstained, 0 absent) upon the following conclusions regarding the TCAs:

Depression

In one meta-analysis, there was a trend in favor of greater efficacy TCAs over SSRIs. There was no difference between TCAs and SSRIs in terms of improvement in the Clinical Global Impression (CGI) scale.

Another meta-analysis showed that there were no apparent differences between SSRIs and TCAs in an indirect comparison of the CGI.

Use of TCAs for depression has largely been replaced by the SSRIs and SNRIs due to safety issues.

DPN: One meta-analysis showed TCAs were significantly more effective than placebo.

Fibromyalgia: The JAMA meta-analysis showed TCAs have large effect sizes for reducing pain, fatigue, and sleep disturbances compared to SSRIs, SNRIs, and MAOIs. There were no significant differences when amitriptyline was compared with cyclobenzaprine and nortriptyline in the DERP review.

PHN: TCAs are significantly more effective than placebo.

DEPRESSION AND NON-OPIOID PAIN SYNDROMES – RELATIVE COST EFFECTIVENESS

(PEC Script)

(Dr. Meade): *Relative Cost-Effectiveness*—The P&T Committee evaluated the relative cost-effectiveness of the depression and non-opioid pain syndrome agents. Based on the clinical findings regarding efficacy, safety, tolerability, other factors, and clinical outcomes with these agents, cost minimization analyses (CMA) were performed to compare individual agents as well as combinations of these agents primarily used in the treatment of depression, non-opioid pain syndromes, or both. Budget impact analyses (BIAs) were also performed to compare competing formulary scenarios in the evaluation of the cost-effectiveness of the various groupings of these agents. Various scenarios incorporating step therapy were also evaluated, based on clinical considerations, available alternatives, and patterns of prior use derived from the PORT analysis outlined above.

Refer to Table 1 for the various subclasses of the drugs.

Depression Analysis: One analysis evaluated the drugs for depression, including the SSRIs, NDRIs (generic Wellbutrin and other bupropion products), and the SARIs (trazodone and Oleptro). The cost of these agents was compared across therapeutic classes in a CMA. The A2RAs (mirtazapine), SPARIs (Viibryd), and TCAs were also included in this CMA.

Depression Analysis—desvenlafaxine (Pristiq) versus venlafaxine: The SNRIs (desvenlafaxine and venlafaxine) were also modeled individually in a CMA and BIA to evaluate use of step therapy, where a trial of venlafaxine would be required for new users of desvenlafaxine.

Non-Opioid Pain Syndromes Analysis—pregabalin (Lyrica) versus gabapentin: This analysis included the GABA analogs, Lyrica and gabapentin (generic Neurontin). The cost-effectiveness of Lyrica versus gabapentin was determined in a CMA and BIA to evaluate use of step therapy, where a trial of gabapentin would be required for new users of Lyrica

Depression and Non-Opioid Pain Syndromes Analysis—duloxetine (Cymbalta) and milnacipran (Savella): CMA and BIA were used to evaluate the cost-effectiveness of duloxetine and milnacipran. The combined depression and non-opioid pain syndromes analyses were grouped into the same categories outlined in the PORT analysis. The depression analysis group ("Group B drugs") included the SSRIs, SNRIs (except Savella), TCAs, mirtazapine, bupropion, SARIs, and MAOIs (which include Marplan, Nardil and Parnate). The non-opioid pain syndrome analysis group ("Group C drugs") included the SNRIs (with Savella), TCAs, cyclobenzaprine (generic Flexeril), and GABA analogs (gabapentin and Lyrica).

The final analysis compared the depression and non-opioid pain syndrome drugs together. Costs for each of the subgroups, along with the individual weighted average costs for Cymbalta and Savella, were used in the CMAs and BIAs to evaluate various step therapy scenarios for the drugs of interest: Cymbalta versus the depression and non-opioid pain syndrome drugs, and Savella versus the non-opioid pain syndrome drugs.

Relative Cost-Effectiveness Conclusion—Based on the results of the economic analysis and other clinical and cost considerations, the P&T Committee concluded (18 for, 0 against, 0 abstained, 0 absent) the following for the depression and/or non-opioid pain syndrome agents:

Depression Analysis: CMA results for the depression drugs [SSRIs, SARIs, NDRIs, A2RAs, SPARIs, TCAs, and MAOIs, (not including the SNRIs)], showed the following ranking, from least costly to most costly: SARIs (predominantly generic trazodone) <TCAs < A2RAs < SSRIs (using current prices for Lexapro) < NDRIs < MAOIs < SPARIs. When looking specifically at new entrants to the class, trazodone ER (Oleptro) and vilazodone (Viibryd) were less cost-effective than other antidepressants. The same is true of bupropion HBr (Aplenzin). Several current NF antidepressants are now available or are expected to become available in cost-effective generic formulations, including escitalopram (Lexapro), fluoxetine in special packaging (Sarafem), fluoxetine weekly (Prozac weekly), and paroxetine CR (Paxil CR).

Desvenlafaxine (Pristiq) versus venlafaxine: CMA results for Pristiq and venlafaxine (generic Effexor) versus the other depression drugs showed SARIs, TCAs, A2RAs, SSRIs, and NDRIs to

be less costly than the SNRIs. Among the SNRIs, venlafaxine was more cost-effective than Pristiq, based on cost per day of treatment.

BIA was used to assess the potential impact of cost scenarios where selected agents were designated formulary or NF on the UF. Cost scenarios evaluating the impact of designating agents on the BCF were also considered. BIA results showed the most cost-effective scenario was venlafaxine IR/ER as step-preferred on the UF/BCF, with desvenlafaxine (Pristiq) designated NF and non-step-preferred; a trial of venlafaxine IR/ER would be required for new users of desvenlafaxine. Cost-effective generic formulations of venlafaxine ER capsules are now available.

Non-Opioid Pain Syndromes Analysis and pregabalin (Lyrica) versus gabapentin: CMA results specifically focusing on pregabalin (Lyrica) versus gabapentin for non-opioid pain syndromes showed that TCAs and generic Flexeril, which are predominantly generic, were less costly than the GABA analogs. Among the GABA analogs, gabapentin was more cost-effective than Lyrica, based on the cost per day of treatment between these two agents.

BIA results showed the most cost-effective scenario was gabapentin as step-preferred on the UF/BCF, with pregabalin (Lyrica) designated NF and non-step-preferred; a trial of gabapentin would be required for new users of pregabalin.

Depression and Non-Opioid Pain Syndromes Analysis and duloxetine (Cymbalta) and milnacipran (Savella): CMA results specifically focused on Cymbalta versus all depression and non-opioid pain syndrome drugs (Groups B and C drugs), and Savella versus all non-opioid pain syndrome drugs (Group C drugs). CMA results showed that generic SSRIs, SNRIs, SARIs, NDRIs, A2RAs, SPARIs, TCAs, MAOIs, GABA analogs and generic Flexeril were less costly for the treatment of depression and non-opioid pain syndromes than Cymbalta or Savella. Savella is less costly than Cymbalta, based on the cost per day of treatment; however, clinical evidence and FDA labeling supports the use of Cymbalta in a wider range of indications than Savella.

BIA results showed that maintaining all depression and non-opioid pain syndrome drugs in their current BCF/UF status, maintaining Cymbalta and Savella both as NF and non-step-preferred, was the most cost-effective scenario. Since indications for use and prior medication history beyond a 180-day lookback window cannot be determined, a trial of any other Group B or C drug will be required for new users of Cymbalta. Similarly, a trial of any Group C drug will be required for Savella.

DEPRESSION AND NON-OPIOID PAIN SYNDROMES – UF RECOMMENDATION

(PEC Script)

(Dr. 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 the following:

Drugs designated with formulary status on UF	For	Opposed	Abstain	Absent
SSRIs: citalopram fluoxetine fluvoxamine paroxetine HCl IR paroxetine HCl CR paroxetine mesylate sertraline *SNRIs:* venlafaxine IR venlafaxine ER venlafaxine ER tablets *SARIs:* nefazodone trazodone *NDRIs:* bupropion HCl IR bupropion HCl SR bupropion HCl ER *TCAs:* amitriptyline desipramine doxepin imipramine HCl imipramine pamoate nortriptyline protriptyline *A2RAs:* mirtazapine tablets mirtazapine ODT	17	0	1	0
GABA analogs: gabapentin	16	1	1	0

Drugs designated with NF status on UF:	For	Opposed	Abstain	Absent
SNRIs: desvenlafaxine (Pristiq)[1]	17	0	1	0

SARIs: trazodone ER (Oleptro) *NDRIs:* bupropion HBr (Aplenzin)				
SNRIs: duloxetine (Cymbalta)[2] milnacipran (Savella)[3] *GABA analogs:* pregabalin (Lyrica)[4] *SPARIs:* vilazodone (Viibryd)	16	1	1	0

Drugs approved to move from NF status to Formulary status on UF, once cost-effective generic formulations become available:	**For**	**Opposed**	**Abstain**	**Absent**
escitalopram (Lexapro) fluoxetine in special packaging (Sarafem) fluoxetine weekly (Prozac weekly)	17	0	1	0

The precedence for moving drugs from NF to UF status once cost-effective generic formulations are available was established at the May 2007 P&T Committee meeting.

DEPRESSION AND NON-OPIOID PAIN SYNDROMES – PA CRITERIA

(PEC Script)

(Dr. Meade):

PRISTIQ PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) that desvenlafaxine (Pristiq) be designated step non-preferred, requiring a trial of venlafaxine in new users. Coverage would be approved if the patient met any of the following step therapy/PA criteria:

a) Automated PA criteria:

   (1) The patient has filled a prescription for any venlafaxine product at any MHS pharmacy point of service [Military Treatment Facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.

b) Manual (paper) PA criteria, if automated criteria are not met: PA criteria will be developed from existing MN criteria. The existing MN criteria are as follows:

(1) The patient requires treatment with an SNRI due to failure of another formulary depression agent or has experienced adverse events from the other formulary antidepressant.

(2) The patient has a contraindication to venlafaxine or failed therapy with venlafaxine, which is not expected to occur with desvenlafaxine (Pristiq).

(3) The patient has experienced adverse events with venlafaxine which is not expected to occur with desvenlafaxine (Pristiq).

(4) The patient has previously responded to desvenlafaxine (Pristiq) and changing to a formulary depression agent would incur unacceptable risk.

LYRICA PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) that pregabalin (Lyrica) be designated non-step-preferred, requiring a trial of gabapentin in new users. Coverage would be approved if the patient met any of the following step therapy/PA criteria:

a) Automated PA criteria:

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

b) Manual (paper) PA criteria, if automated criteria are not met: PA criteria will be developed from existing MN criteria. The existing MN criteria are as follows:

(1) The patient has failed therapy with gabapentin or the formulary non-opioid pain syndrome agents.

(2) The patient has a contraindication to gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with pregabalin (Lyrica).

(3) The patient has experienced adverse events with gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with pregabalin (Lyrica).

(4) The patient has previously responded to pregabalin (Lyrica).and changing to a formulary non-opioid pain syndrome agent would incur unacceptable risk.

CYMBALTA PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) that duloxetine (Cymbalta) be designated non-step-preferred, requiring a trial of any antidepressant [Group B drug—SSRI, SNRI (except milnacipran), TCA, mirtazapine, bupropion, SARI, or MAOI] or non-opioid pain syndrome agent [Group C drug—SNRI including milnacipran, TCA, cyclobenzaprine, gabapentin or pregabalin] in new users. Coverage would be approved if the patient met any of the following step therapy/PA criteria:

a) Automated PA criteria:

(1) The patient has filled a prescription for any antidepressant (Group B) or non-opioid pain medicine (Group C) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

b) Manual (paper) PA criteria, if automated criteria are not met: PA will be developed from existing MN criteria. The existing MN criteria are as follows:

(1) The patient has failed therapy with the formulary depression/non-opioid pain syndrome agents, which is not expected to occur with duloxetine (Cymbalta).

(2) The patient has a contraindication to the formulary depression/non-opioid pain syndrome agents which is not expected to occur with duloxetine (Cymbalta).

(3) The patient has experienced adverse events with the formulary depression/non-opioid pain syndrome agents, which is not expected to occur with duloxetine (Cymbalta).

(4) The patient has previously responded to duloxetine (Cymbalta).and changing to a formulary depression/non-opioid pain syndrome agent would incur unacceptable risk.

SAVELLA PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) that milnacipran (Savella) be designated non-step-preferred requiring a trial of any non-opioid pain syndrome agent [Group C drug—SNRI, including milnacipran, TCA, cyclobenzaprine, gabapentin or pregabalin] in new users. Coverage would be approved if the patient met any of the following criteria:

a) Automated PA criteria:

(1) The patient has filled a prescription for any non-opioid pain syndrome agent (Group C) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

b) Manual (paper) PA criteria, if automated criteria are not met: PA criteria will be developed from existing MN criteria. The existing MN criteria are as follows:

(1) Use of the formulary non-opioid pain syndrome agents is contraindicated.

(2) The patient has experienced adverse effects from the formulary non-opioid pain syndrome agents.

(3) Use of the formulary non-opioid pain syndrome agents has resulted in therapeutic failure.

(4) The patient has previously responded to milnacipran (Savella) and changing to a formulary non-opioid pain syndrome agent would incur unacceptable risk.

DEPRESSION AND NON-OPIOID PAIN SYNDROME AGENTS—UF IMPLEMENTATION PLAN

(PEC Script)

(Dr. Meade): P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service, and 2) TMA send a letter to beneficiaries affected by this UF decision.

DEPRESSION AND NON-OPIOID PAIN SYNDROME AGENTS—COMMITTEE PHYSICIAN'S PERSPECTIVE

Lt Col William Hannah, one of the DoD P&T Committee members, provided the BAP with a physician's perspective on the review and recommendations.

Dr. Hannah began by noting that the Committee recognized that for all of the conditions treated in this drug class, including depression, neuropathic pain and other described previously, the formulary needs to have a variety of drugs because the patient may respond to one drug and not another or may experience adverse effects. The UF recommendations were developed accordingly and several products are on the UF for the various subclasses. However, for clinical and cost- effectiveness reasons the Committee agreed that the proprietary products Pristiq, Lyrica, Cymbalta and Savella should remain non-formulary and that step therapy was appropriate. He noted that there is very good clinical data for the TCAs and Flexura that show efficacy for the neuropathic pain syndrome. However, because these drugs are old and available in generic formulations it is unlikely that they will receive FDA approval as treatment for pain. Nevertheless, the Committee felt that they should be included as preferred drugs for step therapy.

Two new drugs were reviewed in this class: Oleptro and Viibryd. Both were recommended for non-formulary status. There was one dissenting vote for Viibryd and the Committee recognized that it might be effective for some patients; however, Viibryd was not cost-effective compared to the other anti-depressants.

DEPRESSION AND NON-OPIOID PAIN SYNDROME AGENTS—PANEL QUESTIONS AND COMMENTS

The Chair opened the floor to questions and comment from BAP members. Dr. Cohoon asked whether the medications in this class that are going generic would require a PA when they go on the formulary or just remain on the formulary. Dr. Selvester replied that the drugs would automatically go on the formulary when they become cost-effective, noting that there is a little bit of lead time required for that when a drug goes generic. Dr. Cohoon also asked whether the four drugs being made non-formulary were always non step-preferred. The answer was that there was no step preferred requirement for this class, including the four drugs recommended for NF status. Dr. Cohoon then asked what the reason was for adding the step. Dr. Selvester said it was to drive more appropriate prior therapy and get patients to try more cost-effective agents that have better clinical efficacy. Dr. Meade said that step therapy is particularly difficult for retail and mail order patients and the motivation is to drive these patients to the most appropriate

agent.

Ms. LeGette asked whether current users of the four drugs would be grandfathered. Dr. Meade said they would be.

Ms. Fryar asked whether her understanding is correct that this drug class is $490 million annually. Dr. Meade said that is correct.

Ms. Fryar also asked for a definition of "new user." Dr. Selvester said it is someone who did not have any use of drugs in this class during the previous 180 days. He noted that the manual criteria always have an option that would allow patients to establish that they were prior users of the NF drugs. She also asked about using MN criteria as the basis for manual PA criteria. Dr. Selvester replied that MN criteria were previously developed for all four of the NF-recommended drugs. The specific wording of the PA criteria match these MN criteria almost word for word and are absolutely consistent. Ms. Fryar asked if the PA criteria were still to be developed. Dr. Selvester said that they are developed and that they are planning to handle the implementation administratively with explanatory language rather than go back to the P&T Committee again.

Dr. Cohoon noted that there will be increased usage for some of these NF medications, particularly those for chronic back pain. She said the number one complaint from patients coming back from theater is muscle skeletal and these agents are intended primarily for retail sale.

Mr. Chavez noted that returning Iraq-Afghanistan veterans are managed in such a way that the requirements won't be a problem.

DEPRESSION AND NON-OPIOID PAIN SYNDROME AGENTS—PANEL VOTE ON UF RECOMMENDATIONS

The Chair read the UF recommendations for the Depression and Non-Opioid Agents drug class.

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 the following:

Drugs designated with formulary status on the UF:

SSRIs:
citalopram
fluoxetine
fluvoxamine
paroxetine HCl IR
paroxetine HCl CR
paroxetine mesylate
sertraline

SNRIs:
venlafaxine IR
venlafaxine ER
venlafaxine ER tablets

SARIs:
nefazodone
trazodone

NDRIs:
bupropion HCl IR
bupropion HCl SR
bupropion HCl ER

TCAs:
amitriptyline
desipramine
doxepin
imipramine HCl
imipramine pamoate
nortriptyline
protriptyline

A2RAs:
mirtazapine tablets
mirtazapine ODT

GABA analogs:
gabapentin

Drugs designated with non-formulary status on the UF:

SNRIs:
desvenlafaxine (Pristiq)

SARIs:
trazodone ER (Oleptro)

NDRIs:
bupropion HBr (Aplenzin)

SNRIs:
duloxetine (Cymbalta)
milnacipran (Savella)

GABA analogs:
pregabalin (Lyrica)

SPARIs:
vilazodone (Viibryd)

The Panel then voted as follows:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

There were no Panel comments regarding this set of recommendations.

The Chair then read the recommendation for drugs moving from NF to formulary status.

Drugs approved to move from NF status to Formulary status on UF, once cost-effective generic formulations become available:

escitalopram (Lexapro)
fluoxetine in special packaging (Sarafem)
fluoxetine weekly (Prozac weekly)

The Panel vote was:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

DEPRESSION AND NON-OPIOID PAIN SYNDROME AGENTS—PANEL VOTE ON PA CRITERIA RECOMMENDATIONS

Without further discussion, the Panel moved to consider the P&T Committee's recommendations on Prior Authorization criteria. The Chair read the recommendations.

PRISTIQ PA CRITERIA—The P&T Committee recommended desvenlafaxine (Pristiq) be designated step non-preferred, requiring a trial of venlafaxine in new users. Coverage would be approved if the patient met any of the following step therapy/PA criteria:

a) Automated PA criteria:

(1) The patient has filled a prescription for any venlafaxine product at any MHS pharmacy point of service [Military Treatment Facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.

b) Manual (paper) PA criteria, if automated criteria are not met: PA criteria will be developed from existing MN criteria. The existing MN criteria are as follows:

(1) The patient requires treatment with an SNRI due to failure of another formulary depression agent or has experienced adverse events from the other formulary antidepressant.

(2) The patient has a contraindication to venlafaxine or failed therapy with venlafaxine, which is not expected to occur with desvenlafaxine (Pristiq).

(3) The patient has experienced adverse events with venlafaxine which is not expected to occur with desvenlafaxine (Pristiq).

(4) The patient has previously responded to desvenlafaxine (Pristiq) and changing to a formulary depression agent would incur unacceptable risk.

The Panel voted:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

LYRICA PA CRITERIA—The P&T Committee recommended that pregabalin (Lyrica) be designated non-step-preferred, requiring a trial of gabapentin in new users. Coverage would be approved if the patient met any of the following step therapy/PA criteria:

a) Automated PA criteria:

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

b) Manual (paper) PA criteria, if automated criteria are not met: PA criteria will be developed from existing MN criteria. The existing MN criteria are as follows:

(1) The patient has failed therapy with gabapentin or the formulary non-opioid pain syndrome agents.

(2) The patient has a contraindication to gabapentin or the formulary non-opioid pain syndrome agents which is not expected to occur with pregabalin (Lyrica).

(3) The patient has experienced adverse events with gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with pregabalin (Lyrica).

(4) The patient has previously responded to pregabalin (Lyrica).and changing to a formulary non-opioid pain syndrome agent would incur unacceptable risk.

The BAP vote was:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

CYMBALTA PA CRITERIA—The P&T Committee recommended that duloxetine (Cymbalta) be designated non-step-preferred, requiring a trial of any antidepressant [Group B drug—SSRI, SNRI (except milnacipran), TCA, mirtazapine, bupropion, SARI, or MAOI] or non-opioid pain syndrome agent [Group C drug—SNRI including milnacipran, TCA, cyclobenzaprine, gabapentin or pregabalin]

in new users. Coverage would be approved if the patient met any of the following step therapy/PA criteria:

a) Automated PA criteria:

(1) The patient has filled a prescription for any antidepressant (Group B) or non-opioid pain medicine (Group C) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

b) Manual (paper) PA criteria, if automated criteria are not met: PA will be developed from existing MN criteria. The existing MN criteria are as follows:

(1) The patient has failed therapy with the formulary depression/non-opioid pain syndrome agents, which is not expected to occur with duloxetine (Cymbalta).

(2) The patient has a contraindication to the formulary depression/non-opioid pain syndrome agents which is not expected to occur with duloxetine (Cymbalta).

(3) The patient has experienced adverse events with the formulary depression/non-opioid pain syndrome agents, which is not expected to occur with duloxetine (Cymbalta).

(4) The patient has previously responded to duloxetine (Cymbalta).and changing to a formulary depression/non-opioid pain syndrome agent would incur unacceptable risk.

The Panel vote was as follows:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

SAVELLA PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) that milnacipran (Savella) be designated non-step-preferred requiring a trial of any non-opioid pain syndrome agent [Group C drug—SNRI, including milnacipran, TCA, cyclobenzaprine, gabapentin or pregabalin] in new users. Coverage would be approved if the patient met any of the following criteria:

a) Automated PA criteria:

(1) The patient has filled a prescription for any non-opioid pain syndrome agent (Group C) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

b) Manual (paper) PA criteria, if automated criteria are not met: PA criteria will be developed from existing MN criteria. The existing MN criteria are as follows:

(1) Use of the formulary non-opioid pain syndrome agents is contraindicated.

(2) The patient has experienced adverse effects from the formulary non-opioid pain syndrome agents.

(3) Use of the formulary non-opioid pain syndrome agents has resulted in therapeutic failure.

(4) The patient has previously responded to milnacipran (Savella) and changing to a formulary non-opioid pain syndrome agent would incur unacceptable risk.

The Panel vote on the Savella PA criteria was:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

The Panel offered no comments for the record on the PA criteria recommendations in this drug class.

DEPRESSION AND NON-OPIOID PAIN SYNDROME AGENTS—PANEL VOTE ON UF IMPLEMENTATION PLAN

Ms. Fryar next read the P&T Committee's recommendations regarding the UF implementation plan for this drug class:

The P&T Committee recommended an effective date of the first Wednesday after a 60-day implementation period in all points of service, and 2) TMA send a letter to beneficiaries affected by this UF decision.

Without discussion or comment, the BAP voted:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

The Chair then called for the next drug class presentations.

II. UF CLASS REVIEWS—SHORT ACTING BETA AGONISTS (SABAs)

SHORT ACTING BETA AGONISTS—RELATIVE CLINICAL EFFECTIVENESS

(PEC Script)

(Dr. Selvester): *Relative Clinical Effectiveness*—The P&T Committee evaluated the clinical effectiveness of the inhaled Short-Acting Beta Agonists (SABAs). Table 2 of the handout shows the drugs in the class. There are three SABA products marketed in the United States, which are formulated as pressurized metered dose inhalers (MDIs) or solutions for inhalation: albuterol (a racemic mixture), levalbuterol (the (R)-enantiomer form of albuterol), and pirbuterol. The SABA inhaled solutions include albuterol (Accuneb, generics; various concentrations), and levalbuterol (Xopenex).

Hydrofluoroalkane (HFA) replaced chlorofluorocarbon (CFC) as the propellant in albuterol MDIs in December 2008. The SABA MDI formulations include albuterol HFA (Ventolin HFA, Proventil HFA, ProAir), levalbuterol HFA (Xopenex), and pirbuterol (Maxair). Pirbuterol (Maxair) is the sole remaining CFC MDI on the market, and will be discontinued in December 2013. The three albuterol HFA products are not considered therapeutically interchangeable by the FDA.

The SABA drug class was previously reviewed for UF placement in November 2008. In fiscal year 2011, over $43M was spent on the SABAs at all three points of service in the MHS.

Figure 5 of the handout shows that Ventolin HFA has the highest utilization of all the SABAs.

Information regarding the safety, effectiveness, and clinical outcomes of the SABAs was considered by the Committee. The clinical effectiveness review for the SABAs was limited to the outpatient setting; emergency department use was evaluated only when pertinent.

Relative Clinical Effectiveness Conclusion—The P&T Committee voted (18 for, 0 against, 0 abstained, 0 absent) to accept the following clinical effectiveness conclusions:

1. In terms of efficacy/clinical effectiveness, there is little evidence to suggest there are clinically relevant differences between the SABAs for their FDA- approved indications. There is no new significant information to change the clinical effectiveness conclusion from the November 2008 UF review.
    - Evidence-based guidelines from the VA/DoD Clinical Practice Group (updated 2009), Global Initiative for Asthma, National Heart, Lung and Blood Institute/National Asthma Education & Prevention Program, and Global Initiative for Chronic Obstructive Lung Disease do not list a preference for one SABA over another for treating asthma, exercise-induced bronchospasm (EIB) or chronic obstructive pulmonary disease (COPD).
    - For asthma, all the SABAs are more efficacious than placebo at improving the change in forced expiratory volume in one second ≥ 12% from baseline, whether administered via MDI or inhalational solution.
    - There are no head-to-head studies comparing albuterol MDI with levalbuterol (Xopenex) MDI in adults or children.
    - For adults with asthma, there is little evidence to suggest there are clinically relevant differences between albuterol and levalbuterol (Xoponex) when administered via the nebulized route in either the outpatient or emergency department settings—in terms of number of puffs of rescue medication used daily or from hospitalization admission rates.
    - For children with asthma, there are conflicting and inconclusive results as to whether there are efficacy differences between albuterol and Xoponex inhalation solution when administered in the outpatient setting or emergency department.

- EIB—Placebo-controlled trials with albuterol administered via MDI 15 to 30 minutes before exercise reported statistically significant results in terms of preventing exercise-related symptoms compared to placebo. Although levalbuterol MDI (Xopenex) is not currently approved by the FDA for EIB, the results of placebo-controlled phase III trials do not suggest that the effect of levalbuterol at preventing EIB symptoms would differ from albuterol.
- COPD—There is insufficient evidence to compare the SABAs when used in COPD.

2. With regards to safety/tolerability, the following conclusions were made:
    - SABAs are associated with similar systemic adverse effects. A systematic review found no clinically relevant differences in discontinuation rates due to changes in heart rate, blood pressure, palpitations, nervousness, anxiety, tremor, hyperglycemia or hypokalemia between albuterol and levalbuterol inhalation solution.
    - In the outpatient setting, in adults and children, the incidence of the withdrawal rates due to AEs and overall AE rates were similar between albuterol and levalbuterol inhaled solutions. However, in children there is insufficient evidence from the outpatient studies to determine whether there are clinically relevant differences in the incidence of tachycardia, as conflicting results were reported.
    - There is insufficient data with the SABA MDI formulations to assess safety differences between albuterol and levalbuterol.
3. With regards to differences between the SABAs in terms of other factors, the following conclusions were made:
    - Special populations—The P&T Committee recognized that the FDA-approved pediatric age ranges differ between the products.
    - HFA formulations—There are only minor differences between the HFA formulations of albuterol and levalbuterol, including presence of a dose counter (Ventolin HFA is the only product with a dose counter), requirements for priming, storage conditions, and excipients (Ventolin HFA is the only SABA that does not contain alcohol). However, per FDA ruling, the HFA albuterol agents are not interchangeable.
    - Delivery devices—The Ventolin MDI is not compatible with the Lever Haler spacer, but is compatible with all other spacer devices.

SHORT ACTING BETA AGONISTS—RELATIVE COST EFFECTIVENESS

(PEC Script)

(Dr. Meade): *Relative Cost-Effectiveness*—The P&T Committee evaluated the relative cost-effectiveness of the SABAs Drug Class. Based on the clinical findings regarding efficacy, safety, tolerability, and clinical outcomes with SABAs, CMAs were performed to compare the

MDIs and inhalation solutions. Additionally, a BIA was performed to compare competing formulary scenarios for the MDIs.

CMA results with the SABAs MDIs showed albuterol HFA (Ventolin HFA, Proventil HFA, ProAir HFA) inhalers are most cost-effective. While levalbuterol (Xopenex) is comparable to albuterol HFA with regards to cost, pirbuterol (Maxair) is not cost-effective relative to the other MDIs in the class. BIA results indicated that pirbuterol (Maxair) MDI designated with NF status on the UF was the most cost-effective scenario for the MHS. When the inhalation solutions were compared, albuterol (generic; 2.5 mg/3mL concentration) was the most cost-effective inhalation solution.

Relative Cost-Effectiveness Conclusion—Based on the results of the economic analysis and other clinical and cost considerations, the P&T Committee concluded (17 for, 0 opposed, 1 abstained, 0 absent) that the most cost-effective scenario designated albuterol HFA (Ventolin HFA, Proventil HFA, ProAir HFA), levalbuterol HFA (Xopenex HFA), albuterol inhalation solution (Accuneb, generics), and levalbuterol inhalation solution (Xopenex) with formulary status on the UF and pirbuterol CFC (Maxair) inhaler with NF status on the UF.

SHORT ACTING BETA AGONISTS—UF RECOMENDATION

(PEC Script)

(Dr. 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 (17 for, 0 opposed, 1 abstained, 0 absent) albuterol HFA (Ventolin HFA, Proventil HFA, ProAir HFA), levalbuterol HFA (Xopenex HFA), albuterol inhlation solution (Accuneb, generics), and levalbuterol inhalation solution (Xopenex) remain formulary on the UF. The P&T Committee recommended that pirbuterol CFC inhaler (Maxair) be designated NF on the UF.

SHORT ACTING BETA AGONISTS—COMMITTEE PHYSICIAN'S PERSPECTIVE

Dr. Hannah again provided the Panel with the Committee physician's perspective on their recommendations. He said the recommendations weren't controversial; there is no change in the UF status of agents in this class from the prior review. The only non-formulary product – Maxair – will be taken off the market next year because it uses a CFC propellant. CFCs are being replaced by HFAs due to concern with ozone depletion. The main reason this class was re-reviewed was to designate core formulary albuterol products.

SHORT ACTING BETA AGONISTS—PANEL QUESTIONS AND COMMENTS

The BAP had no questions or comments of the presenters regarding the recommendations in this drug class.

SHORT ACTING BETA AGONISTS—PANEL VOTE ON UF RECOMMENDATIONS

Ms. Fryar then read the P&T Committee's UF recommendations for the SABAs:

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: albuterol HFA (Ventolin HFA, Proventil HFA, ProAir HFA), levalbuterol HFA (Xopenex HFA), albuterol inhlation solution (Accuneb, generics), and levalbuterol inhalation solution (Xopenex) remain formulary on the UF. The P&T Committee recommended that pirbuterol CFC inhaler (Maxair) be designated NF on the UF.

Without further discussion or comment for the record, the BAP voted:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

The Chair then asked for the next drug class presentation.

III. UF CLASS REVIEWS—PHOSPHODIESTERASE-5 (PDE-5) INHIBITORS

PDE-5 INHIBITORS—RELATIVE COST EFFECTIVENESS

(PEC Script)

(Dr. Meade): The P&T Committee evaluated the cost-effectiveness analysis for the PDE-5 inhibitors for erectile dysfunction (ED) at an interim meeting held on December 15, 2011. Please refer to the August 2011 P&T Committee minutes for the relative clinical effectiveness review and conclusions.

Table 6 of your handout shows the drugs in the class. The newest product, Staxyn, is an orally dissolving tablet formulation of Levitra. Figure 6 shows that Levitra has the highest utilization in the MHS.

PDE-5 INHIBITORS FOR ED – RELATIVE COST EFFECTIVENESS

(Dr. Meade): The P&T Committee evaluated the relative cost-effectiveness of the PDE-5 inhibitors sildenafil (Viagra), tadalafil (Cialis), and vardenafil (Levitra, Staxyn) for erectile dysfunction. Based on clinical findings regarding efficacy, safety, tolerability, other relevant factors, and clinical outcomes with these agents, CMAs were performed to compare individual agents. BIAs were also performed to compare competing formulary scenarios.
During this drug class evaluation, the DoD joined the VA in a joint national contracting effort. Viagra was selected as the winner of the VA/DoD national contract. To comply with the terms of the joint national contract, all scenarios considered in this review included Viagra as a UF and BCF agent with all other agents designated NF.

Relative Cost Effectiveness Conclusion—Based on the results of the economic analysis and other

clinical and cost considerations, the P&T Committee concluded (11 for, 0 opposed, 0 abstained, 0 absent) the following for the PDE-5 inhibitors:

- CMA results showed that Viagra was the most cost-effective agent across all three points of service.

- BIA was used to compare the potential impact of discontinuing the current step therapy program (which requires a trial of Levitra for new users with prescriptions for Viagra or Cialis) with scenarios where step therapy was maintained, but Viagra replaced Levitra as the step-preferred agent.

  Additional formulary scenarios evaluating the impact of implementing new retail restrictions were also considered. BIA results showed that, among currently available formulary options, the most cost-effective scenario placed Viagra on the BCF and as the step-preferred product on the UF, with Levitra, Staxyn and Cialis designated NF and non-step preferred. Sensitivity analysis results supported the above conclusion.

The P&T committee discussed a potential program designed to strongly encourage the use of mail order instead of retail, for appropriate medications. The P&T committee concluded that the PDE-5s would be well-suited to such a program clinically and including this drug class in such a program, if it becomes available, would most likely generate additional cost avoidance

PDE-5 INHIBITORS FOR ED– UF RECOMMENDATION

(Dr. 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 (11 for, 0 opposed, 0 abstained, 0 absent):

1. Sildenafil (Viagra 25 mg, 50 mg, and 100 mg) be designated with formulary status on the UF.
2. Tadalafil (Cialis 2.5 mg, 5 mg, 10 mg, and 20 mg) and vardenafil (Levitra 2.5 mg, 5 mg, 10 mg, and 20 mg; Staxyn 10 mg) be designated NF on the UF, based on cost-effectiveness.

PDE-5 INHIBITORS FOR ED – UF IMPLEMENTATION PLAN

(Dr. Meade): The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service, and 2) TMA send a letter to beneficiaries affected by this UF decision.

PDE-5 INHIBITORS FOR ED– STEP THERAPY AND PA CRITERIA

(Dr. Meade): The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 0 absent) that

step therapy apply to the PDE-5 inhibitors for the treatment of ED. For all new users of PDE-5 inhibitors, the following criteria apply:

1. Automated Criteria:
   Coverage approved for treatment of ED if:
   a) The patient has received a prescription for sildenafil (Viagra), tadalafil (Cialis), or vardenafil (Levitra and Staxyn) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days, AND
   b) The patient is a male aged 40 years or older.

2. Manual Criteria:
   Coverage approved if:
   a) Patient has tried sildenafil (Viagra) and has had an inadequate response or was unable to tolerate treatment due to adverse effects.
   b) Treatment with sildenafil (Viagra) is contraindicated.
   c) Patient is less than 40 years of age and is being treated for ED of organic or mixed organic/psychogenic origin. [Must try sildenafil (Viagra) first or indicate inability to due to reasons stated above in 2) (a) or 2) (b)].
   d) Patient is less than 40 years of age and is being treated for drug-induced ED where the causative drug cannot be altered or discontinued. [Must try sildenafil (Viagra) first or indicate inability to due to reasons stated above in 2) (a) or 2) (b)].

   Coverage approved for the following non-ED uses requiring daily therapy:
   a) Use of tadalafil (Cialis or Adcirca) for Pulmonary Arterial Hypertension (PAH)
   b) Use of any PDE-5 inhibitor for preservation/restoration of erectile function after prostatectomy
   c) Use of any PDE-5 inhibitor for Raynaud's Phenomenon
   d) Use of Cialis 5 mg for treatment of benign prostatic hyperplasia (BPH)

PDE-5 INHIBITORS FOR ED– PA IMPLEMENTATION PLAN

(Dr. Meade): The P&T Committee voted (11 for, 0 opposed, 0 abstained, 0 absent) to recommend the PA implementation plan be timed to coincide with that established for the UF decision for tadalafil and vardenafil.

PDE-5 INHIBITORS FOR BPH – CIALIS PA CRITERIA

(Dr. Meade): The PDE-5 inhibitor tadalafil (Cialis) 5 mg received FDA approval in October

2011 for treatment of BPH and ED with BPH. All PDE-5 inhibitors are currently subject to prior authorization, step therapy, quantity limits, and MN criteria. Prior authorization and step therapy also apply to the alpha-1 blockers used for BPH.

The DoD P&T Committee reviewed the clinical efficacy of tadalafil for BPH. Although the efficacy of tadalafil and the alpha-1 blockers for BPH cannot be directly compared, alpha-1 blockers provide relief of BPH urinary symptoms to a greater extent than PDE-5 inhibitors, based on changes from baseline in the International Prostate Symptom Scale reported in clinical trials. The P&T Committee also recommended that when used for BPH, new users of tadalafil would be required to try a preferred alpha-1 blocker first.

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) in addition to the existing PDE-5 inhibitors automated and manual PA criteria, the following PA criteria should also apply to the tadalafil when used for BPH.

1. Manual PA criteria:

   a) Patient is being treated for benign prostatic hyperplasia (BPH) and the dosing regimen prescribed is tadalafil 5 mg once daily AND
      (1) The patient has tried tamsulosin or alfuzosin and had an inadequate response;
      OR
      (2) The patient has tried tamsulosin or alfuzosin and was unable to tolerate them due to adverse effects;
      OR
      (3) Treatment with tamsulosin or alfuzosin is contraindicated.
      (4) Prior authorization for the BPH indication will expire after 1 year from input date.

PDE-5 INHIBITORS FOR BPH – CIALIS PA – PA IMPLEMENTATION PLAN

(Dr. Meade): The P&T Committee recommended 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service.

PDE-5 INHIBITORS—COMMITTEE PHYSICIAN'S PERSPECTIVE

Dr. Hannah then presented the Committee physician's perspective on the PDE-5 inhibitors. He said that when the PDE-5 inhibitors are used as directed for erectile dysfunction there are no compelling difference in efficacy or side effects. Levitra has been the preferred product for several years. Now, due to the joint contract with the VA Viagra becomes the preferred PDE-5 inhibitor. The decision to make Viagra the preferred PDE-5 inhibitor applies only to erectile dysfunction indications. For other PDE users there is no requirement to try Viagra first. Manual Prior Authorization criteria have been imposed for other non-PDE users. These manual PA criteria for other PDE-5 users have been imposed since 2009. With respect to the manual PA

criteria for Cialis, Cialis is used to treat benign prostatic hyperplasia in addition to erectile dysfunction. Other drugs, including alpha blockers, are also approved for BPH. The Committee reviewed the data and concluded that the use of an alpha blocker first would be clinically appropriate for patients with BPH indications. The Committee agreed that for patients requiring Cialis to treat BPH, the PA criteria as outlined will allow patients to obtain the PDE-5 inhibitor for this use.

PDE-5 INHIBITORS—PANEL QUESTIONS AND COMMENTS

The Chair asked the BAP members if they had any questions of the presenters. Dr. Crum noted that two-thirds of the volume of patients currently covered are receiving Levitra and asked whether these Levitra users would be grandfathered in. Dr. Meade said there will be no grandfathering; the Levitra users will have to switch. Dr. Crum then asked for clarification of the automated PA criteria, which states that: "Coverage approved for treatment of ED if the patient has received a prescription for … Levitra." Dr. Meade said they would have to work on the wording because there is no grandfathering in this class.

Later in the discussion of this class, Dr. Meade noted that the switch from Levitra to Viagra would not be required for retail network beneficiaries. The joint contract with VA does not apply to the retail network and for those users Levitra is actually the most cost-effective agent.

Dr. Cohoon asked for an explanation of the BPH criterion number 4, "The Prior Authorization will expire after 1 year from input date." Specifically, she asked what is meant by the "input date." Dr. Meade answered that it refers to the date that the prescription was entered into the automated tracking system. Dr. Cohoon also commented that she appreciates the fact that the Committee added the non-ED applications after hearing from beneficiaries during the last meeting.

Ms. LeGette asked about the effect on several PA procedures that her organization has in place today. Dr. Meade indicated there will be no impact on those procedures.

PDE-5 INHIBITORS—PANEL VOTE ON UF RECOMMENDATION

The Chair noted that there would be several votes in this class. She first called for a vote on the Committee's UF recommendation:

Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended:

1. Sildenafil (Viagra 25 mg, 50 mg, and 100 mg) be designated with formulary status on the UF.
2. Tadalafil (Cialis 2.5 mg, 5 mg, 10 mg, and 20 mg) and vardenafil (Levitra 2.5 mg, 5 mg, 10 mg, and 20 mg; Staxyn 10 mg) be designated NF on the UF, based on cost-effectiveness.

Without further discussion, the BAP voted:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

PDE-5 INHIBITORS—PANEL VOTE ON UF IMPLEMENTATION PLAN

Regarding the implementation plan, it was noted that there are a lot of users (450,000) affected by this switch. Dr. Meade noted that the big switch will be in the MTFs and they are confident that they will be able to live with the 60-day timeframe.

The Chair then read the recommended UF implementation plan:

The P&T Committee recommended 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service, and 2) TMA send a letter to beneficiaries affected by this UF decision.

Prior to the Panel vote, Dr. Meade interrupted Ms. Fryar and stated that he had a correction to the questions about grandfathering in the retail network. He indicated that Dr. Crum was correct. Levitra will stay available in the retail network. The reason is because grandfathering Levitra is the most cost effective scenario in the retail network. There were no additional bids in the retail network. While it is non-formulary, patients are already on it and we will not make them switch. You can't start new people but if they are already on it, they can stay on it. To clarify, Ms. Fryar asked if grandfathering was in effect in accordance with the way that it was actually written. Dr. Mead responded, in the retail network.

Dr. Cohoon thank Dr. Meade for making the correction because she, as well as Dr. Salom, had concerns about whether the 60 days was adequate.

Dr. Meade: Commented about the fact that the big switch would be at the MTF where Viagra is currently non-formulary. To clarify, Ms. Fryar asked if 60 days was adequate in the MTF?

The Chair then re-read the recommended UF implementation plan:

The P&T Committee recommended 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service, and 2) TMA send a letter to beneficiaries affected by this UF decision.

Without further discussion, the BAP voted:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

PDE-5 INHIBITORS FOR ED—PANEL VOTE ON STEP THERAPY AND PA CRITERIA

The Panel next considered the Committee's recommendations for step therapy and PA criteria

for ED uses of the PDE-5 inhibitors:

The P&T Committee recommended that step therapy apply to the PDE-5 inhibitors for the treatment of ED. For all new users of PDE-5 inhibitors, the following criteria apply:

1. Automated Criteria:
   Coverage approved for treatment of ED if:
   a) The patient has received a prescription for sildenafil (Viagra), tadalafil (Cialis), or vardenafil (Levitra and Staxyn) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days, AND
   b) The patient is a male aged 40 years or older.

2. Manual Criteria:

   Coverage approved if:

   a) Patient has tried sildenafil (Viagra) and has had an inadequate response or was unable to tolerate treatment due to adverse effects.

   b) Treatment with sildenafil (Viagra) is contraindicated.

   c) Patient is less than 40 years of age and is being treated for ED of organic or mixed organic/psychogenic origin. [Must try sildenafil (Viagra) first or indicate inability to due to reasons stated above in 2) (a) or 2) (b)].

   d) Patient is less than 40 years of age and is being treated for drug-induced ED where the causative drug cannot be altered or discontinued. [Must try sildenafil (Viagra) first or indicate inability to due to reasons stated above in 2) (a) or 2) (b)].

   Coverage approved for the following non-ED uses requiring daily therapy:

   a) Use of tadalafil (Cialis or Adcirca) for Pulmonary Arterial Hypertension (PAH)

   b) Use of any PDE-5 inhibitor for preservation/restoration of erectile function after prostatectomy

   c) Use of any PDE-5 inhibitor for Raynaud's Phenomenon

   d) Use of Cialis 5 mg for treatment of benign prostatic hyperplasia (BPH)

Without further discussion the BAP voted:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

PDE-5 INHIBITORS FOR ED—PANEL VOTE ON PA IMPLEMENTATION PLAN

The Chair next read the implementation plan for the above PA criteria:

The P&T Committee voted to recommend the PA implementation plan be timed to coincide with

that established for the UF decision for tadalafil and vardenafil.

There was a brief discussion as to whether the wording tying the PA criteria implementation to the UF decision meant "60 days" as that was the UF recommendation. Dr. Meade replied that it did.

The Panel voted as follows:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

PDE-5 INHIBITORS FOR BPH CIALIS (Tadalafil)—PANEL VOTE ON CIALIS PA CRITERIA

The Chair read the PA criteria recommendations for treating BPH with Cialis.

The P&T Committee recommended in addition to the existing PDE-5 inhibitors automated and manual PA criteria, the following PA criteria should also apply to the tadalafil when used for BPH.

1. Manual PA criteria:
   a) Patient is being treated for benign prostatic hyperplasia (BPH) and the dosing regimen prescribed is tadalafil 5 mg once daily AND

      (1) The patient has tried tamsulosin or alfuzosin and had an inadequate response;
      OR

      (2) The patient has tried tamsulosin or alfuzosin and was unable to tolerate them due to adverse effects;
      OR

      (3) Treatment with tamsulosin or alfuzosin is contraindicated.

      (4) Prior authorization for the BPH indication will expire after 1 year from input date.

The Chair asked if there were any questions or comments from Panel members. No comments were noted and the Panel voted:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

PDE-5 INHIBITORS FOR BPH—PANEL VOTE ON CIALIS PA IMPLEMENTATION PLAN

Ms. Fryar read the implementation plan recommendation:

The P&T Committee recommended 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service.

The Panel vote was:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

OSTEOPOROSIS DRUGS—RISEDRONATE DELAYED RELEASE (ATELVIA) - RELATIVE CLINICAL EFFECTIVENESS

(PEC Script)

(Dr. Selvester): *Relative Clinical Effectiveness*—The P&T Committee evaluated the relative clinical effectiveness of a newly approved bisphosphonate, risedronate delayed release (DR) tablets (Atelvia). It is only approved for the treatment of postmenopausal osteoporosis. Risedronate is also available in an immediate release (IR) formulation, under the trade name Actonel, which has other FDA indications in addition to postmenopausal osteoporosis. Generic formulations of risedronate IR are expected in 2012. The osteoporosis drug class, which includes the bisphosphonates, was reviewed for UF placement in June 2008.

Table 3 shows the drugs in the osteoporosis drug class. Figure 7 shows that generic Fosamax has the highest MHS utilization, followed by Boniva.

Atelvia was developed to allow coadministration with food, and it is administered immediately after breakfast. Other oral bisphosphonates (alendronate, ibandronate, risedronate IR) require administration with water in the morning 30–60 minutes prior to breakfast. Clinical trials with Atelvia have only evaluated changes in bone mineral density; there are no studies assessing Atelvia's affect on outcomes of fracture prevention.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) risedronate DR (Atelvia) offers some convenience to the patients in terms of administration schedule, but there are no studies assessing patient compliance, and it has limited clinical trial data and safety information compared to risedronate IR (Actonel). Alternative treatments are available for patients who cannot comply with the administration schedule of the other oral bisphosphonates.

OSTEOPOROSIS DRUGS—RISEDRONATE DELAYED RELEASE (ATELVIA) - RELATIVE COST EFFECTIVENESS

(PEC Script)

(Dr.Meade): *Relative Cost-Effectiveness Analysis and Relative Cost-Effectiveness Conclusion*—Cost-minimization analysis (CMA) was performed. Based on the results of the cost analysis and other clinical and cost considerations, the P&T Committee concluded (18 for, 0 opposed, 0

abstained, 0 absent) Atelvia was more costly when compared to other bisphosphonates on the UF.

OSTEOPOROSIS DRUGS—RISEDRONATE DELAYED RELEASE (ATELVIA) – UF RECOMMENDATION

(PEC Script)

(Dr. 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 (17 for, 0 opposed, 1 abstained, 0 absent) risedronate DR (Atelvia) be designated nonformulary (NF) .

OSTEOPOROSIS DRUGS—RISEDRONATE DELAYED RELEASE (ATELVIA) – IMPLEMENTATION PLAN

(PEC Script)

(Dr. Meade): The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period in all points of service.

OSTEOPOROSIS DRUGS—RISEDRONATE DELAYED RELEASE (ATELVIA) – COMMITTEE PHYSICIAN'S PERSPECTIVE

Dr. Hannah began by noting that Atelvia has the same active ingredient as Actonel, which is risendronate. The other drugs in this class are Fosamax and Boniva. Fosamax is a generic formulation that has been available for a couple of years and Actonel becomes generically available later this year and the patent on Boniva could potentially expire this year as well. The Atelvia formulation does offer convenience for the patient in that they don't have to wait until they are eating breakfast as is the case with the other drugs on the formulary. Atelvia has been approved for only one indication: post-menopausal osteoporosis. The other bisphosphonates have more FDA-approved indications and have shown efficacy in dealing with fractures and increasing bone density. The Committee was unanimous in recommending NF status for Atelvia because it was not as cost effective as the other bisphosphonates, all of which are on the UF. Also, there are other drugs on the UF approved for osteoporosis that have different mechanisms.

OSTEOPOROSIS DRUGS—RISEDRONATE DELAYED RELEASE (ATELVIA) – PANEL QUESTIONS AND COMMENTS

Dr. Salom asked how much of this product is dispensed each year. The answer was not readily available. Dr. Meade said he would get an answer for Dr. Salom later.

Dr. Cohoon asked whether it would be a viable option to put the drug on the UF and require a PA and whether the Committee had thought about that. The answer given was that patients who require a product that could be taken without food could get the drug using the Medical Necessity (MN) criteria, which specifically address this situation. The main factors in the UF recommendation were the prohibitive cost of this drug for very little benefit and the fact that generics are coming along soon.

OSTEOPOROSIS DRUGS—RISEDRONATE DELAYED RELEASE (ATELVIA) – PANEL VOTE ON UF RECOMMENDATION

The Chair read the UF recommendation regarding Atelvia:

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 risedronate DR (Atelvia) be designated nonformulary (NF).

Without further discussion or comment, the Panel voted:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

OSTEOPOROSIS DRUGS—RISEDRONATE DELAYED RELEASE (ATELVIA) – PANEL VOTE ON IMPLEMENTATION PLAN RECOMMENDATION

Ms. Fryar then read the implementation plan recommendation:

The P&T Committee recommended an effective date of the first Wednesday after a 60-day implementation period in all points of service.

The Panel voted:

Concur: 8 Non-concur: 0 Abstain: 0 Absent: 1

The Chair called for the next presentation.

IV. UTILIZATION MANAGEMENT

ABATACEPT (ORENCIA)—PA

(PEC Script)

(Dr. Meade): A subcutaneous injection of abatacept (Orencia) has been marketed. Orencia will be reviewed as a new FDA-approved drug in the Targeted Immunomodulatory Biologics (TIBs) Drug Class at an upcoming DoD P&T Committee meeting. PA requirements apply to the other TIBs in the UF. The P&T Committee agreed that the following PA criteria should apply to

Orencia, consistent with the FDA-approved labeling and PA requirements for the other TIBs.

1. Coverage would be approved for the treatment of adult patients with moderate to severely active rheumatoid arthritis.
2. Coverage would not be provided for concomitant use with adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), infliximab (Remicade), golimumab (Simponi), or rituximab (Rituxan).

The P&T Committee recommended approving the PA criteria outlined above.

ABATACEPT (ORENCIA)—PA: PANEL QUESTIONS AND COMMENTS

The BAP members had no questions or comments regarding the Orencia PA recommendation.

ABATACEPT (ORENCIA)—PA: PANEL VOTE ON PA RECOMMENDATION

The P&T Committee recommended that the following PA criteria should apply to Orencia, consistent with the FDA-approved labeling and PA requirements for the other TIBs.

1. Coverage would be approved for the treatment of adult patients with moderate to severely active rheumatoid arthritis.
2. Coverage would not be provided for concomitant use with adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), infliximab (Remicade), golimumab (Simponi), or rituximab (Rituxan).

The Panel voted:

Concur: 8 Non-concur: 0 Abstain: 0

CLOSING COMMENTS

With the agenda completed, Ms. Fryar indicated that the next scheduled meeting of the Panel is March 22, 2012 and thanked everyone for coming and for the work they did in preparation.

CDR Lawrence, the DFO, closed the meeting at 11:15 A.M.

Deborah Fryar

Ms. Deborah Fryar
Chairperson

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 commonly used as acronyms in Panel discussions 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.

- A2RAs — Alpha-2 receptor agonists (a drug subclass)
- AD-1s — Antidepressant agents
- AE — Adverse event
- AHRQ — Agency for Healthcare Research and Quality
- APR — Automated Profile Review
- ARB — Angiotensin receptor blocker (a drug subclass)
- BAP — Uniform Formulary Beneficiary Advisory Panel (the "Panel" referred to above)
- BCF — Basic Core Formulary
- BIA — Budget Impact Analysis
- BP — Blood pressure
- BPH — Benign prostatic hyperplasia
- CEA — Cost-effectiveness analysis
- CFC — Chlorofluorocarbon
- CFR — Code of Federal Regulations
- CGI Scale — Clinical Global Impression scale
- CLBP — Chronic lower back pain
- CMA — Cost-Minimization Analysis
- COPD — Chronic obstructive pulmonary disorder
- CPG — Clinical Practice Guideline
- CR — Controlled Release (a drug formulation)
- DFO — Designated Federal Officer
- DoD — Department of Defense
- ECF — Extended Core Formulary
- ED — Erectile dysfunction
- EIB — Exercise-induced bronchospasm
- ER — Extended Release (a drug formulation)
- ESI — Express-Scripts, Inc.
- FACA — Federal Advisory Committee Act
- FDA — U.S. Food and Drug Administration
- GABA—Gamma-aminobutyric acid
- HRQoL—Health-related quality of life
- IR — Immediate Release (a drug formulation)
- JAMA — Journal of the American Medical Association

- MAOIs — Monoamine oxidase inhibitors
- MDD — Major depressive disorder
- MHS — Military Health System
- MN — Medical Necessity
- MTF — Military Treatment Facility
- NDRI — Norepinephrine/dopamine reuptake inhibitor (a drug subclass)
- NF — Non-formulary
- NIH — National Institutes of Health
- OTC — Over the counter
- PA — Prior Authorization
- PAH — Pulmonary Arterial Hypertension
- P&T Committee — DoD Pharmacy and Therapeutics Committee
- PDE-5 — Phosphodiesterase-5 (a drug class)
- PDTS — Pharmacy Data Transaction Service
- PEC — DoD Pharmacoeconomic Center
- PORT — Pharmacy Outcomes Research Team
- POS — Point of Service
- RCTs — Randomized Control Trials
- SABA — Short Acting Beta Agonist (a drug class)
- SARIs — Serotonin agonist reuptake inhibitors (a drug subclass)
- SPARIs — Serotonin partial agonist/reuptake inhibitors (a drug subclass)
- SR — Sustained release (a drug formulation)
- SSRI — Selective serotonin reuptake inhibitor (a drug subclass)
- TCAs — Tricyclic antidepressants
- TIBs — Targeted immunomodulatory biologics
- TMA — TRICARE Management Activity
- TMOP — TRICARE Mail Order Pharmacy
- TPHARM — TRICARE Pharmacy Program
- TRRx — TRICARE Retail Pharmacy Program
- UF — DoD Uniform Formulary
- USC — United States Code
- VA — U.S. Department of Veterans Affairs